

Bioethics in International Law:
An Analysis of the Intertwining of Bioethical and Legal Discourses

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Mirjam Sophia Clados, aus München
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Referent: **Professor Doktor Julian Nida-Rümelin**

Korreferent: **Professor Doktor Silja Vöneky**

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Abstract

This thesis discusses implications of framing bioethical concerns in international legal discourse. It starts from the observation that legal approaches to questions of bioethical relevance have become dominant frameworks for addressing many bioethical concerns at the international level. In particular, the UN General Assembly has long attempted to regulate human cloning processes through an international Convention. Similarly, UNESCO and the Council of Europe have both addressed a variety of bioethically relevant issues, such as the processing of human genetic data, the ethics of research or organ transplantation within international legal standards.

It is in the context of this strong connection between international law, international legal discourse and bioethics that this thesis seeks to analyse what exactly happens when issues of bioethical relevance are discussed within such a framework, how this affects the way bioethical issues are conceptualized, conceived of and dealt with, and, ultimately, how well-suited or successful international legal discourse is in its attempt to resolve current bioethical questions. Following the methodological approach of discourse theory, this thesis bases its analysis on the assumption that where and when international legal standards, as manifestations of an international legal discourse, serve as framework for bioethical debate that also somewhat defines how bioethically relevant issues are approached, thought of and dealt with within that framework, that it somewhat determines what methods are used to resolve such issues and that it somewhat limits the range of conceivable and viable solutions to these issue.

The thesis thereby does not aim to demonise or abrogate legal approaches to bioethics and it does not understand the implications discussed in this thesis to be necessarily good or bad. To the contrary, it will be shown that legal approaches to bioethics can and have contributed to the development of the field in several important ways. Yet, this thesis also shows that it is worthwhile to closely examine implications that follow from a specific legal approach to bioethical issues as these implications are not always easily perceived. Given the important, and often dominant or near exclusive role of international law and legal discourse in the area of bioethics as well as the former's strong influence on bioethical debates as a whole, the implications of addressing questions of bioethical relevance within an international legal discourse should at least be understood and acknowledged, a contribution that this thesis aims to make. Moreover, only if these implications are understood is it possible to ask whether engaging in that type of discourse is at all a valuable enterprise and whether or not international legal standards directly addressed to questions of bioethical relevance constitute a suitable means to effectively address questions in the area of bioethics.

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Introduction

Over the last decade issues of bioethical relevance have more and more come to be addressed within international legal standards¹, including within human rights standards. For example, the UN General Assembly has long attempted to regulate human cloning processes through an international legal standard.² The patenting of genetic material is equally dealt with in a legal framework, the World Trade Organization's (WTO) TRIPS agreements³. Similarly, the United Nations Educational, Scientific and Cultural Organization (UNESCO)⁴ and the Council of Europe⁵ have both addressed a variety of bioethically relevant issues, such as the processing of human genetic data, the ethics of research and the transplantation of organs within several international human rights standards.⁶

Yet the term bioethics is by no means clearly defined. In much of the recent philosophical, legal, political and scientific literature the term bioethics has become a buzz word, often with no or little defined content. In its broadest sense, bioethics is thereby understood as the subfield of ethics that investigates all ethical issues⁷ arising in the life sciences⁸, including most prominently medicine,

¹ In this thesis the terms "legal standards" and "legal instruments" are used interchangeably to refer to both legally binding and legally enforceable standards (hard law) and to legally non binding and non enforceable standards (soft law). For a discussion of the definition and difference between hard and soft law see chapter V.

² See J. Achenbach/M. Clados, "Cloning, International Regulation", in: R. Wolfrum (ed.), *The Max Planck Encyclopedia of Public International Law*, 2008, online edition, [www.mpepil.com] (last visited 27.04.2012).

³ See Agreement on Trade Related Aspects of Intellectual Property Rights, Marrakesh Agreement Establishing the World Trade Organisation of 15 Apr 1994, Articles 27-28 (hereinafter TRIPS Agreement), Annex 1C Legal Instruments Results of the Uruguay Round, 31, ILM 33 (1994), 81.

⁴ See UNESCO Universal Declaration on the Human Genome and Human Rights, C/Res.19, 1997, adopted by the United Nations General Assembly, G.A.Res. 152, United Nations GAOR, 53rd Sess., UN Doc. A/RES/53/152, 1997 (hereinafter Universal Declaration on the Human Genome); UNESCO International Declaration on Human Genetic Data, 32 C/Res.19, 2003 (hereinafter Declaration on Human Genetic Data); and UNESCO Universal Declaration on Bioethics and Human Rights, C/Res.24, 2005 (hereinafter UDBHR).

⁵ See the Council of Europe's European Convention for the Protection of Human Rights and the Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, ETS No.164, 1997 (hereinafter Oviedo Convention).

⁶ See also generally M. Clados, "Chances for and Limits of International Law and Legal Language in the Area of Bioethics", in: S. Vöneky/C. Hagedorn/M. Clados/J. von Achenbach, *Legitimation Ethischer Entscheidungen im Recht - Beiträge zum Ausländischen Öffentlichen Recht und Völkerrecht*, 2009, 297 et seq.

⁷ Ethics, as will be explained below in Chapter II, 2.1. is understood to be the systematizing, defending, and recommending of concepts of right and wrong behaviour. See J. Nida-Rümelin (ed.), *Angewandte Ethik. Die Bereichsethiken und ihre theoretische Fundierung*, 2005, 3. "Ethical issues" are then taken to be all issues that are of relevance to an ethical inquiry, i.e. all those issues where a systematization, defense or recommendation of a concept of right and wrong behaviour is being sought.

⁸ During negotiations of the UDBHR, note 4, the term "life sciences" was defined as "the sciences concerned with the study of living organisms. They encompass a broad range of disciplines that include, amongst others, biology, biochemistry, microbiology, virology and zoology. In recent years, many of these disciplines have increasingly focused on the characterization of the molecular events that define biological processes (often referred to as 'molecular life sciences')". Broadly speaking, life sciences include any study or research discipline that contributes to the understanding of life processes. They therefore include such diverse disciplines as the study of micro-biology, veterinary sciences, biology, virology, medicine, etc. See the discussions of the term in the Explanatory Memorandum on the Elaboration of the Preliminary Draft Declaration on Universal Norms on Bioethics, SHS/EST/05/CONF.203/4, 2005, at 19 (hereinafter Explanatory Memorandum).

health care and biology.⁹ Others, taking a narrower definition use the term to refer to ethical questions arising in and outside of the field of medicine, thereby including for example ethical questions related to animal rights, to general public welfare or ecology.¹⁰ Content-wise it seems that questions of bioethical interest are very often concerned with some of the most fundamental, oldest and most sensitive questions individuals, families, societies, cultures and nations may face, including questions about the meaning and value of life and death, about what it means to be a human being and about the possibility and permissibility of tempering with that very concept.¹¹ To reach consensus on any of these questions, be that on the level of families or societies or at the level of national or international policy formation or law making, is often elusive. Moreover, bioethics is a fast paced subject field that depends on and has to accommodate rapid changes in science and technology.¹² Together these characteristics render bioethics a challenging field of inquiry, particularly for international legal frameworks that seek to find global, meaningful and lasting regulations in the area.

That international law, and particularly international human rights law, is nevertheless often the chosen avenue through which bioethical concerns are addressed at the international level is no coincidence. Both fields are heavily intertwined.¹³ They have common roots in, for example, the Nazi atrocities committed before and during World War II as well as in last centuries' human rights movements and body of human rights philosophy.¹⁴ Moreover, lawyers are often also bioethicists and serve on for example ethics commissions or bioethicists or ethics commissions are formally or informally consulted in the law making process.¹⁵ Furthermore, bioethical issues have often been framed or emerged for public discussions, be they led nationally or internationally, in legal terms,

⁹ Cf. R. Audi, *The Cambridge Dictionary of Philosophy*, 1999, 439. See also generally H. Kuhse/P. Singer, "What is Bioethics? A Historical Introduction", in: H. Kuhse/P. Singer, *Bioethics: An Anthology*, 2000, 3 et seq.

¹⁰ S. Post (ed.), *Encyclopedia of Bioethics*, 2003, 34.

¹¹ UNESCO, *Ethics of Science and Technology - Exploration of the Frontiers of Science and Ethics*, 2006, 31, at: <http://unesdoc.unesco.org/images/0014/001454/145409e.pdf> (last visited 27.04.2012). J. Heilinger, "Unterwegs zum neuen Menschen?", in: V. Gerhardt/J. Nida-Rümelin (eds.), *Evolution in Natur und Kultur*, 2010, 223, 223, citing the philosopher Ray Kurzweil as stating that "die vorrangige politische und philosophische Aufgabe des kommenden Jahrhunderts [wird] darin liegen zu definieren wer wir sind". See also A. Thyn, "Grundzüge einer Anthropologie des Inter-Subjekts", in: V. Gerhardt/J. Nida-Rümelin (eds.), *Evolution in Natur und Kultur*, 2010, 261 et seq.; A. Jonsen, *The Birth of Bioethics*, 1998, 2; and D. Callahan, "Bioethics as a Discipline", 1 *Hastings Center Studies*, 1973, 66 et seq.

¹² P. Newell, IDS Working paper 142: *Biotechnology and the Politics of Regulation*, 2002, vii, at: http://www.ids.ac.uk/index.cfm?objectID=FA0755E3-5056-8171-7B8A757CBE2523D4&pgno_pub=3 (last visited 27.04.2012).

¹³ W. Van der Burg, "Law and Bioethics", in: H. Kuhse/P. Singer (eds.), *A Companion to Bioethics*, 2001, 49 et seq.

¹⁴ Jonsen, note 11, xii et seq. and 113-116.

¹⁵ See for example the composition of the Deutscher Ethikrat which includes several members with legal training. Deutscher Ethikrat, at: <http://www.ethikrat.org/ueber-uns/mitglieder/mitglieder-des-deutschen-ethikrates> (last visited 27.04.2012). On the potential role or influence of the Deutscher Ethikrat on law-making processes see S. Vöneky, *Recht, Moral und Ethik. Grundlagen und Grenzen Demokratischer Legitimation für Ethikgremien*, Habilitationsschrift, 2010, Chapter 5, I and II, in particular II 2.3. See also S. Vöneky, "Völkerrecht und Ethik: Ethisierung des Völkerrechts", in: *Ancilla Iuris*, Spezialausgabe: Internationales Recht und Ethik / Special Issue: International Law and Ethics, 2012, at: <http://www.anci.ch/doku.php?id=start>

such as in the cases of *Quinlan*¹⁶, *Cruzan*¹⁷ or *Schiavo*¹⁸ and in legislative reform, such as for example the German regulation with regard to the import of embryonic stem cells¹⁹, and other legislative referenda.²⁰ Finally, “the spirit of the law has penetrated into the bosom of many societies generally and bioethics, partaking in the habits and tastes of its time, has adopted and adapted to this style.”²¹ That is to say that in many democratic societies at least, there seems to be a trend towards using law to regulate more and more matters of social interaction instead of relying for example on churches, general morality or social forces to do so, a trend that has been extended to the area of bioethics.

In order to understand how debates in the field of bioethics are affected by that they are often dealt with in a legal framework or through a legal discourse it first needs, however, some further clarification of the term discourse itself. This thesis follows an understanding of the term discourse as advanced by discourse theorists.²² Generally in discourse theory, discourses are seen as groups of statements, actions or symbols which provide the language or code for talking and thinking about a particular topic at a particular historical moment and place.²³ Discourses are also seen as defining and producing the objects of knowledge and as functioning as the determinant of which language, manner, style and actions conform to, are valid or acceptable in any given discourse.²⁴ For example, discourses determine how to behave, what to wear, say and do in different institutions or situations, such as schools, churches, parliament or other government institutions, clubs, a family setting or at funerals, weddings, etc. Discourses deliver the vocabulary, concept, and acts needed to communicate within any of these given institutions.²⁵ A legal discourse in analogy thus is a discourse that takes place within the field of law, i.e. it is the "legal" way of thinking about issues at stake and the analysis of concerns within legal language, logic and concepts.²⁶

Transferred to the area of bioethics that means that this thesis aims to understand how international legal discourse when concerned with issues of bioethical relevance, and the framing of bioethical concerns in the structure and logic of international law specifically affect bioethical debates. The hypothesis is that where and when international law and legal language serve as

¹⁶ *Quinlan v. US*, 355 A.2d 647 N.J., 1976.

¹⁷ *Cruzan v. Director, Missouri Department of Health*, 497 U.S. 261, 1990.

¹⁸ *Bush v. Schiavo*, 861 So. 2d 505, Fla. Dist. Ct. App., 2005.

¹⁹ "Gesetz zur Sicherstellung des Embryonenschutzes im Zusammenhang mit Einfuhr und Verwendung menschlicher embryonaler Stammzellen (hereinafter Stammzellgesetz – StZG)" of 28 June 2002 (entry into force 1 June 2002), BGBl. I 2277; and its subsequent change by the act of 14 August 2008, BGBl. 2008, 1708.

²⁰ For further examples see A. Lohninger, *Interdisziplinäre, Völker- und Europarechtliche Grundlagen der Gen- und Biotechnologie*, 2007.

²¹ C. Schneider, "Bioethics in the Language of the Law", 24 *The Hastings Center Report*, 1999, 16, 16. See generally also M. Glendon, *Rights Talk: The Impoverishment of Political Discourse*, 1991.

²² See discussion in Chapter II, 1.1. and 1.2.

²³ S. Hall, *Representation: Cultural Representations and Signifying Practices*, 1997, 44.

²⁴ Cf. for example M. Foucault, *Power/Knowledge*, 1980, 131 et seq.

²⁵ M. Foucault, "Die Ordnung des Diskurses. Inauguralvorlesung am College de France am 2. Dezember 1970", in: M. Foucault, *Die Ordnung des Diskurses*, 1979, 1, 10 et seq. See generally E. Laclau, "Discourse", in: R. Goodin/P. Pettit/T. Pogge, *A companion to contemporary political philosophy*, 2007, 541 et seq.

²⁶ See also Clados, note 6, 298.

framework for bioethical debate they also somewhat define how bioethically relevant issues are approached, thought of and dealt with, that they somewhat determine what methods are used to resolve such issues and that they somewhat limit the range of possible resolutions to these issue.²⁷

This thesis thereby does not aim to abrogate or even judge the suitability of legal approaches to bioethics. Rather it reflects on some of the implications that follow from such an approach and that are not always easily perceived. It is this thesis' hypothesis that legal discourse can and does contribute to bioethical debates in significant ways, but that it can also powerfully affect and limit such debates in several important ways. Given the important, and often dominant or near exclusive role of international law and legal discourse in the area of bioethics as well as the former's strong influence on bioethical debates as a whole, the implications of addressing questions of bioethical relevance within an international legal discourse should at least be better understood and acknowledged.

An Outline of the Analysis

This thesis proceeds in three parts. Part I is introductory, specifying the most basic terms and concepts used in this thesis. In particular, it provides in chapter I an overview of the field of bioethics. In order to do so it discusses several possible definitions of the term 'bioethics' (Chapter I, 1.1), analyses the field's foundations, including most prominently medical ethics and moral philosophy and outlines some of the events that are often depicted as highly formative of the whole discipline (Chapter I, 1.2). It also discusses some of the characteristics that, in many scholars' writing on the subject, are often ascribed to the field of bioethics, including the field's interdisciplinarity, the fast-moving context in which it operates and the perceived 'special' nature of questions that arise in the area (Chapter I, 1.3). As this thesis deals with legal discourses in the area of bioethics at the international level it is also important to discuss global perspectives on bioethics and the 'internationalisation' of bioethically relevant issues²⁸ a task which is undertaken in chapter I, 1.4. Based on the preceding analysis a definition of the term bioethics as used in the context of this thesis is formulated in Chapter I, 1.5 that defines bioethics as “ethical issues related to medicine, life sciences and associated technologies as applied to human beings, taking into account their social, legal and environmental dimensions.”²⁹ In using this definition this thesis follows UNESCO's definition of the term bioethics as put forward in its UDBHR.

²⁷ Ibid. On an analysis of national legal approaches and their effect on bioethics see Schneider, Bioethics in the Language of the Law, note 21.

²⁸ See UNESCO, International Bioethics Committee of UNESCO, 12th session, 2005, at: http://www.unesco.org/new/fileadmin/MULTIMEDIA/HQ/SHS/pdf/Programme12IBC_enREV.pdf (last visited 27.04.2012)

²⁹ See UDBHR, note 4, Article 1 para 1. It should be noted that because of this thesis' broad definition of the term bioethics, this thesis usually does not use the term bioethics per se but the expressions "issues of bioethical concerns" or "issues of bioethical relevance". It does so because the international legal standards examined here only deal with small

Chapter two then introduces the term discourse as is relevant to this thesis, providing an overview of various meanings and uses of the term, in particular the everyday understanding of the term and two more specialised meanings, that of discourse ethics and that of discourse theory (Chapter II, 1.1 and 1.2) As this thesis derives its methodological approach from discourse theory the remainder of this chapter (Chapter II, 2) subsequently explains the concept of discourse theory in more detail.

Having thus clarified the underpinnings, concept and methodological approach of this thesis the next part of this thesis, part II, introduces the legal standards directly and less directly addressed to matters of bioethical relevance as elements of the discourse that is under scrutiny. To that extent chapter III analyses whether or in how far international legal standards directly addressed to matters of bioethical relevance may at all be considered 'legal' and hence whether or to what extent it is justified to speak of a 'legal' discourse at all when referring to the discourse under scrutiny in this thesis. To that purpose this chapter first provides an introduction to the terms soft law and hard law. Since it is regularly debated what the term soft law means, what type of law soft law is and whether soft law constitutes law at all and as these questions therefore ask about properties of the institutionalised framework within which the presently examined discourse in the area of bioethics takes place these questions are also addressed here. The next subsections of chapter III then discusses reasons for soft law to emerge, provides a short overview of areas in which soft law instruments are frequently used and then provides a short definition of this thesis' understanding of the terms soft and hard law and categorises the standards dealt with in this thesis under either heading (Chapter III, 1.1 and 1.2). Aiming to still better understand the next sections discuss the degree to which standards concerned with questions of bioethical interest are binding and enforceable, how they differ in terms of impact, style and effect (Chapter III, 2).

Chapter IV then introduces the legal standards in the area of bioethics and its legal and non-legal precursors. It thus first provides an overview of legal and non-legal precursors that together paved the way for some of the current international legal standards in the area of bioethics (Chapter IV, 1). This is followed by an introduction to the Council of Europe's Oviedo Convention³⁰, the first binding international or rather regional standard in the area of bioethics as well as to the additional protocols to this Convention³¹ (Chapter IV, 2.1) and by a discussion of UNESCO's

fractions of the wider range of issues that could potentially be dealt with under the heading of bioethics. The expressions "issues of bioethical concerns" or "issues of bioethical relevance" therefore recognize that the field of bioethics is much wider than the scope of international legal standards in the area. Ethical issues related to biomedicine, according to this broad definition, then also form one part of the wider scope of issues that can be addressed under the heading bioethics, while in reverse the field bioethics cannot be limited to ethical questions arising in relation to biomedicine only. In that sense it is coherent and correct for this thesis to refer to a "standard directly addressed to questions of bioethical relevance" when referring to the Oviedo Convention, note 5, one of the standards discussed in more detail in this thesis, which is formally only addressed to 'biomedicine'.

³⁰ Oviedo Convention, note 5.

³¹ Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings, ETS No.168, 1998 (hereinafter Additional Protocol on the Prohibition of Cloning Human Beings). Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin, ETS No.186, 2002 (hereinafter Additional Protocol concerning Transplantation of

standards in the area of bioethics, in particular the UNESCO Declaration on the Human Genome and Human Rights³², the Declaration on Human Genetic Data³³ and the Universal Declaration of Bioethics and Human Rights³⁴ (Chapter IV, 2.3). The United Nations Declaration on Human Cloning³⁵ as one further example of an international legal standard that is directly concerned with a question of bioethical relevance and that has been elaborated by yet another international organisation is also presented in this chapter (Chapter IV, 3.1). In the final part of this chapter, the WTO's TRIPS agreement³⁶ will be discussed as an example of an organisation and its standard that does not, at least not by its title, directly concern questions of bioethical relevance but that still has considerable influence on how some matters of bioethical relevance are ultimately resolved at the international level (Chapter IV, 3.2). In concluding this first introduction to how law and bioethics intersect at the international level the chapter also addresses the question of the extent to which issues of bioethical interest are already covered by norms of customary international law and general principles of international law (Chapter IV, 3.3).³⁷

As chapter IV more describes than analyses or compares standards relevant to the presently examined discourse chapter V discusses some of the shared characteristics of the international legal standards specifically directed to issues of bioethical relevance. Chapter V therefore starts with a discussion of one particularly noteworthy characteristic that can be found across all standards directly addressed to matters of bioethical interest, which is that they all use the same conceptual framework, i.e. human rights, through which they address issues of bioethical interest (Chapter V, 1). Having established the standards' affinity to human rights, chapter V then states some of the aims specified in the standards, including in particular their aim to promote respect for human dignity and to protect human rights (Chapter V, 2.1). The chapter's next subsection goes on to discuss some of the bioethical principles that are regularly promulgated in the standards, including for example the preservation of human dignity, the primacy of the human being over the sole interest of science and society and that biomedical activities should not harm patients or research subjects (Chapter V, 2.2). In the final section of this chapter the delimitations of and relationship between human rights on the one hand and the bioethical principles on the other are further analysed, showing that bioethical principles operate within a human rights framework and,

Organs and Tissues of Human Origin); Additional Protocol to the Convention on Human Rights and Biomedicine concerning Biomedical Research, ETS No.195, 2005 (hereinafter Additional Protocol concerning Biomedical Research); Additional Protocol to the Convention on Human Rights and Biomedicine concerning Genetic Testing for Health Purposes, CETS No.: 203 - not yet entered into force (hereinafter Additional Protocol on Genetic Testing).

³² Universal Declaration on the Human Genome, note 4.

³³ Universal Declaration on the Human Genetic Data, note 4.

³⁴ UDBHR, note 4.

³⁵ United Nations Declaration on Human Cloning, GA A/Res/59/280, 2005 (hereinafter UN Declaration on Human Cloning).

³⁶ TRIPS Agreement, note 3, 81.

³⁷ Given the limited scope of this work this thesis cannot analyse all relevant legal instruments in the area of bioethics but has to focus on some selected standards in the field.

as long as they do not conflict with human rights, complement or further specify these rights (Chapter V, 3).

Having set the groundwork for the analysis of the implications of legal discourses in the area of bioethics Part III moves on to the actual analysis of the implications for bioethical debates. To that extend chapter VI further elaborates and defines the structure and epistemological grid-points of the presently examined discourse. In order to do so this chapter first embeds the standards in the area of bioethics in their wider human rights framework and, more specifically, in the traditions, socio-historical roots and philosophical underpinnings of human rights philosophy, in particular liberal and enlightenment traditions of thought, and natural rights ideas and philosophies as relevant to the human rights project (Chapter VI, 1). The assumption is that much of the structure or episteme through which human rights are taught and analysed have been growing historically and can only be fully understood if read against that backdrop. Having discussed the background to and roots of human rights the thesis briefly considers how these traditions live on in modern human rights law through forming part of the human rights *nomos*³⁸, i.e. human rights' normative universe or the narratives that locate human rights (Chapter VI, 2.1). In the final section of this chapter several selected major epistemological grid points, constitutive of and important to a human rights discourse generally and to the one taking place in the area of bioethics in particular, are singled out and their meaning and scope is explained (Chapter VI, 2.2). First, the discourse uses a language of rights or principles and the subsection reflects on modern notions of rights and principles as far as relevant to a human rights discourse (Chapter VI, 2.2.1). Second, the role of human dignity as used in a human rights discourse needs further clarification (Chapter VI, 2.2.2). Third, the discourse uses the concept of sovereignty which also warrants further conceptual clarification (Chapter VI, 2.2.3). Fourth, the standards' references to notions of 'universal validity' are more closely examined (Chapter VI, 2.2.4). Finally, the standards in the area of bioethics heavily rely on the principle of autonomy, a concept that in its modern day form also needs some further reflection (Chapter VI, 2.2.5).

Having established the properties and nature of the legal discourse that operates in the area of bioethics as well as having explained and characterised the grid points that operate in this discourse chapter VII then turns to a discussion of the implications of approaching issues of bioethical relevance through this discourse. It starts off by analysing implications of framing bioethically relevant issues in a framework of rights or principles. Among other implications it shows that rights or principles can sometimes be too rigid and simplistic to be really helpful, too indeterminate or conflicting with other rights to regulate much at all, and that excessive use of "rights talk" can make the use of rights or legal language generally ineffective (Chapter VII, 1). The second section deals with the implications of framing bioethical issues in standards that assign a strong role to the concept of human dignity, showing in particular that the lack of a clear definition

³⁸ On the term *nomos* see R. Cover, "Nomos and Narrative", in: M. Minow/A. Sadt et al., *Narrative, Violence and the Law: The Essays of Robert Cover*, 1995, 95 et seq.

of the concept of human dignity makes it difficult to determine who the bearer of that dignity is, what actions are in conformity with dignity and what role the state has vis-à-vis the protection of human dignity (Chapter VII, 2). The next section discusses implications of framing bioethical debate in a state centric framework. In particular this thesis shows that standards, because all states have to agree to these standards and cannot be bound against their will, are destined to result either in minimum consensus, vague formulas, or non or only partial regulation or that they often de facto hide several forms of hegemony, meaning that either more powerful states effectively dictate the outcome of negotiations or that negotiations are moved to forums in which certain states can exert greater powers (Chapter VII, 3). That the discourse to some extent invokes notions of universal validity of human rights also has several implications that are discussed in the fourth section, including that it is not quite clear what is actually meant by referring to the notion of universality, that it can be difficult to actually justify human rights' claim to universality and that it can sometimes conflict with the value of diversity (Chapter VII, 4). The final section deals with implications that flow from using the concept of autonomy in bioethical debates, showing in particular that the requirements of 'informed consent' and how they have or can be operationalised in day-to-day medical practice can be difficult and sometimes impossible to meet, that some demands of autonomy might be incompatible with human nature, and questioning whether patients should be forced to execute their autonomy even if doing so is against their wish (Chapter VII, 5).

The final and concluding chapter of this thesis evaluates, to the extent possible, whether engaging in the type of discourse discussed here is at all a valuable enterprise. In that respect this chapter first shows some of the difficulties that arise if an empirical attempt is being made to assess the success of international legal standards directed to issues of bioethical relevance (Chapter VIII, 1). Concluding that a quantitative assessment does not say much about the actual success of standards and that a qualitative analysis is well beyond the scope of this project the remainder of this chapter offers some general reflections on the success of the standards. It shows that each of the aims stated in the standards needs further specification for an analysis of its success to become meaningful and makes some observations regarding the usefulness of international law and international human rights law in addressing questions of bioethical relevance (Chapter VIII, 2).

Delimitations

As with any work of such a scope several delimitations should be noted. For one, as stated before, it is not possible to treat the material exhaustively. This thesis certainly cannot claim to discuss all possible implications of legal discourse nor can it claim to deliver an ultimate account of discourse in the area of bioethics. Quite besides the fact that discourses are constantly changing and contested so that in effect also the implications of using a discourse are in constant flux such an enterprise would go beyond the limits of this thesis.

Secondly, as practical as the subject that is addressed in this thesis is, the bulk of this thesis' analysis and its major contribution is on a theoretical not an empirical level. It does not so much try to understand state practice of human rights in the area of bioethics or deal with specific bioethical problems. Rather, this thesis is about uncovering a structure that determines outcomes. Working at a high level of abstraction is thereby necessary. Nevertheless, high levels of abstraction come at a price. In this case the price to pay is that of being somewhat further removed from the specific, challenging and interesting problems that questions of bioethical relevance pose.

Finally, for all its evaluation this thesis is not about determining whether legal approaches to questions of bioethical interest are right or wrong from a moral or ethical point of view. It is mostly concerned with how a certain structure causes certain outcomes and only to a very limited extent with the evaluation of this structure.

Part I:
Clarification of Terms

Chapter I An Introduction to the Field of Bioethics

Bioethics has become a rather fashionable term in recent philosophical, legal, political, scientific and other literature, often with no or little defined content. This chapter discusses the meanings and scope of the term as is relevant to this thesis.

1. Definitions of Bioethics

In its broadest sense bioethics is the subfield of ethics that investigates all ethical issues arising in the life sciences³⁹, including most prominently medicine, biomedicine, health care and biology.⁴⁰

The term has, however, never been uniformly or terminally defined. Etymologically it roots in the Greek words of *bios* – meaning life – and *ethike* – meaning ethics.⁴¹ As a neologism it was apparently first employed by the biologist Van Rensselaer Potter who used the term to refer by it to a new discipline which would build a bridge between the sciences and humanities and that was devoted to human survival and an improved quality of life.⁴² Shortly afterwards, however, the term was also used in a somewhat different sense by André Hellegers, one of the founders of the Kennedy Institute of Human Reproduction and Bioethics at Georgetown University. In contrast to Van Potters' broad vision of bioethics, Hellegers used the term more narrowly, referring by it to the ethics of medicine and biomedical research only.⁴³

The division and debate that already surrounded the term's inception is symptomatic for its subsequent development and current uses.⁴⁴ Today varying definitions coexist that all include or exclude, and emphasise or minimize slightly different and sometimes more and sometimes less related aspects of what seems to be a diffuse and vast subject field. For example, the *Encyclopaedia of Bioethics* defines bioethics as the “systematic study of the moral dimensions – including moral vision, decision, conduct and policies – of the life sciences and health care, employing a variety of ethical methodologies in an interdisciplinary setting.”⁴⁵ The International Association of Bioethics again somewhat more narrowly understands bioethics to be the “study of ethical, social, legal,

³⁹ The term “life sciences” does not have a fixed meaning. See text in note 8.

⁴⁰ See the definition in Audi, note 9, 439.

⁴¹ R. Gillion, “Bioethics, Overview”, in: R. Chadwick (ed.), *The Concise Encyclopedia of the Ethics of the New Technologies*, 2001, 2, 2.

⁴² Potter's definition reads as follows: “Biology combined with diverse humanistic knowledge forging a science that sets a system of medical and environmental priorities for acceptable survival.” This is printed on the cover of V. Potter, *Global Bioethics: Building on the Leopold Legacy*, 1988; see also V. Potter, *Bioethics. Bridge to the Future*, 1971, 66; for further background see K. Kuhse/P. Singer, “What is Bioethics? A Historical Introduction”, in: K. Kuhse/P. Singer (eds.), *A Companion to Bioethics*, 2001, 3, 4 et seq. or H. Kuhse/P. Singer, “Introduction”, in: H. Kuhse/P. Singer (eds.), *Bioethics. An Anthology*, 2006, 1, 1-3.

⁴³ R. Gillion, “Bioethics, Overview”, in: R. Chadwick/D. Callahan/P. Singer (eds.), *Encyclopaedia of Applied Ethics*, 1998, 305, 306.

⁴⁴ *Ibid.*, 306.

⁴⁵ W. Reich (ed.), *Encyclopaedia of Bioethics*, 1995, xxi.

philosophical and related issues arising in health care and the biological sciences.”⁴⁶ And with a more practical and policy oriented focus the UNESCO defines bioethics as “ethical issues related to medicine, life sciences and associated technologies as applied to human beings, taking into account their social, legal and environmental dimensions.”⁴⁷ In addition to these sample definitions there exists a variety of further definitions or conceptualisations of the term bioethics in the vast philosophical, legal, religious, political and other literature on bioethics.⁴⁸

The sheer numbers and ramifications of these definitions make prospects of formulating one terminal and neat definition of bioethics elusive. It is, however, possible to discern from these definitions some common characteristics of the field. This will be done once bioethics' origins and major foundations have been analysed in the next section.

2. Origins of Bioethics

Bioethics is conventionally said to have two origins, one lying in medical ethics and one in moral philosophy.

2.1. Medical Ethics

Medical ethics is commonly understood as all considerations about ethical implications of and within medical practice, dealing with questions of ethics⁴⁹ as they arise with regard to, for example, the diagnosis and treatment of disease, health promotion and disease prevention, the relief of pain and suffering, and the care of the ill.⁵⁰ Based on that understanding medical ethics has existed since the dawn of human history given that it can be assumed that all societies knew and know

⁴⁶ Constitution of the International Association of Bioethics, 1992, Article 2, at: <http://bioethics-international.org/iab-2.0/index.php?show=constitution> (last visited 27.04.2012).

⁴⁷ UDBHR, note 4.

⁴⁸ It should be noted, however, that many books and articles and even some encyclopaedias on bioethics, philosophy or applied ethics stop short of formulating one definition of the term bioethics. Rather, they offer some general reflections on the history of bioethics, followed by several chapters on specific issues of bioethical relevance, such as abortion, euthanasia, genetics, etc. See for example B. Steinbock, *The Oxford Handbook of Bioethics*, 2007; N. Jecker/A. Jonsen/R. Pearlman (eds.), *Bioethics. An Introduction to the History, Methods and Practice*, 1997; or W. Korff/L. Beck/P. Mikat (eds.), *Lexikon der Bioethik*, 2002.

⁴⁹ There are numerous ways of defining the terms "ethics" and "morality". For sake of clarity this thesis will distinguish between both terms in the following way: Morality is used to refer to a code of conduct put forward by a society or some other group, such as a religion, or a code of conduct accepted by an individual for his or her own behaviour. Ethics, in contrast, then is the science of morality. It involves systematising, defending, and recommending concepts of right and wrong behaviour and thus must be allocated one level 'above' moral considerations in the sense of that it validates, evaluates and tests moral codes. See J. Nida-Rümelin, "Theoretische und Angewandte Ethik: Paradigmen, Begründungen, Bereiche", in: J. Nida-Rümelin (ed.), *Angewandte Ethik. Die Bereichsethiken und ihre theoretische Fundierung. Ein Handbuch*, 2005, 2, 3 et seq.

⁵⁰ For background see M. Schöne-Seifert, "Medizinethik", in: J. Nida-Rümelin (ed.), *Angewandte Ethik. Die Bereichsethiken und ihre theoretische Fundierung. Ein Handbuch*, 2005, 552 et seq. It should be noted that 'medical ethics' itself, in the same way as bioethics, is not a static term. Rather its meanings and principal concerns have and continue to shift over time, place, and cultural, political and economic context. See J. Horner, "Medical Ethics, History of", in: R. Chadwick/D. Callahan/P. Singer (eds.), *Encyclopaedia of Applied Ethics*, 1998, 165 et seq.

values to direct the provision of health care by such persons as shamans, midwives, priests, physicians, nurses and doctors.⁵¹

Although bioethics to a large degree is equally concerned with these issues, it may not simply be equated with or reduced to medical ethics. Rather, bioethics is much wider than medical ethics. It emerged along with a variety of other branches of applied ethics, including for example clinical ethics,⁵² health care ethics,⁵³ and research ethics⁵⁴ in response to some of the revolutionary and fast paced scientific and technological discoveries and to some of the more general political and social developments that together unsettled the field of medical ethics from the 1940s onwards.⁵⁵ For example, the Nuremberg Doctors Trial of 1946/47⁵⁶ that revealed the horrifying details of Nazi physician involvement in human experimentation and, several years later, the incidents described in the Beecher report⁵⁷, revealing among other things that black men in Tuskegee (Alabama/USA) were not treated of syphilis to overview the “natural history of syphilis”, made apparent the lack of ethical guidelines in such fields as medical experimentation on human subjects. The discovery of the double helical structure of the DNA molecule in 1953 again opened the floodgates to a stream of scientific advances around such issues as biological organisms, gene defects, and gene modifications, thereby raising questions about the desirability of positive eugenics or the possibility of the creation of new life forms.⁵⁸ Further discoveries in bacteriology, physiology and pathology also dramatically improved the ability of physicians to diagnose and treat their patients which then again raised difficult questions concerning the use of these new powers.⁵⁹ In the same way did technical innovations, such as the invention of the dialysis machine, open up so far unknown treatment options in the area of life-extending measures, thereby raising fundamental

⁵¹ See V. Nutton, "The Rise of Medicine", in: R. Porter (ed.), *The Cambridge History of Medicine*, 2006, 46, 50. Famous examples of such codes of ethical reflections in earlier societies are the Hippocratic Oath, commonly dated to around 400 BC, the Code of Hammurabi, Vedic and Sanskrit texts, such as Caraka Samhita and Susruta Samhita, and in writings of Chinese philosophers. See generally E. Keyserlingk, "Medical Codes and Oathes", in: R. Chadwick/D. Callahan/P. Singer (eds.), *Encyclopaedia of Applied Ethics*, 1998, 155 et seq.

⁵² Clinical ethics generally focus on hospital case decisions that are made with or without the help of ethics committees or review boards. Clinical medicine thereby is the field of activities that concerns the study of disease by direct examination of or interaction with the living patient. A. Jonsen/M. Siegler/W. Winslade, *Clinical Ethics. A Practical Approach to Ethical Decisions in Clinical Medicine*, 2002, 1.

⁵³ Health care ethics generally focus on issues of access to health care, health care financing systems, rationing, and resource allocation. See R. Ashcroft, "Health Technology Assessment", in: R. Chadwick/D. Callahan/P. Singer (eds.), *Encyclopaedia of Applied Ethics*, 1998, 235, 235–236.

⁵⁴ Research ethics focus on questions related to proper and ethically conducted research. See D. Elliott/J. Stern (eds.), *Research Ethics. A Reader*, 1997, 2.

⁵⁵ See Gillion, Bioethics, Overview, in: R. Chadwick/D. Callahan/P. Singer (eds.), *Encyclopaedia of Applied Ethics*, note 43, 307.

⁵⁶ The proceedings are reported in the Trial of the Major War Criminals before the International Military Tribunal, Nuremberg, 1945, UNTS 82 (hereinafter TMWC).

⁵⁷ H. Beecher, "Ethics in Clinical Research", 274 *New England Journal of Medicine*, 1973, 1354 et seq.; See also United States Department of Health, Education, and Welfare, *Final Report of the Tuskegee Syphilis Study Ad Hoc Advisory Panel*, 1973.

⁵⁸ Jonsen, note 11, 2; J. Watson/F. Crick, "Molecular Structure of Nucleic Acids. A Structure for Deoxyribose Nucleic Acid", 171 *Nature*, 1953, 737 et seq.

⁵⁹ Jonsen, note 11, 5. See also J. Nida-Rümelin, "Ethik des Risikos", in: J. Nida-Rümelin (ed.), *Angewandte Ethik. Die Bereichsethiken und ihre theoretische Fundierung. Ein Handbuch*, 2005, 806 et seq.

questions about, for example, the ethical limits of such treatment.⁶⁰ A final event noteworthy in that context is the still ongoing phenomenon of 'globalisation'.⁶¹ From the 1960s onwards in particular the increasing interconnectedness of global markets that also had an effect on pharmacological and other industries related to medicine as well as better means of world wide communication began to affect medical practice ever more strongly by e.g. facilitating worldwide access to medical plants, thereby raising questions about the ethics of patenting of certain plants, or about a just worldwide distribution of scarce medical resources.⁶²

Together these factors fundamentally changed the face of medical ethics and ultimately made it necessary to restate the field's traditional boundaries. Bioethics and a host of other fields of ethics, mentioned above, quickly emerged to fill the gap. If anywhere, bioethics contrasts with these other fields and with its parent field medical ethics by its specific focus on the ethics of biomedicine⁶³, biomedical research⁶⁴ and biotechnology.⁶⁵ Since, however, also these terms lack a fixed meaning and since all of the newly emerging areas of ethics developed rather unstructured, filling gaps haphazardly and responding to needs as they emerged, they often considerably overlap among each other as well as with medical ethics.⁶⁶ Any attempt to clearly demarcate them from one another and from medical ethics is therefore to some extent artificial.⁶⁷

⁶⁰ Jonsen, note 11, 4; see also J. Dolgin/L. Shepherd, *Bioethics and the Law*, 2005, 5-6.

⁶¹ For a compendium of several definitions of the term see J. Baylis/S. Smith (eds.), *The Globalization of World Politics. An Introduction to International Relations*, 1997, 15. Despite the multitude of definitions and theories associated with the term "globalisation", for many scholars the term seems to be associated with a development where "impersonal economic and technological forces are growing ever more important ... [and] ultimately appear to outstrip the capacity of national governments or citizens to control, contest or resist that change." D. Held/A. McGrew/D. Goldblatt/J. Perraton, *Global Transformations*, 1997, 1.

⁶² On the issue of patents and their role in access to medicine see for example UNCTAD, *Resource Book on TRIPS and Development: An Authoritative and Practical Guide to the TRIPS Agreement*, 2005, Part 2.

⁶³ To date, as was the case with the term bioethics, there exists no one authoritative definition of the term biomedicine. W. Dorland, *Dorland's Illustrated Medical Dictionary*, 2003, 30, for example defines biomedicine as "clinical medicine based on the principles of the natural sciences (biology, biochemistry, biophysics, etc.)" but for a broader discussion of the term's scope see the Council of Europe Steering Committee on Bioethics' Preparatory Work of the European Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine, CDBI/INF 1, 2000, iv et seq. and the discussion of the term in C. Hagedorn, *Strategien der Dissensbewältigung. Ein Internationaler Vergleich von Rechtsetzungsverfahren im Bereich der Biomedizin*, (forthcoming dissertation), chapter 1.

⁶⁴ Biomedical research is generally understood to be concerned with research around biological and physiological processes. Cf. A. Plomer, *The Law and Ethics of Medical Research*, 2005, xv, but see discussion of the term 'biomedicine' in note 63 above.

⁶⁵ Biotechnology is generally understood as any technique that is used to make or modify products of living organisms in order to improve plants, animals or human beings or to generate unique organisms with new traits or organisms that have the potential to produce specific products. M. Reiss, "Biotechnology", in: R. Chadwick/D. Callahan/P. Singer (eds.), *Encyclopaedia of Applied Ethics*, 1998, 319, 319-320; for background see F. Francioni (ed.), *Biotechnology and International Law*, 2006.

⁶⁶ M. Grodin (ed.), *Meta Medical Ethics: The Philosophical Foundations of Bioethics*, 1995, 7 et seq.; see also Nida-Rümelin, *Theoretische und angewandte Ethik*, note 491, 64 et seq. and J. Nida-Rümelin, "Wert des Lebens", in: J. Nida-Rümelin, *Angewandte Ethik. Die Bereichsethiken und ihre theoretische Fundierung. Ein Handbuch*, 2005, 886 et seq.

⁶⁷ In the context of this thesis a distinction will therefore only be drawn where such a differentiation helps clarify the issues at stake.

Overall, it may be safe to conclude that medical ethics constitute one principal origin of bioethics as well as that medical ethics' concerns often lie at the heart of bioethical considerations. Bioethics is, however, wider in scope than medical ethics as it not only incorporates medical ethics' concern with all ethical implications of and within medical practice but also includes such a broader range of subject fields as ecology, patient rights and environmental considerations.

2.2. Moral Philosophy

The second origin of bioethics is moral philosophy.⁶⁸ Moral philosophy is conventionally understood as the branch of philosophy that is concerned with the systematising, defending, and recommending of concepts of right and wrong behaviour and the study of values and customs as well as the employment and application of concepts such as right and wrong, good and evil.⁶⁹ The field is customarily divided in two parts: Meta-ethics and normative ethics, with the latter being again divided into normative theory and applied ethics. While meta-ethics is the analysis of the meaning and justification of ethical claims and the quest to understand the nature and properties of ethical statements and claims, seeking to answer such questions as “what is justice” or “what is time” or “what is good”, normative ethics pertains to the development of theories that systematically denominate right and wrong actions. Normative ethics therefore deals with the general principles, rules and guidelines that should be followed or the virtues that should be adopted and fostered. Applied ethics again is commonly understood as the attempt to implement either general ethical norms or general ethical theories with the aim of resolving specific practical problems.⁷⁰

The field of bioethics is usually classified as forming part of applied ethics. It qualifies as such because it is generally concerned with the study of ethical and moral issues that arise in the context of real and concrete activity, such as in the making of active decisions on whether or not to apply life-extending measures to a patient or in considerations surrounding such issues as removal or allocation of transplant organs.⁷¹ Moral philosophy's mounting interest in matters of bioethics must be understood in the context of some of the scientific and social developments, already mentioned above, that took place from the 1940s onwards.⁷² Particularly, the extraordinary technological progress of the 1950s and 60s, while opening up the opportunity for great medical benefit to thousands of people, also led to many critical ethical questions, such as the appropriateness of a “quality of life analysis”, or “expense analysis approaches” in the practice of

⁶⁸ The terms “moral philosophy” and “ethics” are used synonymously in the context of this thesis.

⁶⁹ R. Norman, “Moral Philosophy, History of”, in: T. Honderich (ed.), *The Oxford Companion to Philosophy*, 2005, 622 et seq.; for background see Nida-Rümelin, *Theoretische und angewandte Ethik: Paradigmen, Begründungen, Bereiche*, note 49, 3 et seq.

⁷⁰ See S. Darwall, “Theories of Ethics”, in: R. Frey/C. Wellman (eds.), *A Companion to Applied Ethics*, 2005, Blackwell Reference Online (last visited 27.04.2012); see also Nida-Rümelin, *Theoretische und angewandte Ethik: Paradigmen, Begründungen, Bereiche*, note 49, 2.

⁷¹ M. Battin, “Bioethics”, in: R. Frey/C. Wellman (eds.), *A Companion to Applied Ethics*, 2003, 295, 295-296.

⁷² See also UNESCO, International Bioethics Committee of UNESCO, 12th session, note 28.

medicine and allocation of resources.⁷³ These questions, touching upon many of moral philosophers' primary areas of concern, i.e. on questions regarding the worth and meaning of life, consequently sparked these philosophers' interest also in the wider field of bioethics. The gradual awakening to environmental hazards in the 1960s equally called for moral philosophical reflections on such questions as how to assume responsibility vis-à-vis rapidly developing technologies.⁷⁴ Finally, the advent of the civil rights movement and the resurgence of the feminist movement in the 1960s with their renewed questioning of patterns of discrimination and unfair standards of equality proved stimulating for moral philosophers' reflections – an enterprise that was soon extended into the bioethical field.⁷⁵ As a result of all these factors, moral philosophers increasingly began to turn to the difficult and seemingly new⁷⁶ moral concerns in the field of bioethics.

Until today bioethics remains heavily indebted to moral philosophy and its methodological approach.⁷⁷ The latter thereby stands for an approach that aims to resolve bioethical questions by applying, defending and recommending theories and concepts of right or wrong.⁷⁸ Different conceptions of how to derive or the content of "right" or "wrong" can thereby be distinguished, including utilitarian approaches,⁷⁹ absolute rules based approaches,⁸⁰ principled based approaches⁸¹ or virtue ethics.⁸² These approaches, i.e. their theoretical underpinnings have differing ideas about what conduct, action or motivation might qualify as right (ethically valuable)

⁷³ Jonsen, note 11, 5.

⁷⁴ Gillion, Bioethics, Overview, in: R. Chadwick/D. Callahan/P. Singer (eds.), *Encyclopaedia of Applied Ethics*, note 43, 310. Grodin, note 67, 6.

⁷⁵ Grodin, note 66, 5.

⁷⁶ On the question of whether bioethics constitutes something 'new' see discussion in section 1.3.3 in this chapter. See also J. Nida-Rümelin, Freiheit und Kausalität, Tonband-Mitschrift der frei gehaltenen Akademievorlesung am 12. April 2007 an der Berlin-Brandenburgischen Akademie der Wissenschaften, at: http://www.nida-ruemelin.de/cms/wp-content/uploads/downloads/2010/11/jnr_freiheit_kausa.pdf (last visited 27.04.2012).

⁷⁷ J. Harris (ed.), *Bioethics. Oxford Readings in Philosophy*, 2004, 4. On the question of the role of philosophy in the area of bioethics see J. Nida-Rümelin, "Bioethik und Menschenwürde: Dokumentation einer Debatte", in: J. Nida-Rümelin, *Ethische Essays*, 2002, 401, 409 et seq.; Nida-Rümelin, Theoretische und Angewandte Ethik: Paradigmen, Begründungen, Bereiche, note 49, 2 and J. Nida-Rümelin, „Der Ethische Diskurs in der Modernen Medizin“, Vortrag im Max-Delbrück-Zentrum für Molekulare Medizin, MDC, Berlin, 2003, at: <http://www.bioethikdiskurs.de/Buergerkonferenz/Vortraege/KummerRuemelin.html/Vortrag%20Nida-Ruemelin%20offiziell.pdf/view> (last visited 27.04.2012).

⁷⁸ Cf. footnote 7.

⁷⁹ Jeremy Bentham and John Stuart Mill are among the most prominent representatives of this approach; see J. Mill, *Utilitarianism*, 1881; J. Bentham, *The Principles of Morals and Legislation*, 1789; for background see R. Hare, "A Utilitarian Approach", in: H. Kuhse/P. Singer (eds.), *A Companion to Bioethics*, 2001, 80 et seq.; and for a critique see J. Nida-Rümelin, *Kritik des Konsequentialismus*, 1993.

⁸⁰ J. Boyle, "An Absolute Rule Approach", in: H. Kuhse/P. Singer (eds.), *A Companion to Bioethics*, 2001, 72 et seq.; for further background see J. Finnis, *Moral Absolutes: Tradition, Revision and Truth*, 1991.

⁸¹ The probably most famous book on principled approaches to bioethics has been written by T. Beauchamp/J. Childress, *Principles of Biomedical Ethics*, 2001; For a summary see J. Childress, "A Principle-based Approach", in: H. Kuhse/P. Singer (eds.), *A Companion to Bioethics*, 2001, 61 et seq.; for other principled approaches see W. Solomon, "Rules and Principles", in: W. Reich (ed.), *Encyclopaedia of Bioethics*, 1995, 470 et seq.

⁸² J. Oakley, "A Virtue Ethics Approach", in: H. Kuhse/P. Singer (eds.), *A Companion to Bioethics*, 2001, 86 et seq.

or wrong (ethically dismissible). Despite much debate as to the superiority of one of these approaches so far none of them has yet been acquired authority over all others.⁸³

3. Themes in the Field of Bioethics

Besides its ties with medical ethics and moral philosophy, several common characteristics of the field of bioethics may be made out.

3.1. Interdisciplinarity

For one, while moral philosophy and medical ethics certainly assume a fundamental role in the development and analysis of the field of bioethics it should be noted that bioethics has never been a mere crossing of these two fields. Rather it is a complex interplay of various different disciplines including the disciplines of philosophy, law, religion, political science, anthropology, sociology, economics, humanities and many others.⁸⁴ As regards law, for example, the bioethical debate has long found its way into court rooms and legislative processes, lawyers sit in ethics committees or hospital review boards, while ethicists, conversely, help elaborate legal regulations in the field.⁸⁵ That bioethics has to be dealt with on a public policy level is evident from e.g. ongoing discussions about how best to restructure public health care systems in several countries around the world.⁸⁶ And with regard to religions, bioethics has long been part of religious debates that have traditionally been interested in questions of life and death or the good life.⁸⁷ At the national level considerations of religious beliefs or sentiments, on the other hand, have long been incorporated in bioethical debates and often into their legislative, political or policy extensions, for example when it comes to such issues as abortion, euthanasia and genetic manipulation.⁸⁸ Even if at the international level bioethically relevant questions can never be left to the realm of one or another sectarian religion, religious considerations clearly still matter when it comes to negotiating provisions of legal instruments, including for example when it comes to such issues as human cloning, stem cell research or organ transplantation.⁸⁹

⁸³ G. Kuhse, *Bioethics: A Philosophical Overview*, 2004, 2. M. Spranger, *Recht und Bioethik*, 2010, introduction.

⁸⁴ Battin, note 71, 231. See also G. Kaebnick, "Normative Slogging", 39 *Hastings Center Report*, 2009, 2 et seq.

⁸⁵ See van der Burg, note 13.

⁸⁶ See for example P. Watson, *Health Care Reform and Globalisation: the US, China, and Europe in Comparative Perspective*, 2012; M. Kerleau/N. Pelletier-Fleury, "Restructuring of the Healthcare System and the Diffusion of Telemedicine", 3 *The European Journal of Health Economics*, 2002, 207 et seq.

⁸⁷ B. Brody, "Religion and Bioethics", in: H. Kuhse/P. Singer (eds.), *A Companion to Bioethics*, 2001, 41 et seq.

⁸⁸ Brody, Religion and Bioethics, note 87, 44.; and A. Kuhlmann, "Der Embryo als öffentliches Gut: Alte und Neue Kontroversen", in: A. Kuhlmann, *An den Grenzen unserer Lebensform: Texte zur Bioethik und zur Anthropologie*, 2010, 77 et seq. Battin, note 71, 305, noting, however, a diminishing influence of religions on the field of bioethics.

⁸⁹ As an example for an area in which religiously charged arguments at least still shine through states' arguments see states' explanation of the voting with regard to the United Nations Declaration on Human Cloning, note 35, 2005, at: <http://www.un.org/News/Press/docs/2005/ga10333.doc.htm> (last visited 27.04.2012).

All of these disciplines and their methodological approaches are thus relevant to the field of bioethics. Together they constantly shape and further develop the field of bioethics. This trend is also likely to stay: No discipline so far can claim a monopoly on bioethics.⁹⁰ Also, there exists no unified professional group of “bioethicists” with their own permanent careers and distinctive (or consistent) professional ethos.⁹¹ Hence everyone – no matter from which disciplinary background – may declare him- or herself to be a 'bioethicist' and thus may take part in the field's development.⁹² It therefore seems that interdisciplinarity will remain one pronounced and important characteristic of bioethics.

3.2. Fast-moving Character and the Problem of Dissent

A second characteristic of bioethics is its fast-moving character. Bioethics, as discussed above is intimately linked with scientific and technological progress, in that it is concerned with the applications and the moral or ethical implications of this progress in real life situations.⁹³ The faster the progress and the bigger its implications from a moral or ethical point of view the more it then also affects the field of bioethics. But fast progress not only implies that bioethicists constantly have to face up to ever new challenging questions. It also means that many of the answers already delivered in response to such questions might rather sooner than later lose their topicality and need to be revised.⁹⁴ This is true as much for single decisions taken at the patient's bedside as it is for those taken on a public policy or legal level.

For example, the scientific community several years ago considered it rather unlikely that embryonic stem cells could be produced without the destruction of embryos.⁹⁵ It also repeatedly maintained that the successful cloning of mammals was – if at all ever to happen – very unlikely to take place within the next few years.⁹⁶ Both propositions have been, at least partly, refuted by

⁹⁰ Battin, note 71, 305-306; several authors, however, argue that moral philosophy should be considered the primary discipline or approach to bioethics. See for example Harris, note 77, 4.

⁹¹ M. Hayry/T. Takala, "Do Bioethicists need Professional Ethics?", in M. Hayry/T. Takala (eds.), *Bioethics and Social Reality*, 2005, 92, 93, identifying specialised knowledge, long and intensive academic studies, organisation and self-rule within the group and ability to arrange and organise as a group the relevant studies and to participate in the recruitment of new members as signs of the emergence of a unified professional group. While some bioethicists arguably have developed one or more of these characteristics it is hard to find these standards around the world as in e.g. the 'model'-profession of 'physicians' or 'medicines'. On the role of 'experts' in the area of bioethics see J. Nida-Rümelin, "Der Ethische Diskurs in der modernen Medizin", note 77, and Vöneky, Recht, Moral und Ethik. Grundlagen und Grenzen Demokratischer Legitimation für Ethikgremien, note 15, chapter 2 III. 2.

⁹² Hayry/Takala, note 91, 93.

⁹³ Jonsen, The birth of Bioethics, note 11, 4-6.

⁹⁴ Ibid., 3.

⁹⁵ See for example S. Holm, "Going to the Roots of the Stem Cell Controversy", 16 *Bioethics*, 2002, 493, 496-97.

⁹⁶ See for example E. Winnacker, "Human Cloning from a Scientific Perspective", in: S. Vöneky/R. Wolfrum (eds.), *Human Dignity and Human Cloning*, 2004, 55, 56.

recent developments in the field of genetics.⁹⁷ Bioethicists, as much as scientists, politicians, legal professionals and in fact everyone will have to address the fundamental questions that travel in the wake of such developments.

Yet, finding adequate answers to such developments often comes with some difficulty.⁹⁸ That is so because there hardly ever exists consensus within any given society, nation, political party or any other relevant unit on the question of how to deal with such concerns.⁹⁹ This may be so because either these units have not yet had the time to develop a common position on such issues or because some bioethically relevant issues might simply be too controversial for a consensus to build. Several long-standing debates in the area of, for example, abortion or embryonic stem cell research seem to support both views.¹⁰⁰

3.3. The “special” Nature of Bioethics

Another characteristic often associated with the field of bioethics is that bioethics is often depicted as somehow 'more' special or 'more' different than other fields of ethics. The presumption seems to be that bioethically relevant questions generally form part of the most fundamental and sensitive issues individuals or societies might be confronted with and that bioethically relevant actions have the potential to influence humanity in its most profound sense.¹⁰¹

Habermas e.g. argues that bioethics stand out from other fields of ethical inquiry because some of its practices such as positive eugenics¹⁰² – if applied – make it impossible for the human species to

⁹⁷ E. Pilkington, "I am Creating Artificial Life, Declares US Gene Pioneer", in: *The Guardian*, 6 October 2007, 3; A. Viciano, "Forscher Programmieren Haut- zu Stammzellen um", in: *Der Spiegel*, 20 November 2007, 36; J. Lubbaddeh, "Stammzellforschung: Wissenschaftler klonen menschlichen Embryo aus Hautzelle", in: *Der Spiegel*, 17 January 2008; Deutsche Presse Agentur, "Therapeutisches Klonen für „Parkinson“-Mäuse", in: *Frankfurter Allgemeine Zeitung*, 25 March 2008; "Forscher schufen Mensch-Tier-Embryo", in: *Frankfurter Allgemeine Zeitung*, 2 April 2008, 9; Deutsche Presse Agentur, "Neue Hoffnung - Vielseitige Stammzellen aus Männerhoden Gewonnen", in: *Der Spiegel*, 9 October 2008; J. Lubbaddeh, "Regenerative Medizin. Die Saubere Stammzelle Rückt Näher", in: *Der Spiegel*, 26 March 2009; C. Briseño, "Stammzellen-Streit. Forscher Zanken um Vermeintliche Wunderzellen", in: *Der Spiegel*, 24 June 2010. L. Warren/P. Manos et al., "Highly Efficient Reprogramming to Pluripotency and Directed Differentiation of Human Cells with Synthetic Modified mRNA", 7 *Stem Cells*, 2010, 618 et seq.

⁹⁸ See Hagedorn, note 63, Chapter I. See also Nida-Rümelin, *Bioethik und Menschenwürde: Dokumentation einer Debatte*, note 78, 401 et seq., in particular 405 et seq. which documents some of the public debate that took place in Germany in relation to the change in the English Law regarding therapeutic cloning.

⁹⁹ Hagedorn, note 63, Chapter 1. Hagedorn in her dissertation analyses some of the implications for democratic law-giving authorities of this lack of consensus, discussing strategies of how dissent can be coped with and how legislation can be arrived at in a democratically justifiable manner even when no consensus with regard to the content of the legislation can be achieved within a society. See also Nida-Rümelin, *Bioethik und Menschenwürde: Dokumentation einer Debatte*, note 77, 364 et seq., arguing that many societies while they do not reach consensus on the content of a certain legislation know how they want to facilitate the decision making process to realise a content.

¹⁰⁰ Dissent thereby arises not only across different nations or societies, but also within the single state, and even within families, societies. H. Engelhardt, "Global Bioethics. The Collapse of Consensus", in: H. Engelhardt (ed.), *Global Bioethics*, 2006, 1, 2; see also J. Po-wah, *Cross-Cultural Perspectives on the (Im)Possibility of Global Bioethics*, 2002, 3 et seq.

¹⁰¹ See for example F. Fukuyama, *Our Posthuman Future. Consequences of the Biotechnology Revolution*, 2002, 101.

¹⁰² In this context positive eugenics should be understood as "genetic enhancements" of human beings, i.e. to use genetic engineering to improve a person's body, body functions or capacities.

live a moral life.¹⁰³ The argument is that positive eugenics affect the self-conception of the autonomous person and thus inhibit that person from being an equal subject of the mutual communications processes in society necessary for a moral life.¹⁰⁴

In the same vein argues Michael Shapiro that bioethical concerns are of an exceptional nature and that they are different from other areas of applied ethics.¹⁰⁵ According to Shapiro this is so as bioethics deals with those science technologies that fragment and reassemble life processes. While he concedes that technological revolutions are nothing new as such the intensification and possible radicalisation of this fragmentation and reassembly processes is new and radical as it is bound to result in a transformation of ourselves.¹⁰⁶

Francis Fukuyama again holds that bioethics is different as it often presents a special moral dilemma that arises from the fact that any reservation one might have about biotechnological progress needs to be tempered with a recognition of its undisputed promise.¹⁰⁷ He further argues that bioethically relevant questions dissolved “one of the most basic and traditional of distinctions, that between what is given and what is done” and hence involved playing god.¹⁰⁸ According to Fukuyama bioethics thus changes the “understandings of responsibility towards the entire humanity”¹⁰⁹ and the environment within which we live.

None of these arguments convincingly establishes that bioethical discourse is radically different or more special than discourses that take place in other fields of ethics,¹¹⁰ such as in the fields of the ethics of nuclear warfare or environmental ethics, where questions of similar scope must be addressed. Yet they reflect a general unease in dealing with many questions in the area of bioethics. That unease thereby seems to not so much stem from bioethics' otherness or in fact from any objectifiable argument about bioethics' special character. Rather it seems to arise from that

¹⁰³ J. Habermas, *Die Zukunft der Menschlichen Natur – Auf dem Weg zu einer liberalen Eugenik?*, 2001, 25. For a summary of ethical positions regarding genetic enhancement see Heilinger, "Unterwegs zum neuen Menschen?", note 11, 227 et seq.

¹⁰⁴ Ibid., 21.

¹⁰⁵ M. Shapiro, "Is Bioethics Broke? On the Idea of Ethics and Law "Catching Up" with Technology", 33 *Indiana Law Review*, 1999, 17 et seq.; M. Shapiro, "The Impact of Genetic Enhancement on Equality", 34 *Wake Forest Law Review*, 1999, 561 et seq.

¹⁰⁶ Shapiro, *The Impact of Genetic Enhancement on Equality*, note 105, 566. See also H. Murray/K. Maschke/A. Wasunna (eds.), *Performance-Enhancing Technologies in Sports. Ethical, Conceptual, and Scientific Issues*, 2009

¹⁰⁷ Fukuyama, note 101, 84.

¹⁰⁸ Ibid., 85; Fukuyama similarly claims that "bioethics is concerned with the ultimate questions of life", *ibid.*, 101. Harris, note 77, at 15-16 argues that while bioethically relevant questions might be among the oldest of mankind, still, the background to these questions had changed to such an extent, that it rendered a resolution of these questions more urgent and more difficult than before; similar thoughts are captured by for example R. Chadwick, "Playing God", 9 *Bioethics News*, 1990, 38 et seq.; J. Evans, *Playing God: Human Genetic Engineering and the Rationalization of Public Bioethical Debate*, 2002, 6 and R. Elliot, "Faking Nature", 25 *Inquiry*, 1982, 81 et seq.

¹⁰⁹ Fukuyama, note 101, 106. See also H. Jonas, *Das Prinzip Verantwortung. Versuch einer Ethik für die Technologische Zivilisation*, 1998.

¹¹⁰ Elizabeth Fenton for example criticises and refutes Jürgen Habermas' and thus others' notion of the special character of bioethical concerns in E. Fenton, "Liberal Eugenics and Human Nature – Against Habermas", 36 *Hastings Center Report*, 2006, 35 et seq.

bioethically relevant questions very often imply fundamental questions about human's nature and self-understanding, about what we, as humans, want to be, about how we want to live and about the value of life.¹¹¹ It is these fundamental questions and the deep seated emotions that they trigger that often render the resolution of bioethically relevant questions so difficult – be that justified from a rational point of view or not.

4. The Internationalisation of Bioethics

Bioethics increasingly has become relevant not only in a national but also in an international context.

4.1. The Broadening in Scope of Bioethically Relevant Topics

While the field might first have been conceptualised in the realm of medical ethics of the industrialised world, today bioethics has expanded well beyond this scope.¹¹² In particular, bioethics has amplified the range of issues it is concerned with along three axes. On the one hand it has added to its agenda many ethical questions that are predominantly relevant in the context of developing countries, including questions related to inadequate reproductive health care, poverty and certain infectious disease or generally the gross lack of health care resources.¹¹³ Secondly, also issues of particular concern to certain trans-nationally defined groups of people, such as for example the specific concerns of women, indigenous people or those inflicted with HIV/Aids now feature more prominently on bioethical agendas.¹¹⁴ And finally, bioethics has broadened its list of concerns along with new scientific developments and their implications for the medical field or society as a whole. It, for example, has to address implications of new treatment options for diseases, of new findings in the field of genetics or in the field of assisted reproduction.¹¹⁵

Bioethics has, however, not only added new issues to its list of concerns but has also broadened its perspective on already well established issues.¹¹⁶ The range of issues now no longer primarily or exclusively considered at the national but also at the international level is vast, including issues in

¹¹¹ Nida-Rümelin, *Wert des Lebens*, note 66, 886 et seq., arguing that bioethics is not characterized by a certain moral or ethical position but by its core theme and question: How to adequately treat human and non-human beings. See also J. Nida-Rümelin, "Die Anthropologische als Normativ-Ethische Frage", in: D. Ganten/V. Gerhardt/J. Heilinger/J. Nida-Rümelin (eds.), *Was ist der Mensch? (Humanprojekt)*, 2008, 197 et seq. Similarly, Vöneky, *Recht, Moral und Ethik. Grundlagen und Grenzen Demokratischer Legitimation für Ethikgremien*, note 15, Chapter 1, IV.

¹¹² Battin, note 71, 304.

¹¹³ *Ibid.*, 305; for background see also Nuffield Council of Bioethics: *The Ethics of Research Related to Healthcare in Developing Countries*, 2002, at: <http://www.nuffieldbioethics.org/go/ourwork/developingcountries/introduction> (last visited 27.04.2012).

¹¹⁴ See L. Knowles, "The Lingua Franca of Human Rights and the Rise of a Global Bioethics", 10 *Cambridge Quarterly of Healthcare Ethics*, 2001, 253 et seq.; see also attempts to protect indigenous people from genetic exploitation in C. Hamilton, "The Human Genome Diversity Project and the New Biological Imperialism", 41 *Santa Clara Law Review*, 2004, 619 et seq.

¹¹⁵ Battin, note 71, 296.

¹¹⁶ Grodin, note 66, 12.

such diverse areas as reproduction,¹¹⁷ issues of organ transplantation,¹¹⁸ and issues related to the experimentation with human subjects.¹¹⁹ It should be noted, however, that none of these issues has a strictly defined national or international dimension. Rather different aspects of these issues are relevant at different levels.¹²⁰

4.2. The Increasingly Felt Need for a Global Perspective and Approach to Bioethics

While the fact that often the same issues are addressed at a national and international level might suggest that an international approach to bioethics is redundant, several arguments indicate that some form of a global view on bioethics is necessary. For one, modern biotechnology is more and more becoming a global phenomenon in terms of research, production and trade.¹²¹ As Heiner Roetz remarks it is quickly mastered outside the traditional industrial countries and is being promoted in many parts of the world since it promises great social and economic benefit.¹²² "Restrictions in one country may quickly lead to the relocation of research to more permissive regions"¹²³ with a low degree of public information, less strict legal standards and less rigid enforcement of such standards.¹²⁴ As local partners offer their capacities to enter into joint ventures with the foreign investors, it becomes less and less clear whose standards, values and laws

¹¹⁷ For example, UN Declaration on Human Cloning, note 35, deals inter alia with reproductive cloning.

¹¹⁸ See for example Additional Protocol concerning Transplantation of Organs and Tissues of Human Origin, note 31.

¹¹⁹ See for example Additional Protocol concerning Biomedical Research, note 31.

¹²⁰ UNESCO, Report of the International Bioethics Committee of UNESCO (IBC) on social responsibility and health, 2005, at: <http://unesdoc.unesco.org/images/0018/001878/187899e.pdf> (last visited 27.04.2012).

¹²¹ H. Roetz (ed.), *Cross-Cultural Issues in Bioethics. The Example of Human Cloning*, 2006, x.

¹²² Ibid.

¹²³ Ibid.

¹²⁴ Ibid. Of course the question of whether or not a country has research-friendly laws will not be the only criteria based upon which pharmaceutical companies decide where to base their enterprise. Yet that these questions do play a role in the wider scheme of events is evidenced by that it was probably also the fear of loosing highly qualified researches to more permissive research environments that prompted the German Bundestag in 2008 to ease restrictions on stem cell research, allowing German researchers to import stem cells created before 1 May 2007, rather than only use cells existing before 2002, as the previous law prescribed. See Stammzellgesetz – StZG, note 19, and its subsequent change by the act of 14 August 2008, BGBl. 2008, 1708; see also the discussion by the Nationaler Ethikrat, "Should the Stem Cell law be amended?", 2007, at: [http://www.ethikrat.org/english/publications/Opinion Should the Stem Cell Law be amended.pdf](http://www.ethikrat.org/english/publications/Opinion%20Should%20the%20Stem%20Cell%20Law%20be%20amended.pdf) (last visited 27.04.2012); in particular the statement by Prof. Dr. Ernst-Ludwig Winnacker, "Deutsche Forschungsgemeinschaft - Stellungnahme zur Forschung mit menschlichen Stammzellen" of 3 Mai 2001, at: http://www.dfg.de/download/pdf/dfg_magazin/forschungspolitik/stammzellforschung/statement_winnacker_03_05_01.pdf (last visited 27.04.2012); and Deutsche Forschungsgemeinschaft, "Empfehlung der Deutschen Forschungsgemeinschaft zur Forschung mit Menschlichen Stammzellen" of 3 May 2001, at: http://www.dfg.de/download/pdf/dfg_magazin/forschungspolitik/stammzellforschung/empfehlungen_stammzellen_03_05_01.pdf (last visited 27.04.2012); similarly on 9 March 2009, United States President Barack Obama issued Executive Order 13505, entitled "Removing Barriers to Responsible Scientific Research Involving Human Stem Cells", a decision that was taken "to enhance America's contribution to important new discoveries and new therapies for the benefit of mankind" and hence a decision which can be interpreted as a move to prevent the US from falling behind other more research permissive regions. See Executive Order 13505, 74 Fed. Reg. 10667, 2009.

count in these transactions.¹²⁵ Besides a jurisprudentially inspired need for clarity in legal regulations, states also have a strong economic interest in exporting their own moral and legal standards. By this they prevent economical repercussions in their own country that could result from e.g. less restrictive standards in other states.¹²⁶

Also UNESCO's International Bioethics Committee (IBC)¹²⁷ in a report on the possibility of a development of a Declaration on Bioethics notes a variety of factors, such as the import and export of embryos and embryonic stem cells, organs, tissues and cells

“that have called attention to disparities between policies promulgated in the countries involved... [and that have] also raised questions about the need for harmony among the pertinent regulations in different countries.”¹²⁸

The report then goes on to list ten areas, including healthcare, genetic enhancement, gene therapy and genetic modification, research involving human subjects, and intellectual property rights, illustrating for each of these fields the nature and the range of problems “that confront us and [that] support the search for a common ground that can be the starting point for harmonizing divergent bioethical positions.”¹²⁹

Implicit in such reasoning is also one further argument in favour of a global approach to bioethics, namely that of global justice and fairness: Practices such as the undertaking of clinical trials or research surveys in poorer countries often with less strict regulations and lesser degrees of enforcement of ethical standards raise serious questions of global justice and therefore warrant a global approach.¹³⁰ Similarly, technology and investment in scientific research is expensive. Even in technologically advanced societies and countries, the effects of advances in the medical science are likely to benefit only a minority of the population.¹³¹ In global terms this divide will be even

¹²⁵ See for example M. Chang, *Ethische und Rechtliche Herausforderungen einer Globalisierten Arzneimittelprüfung. Normative Standards Klinischer Versuche an Menschen in Entwicklungsländern*, (forthcoming dissertation).

¹²⁶ Cf. discussion of England's economic interest in the abolition of slave trade in for example S. Everette, *The History of Slavery*, 1997, 135 et seq.

¹²⁷ The IBC is a body of 36 independent experts that follows progress in the life sciences and their applications in order to ensure respect for human dignity and freedom. It was created in 1993. See Statutes of the International Bioethics Committee of 7 May 1998 at: http://portal.unesco.org/shs/en/ev.php-URL_ID=1879&URL_DO=DO_TOPIC&URL_SECTION=201.html. (last visited 27.04.2012); see also below, Chapter IV, 2.3.1. and Vöneky, *Recht, Moral und Ethik. Grundlagen und Grenzen Demokratischer Legitimation für Ethikgremien*, note 15, Chapter 6 II.

¹²⁸ Report on the Possibility of Elaborating a Universal Instrument on Bioethics, SHS/EST/02/CIB-9/5 (Rev. 3), 2003 para 14.

¹²⁹ *Ibid.*, 15-26. For the area of health care the report for example notes at 17 that “while poor people have at least as much need for these medicines as everybody else, many do not have the resources to guarantee access...[] ... Our global society must face the responsibility to use science and technology to promote public health and to equalize access to healthcare and medicines. A universal instrument on bioethics can contribute to ... increase poor people's access to life-saving drugs and treatments worldwide.” For a definition of and discussion of such terms as genetic enhancement and modification see Heilinger, note 11, 224 et seq. See also B. Irrgang, “Genethik”, in J. Nida-Rümelin, *Angewandte Ethik. Die Bereichsethiken und ihre theoretische Fundierung. Ein Handbuch*, 2005, 512 et seq.

¹³⁰ Roetz, note 123, x. On international justice see J. Nida-Rümelin, “Internationale Gerechtigkeit”, in: J. Nida-Rümelin, *Philosophie und Lebensform*, 2009, 314 et seq. See also Chang, note 125, chapter I.

¹³¹ Harris, note 77, 22.

more dramatic between low-income and high-income countries.¹³² A final argument for some kind of a global approach is that modern biotechnology may really influence humanity in its most profound sense in that it could, for example, permanently alter the genetic make-up of the entire mankind.¹³³ Positive decisions of such sincerity and scope cannot or at least should not be taken by individuals, corporate groups, scientific communities or countries.¹³⁴

Thus, the world's growing interdependency coupled with the fact that bioethics raise fundamental questions about human nature and about what it means to be human clearly warrant a global perspective on bioethics.

5. Conclusion: A Working Definition of the Term Bioethics

In the context of this thesis the term bioethics then will be used to mark a discipline that incorporates an inquiry into all situations where biology, medicine, biomedicine, clinical practice, genetics, and generally the life sciences are affected. In effect, this thesis thus follows UNESCO's definition of bioethics as “ethical issues related to medicine, life sciences and associated technologies as applied to human beings, taking into account their social, legal and environmental dimensions.”¹³⁵ In their concretisation issues of bioethical relevance are then most often related to medicine and medical ethics, such as for example questions arising with respect to certain health care practices, public health systems or the treatment of certain diseases. But they may also be non-medical in the sense that they can for example include such concerns as patient rights, questions of general public welfare or ecology.

For present purposes there is no need to go beyond this admittedly rather broad definition of the term bioethics. That is so for three reasons. For one, as could be seen above, attempts to abstractly and technically demarcate the discipline's exact boundaries are likely to fail sooner or later. Bioethics has always been and remains a dynamic field that expands and develops as science, technology and medicine progresses and as, in that wake, there arise ethical questions. Given the speed of this progress, its ramifications for other disciplines and the vast array of potential ethical questions to arise in response to it, any substantially narrow or dogmatic definition of the subject matter of bioethics is likely to fail or will soon have to be amended to meet new realities. Secondly, in the present context of this thesis it is much more important to have an understanding of the nature and general character of questions arising in the field of bioethics rather than to provide specific answers to specific questions or problems of bioethical relevance. This thesis is concerned

¹³² Ibid.

¹³³ Roetz, note 123, xi. See also J. Nida-Rümelin, *Ethische Essays*, note 77, 344 et seq. on a discussion of ethics in situations of risk [Ethik des Risikos].

¹³⁴ Ibid. See also Heilinger, note 11, 223 et seq. arguing that decisions related to genetic enhancement can also have wider impacts, e.g. on groups of human beings.

¹³⁵ See UDBHR, note 4, Article 1, para 1.

with the structures in which questions of bioethical relevance are being answered and the implications of these structures for how questions of bioethical relevance are being answered. For that the general character and nature of the subject field that is being addressed in these structures matters more than the specifics of that field. Finally, as this thesis is about international legal discourse in the area of bioethics it seems reasonable to adopt UNESCO's use of the term bioethics. As will be shown below UNESCO is one of the most active and relevant actors in the field of bioethics at the international level so that it seems suitable to follow UNESCO's lead in that respect.

Having said that, in its discussions and case studies this thesis will often limit the range of issues that it will be concerned with to those issues and aspects related to the field of bioethics that are relevant or discussed at the international level and, particularly, in selected international legal instruments.¹³⁶ These are mainly issues that are related to the field of medicine and medical ethics, including for example such issues as research on human beings, organ transplantation and human cloning processes. Topics not featuring in the relevant international standards, such as certain issues in the area of reproduction, animal rights and questions on the environment¹³⁷ will be discussed only to the extent that they are relevant. For example, it might be that their absence from international legal standards is relevant to illustrate a point this thesis seeks to make.

¹³⁶ See in particular the UDBHR, note 4; and the Oviedo Convention, note 5, and its various protocols, note 31.

¹³⁷ The UDBHR, note 4, has, however, in Article 14 started to address environmental concerns.

Chapter II Legal Discourse

Increasingly, bioethics has come to be addressed within legal contexts, including within legal texts such as statutes, acts, declarations, conventions, as well as through the case law of national and international courts. The language and logic of the law have thereby become dominant frameworks for addressing many bioethical concerns.¹³⁸ Most prominently, UNESCO, the UN and the Council of Europe have issued several standards that specifically and directly are concerned with questions related to bioethics, to be discussed in more detail in the next chapter. Besides there exists a wide range of standards that indirectly deal with questions of bioethical relevance, including for example several WTO agreements concerned with the patenting of for example medical treatment options or human rights standards that contain the right to access to adequate health care or standard of living.¹³⁹

Legal discourses thus often effectively frame debates in the area of bioethics. The use of the word 'discourse' in recent social, legal, political and other theory has, however, become so pervasive that there is a need to clarify what this concept entails and how it is used in the context of this thesis before it may be further used in this thesis. This chapter therefore seeks to clarify scope and meaning of the term discourse.

1. An Introduction to the Term Discourse

Although the term discourse is widely used by for example the media and in day to day habitual language, it is rarely defined. Etymologically the term stems from the Latin word *discursus*, meaning 'argument', and/or from its related verb *discurrere*, meaning 'running to and fro'.¹⁴⁰ Today the term has various meanings. In its' common, everyday meaning, discourse is usually understood as a "continuous stretch of language containing more than one sentence, as in, for example, conversations, narratives, arguments, speeches."¹⁴¹ Here, the term discourse simply stands for a succession of related and interconnected sentences,¹⁴² i.e. "the orderly expression of ideas in speech or writing...."¹⁴³

However, the term can also carry more specialised meanings. The literature generally distinguishes between two such specialised meanings, i.e. two approaches to the topic of discourse, that of

¹³⁸ Schneider, *Bioethics in the Language of the Law*, note 21, 16 et seq. On the trend of framing more and more issues in law see for example also B. Schlink, "Der Preis der Gerechtigkeit", 11 *Deutsche Zeitschrift für europäisches Denken*, 2004, 983 et seq. and Glendon, *Rights Talk*, note 21.

¹³⁹ See Chapter IV, 3.2.

¹⁴⁰ S. Mills, *Discourse*, 1997, 2.

¹⁴¹ S. Blackburn, *Oxford Dictionary of Philosophy*, 1996, 102.

¹⁴² S. Pinker, *The Language Instinct*, 1994, 506.

¹⁴³ "The Longman Dictionary of the English Language", 1984, cited in Mills, note 140, 2.

discourse ethics and that of discourse theory or discourse analysis.¹⁴⁴ The latter roughly consists of the assumption that the performance and content of human language or other human interaction is determined by the structure in which it takes place.¹⁴⁵ The former idea refers to the assumption that linguistic and communicative structures have moral implications as well.¹⁴⁶

1.1. A Brief Overview of Discourse Ethics

As just mentioned, one specific approach to the study of discourses is discourse ethics, often very prominently associated with the work of Jürgen Habermas.¹⁴⁷ Central to his theory is the argument that some presuppositions of discourse or of communications among reasonable people have universally valid moral content and that discourse that builds on these presuppositions leads to legitimate outcomes, such as legitimate norms.¹⁴⁸ Discourse ethics is thus closely linked with the procedural aspects of a certain piece of communications and with the legitimating power of that procedure.¹⁴⁹ The goal of Habermas's theory of discourse ethics is to clarify the presuppositions of the rationality of processes and thereby to establish an ethics of discourse that makes it possible to arrive at such legitimate valid norms that can be accepted by all involved.¹⁵⁰

Habermas argues that in making utterances, speakers at least implicitly raise different types of validity-claims, for example, claims to truth, normative rightness, sincerity or truthfulness. These validity claims, norms or maxims of action are, however, only morally legitimate, if they have been

¹⁴⁴ Of course, these two categories are neither the only approaches to discourses nor are these approaches closed or fixed in themselves. For the sake of brevity and clarity this thesis will, however, limit its discussion to the conceptually broad and rough categories of discourse ethics and discourse theory or analysis. For background to the term discourse and its various meanings see for example N. Coupland (ed.), *Styles of Discourse*, 1988; and Mills, note 140.

¹⁴⁵ See under 1.2. below.

¹⁴⁶ See under 1.1. below.

¹⁴⁷ Given the breadth and complexity of Habermas's work, these brief notes on discourse ethics can do no more than sketch the outlines of some of the relevant parts of his argument. For a fuller account see in particular J. Habermas, *Justification and Application, Remarks on Discourse Ethics*, 1993; - *Moral Consciousness and Communicative Action*, 1990; - *The Theory of Communicative Action, Volume 1*, 1984. For background see M. Schröter, "Habermas" in: J. Nida-Rümelin/E. Oezmen (eds.), *Philosophie der Gegenwart in Einzeldarstellungen*, 2007, 240 et seq.; K. White (ed.), *The Cambridge Companion to Habermas*, 1995; W. Outhwaite, *The Habermas Reader*, 2001; P. Dews, *Habermas, a Critical Reader*, 1999. It should also be noted that Habermas' conceptualisation of discourse ethics is one of the most famous, yet not the sole representative of the various strands of thought that are often subsumed under the heading of "discourse ethics". Other prominent scholars often associated with discourse ethics are for example Karl Otto Apel and Roberto Alexy.

¹⁴⁸ J. Habermas, *Justification and Application: Remarks on Discourse Ethics*, note 147, 50.

¹⁴⁹ J. Habermas, *Moralbewusstsein und Kommunikatives Handeln*, note 147, 211: "What moral theory cannot do is make any kind of substantive contribution ... Moral philosophy does not have privileged access to particular moral truths." Yet, Habermas argues that "it is incumbent on moral theory to explain and ground the moral point of view. What moral theory can do and should be trusted to do is to clarify the universal core of our moral intuitions and thereby refute value skepticism.". See also P. Gehring, "Ist die Bioethik ein Diskurs im Sinne Foucaults?", in: P. Gehring, *Was ist Biomacht; Vom Zweifelhafte Mehrwert des Lebens*, 2006, 128 et seq.

¹⁵⁰ B. Flyvbjerg, "Habermas and Foucault: Thinkers for Civil Society?", 49 *The British Journal of Sociology*, 1998, 210, 213 and J. Habermas, *Justification and Application: Remarks on Discourse Ethics*, note 147, 67.

constituted through an ethically correct process or procedure, i.e. in a moral practical discourse.¹⁵¹ There are two principles of such a moral practical discourse, i.e. of discourse ethics that must be observed in order to arrive at legitimate norms. The first is that “only those norms are valid to which all possible affected persons could agree as participants in rational discourse (also often referred to as principle (D) i.e. discourse principle or principle of justification).”¹⁵² Secondly, a norm is justified and valid if the principle of universalization is met. That principle is expressed as “for a norm to be valid, the consequences and side effects of its general observance for the satisfaction of each person's particular interests must be acceptable to all.”¹⁵³ In essence, only those norms can claim to be valid that meet with the approval of all affected in their capacity as participants in a practical discourse.

Such reasoned agreement, of course, can only take place if certain idealized properties of communication are met, i.e. if it takes place within an ideal speech situation that is freed from all external constraints and in which nothing but the force of the better argument prevails.¹⁵⁴ The most important of these idealized properties are that no one capable of making a relevant contribution has been excluded, that participants have equal voice, that they are internally free to speak their honest opinion without deception or self-deception, and that there are no sources of coercion built into the process and procedures of discourse.¹⁵⁵ Habermas' model of discourse ethics also rests on several strong assumptions about the capacity of persons for moral dialogue, including for example an individual's willingness to seek the input of others in forming one's conscience. Only if these conditions and assumptions are met will “the unforced force of the better argument prevail” and the resulting norm is legitimized, thus leading to a morally valuable norm.¹⁵⁶

Important and relevant as theories of discourse ethics are to the context of bioethics and the legal standards in that area, given this study's overall purpose this thesis will, however, focus on a different set of discourse studies which are conventionally subsumed under the heading 'discourse

¹⁵¹ J. Habermas, *Justification and Application, Remarks on Discourse Ethics*, note 147, 65. His theory is a universal one. It goes “beyond the perspective of a particular culture” (ibid., 116) It is based “on a transcendental-pragmatic demonstration of universal and necessary presuppositions of argumentation” (ibid., 116).

¹⁵² J. Habermas, *Justification and Application, Remarks on Discourse Ethics*, note 147, 65. This principle demands that a rational discourse among all possible affected persons takes place. Therefore, while discourse can lead to a legitimate outcome if it is led through elected representatives of all possible affected persons, e.g. in a parliament, legitimate outcomes for example in the form of national legislation cannot result from a discourse that is led by selected experts only. J. Habermas, *Moralbewußtsein und Kommunikatives Handeln*, note 147, 67.

¹⁵³ J. Habermas, *Justification and Application, Remarks on Discourse Ethics*, note 147, 65. For a discussion of the differences between both principles see K. White, note 147, 143 et seq.

¹⁵⁴ J. Habermas, *Justification and Application, Remarks on Discourse Ethics*, note 147, 66.

¹⁵⁵ W. Outhwaite, note 147, 31-38.

¹⁵⁶ J. Habermas, *Justification and Application, Remarks on Discourse Ethics*, note 147, 31 et seq., arguing also that a society whose institutions and practices are governed by valid norms derived from such ethically relevant procedures instantiate the ideal of a moral community. For background see Flyvbjerg, note 150, 213.

analysis' or 'discourse theory'.¹⁵⁷ That is, since this thesis is not concerned with legitimate, truthful or valid outcomes of the discourse that takes place in the area of bioethics but with the way the structure within which this debate takes place constitutes, constructs and limits the field of bioethics, this thesis will be concerned with discourse theory and analysis.

1.2. A Brief Overview of Discourse Theory and Analysis

Discourse theory or analysis is often famously ascribed to the work of such philosophers and thinkers as Michel Foucault, Jaques Derrida, and more recently Ernesto Laclau, Chantal Mouffe and Judith Butler.¹⁵⁸ In essence, to these scholars language and other elements of discourse, such as non-verbal communications or physical acts or any other interaction between human beings, are not neutral means for describing or analysing the social, metaphysical and biological world. Rather they effectively construct, regulate and control knowledge and institutions¹⁵⁹, as well as all human interactions. Discourse theory is concerned with the processes that produce such knowledge and institutions and that determine the form and outcome of human interactions.¹⁶⁰ In contrast to discourse ethics discourse analysis then, however, asks not so much about legitimate or morally valuable ways of human interaction. Instead it tries to understand how a certain interaction, field of knowledge or institution came about or was constituted from the structures within which it took place.

2. Discourse Analysis

Foucault, one of the most prominent philosophers associated with discourse theory, holds discourses to constitute constructive phenomena, shaping the identities and practices of human subjects. In his study of various discourses he investigates the rules and practices that produce

¹⁵⁷ In this thesis the terms discourse theory and discourse analysis will be used interchangeably.

¹⁵⁸ However, discourse theory or analysis is also often in one way or another associated with the work of such diverse philosophers as John Austin, Ferdinand Saussure and Ludwig Wittgenstein. For a comparison of different conceptualisation of discourse theory see for example D. Macdonnell, *Theories of Discourse*, 1986; D. Howarth, *Discourse*, 2000, 16 et seq.; Mills, note 140, 32 et seq.

¹⁵⁹ In this thesis institutions are understood as "persistent and connected sets of rules that prescribe behavioural roles, constrain activity, and shape expectations" R. Keohane/R. Nye, *Power and Interdependence*, 1989, 3. It should, however, be noted that the term institution has various meanings. Cf, for example, the Oxford English Dictionary's definition of institutions as inter alia "an organization" or "an established law, custom, usage, practice, organization, or other element in the political or social life of a people; a regulative principle or convention subservient to the needs of an organized community or the general ends of civilization." J. Simpson/E. Weiner, *Oxford English Dictionary*, 1989, 433, 1 and 6.a. In sociology institutions are often defined as "structures, norms and mechanisms of social order that shape the behaviour of a group of individuals or people." A. Gimmler, *Institution und Individuum. Zur Institutionentheorie von Max Weber und Jürgen Habermas*, 1998, 21. See also N. Luhmann, *Das Recht der Gesellschaft*, 1993, 13, defining institutions as "zeitlich, sachlich und sozial generalisierte Verhaltenserwartungen...".

¹⁶⁰ Foucault, *Die Ordnung des Diskurses*. Inauguralvorlesung am College de France am 2. Dezember 1970, note 25, 1, 10 et seq.

meaningful statements and regulate discourses in different historical periods.¹⁶¹ Discourses to him are “groups of statements which provide a language for talking about ...a particular topic at a particular historical moment.”¹⁶² Discourses, Foucault argues, thereby construct the topic itself. They define and produce the objects of our knowledge.¹⁶³ They determine the way a topic is talked about, reasoned about, resolved or analysed.¹⁶⁴ In short, to Foucault nothing has meaning outside of the discourse that constitutes and constructs it.¹⁶⁵

Discourse then shows itself in and consists of the general domain of all statements or utterances, including speech and writing but also non-verbal communications, such as physical acts or visual symbol, in silence and generally in any other 'discursive practice', defined as any “habituated patterns of activity and thought, speaking and doing”.¹⁶⁶ Thus a simple social practice such as shaking hands is as much part of a discourse that can be understood by others taking part in this discourse as are conversations, the wearing of specific cloths, such as ties or suits, or symbols, such as the displaying of the cross in some churches or class rooms.¹⁶⁷

Institutions, defined as fields that come with “persistent and connected sets of rules that prescribe behavioural roles, constrain activity, and shape expectations”¹⁶⁸ such as for example the family, governmental institutions, a legal system, a church etc., play an important role in the development, maintenance and circulation of discourses.¹⁶⁹ That is so because within institutions certain episteme, i.e. “classificatory grids” along which knowledge is ordered and meaning is allocated, operate.¹⁷⁰ Episteme impose the framework of categories and classifications within which thought, communication and action are ordered, they are what “gives meaning to actions by relating them to their wider context of knowledge in a given context.”¹⁷¹ It is thus only by applying a certain episteme that a coherent interpretation of the social world becomes possible at all.

One example of an imaginary episteme is provided by Foucault. It is that of an imaginary Chinese encyclopaedia which classifies animals as animals divided among others into a) belonging to the Emperor (b) embalmed, (c) tame, (d) sucking pigs, (e) sirens, (f) fabulous (g) stray dogs...(n) that

¹⁶¹ See for example M. Foucault, *The History of Sexuality: The Will to Knowledge*, 1998; -*The Archeology of Knowledge*, 1972; - *Power/Knowledge*, note 24.

¹⁶² Hall, note 23, 44.

¹⁶³ Ibid.

¹⁶⁴ M. Foucault, *The Order of Things*, 1970, 3.

¹⁶⁵ Hall, note 23, 44. And A. Hunt/G. Wickham, *Foucault and the Law*, 1994, 14.

¹⁶⁶ M. Foucault, *The Archeology of Knowledge*, note 161, 49.

¹⁶⁷ H. Dreyfus/P. Rabinow, *Michel Foucault*, 1982, 155.

¹⁶⁸ Keohane/Nye, note 159, 3.

¹⁶⁹ Mills, note 140, 10.

¹⁷⁰ Foucault, *The Archeology of Knowledge*, note 161, defining episteme at 211 as "the total set of relations that unite, at a given period, the discursive practices that give rise to epistemological figures, sciences, and possibly formalized systems; the way in which, in each of these discursive formations, the transitions to epistemologization, scientificity, and formalization are situated and operate".

¹⁷¹ Hunt/Wickham, note 165, 14.

look from a long way like flies.¹⁷² An example of a real-world episteme that is of relevance to the area of bioethics is the categorisation of diseases over centuries and in different societies, as evidenced for example in medical dictionaries or related records. The Greek physician Galen, for example, divided types of diseases based on the idea that bodies are ruled by four types of fluids, which determine an individual's personality and his or her reaction to various diseases.¹⁷³ Another much observed categorisation of illnesses in 17th century Britain grouped diseases according to a patient's zodiac sign.¹⁷⁴ The different categorisation or episteme applied in both, the fictitious and the real world example, make it clear that episteme generally are not fixed, premeditated or necessarily coherent categories of ordering knowledge. That is, any present reader's most likely initial response to the suggested episteme in Foucault's and the other stated examples will either be to consider them incoherent and arbitrary or to acknowledge that the offered categorisation of animals or diseases may have made or still make sense to someone part of the discourse that gave rise to this classification of animals or diseases, i.e. to someone living in the context, time and space in which this fictitious encyclopaedia or the above mentioned categorisation of diseases constituted common knowledge. If that, however, holds true for the stated examples it seems logical that other, more contemporarily used episteme, too, will seem equally incoherent and arbitrary if judged from someone outside of the particular discourse. That is so because according to discourse theory, episteme never exist self-evidently, primary or outside of human consciousness. Rather, human consciousness uses these categories or episteme to divide and order knowledge along certain, more or less arbitrarily defined grid-points, in an effort to make sense of the world.¹⁷⁵

Yet the stated examples also point to another finding which is that the 'institutions', in the present examples, the institutions of the study of diseases (medicine) or of the study of animals (zoology), in their respective forms are only constituted by an episteme, and, consequently, must be adapted or are sometimes rendered irrelevant if the episteme that construct and define them change or are no longer used. For example, today, the institution of medicine has generally expanded to include such areas as bacteriology, virology etc. while it commonly excludes fields of knowledge previously relevant to the subject, such as the study of star signs or the study of Galen's concept of body fluids.¹⁷⁶ The institution of medicine thereby changes with the episteme that is used to think about medicine. In the same way are new institutions constituted by the development of new episteme,

¹⁷² Foucault, *The Order of Things*, note 164, xv.

¹⁷³ P. Ekman, "Galen", in: C. Blakemore/S. Jennett, *The Oxford Companion to the Body*, 2001, 225 et seq.

¹⁷⁴ B. Woolley, *Heal Thyself, Nicholas Culpeper and the Seventeenth-Century Struggle to Bring Medicine to the People*, 2004, 1 et seq.

¹⁷⁵ Examples for episteme and their influence on the ordering of knowledge abound, ranging for example, from the way history is usually taught (at for example German higher schools) according to certain eras, such as the stone or bronze era, over the way different cast or class systems are applied to divide human beings into different segments of society with specific attributes, functions and roles, to how law is for example divided into different segments of expertise, such as family law, tax law, corporate law etc. to the way appropriate sexual behaviour is construed at any one point in various cultures and times. See for example T. Höhne, "Die Thematische Diskursanalyse dargestellt am Beispiel von Schulbüchern", in: R. Keller/A. Hirsland/W. Schneider/W. Viehöfer (eds.), *Handbuch Sozialwissenschaftlicher Diskursanalyse. Forschungspraxis*, 2010, 423 et seq.

¹⁷⁶ W. Bynum/R. Porter (eds.), *Companion Encyclopedia of the History of Medicine*, 1993, 1; see generally W. Cockerham (ed.), *The Blackwell Companion to Medical Sociology*, 2001, introduction.

while other institutions are rendered meaningless by the abrogation of a certain episteme. For example, gay or queer studies at Universities only came into existence because there exists a categorisation of human beings and their experiences along the line of sexual orientation. Would no one categorise human beings along the line of sexual orientation (or not anymore) or would a different categorisation of human beings and their experiences be applied altogether, for example one that categorises human beings along such lines as height, body weight or number of atoms in the body, the institution of gay or queer study would be rendered meaningless and likely be replaced by other institutions.

In essence episteme and the discourses that are built on and around them enable and delimit fields of knowledge and inquiry.¹⁷⁷ They govern what can be said, thought and done within institutions. They authorise some to speak, certain things to be said, thought and done and some views to be taken seriously while others are excluded, marginalised or prevented from being said, thought or done.¹⁷⁸ For example, regular medical course curriculums at Universities, at least in most European Union countries, no longer teach Galen's concept of body fluid as a valid source of knowledge and any approbated physician trying to treat patients according to Galen's concept of body fluids would likely face charges of misconduct. Understood in that way it is obvious that discourses are inextricably linked to concepts of power and that power relationships necessarily show in discourse.¹⁷⁹ Discourses never exist in a vacuum but are constantly conflicting with other discourses and other social practices.¹⁸⁰ Power is what determines the dominant discourses, and their episteme, in this example power is what determines whether Galen (or homeopathy, for example) are considered relevant to medical studies. But such power, according to discourse theory, must not be confused with repression. Since discourse theory is not interested in which discourse is a true or accurate representation of the real world, power is neither good nor bad. Rather, it inevitably exists everywhere and inevitably shows in every form of social relations as the condition of all speech.¹⁸¹ Power produces reality and generates knowledge and truth-claims

“...[] ...power produces knowledge (and not simply by encouraging it because it served power or by applying it because it is useful); that power and knowledge directly imply one another; that there is no power relation without the correlative constitution of a field of knowledge, nor any knowledge that does not presuppose and constitute at the same time power relations...[]...”¹⁸²

Knowledge can thus never "flourish independently of power. To understand the formation of any body of knowledge always involves the consideration of the power structures and dimensions

¹⁷⁷ Hunt/Wickham, note 165, 7.

¹⁷⁸ Ibid. For an example see M. Foucault, *Discipline & Punish*, 1975, 195 et seq.

¹⁷⁹ H. Dreyfus, "Being and Power: Heidegger and Foucault", 2004, *Selected papers*, 1, available online at: http://garnet.berkeley.edu/~hdreyfus/html/paper_being.html (last visited 27.04.2012).

¹⁸⁰ Foucault, *The Order of Things*, note 164, 57; Mills, note 140, 11.

¹⁸¹ Foucault, *The Order of Things*, note 164, 194; Foucault, *Power/Knowledge*, note 24, 125.

¹⁸² Foucault, *The Order of Things*, note 164, 27-28.

within which knowledge is produced.¹⁸³ Knowledge is a resource of power in the sense that experience always involves some kind of power/knowledge relationship.¹⁸⁴ Similarly, truth-claims are wedded to the concept of power and hence part of discourses. Truth thereby is not the opposite of false or error. Truth regimes simply set out what truth is, i.e. the truth claims in which current power formations in discourses have resulted in

“Each society has its regime of truth, its general politics of truth: That is, the type of discourse which accepts and makes function as true; the mechanisms and instances which enable one to distinguish true and false statements, the means by which each is sanctioned; the techniques and procedures accorded value in the acquisition of truth; the status of those who are charged with saying what counts as truth.”¹⁸⁵

Knowledge, power and corresponding truth claims are thus fundamentally linked in discourse, in fact “power and knowledge are joined together in discourse...”¹⁸⁶ The questions of whether or not a patient's treatment based on Galen's idea of the physical body is considered sound or 'medical' is then not so much a matter of inherent moral truth or accurate representation of reality but a question of discourses and of the particular power/truth constellation displayed in them.

However, while discourses are inevitable their specific power/knowledge and truth-claim set up is not.¹⁸⁷ Exactly because the concept of a discourse is wedded to power and thus means the marginalisation of certain views there is always inbuilt in discourses a site of resistance: “Power reinforces it [discourse], but also undermines and exposes it, renders it fragile and makes it possible to thwart it.”¹⁸⁸ Again, the question of whether or not Galen or homeopathy are considered 'proper' medicine is a question of the power set up and its corresponding truth claim. Yet particularly the example of homeopathy, which has long been excluded from European University medical course curricula but by now has become a much more accepted practice in these countries, also shows that discourses can change.¹⁸⁹

¹⁸³ Hunt/Wickham, note 165, 7. Foucault, *The History of Sexuality*, note 161, 93 et seq.

¹⁸⁴ Hunt/Wickham, note 165, 7.

¹⁸⁵ Foucault, *Power/Knowledge*, note 24, 131.

¹⁸⁶ Foucault, *The Archeology of Knowledge*, note 161, 101.

¹⁸⁷ *Ibid.*

¹⁸⁸ *Ibid.*

¹⁸⁹ See e.g. V. Prasad, "Toward a Meaningful Alternative Medicine", 39 *Hastings Center Report*, 2009, 16 et seq. Foucault's concept of power has been the subject of severe criticism from a variety of authors, including maybe most prominently by Habermas. One point of critique is that Foucault conflates power with truth and that there may be legitimate reasons to oppose dominant power regimes. Another point of critique is that Foucault's engages in a retorsion: His concept of power cannot be overcome as any new discourse that might replace a previous power constellation inevitably only represents another, new power constellation. Yet, by critiquing current discourses and power constellations Foucault (or any other engaging in critical theory), performs a retorsion (performativer Widerspruch). See in particular, J. Habermas, *Der philosophische Diskurs der Moderne*, 1985; M. Kögler, *Foucault*, 2004; N. Hartsock, "Foucault on Power", in N. Hartsock, *Feminism and Postmodernism*, 1990, 157 et seq.; M. Hardt/A. Negri, *Empire*, 2000, 22-28 and 327-330; S. Žižek, *The Ticklish Subject: The Absent Centre of Political Ontology*, 2000; B. Flynn, "Derrida and Foucault: Madness and Writing", in: H. Silverman, *Derrida and Deconstruction*, 1989, 45 et seq. and T. Lemke, *Foucault, Governmentality, and Critique*, 2011.

3. Biopower

In the context of discourse theory and the topical focus of this thesis one further concept promulgated among others by Foucault deserves mentioning, which is that of biopower. According to Foucault biopower is the "explosion of numerous and diverse techniques for achieving the subjugations of bodies and the control of populations".¹⁹⁰ That is, through introducing biopolitics (the form of sovereign governmentality that practices biopower) states seek to control and regulate all processes related to the 'life sciences', including most prominently questions that pertain to birth, death, sexuality, health, etc. The aim is the standardization or normalization of a population.¹⁹¹ Biopolitics is concerned with populations rather than individuals. Its legitimacy and general acceptance in populations usually derives from its claimed preoccupation with optimising lives and life chances. That is, it is concerned with economic nurture and physical protection, rather than the threat of death.¹⁹² Biopower is connected to a shift in sovereign powers from the ancient sovereign's power to give and take an individual's life to modern sovereign states power to 'make life' and 'regulate death'.

The goal of a population's normalization and standardization is achieved through modern states' regulation of all questions pertaining to 'life processes'. For example, modern nation states endorse commonly applicable health care systems with mandatory enrolment schemes¹⁹³ or vaccinations requirements¹⁹⁴, define what a drug is and set rules for the use of it¹⁹⁵ and regulate questions pertaining to abortion¹⁹⁶. These measures seek control yet are often masked and hence may gain more easily acceptance as 'concern for the prosperity of the population in all questions from birth to death'.¹⁹⁷

Medical and generally life-science related discourses thus constitute a site of power, where one discourse, for example a discourse that only allows abortion to be undertaken under very limited

¹⁹⁰ M. Foucault, *The History of Sexuality*, note 161, 140. For background and the distinction between biopower and biopolitics see S. Martens, "Le Concept de Biopolitique chez Foucault: Entre Souveraineté et Gouvernementalité", in: A. Kiefer/S. Risse, *La Biopolitique outre-Atlantique après Foucault*, 2012, 37 et seq. and C. Blencowe, *Biopolitical Experience : Foucault, Power and Positive Critique*, 2012.

¹⁹¹ Foucault, *History of Sexuality*, note 161, 139.

¹⁹² Cf M. Foucault, *Security, Territory, Population: Lectures at the Collège de France 1977-1978*, 2007, 1-27 and M. Foucault, *Society Must Be Defended: Lectures at the Collège de France 1975-1976*, 2003, 240 et seq.

¹⁹³ For example Schweizer Bundesgesetz über die Krankenversicherung (KVG), 832.10, 1994.

¹⁹⁴ Any visitor to the Democratic Republic of Congo is required to be vaccinated against yellow fever. Cf. *Einreisebestimmungen in die Demokratische Republik Kongo*, at <http://www.auswaertiges-amt.de/DE/Laenderinformationen/00-SiHi/KongoDemokratischeRepublikSicherheit.html> (last visited 29.09.2012).

¹⁹⁵ Gesetz über den Verkehr mit Arzneimitteln, BGBl. I S. 533, 1961. This law has since been changed which has, however, not changed the purpose and principles underlying this law.

¹⁹⁶ Deutsches Strafgesetzbuch, BGBl. I S. 3322 of 13.11.1998, para 218.

¹⁹⁷ Foucault, *History of Sexuality*, note 161, 143. See also A. Guta/M. Gagnon, "Using Foucault to Recast the Telecare Debate", 12 *American Journal of Bioethics*, 2012, 57 et seq. See also J. Moreno, *The Body Politic: The Battle Over Science in America*, 2011.

circumstances, is endorsed and where technologies, such as for example those pertaining to the excessive application of pain relief for dying patients, become a tool of power used to control and exercise surveillance over a population. Often national laws are used to formalize these processes, including through laws that regulate abortion, substance (ab)use and health care reforms.¹⁹⁸

Foucault's theory of biopower cannot be proven historically or otherwise and is subject to the same points of critique as his general concept of power.¹⁹⁹ In the context of this thesis the concept of biopower is relevant as it generally undergirds this thesis' claim that more and more issues of bioethical interest are framed in legal terms: If states seek control over populations in questions pertaining to life processes then this will likely more often than not be done in a legal, binding form, i.e. a form that obliges the population to act in conformity to this legal text. The concept is also relevant in that Foucault's concept of biopower gives one perspective on the current discourses led in the area of bioethics and as such is of interest to this thesis. Finally, the concept serves as trigger for many critical and interesting questions regarding current discourses in the area of bioethics, such as the question of whether it is at all desirable or necessary for states to set national or international norms in the area of bioethics.²⁰⁰ This thesis will thus often implicitly use and build on Foucault's analysis of biopower and biopolitics in the chapters to follow. Yet, by limiting itself to an analysis of the implications of leading bioethics in a legal discourse at the international level, this thesis is not so much interested in one of the core question often debated in the context of the concept of biopower, which is whether or not the exercise of biopolitics and biopower, i.e. of control and surveillance, is 'good' or 'bad' and whether and how the particular discourse summarised by this concept should be changed and if so how. Instead this thesis will use Foucault's concept of discourse and power and scrutinise implications of one particular discourse that takes currently place, without seeking to judge the outcome of the discourse itself.

4. Conclusion: The Meaning of Discourse in the Context of this Thesis

This thesis takes the approach associated with discourse theory and analysis while applying it to international legal standards in the area of bioethics. It understands discourses to be practices which humans impose on everything and by which humans make sense of the world. Discourses construct, regulate and control human interactions. Truth and morality are essentially constituted through discourse.

¹⁹⁸ Cf footnotes 193-195.

¹⁹⁹ Cf footnote 189.

²⁰⁰ Instead of setting a standard a state could also leave the regulation of many of these questions, such as pertaining to for example abortion or euthanasia to the individual. J. Coggon, *What Makes Health Public: A Critical Evaluation of Moral, Legal, and Political Claims in Public Health*, 2012.

To the extent that it is possible to demarcate a field or institution of international law with its particular episteme and thereby a to some extent at least stable and, in the context of this thesis, distinct concept of legality, international legal discourse in the present context is understood as an institutionalized, i.e. international legal way of thinking about issues at stake and as the analysis of concerns within international legal language, logic and concepts. Of course, this so far circular definition hinges on the very concept and meaning of the term legality which is not a fixed term but can only be defined relative to a certain episteme, i.e. to the episteme that defines what is considered legal and what not.²⁰¹ Moreover, the presently stated definition also recognises that at any time there are several international legal discourses competing with each other and that such legal discourses will differ over times, places, cultures, etc. It goes without saying that any legal discourse analysis that is based on the present understanding of discourses does not believe in the existence of a “right” or “correct” legal discourse. Rather, a multiplicity of legal discourses exists at any time which and they depend on episteme that underpin and define them and the specific power/truth relationships of the respective discourse. Legal discourse in this thesis therefore must be understood and is analysed “as a multiple and mobile field of force relations, wherein far-reaching, but never completely stable effects of domination are produced”.²⁰² Hence while this thesis depicts one version of a legal discourse this is not to be understood as a static field of inquiry. Only to the extent that such a fluid and never completely stable concept of a legal discourse allows for it, does legal discourses in the present context, by means of the specific episteme that construes it, define what is considered to be of legal relevance, what can be acceptably (legally) said about a specific topic and act as a determinant of a valid (legal) argument in that what is said and of the process of how such a (legal) argument must be made to be valid.

With regard to the area of bioethics that means that the international legal discourse at work in this area, i.e. the way legal discourse construes and operates the area of bioethics, defines what is considered to be of relevance in that discourse, what can be acceptably said about issues of bioethical relevance, and how questions of bioethical relevance are to be addressed and to be resolved. It will be left to Part II to discuss in more detail the units of this discourse, their content and scope and the institutional framework within which this discourse takes place. Part III will then discuss the epistemological framework used in this discourse, how this discourse works to construe, discuss and resolve issues of bioethical relevance and some of the implications thereof.

²⁰¹ See Chapter III for further discussion.

²⁰² Foucault, *History of Sexuality*, note 161, 102.

Part II:

**Units of Discourse, the Institution of Law and the Episteme of
International Legal Discourse in the Area of Bioethics**

Chapter III The Institution of Law and the Legal Character of bioethically relevant Standards

Since most international legal standards of interest to the present analysis, in fact all except for the ones issued by the Council of Europe, lack legal enforceability and remain legally non binding, these standards are conventionally classified as “soft law”.²⁰³ Soft law standards in turn are often located by scholars “in a grey zone between law and politics” and declared to be “neither strictly binding norms of law, nor completely irrelevant political maxims.”²⁰⁴ Most scholars would, however, also agree that “soft” law in actual practice often “acquire(s) considerable strength in structuring international conduct.”²⁰⁵ Since it is regularly debated what the term soft law means, what type of law soft law is and whether soft law constitutes law at all²⁰⁶ and as these questions therefore ask about properties of the institutionalised framework within which the presently examined discourse in the area of bioethics takes place these questions also have to be addressed in this thesis.²⁰⁷ That is, this chapter debates whether it is at all in order to refer to an international legal discourse when referring to the presently examined discourse that mostly builds on soft legal human rights standards (Chapter V) and if so (or if not) what type of discourse it is. Understanding the nature, kind and properties of so-called “soft law” will thus clarify what type of 'legal' discourse, if at all, is at work in the area of bioethics.

1. An Introduction to the Term Soft Law

1.1. Emergence and Range of Soft Law

Soft law is often said to be a rather recent phenomenon, responding to the fact that the reality of international law-making has moved beyond the procedures that states traditionally agreed are “legislative,” that is, procedures identified by them as the appropriate means to create legally-binding obligations. These procedures or sources of law, at least for the purpose of resolving inter-state disputes, are identified in Article 38 of the Statute of the International Court of Justice (hereinafter ICJ).²⁰⁸ This Article provides that

²⁰³ On the development and historical use of the term soft law see A. di Robilant, “Genealogies of Soft Law”, 54 *American Journal of Comparative Law*, 2006, 499 et seq. In recent years the term has also increasingly been used in a national context. A. Cassese, *International Law*, 2005, 196.

²⁰⁴ P. Malanczuk, *Akehurst's Modern Introduction to International Law*, 1997, 54.

²⁰⁵ Malanczuk, note 204, 54. See also M. Bothe, “Legal and Non-Legal Norms – A Meaningful Distinction in International Relations?”, 11 *Netherlands Yearbook of International Law*, 1980, 65, 65.

²⁰⁶ See for example Cassese, note 203, 196.

²⁰⁷ The more general question of whether or not international law may be termed law at all will not be further discussed in this work. For an overview of different theories and positions regarding that question see for example W. Morrison, *Jurisprudence From The Greeks To Post-Modernity*, 1995, 293 – 43; H. Hart, *A Concept of Law*, 1994, 231 et seq., holding that international law if at all law is not a fully developed legal system. H. Kelsen, *Principles of International Law*, 1959, 18 et seq. G. Simpson, “On the Magic Mountain: Teaching Public International law”, 10 *European Journal of International Law*, 1999, 72 et seq., arguing that international law can be regarded as law.

²⁰⁸ Statute of the International Court of Justice, Annex to the Charter of the United Nations, of 26 June 1945, 59 Stat. 1031, T.S. 993, 3 Bevans 1153, 1945, Article 1(3) (hereinafter UN Charter).

The Court...[]... shall apply:

- a. international conventions²⁰⁹, whether general or particular, establishing rules expressly recognized by the contesting states;
- b. international custom, as evidence of a general practice accepted as law;
- c. the general principles of law recognized by civilized nations;
- d. []... judicial decisions and the teachings of the most highly qualified publicists of the various nations, as subsidiary means for the determination of rules of law.

According to the Statute conventions, i.e. treaties, and customary international law then constitute the primary and most relevant sources of international law. The inclusion into Article 38 of such sources as general principles, judicial decision and scholarly opinion, however, already indicates that international law cannot be reduced to treaties or international customary law only.²¹⁰ It shows that international law is a complex, evolving and sometimes vague entity, the development of which partly is also a matter of discretion of international judges and scholars as authors of such 'judicial decisions' and teachings.

In addition, scholars over the last decades have noted that the categories of the sources of international law enshrined in the ICJ statute sometimes are no longer wholly adequate or sufficient in describing international legal reality.²¹¹ Rüdiger Wolfrum, for example, notes that international law has been expanded so that it today governs issues which would have been considered domestic affairs up to the middle of the 20th century and that new actors have become involved in the shaping of international norms apart from states, including individuals, groups of individuals, multinational organisations and other international non-governmental organisations.²¹² Besides, multiple arenas exist today for the application of international law, including for example the development of international law through the influence of national and regional courts and legal systems and the growing influence on international law through civil

²⁰⁹ The word Convention thereby is commonly understood to mean a treaty. See Malanczuk, note 204, 36.

²¹⁰ Judicial decisions and juristic writings are usually described as mere 'auxiliary sources of international law' that are then also less frequently invoked. In the case of the general principles of law there is considerable debate about whether these should be recognized as a principal or auxiliary source of international law. For further discussion see Cassese, note 203, 52 et seq. and Malanczuk, note 204, 48 and below Chapter IV 3.3.

²¹¹ In particular, treaties and customary law have been shown to be often too slow in answering to new challenges at the international legal level, too limited in their scope to cover all newly arising eventualities and too inflexible to respond adequately to new developments. H. Neuhold, "The Inadequacies of Law-Making by International Treaties: "Soft-Law" as an Alternative?", in: R. Wolfrum, *Developments of International Law in International Treaty Making*, 2005, 40 et seq.

²¹² R. Wolfrum, "Introduction", in: R. Wolfrum, *Developments of International Law in International Treaty Making*, 2005, 1. Similarly, Jose Alvarez questions whether - in an age in which International Organisations have an ever more important role in international law making - the "state-centric sources of international law listed in Article 38 remain exhaustive descriptions of the types of international obligations that today matter to a variety of actors." J. Alvarez, *International Organizations as Law-Makers*, 2005, x-xi. He thereby notes that "although we have turned to ...[international organisations] for the making of much of today's international law, the lawyers most familiar with such rules remain in the grip of a positivistic preoccupation with an ostensibly sacrosanct doctrine of sources, codified in Article 38 of the Statute of the International Court of Justice, which originated before most modern International Organisations were established and which, not surprisingly, does not mention them." Ibid., x.

society, so that it seems that the development and implementation of international law, are no longer exclusively reserved to the ICJ and its judges.²¹³ Many of these developments have also been particularly instigated through the emergence, development and promotion of human rights norms.²¹⁴ Quite apart from the questions of whether it ever has, what has traditionally been considered international law thus no longer adequately depicts reality.

Alternative forms of international law making are then generally prospering in areas where states have not yet had the time or where they have yet been unwilling to formulate a formal and binding agreement on a subject, i.e. in those areas where there (yet) exists no customary international rule and/or where treaties are unlikely to come into existence.²¹⁵ Also in areas, where there is a general need or desire for mutual confidence-building, a need or desire to stimulate developments still in progress but where there is also some concern that international relations otherwise will be overburdened by a legally binding and enforceable treaty, with the risk of failure and/or deteriorations in relations, alternative law making might present a 'compromise.'²¹⁶ Alternative law-making is also often more attractive in areas where there is a need for simpler procedures than those required by treaties so that a more rapid finalization and implementation may be achieved.²¹⁷ Avoidance of for example a treaty form means that states are not bound by international rules relating to treaties, such as the rules regulating the termination²¹⁸ and amendment²¹⁹ of treaties which can be restrictive.²²⁰ States may also opt for alternative law making because they feel that the agreement in question still needs to be tested for its practicality or when it is unclear how long the situation that gave rise to the agreement will last. In such cases a treaty might foreclose the possibility for necessary change.²²¹ Finally, alternative law making may be the choice if there is a need or desire to involve in agreements a broader range of stakeholders other than states, such as

²¹³ M. Reisman "The Democratization of International Law Making", in: R. Wolfrum, *Developments of International Law in International Treaty Making*, 2005, 26, 26.

²¹⁴ P. Alston/H. Steiner, *International Human Rights in Context*, 2007, 1023 et seq. D. Sheldon, "Law, Non-Law and the Problem of Soft Law", in: D. Sheldon, *Commitment and Compliance: The Role of Non-Binding Norms in the International Legal System*, 2003, 2, 10.

²¹⁵ That is, for example, often the case in areas where states have not yet reached a full convergence of views on, for example, new phenomena and concerns so as to agree upon legally binding commitments. Cassese, note 203, 196.

²¹⁶ H. Hillgenberg, "A Fresh Look at Soft Law", 10 *European Journal of International Law*, 1999, 499, 501. One obvious example is environmental law. Here states that want some form of international agreement may conclude that some form of agreement, i.e. a soft law agreement, may be better than none. See generally J. Kirton/M. Trebilcock (eds.), *Hard Choices, Soft Law: Voluntary Standards in Global Trade, Environment And Social Governance*, 2004, 2 et seq.

²¹⁷ States may, for example, avoid the domestic treaty ratification process, and thus perhaps escape democratic accountability for the policy to which they have agreed. Alvarez, note 212, 14. A. Boyle, "Some Reflections on Treaties and Soft Law", 48 *The International and Comparative Law Quarterly*, 1999, 901, 903

²¹⁸ Vienna Convention on the Law of Treaties, A/Conf.39/127, 1969, Articles 54 - 64 (hereinafter Vienna Convention).

²¹⁹ Ibid., Articles 39 - 41.

²²⁰ C. Chinkin, "The Challenge of Soft Law: Development and Change in International Law", 38 *International & Comparative Law Quarterly*, 1989, 850, 853. Boyle, note 217, 901 et seq., noting at 903 that treaties often take time to be replaced or amended, and that the attempt to do so can result in an awkward and overlapping network of old and new obligations between different sets of parties. Alternative or soft law-making in contrast will often be easier to amend or replace than either treaties or customary law particularly when all that is required is the adoption of a new resolution by an international institution.

²²¹ Chinkin, note 220, 853.

organisations, communities, corporations etc. which cannot be included through traditional treaties that, as a rule, only bind states.²²²

From the discussion thus far it is evident that the field of bioethics, as do areas of interest to human rights generally, make a good example of an area where soft law standards offer an attractive choice.²²³ For one, the field of bioethics has only rather recently come to the attention of international law makers. The perceived novelty of its subject matter as well as the sensitive and complex questions involved thereby result in that many states have not yet formed an opinion on how they want bioethically relevant topics to be dealt with.²²⁴ Prospects for reaching universally accepted treaties in the area are therefore rather limited. The process of drafting an alternative or soft law agreement then still might provide states with an opportunity to exchange opinions, to shape and share common values, to foster consensus and to negotiate substantive provisions without high risk of failure.²²⁵ Moreover, as could be seen in chapter 1, what is true in the area of bioethics today might no longer hold true tomorrow with new findings in related science and technologies changing the field of bioethics and by this challenging the adequacy of established normative order in that area.²²⁶ Here the flexibility of soft law may offer a more attractive governance option than many hard law standards. In analogy, soft law is an attractive choice for areas of human rights interests, such as a newly emerging “right to water”²²⁷, that have only recently gained prominence, where there is not yet consensus on how to deal with it or what it entails, where prospects of reaching agreement are fairly limited, where states want to exchange opinions and seek some form of agreement.

Most such alternative international law-making, if it cannot be subsumed under either of the categories described in Article 38 of the ICJ, is then often generally referred to as 'soft law'. However, it should be noted that the term soft law so far lacks an authoritative definition and is, depending on which scholar uses it, presented in a nearly infinite variety of forms, including in forms that do not involve states. That is, as Christine Chinkin points out on the one end of the spectrum scholars have sometimes used the term "with regard to non-binding or voluntary resolutions and codes of conduct formulated and accepted by international and regional organisations²²⁸, statements prepared by individuals in a non-governmental capacity, but which

²²² Sheldon, note 214, 2; Hillgenberg, note 216, 501. See also UDBHR, note 4, Article 2 a.

²²³ R. Andorno, "First Steps in the Development of an International Biolaw", in: C. Gastmans/K. Dierickx/H. Nys/P. Schotmans (eds.), *New Pathways for European Bioethics*, 2007, 121, 122.

²²⁴ See Chapter I, 3.3 in this thesis.

²²⁵ See discussion in the Report on the Possibility of Elaborating a Universal Instrument on Bioethics, note 128, paras. 44-46.

²²⁶ See Chapter I, 1.3.2 and 1.3.3.

²²⁷ See for example WHO, The Right to Water, 2003, at: http://www.who.int/water_sanitation_health/rtwrev.pdf (last visited 27.04.2012).

²²⁸ See for example the Guidelines on Occupational Safety and Health Management Systems by the International Labour Organisation. ILO-OSH, 2001.

purport to lay down international principle"²²⁹ as well as action plans, guidelines and recommendations of international organisations, such as by the International Atomic Energy Agency (hereinafter IAEA), the United Nations Environment Programme (hereinafter UNEP) or the Food and Agricultural Organisation (hereinafter FAO).²³⁰ The terms soft law is also sometimes taken to refer to "declarations of intergovernmental conferences, such as the Rio Declaration on Environment and Development or the UNESCO UDBHR, and to resolutions of the UN General Assembly, such as those dealing with outer space, the deep seabed, or permanent sovereignty over natural resources."²³¹ And it is sometimes used with regard to documents or standards agreed on at international conferences, such as Yalta²³² and Potsdam²³³, the Conference for Security and Co-operation/Organization for Security and Co-operation's (hereinafter CSCE/OSCE) Helsinki Final Act of 1975²³⁴ or at the level of the G7/8.²³⁵ Finally, at the very other end of the spectrum some authors even include certain 'soft' types of treaties in this category, a proposition that will be further discussed below.²³⁶

1.2. Use of the Terms 'Soft Law' and 'Hard Law' for the Purpose of this Thesis

Generally, it may be safe to say that as unique and manifold as the circumstances that lead to the adoption of international legal instruments that do not or barely at all fall under Article 38 of the ICJ statute as unique and manifold are the potential specifications of resulting agreements. Discussing the breadth of range of instruments potentially covered under the heading of soft law would go beyond the scope of this thesis. In the same way will it have to be left to other projects to elaborate a more concise and universally applicable definition of the term soft law. This thesis will merely define how it uses the terms soft and hard law with regard to standards in the area of bioethics. That should, however, not be interpreted as an attempt to lay down a generally applicable definition of the categories of hard and soft law.

For clarity this thesis, in the following thus employs the following nomenclature with regard to the standards in the area of bioethics. The below (Chapter IV, 3) discussed UNESCO standards and the

²²⁹ Chinkin, note 220, 855. E.g. the Universal Declaration of the Rights of Peoples of 4 July 1976. See also P. Eisemann, "Le Gentlemen's Agreement Comme Source du Droit Internationale", 106 *Journal du Droit Internationale*, 1979, 326 et seq.

²³⁰ E.g. UNEP, Mediterranean Action Plan, UNEP/WG.2/5, 1975; FAO Guidelines for Benzoyl-urea Insect Growth Barrier Trials, 2005; and IAEA, Combating Illicit Trafficking in Nuclear and Other Radioactive Material, IAEA Nuclear Security Series No. 6, 2007.

²³¹ Boyle, note 217, 903. See for example UNEP, Rio Declaration on Environment and Development, E.73.II.A.14, 1992; UN Declaration on Human Cloning, note 35; UN General Assembly Resolution on Peaceful Uses of the Sea-Bed, Res.2749, 1970; see generally also Hillgenberg, note 216, 503.

²³² Protocol of the Proceedings of the Crimea Conference of 4-11 February 1945.

²³³ Protocol of the Proceedings of the Berlin (Potsdam) Conference of 17 July to 2 August 1945.

²³⁴ Final Act of the Conference on Security and Cooperation in Europe of 1 August 1975.

²³⁵ Neuhold, note 211, 48. See for example Joint Statement by the German G8 Presidency and the Heads of State and/or Government of Brazil, China, India, Mexico and South Africa on the occasion of the G8 Summit in Heiligendamm of 8 June 2007.

²³⁶ Chinkin, note 220, 851.

UN cloning declaration, as they have been elaborated between states or rather their official extensions and by virtue of their legal non-bindingness and legal non-enforceability, constitute soft law. The Oviedo Convention (Chapter IV, 2) and the TRIPS agreements (Chapter IV, 4) constitute hard law as they are, formally at least, legally binding and legally enforceable treaties that are governed by the Vienna Convention and that have also been elaborated by states or their legal extensions. For the purpose of this thesis standards, statements, texts, or acts that have not been elaborated between states or their extensions in International Governmental Organisations, such as for example the below mentioned WMA Guidelines (Chapter IV, 1), will not be referred to under the heading of soft law. In short, all standards directly addressed to matters of bioethical interest that have been issued by states yet remain legally non binding and legally unenforceable are referred to as soft law. Legally enforceable and binding standards issued by the states are referred to as hard law. Nevertheless it should be noted that a categorisation as soft or hard law should not be confused with a general statement on the relevance of a standard for a legal discourse. That is, the label soft law does not necessarily preclude a soft legal standard from being relevant to a legal discourse.

2. International Law and Legal Status

The question about what type of standards, i.e. whether generally only hard law standards or also soft law (human rights) standards or both or none or only the latter, qualify as 'legal standards' and the question of whether or not it is justified to speak of a legal discourse if that discourse builds on hard or soft law or either or both type of standards can be answered or ascertained from two perspective. One is to define the discipline of law with a view to assessing whether soft or hard law standards form part of that entity of law. If either or both can be shown to form part of that entity it seems justified to also speak of the discourse that builds around soft or hard legal standards as a legal one. This approach will be discussed in the following sections. The other perspective, considered further below, is to assess the qualities of the soft and hard law standards in question and to understand whether they, based on an assessment of their properties, may be considered to be sufficiently 'legal' so that it seems justified to speak of an international legal discourse when referring to discourses that build on and around them.

2.1. International Law's Distinct Feature

The question 'what is (international) law' and hence the question about (international) law's distinct identity and of the boundaries of what constitutes 'legal', is as old as the field of jurisprudence. No school of jurisprudence, however, has so far provided an uncontested answer to

this question.²³⁷ With a view to assessing the possibility of a definition of complex terms, such as law, politics or morality, Ludwig Wittgenstein has convincingly argued that any such complex term that comprises several entities cannot be defined or connected by one essential common feature.²³⁸ Rather, these entities exhibit a number of similarities, family resemblances, which usually overlap but which are not necessarily shared by all.²³⁹ As such neither law nor politics nor morality has one or a set of core features that can be found in all of the respective discipline's units and that hence clearly defines each of these disciplines and sets them apart from those belonging to other terms. Rather, terms like (international) law, politics, morality or ethics are fluid, their limits and borders cannot be decisively determined.²⁴⁰ A final definition of international law that is based on some inherent, objective and immutable characteristic of all pieces that together make up the field of (international) law is therefore impossible. However, even if such disciplines as 'law', 'politics' or 'morality' cannot be clearly demarcated from one another based on some objective feature or characteristic that does not mean that terms such as international law are devoid of meaning. Rather, according to Wittgenstein, borders and limits of these terms can be drawn for certain purposes.²⁴¹ This is, for example done when, as exemplified above, a definition of soft and hard law is undertaken for the purpose of an argument or this thesis. In analogy, soft law could simply be defined, for the purpose of this thesis, to be legal so that any discourse that builds around soft law standards would also have to be considered a legal one. Yet, stating a mere definition would say little about the qualities and characteristics of the thereby defined discourse.

Moreover, in the light of this thesis' methodological approach, another question might be asked and that is how (and why) definitional boundaries are drawn the way they are drawn and how it is that a discipline, that cannot be unequivocally defined through one or a set of certain objectifiable characteristics, nevertheless can generally be accepted and recognised as a distinct field of inquiry. In order to answer this question it can be helpful to return to discourse theory, discussed above. The argument there was that any discipline's, such as law's or politics' meaning, derives not from characteristics of the units of this discourse but from the discourse that constitutes them. That is, by using a certain episteme a discourse is built around it which then again defines the subject matter of the discourse itself. Once a discipline, such as law, is constituted in that way it is also

²³⁷ One of the most dominant contemporary schools in jurisprudence seeking to provide an answer to the question 'what is law' is that of legal positivism. In general, legal positivism asserts that law is a human creation, it is posited by humans in a certain way, such as through legislation or the rulings of a sovereign. There is therefore no necessary connection between law and morals. See in particular H. Kelsen, *Reine Rechtslehre*, 1960 and for a more moderate approach Hart, note 207. In contrast, the school of natural law generally asserts that some pre-existing laws are valid independent of what humans make or consider to be the law. They usually stress the connection between law and morals. These natural laws can be found through a variety of approaches, including revelation through god, capability approaches, logical approaches etc. For most recent proponent of the natural law theory see in particular, J. Finnis, *Natural Law and Natural Rights*, 1980. See generally M. Freeman, *Lloyd's Introduction to Jurisprudence*, 2008, introduction.

²³⁸ L. Wittgenstein, *Philosophische Untersuchungen*, 2003, para 64 et seq.

²³⁹ Ibid., paras 65 - 66.

²⁴⁰ Ibid., arguing at para 67 "And the upshot of these considerations is: we see a complicated network of similarities overlapping and criss-crossing : similarities in the large and in the small".

²⁴¹ Ibid., para 68.

possible to understand the formation of a distinct disciplinary discourse that builds on that discipline and its units.²⁴²

Judith Shklar makes a similar statement by referring to what she terms 'legalism'. According to her, for a text to be considered 'legal' it requires a certain mindset on the part of the observer or entity that chooses to treat and analyse the material as such. To treat documents, acts or movements as distinctively 'legal', according to Shklar, is a political choice. This political choice and the mindset that comes with it Shklar termed 'legalism'.²⁴³ Once this mindset is set to work law is treated as something distinct and by that a specifically legal discourse is constituted where law is defined and analysed "as if this could be done on its own terms".²⁴⁴ Similarly, Koskenniemi holds that international legal discourse is inherent "political" in nature, yet interpreted by most scholars as an argumentative distinctive legal practice and as a unified legal discourse. Legal advisers, scholars and judges use the language of international law and, thus, constitute international law.²⁴⁵ One example for how this is being done, i.e. how this political choice is facilitated and how a particular school of law is constituted through the application of a certain episteme, is provided by Armin von Bogdandy. Reflecting on the recognition of constitutional legal theory as a distinct area of study within positivist legal discourse he argues that

"law is detached from social reality and tied to legal instruments that flow from sources of law. From this foundation, the positive material is transcended, not by way of political, historical, or philosophical reflection, but through structure-giving concepts such as state, sovereignty, treaty, peremptory norms, or monism and dualism. Even though many of these concepts, in retrospect, clearly have connotations in natural law they are conceived of as specifically legal [sic] and, thus, autonomous. As a consequence they fall under the exclusive competence of legal science. The highest scientific goal is to present, or rather: to reconstruct and represent law as complexes of systematically coordinated concepts. The key scientific competencies thus become abstraction, the development of concepts, and the corresponding arrangement of the legal material. In crafting such concepts, legal scholarship creates for itself an autonomous area of discourse and argumentation...[.]"²⁴⁶

²⁴² Cf. also O. Yasuaki, "International Law in and With International Politics: The Functions of International law in International Society," 14 *European Journal of International Law*, 2004, 105, 122.

²⁴³ J. Shklar, *Legalism*, 1966, 10, arguing that legalism's most important achievement is that it resulted in a mindset where the law is defined and analysed "as if this could be done on its own terms". To her legalism comes with a "dislike of vague generalities, the preference for case by case treatment of all social issues, the structuring of all possible human relations into the form of claims and counter-claims under established rules, and the belief that the rules are "there"."

²⁴⁴ *Ibid.*, 2, arguing that "...law [is] completely [isolated] from the social context within which it exists. Law is endowed with its own discrete, integral history its own science and its own values, which are treated as a single block sealed off from general history, from politics and from morality." See also R. Alexy, *A Theory of Legal Argumentation*, 1989, 2, arguing that legal argumentation constitutes a special case of moral argumentation.

²⁴⁵ J. von Bernstorff, "Sisyphus was an International Lawyer. On Martti Koskenniemi's 'From Apology to Utopia' and the Place of Law in International Politics", 7 *German Law Journal*, 1015, 1016. M. Koskenniemi, *From Apology to Utopia*, 2006, 2 et seq., contending that it is impossible for international lawyers to maintain a specifically "legal" identity separated from that of a social scientist or politician as well as arguing that there is no room for a neutral legal sphere outside politics and that lawyers should integrate this basic insight in their professional identity.

²⁴⁶ A. von Bogdandy, "The Past and Promise of Doctrinal Constructivism: A Strategy for Responding to the Challenges Facing Constitutional Scholarship in Europe", 7 *International Journal of Constitutional Law Advance Access*, 2009, 6, 7.

In other words, an autonomous area of discourse is constituted because texts are transcended through structure giving concepts (an episteme) and thereby presented as legal.²⁴⁷ Applied to the area of international law generally that means that international law can and is regarded or treated as a discrete system and hence can be the basis of a distinctively legal discourse because prima facie neutral texts or generally utterances are transcended by being structured according to certain episteme, i.e. according to structure giving concepts, such as in the above stated example state, treaty, peremptory norm, etc. which then make the text legal or give it legal significance. Only based on this episteme is it possible to build a – to some extent – specific, distinct and autonomous discourse, a particularly international legal discourse. For the area of bioethics that means that if standards, according to the relevant structure giving concepts in the area, can be classified as law they may be considered law. The following sections will therefore turn to a discussion of certain aspects of this episteme of international law and, therein, to an assessment of the standards in the area of bioethics.

2.2. The Properties of Standards in the Area of Bioethics

In this section this thesis will then take the material texts in the area of bioethics, i.e. the standards in the area of bioethics and discuss them through the prism of several 'structure giving concepts' in order to assess whether they may be considered sufficiently legal so that it seems justified to refer to the discourse that builds around them in the area of bioethics as a legal discourse. The episteme used in the following section thereby will be a well established one. That is, this thesis uses the episteme encapsulated in traditional legal textbook discussions on how to distinguish between hard law, i.e. between what is conventionally considered international law, and soft law. Reflecting on whether or not the standards in the area of bioethics can be deemed to be sufficiently hard and thereby sufficiently 'legal', at least according to classical textbook analysis, will make clearer the type of legal or other discourse that is led through the standards in the area of bioethics, be that a legal, soft-legal or not-legal one.

2.2.1. Non-Binding Non-Treaty Standard

One property usually exclusively assigned to hard law and thereby to standards that conventionally are considered to be of legal relevance and status is that they come in the form of a binding treaty. Soft law in contrast is usually considered to be a legally non-binding instrument in a non-treaty

²⁴⁷ The example made here only serves to illustrate how a certain discourse is constituted. That is, it is merely one example of how a certain discourse is being constituted, not a statement on whether that is the most authoritative or correct discourse. A non-positivistic legal discourse, such as a natural law discourse, of course would be built by using different epistemeological categories and hence arrive at another definition of what constitutes law.

form.²⁴⁸ That is, although states have issued and formulated such instruments they are not legally bound by them and following soft law provisions is optional. Moreover, these agreements are not governed by international law i.e. by the provisions of the Vienna Convention for the law of treaties. Article 2 para 1 of the Vienna Convention defines a treaty for the purpose of the Convention as “an international agreement concluded between states in written form and governed by international law whether embodied in a single instrument or in two or more related instruments, and whatever its particular designation.”²⁴⁹ It further states in Article 2 (1) b that an agreement is contractually binding and thus legally relevant for the purpose of the Convention only if the parties want it to be binding, if it is in writing and subject to international law.²⁵⁰ In reverse most scholars agree that if the parties to an agreement “expressly or implicitly do not want a treaty, the provisions of the Vienna Convention do not apply.”²⁵¹ If an instrument is a treaty concluded by states, in writing and if states want it to be binding, by definition, it is then also binding law. If not, and if it cannot be shown to constitute part of international customary law²⁵² or a norm of *jus cogens*²⁵³, international legal standards will often be placed in the category of non-binding soft law, the legal status of which is then subject to debate.²⁵⁴

Formally this distinction can certainly be applied to standards in the area of bioethics. With the exception of the Oviedo Convention all instruments in the area of bioethics remain legally non-binding non treaty standards at least according to the Vienna Convention.²⁵⁵ That is so because there can be no doubt that states intended the declarations in the area of bioethics, to be discussed in the next chapter, to be non-binding non treaty standards. The question about the form of the future instrument in the area of bioethics was, for example, discussed in the Draft Report of the International Bioethics Committee on the Possibility of Elaborating a Universal Instrument on Bioethics. It states that the IBC's goal was to create an “international instrument” but that overall it was preferable to settle on a non-binding declaration.²⁵⁶ Intentions to create a non-binding non-treaty instrument were even more explicitly voiced in the case of the UN Cloning Declaration.²⁵⁷ In contrast, in the case of the Oviedo Convention²⁵⁸ it is evident that states deliberately opted for the form of a binding and enforceable treaty: Throughout the 1980s and 1990s the Council of

²⁴⁸ P. Weil, “Towards Relative Normativity in International Law”, 77 *American Journal of International Law*, 1983, 413, 433, noting that “Thrice nothing is still nothing”.

²⁴⁹ Vienna Convention, note 218, Article 2 para 1 clause a.

²⁵⁰ Hillgenberg, note 216, 504.

²⁵¹ *Ibid.*, 505.

²⁵² See discussion below under Chapter IV, 3.3.

²⁵³ *Ibid.*

²⁵⁴ One further exception, however, might be obiter dicta or general principles agreed upon by all ‘civilized nations.’ See discussion below Chapter IV, 3.3.

²⁵⁵ Vienna Convention, note 206.

²⁵⁶ See discussion in Report on the Possibility of Elaborating a Universal Instrument on Bioethics, note 128, paras 42 and 44. See also R. Andorno, “The Invaluable Role of Soft Law in the Development of Universal Norms in Bioethics”, Ein Beitrag zum Workshop „Die Umsetzung Bioethischer Prinzipien im Internationalen Vergleich“, Auswärtiges Amt of 15 February 2007, at: <http://www.unesco.de/1507.html?&L=0> (last visited 27.04.2012).

²⁵⁷ See discussion below Chapter IV, 3.1.

²⁵⁸ Oviedo Convention, note 5.

Europe in the area of bioethics remained in the non-binding area of recommendations and declarations.²⁵⁹ The drafting of a Convention only became a real option when in the 1990s the Council's Committee of Ministers explicitly formed CAHDI/CBDI and asked it to examine the possibility of preparing a framework convention.²⁶⁰ The fact that until then the field of bioethics was regulated by recommendations indicates that states here again clearly and intentionally opted for a treaty.

Since it is the intentions of states that determine whether or not a binding treaty has been established the Oviedo Convention must formally be regarded as a binding treaty under the Vienna Convention whereas other Declarations in this area formally may not be regarded as such. Yet, by itself this fact does not say much about the standards' relevance to a legal discourse. That is so for several reasons. For one, the line between what is and what is not legally binding runs not always along the line of whether or not a treaty is regarded as a binding treaty under the Vienna Convention.²⁶¹ As Hillgenberg notes there is no provision of international law which prohibits non-treaty agreements as legally relevant and binding sources of law²⁶² some agreements involving states, such as for example agreements between states which are governed by municipal law, are binding and legally relevant even if they are not considered a treaty for the purpose of the Vienna Convention.²⁶³ Moreover, it is at least debatable whether declarations are necessarily legally non-binding. Both, treaties and soft law agreements can as Hillgenberg notes be "based on a coincidence of declared intentions. Since the decisive factor in international law, and especially in the field of international agreements, is the intention of states, there appears to be no reason for why states should be denied the possibility to take on a commitment with lesser legal consequences than a treaty would have"²⁶⁴, i.e. to commit to a binding commitment below treaty level.²⁶⁵ In such a case there may well be a binding agreement but one which is only of limited legal effect.²⁶⁶ Declarations, such as the UDBHR and other non-treaty agreements may also be binding in a less than legal way. There can be normative statements which derive their bindingness not from a legal source but from other sources such as reciprocity or moral commitment.²⁶⁷ Another point of note is that soft law instruments may become legally binding. As Boyle notes this can happen when they "are used as mechanisms for authoritative interpretation or amplification of the terms of a

²⁵⁹ Thus a comprehensive recommendation of 1987 and 1988 first urged efforts to provide for joint action in the area of bioethics by all Council of Europe member states. During the 1980s and early 1990s the Council then issued further numerous resolutions and recommendations in the field of bioethics on topics such as genetic engineering (1982), medical research on human beings (1990), prenatal genetic testing (1990), and DNA analysis (1992). See M. de Wachter, "The European Convention on Bioethics", 1 *Hastings Center Report*, 1997, 13, 14.

²⁶⁰ De Wachter, note 259, 14.

²⁶¹ Boyle, note 217, 903, citing the *ICJ Qatar-Bahrain Maritime Delimitation Case*, ICJ. Rep., 1994, 112 as a decision in which the question of whether or not an agreement is a binding treaty was discussed.

²⁶² Hillgenberg, note 216, 505. Cf. The Vienna Convention, note 218, Article 3 a.

²⁶³ For example a binding agreement between a state and a multinational company, see ICJ, *Anglo-Iranian Oil Case* ICJ. Rep 93, 1952. See also Hillgenberg, note 216, 504.

²⁶⁴ Hillgenberg, note 216, 505.

²⁶⁵ *Ibid.*, 505.

²⁶⁶ Chinkin, note 220, 865.

²⁶⁷ Sheldon, note 214, 2.

treaty",²⁶⁸ are incorporated into the terms of a treaty by implied reference,²⁶⁹ or when they are taken as a first step in a process eventually leading to the conclusion of a treaty or the emergence of a customary international law.²⁷⁰ Diana Sheldon has shown that the latter function of soft law is particularly prevalent in the area of human rights, where soft law is used "primarily as a precursor to binding treaties."²⁷¹ In the area of bioethics it is, for example, arguable that some of the principles, such as those on informed consent, endorsed in the precursors to contemporary standards in the area of bioethics and the early UNESCO Declarations²⁷² were later affirmed in the legally binding Oviedo Convention.²⁷³ One further indication of that the distinction between what is and what is not legally binding according to the Vienna Convention is not absolutely telling with regard to legal status is the fact that states entered declarations of vote on the UDBHR, equalling in many respects the way states enter reservations with regard to treaties.²⁷⁴ This suggests that they expect the UDBHR to have or to develop some binding and normative force and hence to be (or become) of some sort of legal status.²⁷⁵

On the other hand the mere status of a binding treaty is also not an authoritative statement on the relevance to a legal discourse of a specific treaty.²⁷⁶ In the case of the Oviedo Convention it must for example be noted that several of its provisions are vaguely and cautiously worded.²⁷⁷ Such provisions then raise some uncertainty as to whether any real obligations are created by them at all, as well as whether it is at all possible to breach such treaty provisions.²⁷⁸ Also, if the

²⁶⁸ Boyle, note 217, 901. It was a resolution of the parties to the Montreal Protocol to the Ozone Convention which first set out the terms of the non-compliance procedure provided for in the protocol. The procedure was subsequently revised and then incorporated by amendment as an annex in the protocol showing again how non-binding soft law can be readily transformed into binding form. UNEP, Handbook for the Montreal Protocol on Substances that Deplete the Ozone Layer, 2006, section 3.5.

²⁶⁹ Boyle, note 217, 905. The UN Convention on the Law of the Sea, of 10 December 1982 (hereinafter UNCLOS), for example impliedly incorporates recommendations and resolutions of the International Maritime Organisation (hereinafter IMO). Thus although IMO has no power to take formally binding decisions, UNCLOS may indirectly render some of these decisions obligatory.

²⁷⁰ Boyle, note 217, 903. The Universal Declaration of Human Rights, GA Res.217A(III),1948 (hereinafter UDHR), is often cited as an example for such a development. See also D. Hollis, "Why State Consent Still Matters: Non-State Actors, Treaties, and the Changing Sources of International Law", 23 *Berkeley Journal of International Law*, 2005, 1, 5.

²⁷¹ Soft law is perceived "as a way to establish a consensus of norms between members of an agreement that could later be codified through binding law." At the global level, general binding treaties on human rights have decreased over time (i.e. broad declarations on human rights), while more specific non-binding agreements that tackle such complex issues as religious and indigenous rights have increased. Sheldon, note 214, 2.

²⁷² Declaration on Human Genetic Data, note 4; UNESCO Universal Declaration on the Human Genome, note 4.

²⁷³ Universal Declaration on the Human Genome, note 4, Article 5 (b) is reflected in the Oviedo Convention, note 5, Articles 5-7 and 15-18.

²⁷⁴ See for example, the Explanation of Germany's Vote concerning the UDBHR contained in the Protocol of Commission III to the 33rd UNESCO General Conference, 33 C/83, 2005.

²⁷⁵ The very action of ensuring that dissent is on record reveals the concern of states that claims will be made that this non-legal form represents international law and then can be enforced on them. Hillgenberg, note 216, 50. See also De Wachter, note 259, 13.

²⁷⁶ Chinkin, note 220, 861.

²⁷⁷ It is for example unclear to what extent the interests and welfare of the human being shall prevail over the sole interest of society or science, Article 2, Oviedo Convention, note 5.

²⁷⁸ Ibid. While the Council of Europe explicates that "this article is not intended to prohibit all research not beneficial to the person who is the subject of it, but there must be rules setting out the conditions on which such research may be carried out on the persons in question, such as for example, those foreseen for research on incapacitated persons" the

justification for non-fulfilment, or where withdrawal from or implementation of a treaty is largely left to the discretion of the state under obligation, as it is the case with regard to the Oviedo Convention, it is arguable that no or only a semi-binding treaty has been formed.²⁷⁹ Here it is arguable that “the mere use of a treaty form does not of itself ensure a hard or binding obligation.”²⁸⁰

To conclude, the simple rule that legally binding treaties are always legally relevant and hence relevant to a legal discourse and that in reverse legally non-binding instruments are not legally relevant and not relevant to a legal discourse is in many ways too simple. Rather, simply because a standard is soft law and not legally binding according to the Vienna Convention does not mean that it cannot be legally relevant and/or the foundation of a legal discourse. The fact that the soft law standards in the area of bioethics are not legally binding thus does not per se prevent them from giving rise to a legal discourse nor does the fact that the Oviedo Convention is binding per se mandate it to give rise to a legal discourse.

2.2.2. The Level of Enforceability

A second distinction between soft and hard law which is also usually taken as an indicator of soft and hard law's legal (ir)relevance, is that only hard law is legally enforceable. That is, soft law instruments generally do not stipulate for any legal way to enforce their provisions. Hard law in contrast is legally enforceable, for example, in courts or equivalents. If a hard law provision is breached an injured State may even take countermeasures against a State which is responsible for an internationally wrongful act in order to induce that State to comply with its obligations, i.e. may itself breach international law.²⁸¹

Convention is here far from being precisely worded and from specifying the exact obligations undertaken or rights granted. Council of Europe, Parliamentary Assembly, *Projet de convention de bioethique*, doc 7124, 1994, at 25.

²⁷⁹ Hillgenberg, note 216, 504. Article 1 paragraph 2 of the Oviedo Convention, note 5, stipulates that each Party shall take in its internal law the necessary measures to give effect to the provisions of this Convention. This paragraph has been added in the last preparatory stage of the Convention in an effort to enhance the conformity between the Convention and the internal law of the Parties. According to the Explanatory Report on the Oviedo Convention it is largely up to the Parties to determine how they endeavour to comply with this obligation: "With regard to each provision, the means will have to be determined by each Party in accordance with its constitutional law and taking into account the provision in question." Explanatory Report Council of Europe European Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine DIR/JUR, 1997, 54.

²⁸⁰ Chinkin, note 220, 851, arguing that the Vienna Convention, note 218, does not require treaties between States to create any identifiable rights and obligations to be subject to its regime. "It is sufficient that the agreement is in writing and subject to international law. However, if a treaty is to be regarded as "hard", it must be precisely worded and specify the exact obligations undertaken or the rights granted. Where a treaty provides only for the gradual acquiring of standards or for general goals and programmed action it is itself soft for what is apparently a treaty may be devoid of legal content".

²⁸¹ International Law Commission, Articles on State Responsibility, A/56/589 and Corr.1, 2001, Article 49.

Again, formally this characteristic holds true with regard to declarations and conventions, including those in the area of bioethics. The UDBHR, for example, if breached, stipulates for no legal consequence. No state could take another state to court in order to have the provisions of the UDBHR enforced on the 'perpetrating' state. Similarly, no state could legally demand the imposition of sanctions on another state in order to press for the implementation of the Declaration's provisions. The Oviedo Convention, in contrast, stipulates for a variety of enforcement methods, including in Article 25 the application of sanctions in the event of infringement of the provisions contained in the Convention. Other hard law standards in the area, such as for example WTO agreements, come with mandatory dispute resolution processes.²⁸²

Practically speaking, however the difference at least between the Oviedo and the UNESCO standards, should not be overstated and again is of limited informative value with regard to the question of whether or not it is justified to speak of a legal discourse when that discourse builds (also) on legally non enforceable standards. First, in contrast to the theory behind it, practically, the legal enforcement of provisions seems to be only of limited relevance. In cases like the Oviedo Convention, for example, the likelihood that a treaty will give rise to court proceedings or sanctions is so low that it might as well be said that enforcement structures are de facto non-existent. One reason for that is certainly the aforementioned weak and cautious wording of the Oviedo Convention which then makes it difficult to breach its provisions at all.²⁸³ In fact, in many ways the Convention itself seems so softly and vaguely worded that what is apparently a treaty in fact is devoid of legal content.²⁸⁴ Moreover, even with regard to those provisions of the Oviedo Convention which might be specific enough, such as in the area of informed consent to trigger legal action in case of infringement²⁸⁵ it seems unlikely that any state would refer to sanctions to enforce them. States' tendency not to resort to sanctions if their aim can also be achieved via other, usually softer means stems from the fact that the application of sanctions often hurts the state imposing the sanction as much as the state against which they are directed if they lead to a deterioration of relations between the states.²⁸⁶ Another reason is that sanctions are hardly ever effective.²⁸⁷ Thus, even if states in theory can rely on sanctions and other means to enforce a treaty the supposed efficacy of sanctions has been frequently challenged and their use, at least at the multilateral level, has remained fairly limited.²⁸⁸

States instead often have replaced conventional dispute mechanisms by the establishment of mechanisms that monitor compliance with international legal standards on a permanent basis, and

²⁸² See discussion below in Chapter IV, 3.2..

²⁸³ See discussion in the preceding section.

²⁸⁴ Ibid. On the argument generally see also Chinkin, note 220, 851.

²⁸⁵ Oviedo Convention, note 5, Articles 5-7, 15-18.

²⁸⁶ Malanczuk, note 204, 4

²⁸⁷ Ibid, 5.

²⁸⁸ L. Wolcott, "Ongoing at the Carter Center: Seeking Effective Sanctions", 11 *Emory International Law Review*, 1997, 351, 357; P. Kozal, "Is the Continued Use of Sanctions as Implemented Against Iraq a Violation of International Human Rights?", 28 *Denver Journal International Law & Policy*, 2000, 383, 389.

thus prevent or deter as much as possible deviation from standards.²⁸⁹ The establishment of such formal and informal mechanism can, however, also be observed in the area of soft law. States for example rely on a variety of non-legal compliance inducing strategies at their disposal including most prominently naming and shaming strategies,²⁹⁰ strategies which are also available with regard to soft law. Finally, it should be noted that courts have referred to both soft and hard law instruments in the area of bioethics. Like the Oviedo Convention, the UDBHR was thereby cited as a relevant standard with no apparent distinction as to its legal standing.²⁹¹ Moreover, the European Court of Human Rights has already referred to the Oviedo Convention as a standard in cases where Member States of the Council of Europe were involved that had not ratified, in this case France²⁹² or not even sign it, in this case the United Kingdom.²⁹³ The fact that the courts referred to both types of standards in an indiscriminate way and even considered standards applicable to states that had not ratified or signed them implies that the court does not think it necessary to always draw a distinction between formally legally binding and enforceable and formally legally not binding and not enforceable standards. In both instances the standards in question were used as legal instruments from which states should derive normative guidance.

To conclude, legal enforceability certainly is not all that is to be said about law and is not necessarily indicative of legal relevance. Moreover, practically the difference between what is and what is not legally enforceable is not always easy to discern. Most importantly, as shown by the courts lack of legal enforceability certainly does not by itself mean that soft law standards in the area of bioethics cannot give rise to a legal discourse.

2.2.3. Effect and Impact

A further distinction sometimes made between soft and hard law and thereby between legal (ir)relevance is that the former is usually said to be of limited effect and impact. Since states are

²⁸⁹ The UN Human Rights Committees for example are supposed to fulfil such a function. Boyle, note 217, 904.

²⁹⁰ Other such strategies are boycotts of products, changes of trade policies, and other soft reprisals etc. See for example V. Gowlland-Debbas/H. Hadj-Sahraoui/N. Hayashi (eds.), *Multilateral Treaty-Making: The Current Status of Challenges to and Reforms Needed in the International Legislative Process*, 2000, 2 et seq.; and P. Moremen, "Costs and Benefits of Adding a Private Right of Action to the WTO", 11 *UCLA Journal of International Law & Foreign Affairs*, 2006, 189 et seq.

²⁹¹ The Oviedo Convention, note 5, and the UDBHR, note 4, have been cited by international courts as relevant documents. See the European Court of Human Rights, *Evans v. The United Kingdom*, Application No.6339/05 of 7 March 2006, EHRR 43, 2007, 21, citing the UDBHR as a relevant international text at para 42; and European Court of Human Rights, *Vo v. France*, Application No.53924/00 of 8 July 2004, EHRR 10, 2005, 71 para 84.

²⁹² In *Vo v. France*, note 728, the Court referred to the "Oviedo Convention on Human Rights and Biomedicine" and also to its first additional protocol on human cloning and the, at that moment, draft protocol on biomedical research with human beings. Cf. *Vo v. France*, 71 para 84.

²⁹³ In *Glass v. United Kingdom* the Court remarked "that it does not consider the regulatory framework in place in the United Kingdom is in any way inconsistent with the standards laid down in the Bioethics (sic) and Human Rights Convention in the area of consent." See the European Court of Human Rights, *Glass v. United Kingdom*, Application N° 61827/00, para 75, 2004.

free to follow the provisions of a soft law instrument the effect of these instruments is said to be at best unpredictable.²⁹⁴ Hard law in contrast is generally perceived to have a significant impact on states' behaviour.

Depending on what is involved, treaties and/or customary law in fact often are more effective than soft law instruments.²⁹⁵ That is so according to Boyle because they usually indicate a stronger commitment to the principles or rules in question and to that extent carry greater weight than a soft law instrument.²⁹⁶ But the assumption that treaties are necessarily more authoritative is misplaced".²⁹⁷ In most cases as Boyle points out "treaties do not generate or codify customary or other hard law because of their binding form but because they either influence state practice and provide evidence of opinion juris" for new or emerging rules, or because they are good evidence of what the existing law is already".²⁹⁸ In many cases this is no different in the case of non-binding and non enforceable soft law instruments.²⁹⁹ They are generally the more effective the more they reflect an already existing agreement in a certain area of law and the better they are suited to influence states' behaviour.³⁰⁰ In the area of bioethics instruments of the hard and the soft law seem to be most accepted and effective in those respects where they endorse already established principles of international law. That is for example the case when it comes to the principle of autonomy and its formulation in the rules regarding the area of informed consent.³⁰¹ They are less strong when it comes to endorsing new, contested principles, such as protection of the integrity of future generations or the recognition of previously expressed wishes with regard to a medical intervention.³⁰² Yet that assessment applies to all standards, not only the soft law standards which somewhat defies the original statement that held that only hard law standards are effective.

The exact demarcation line between hard and soft law measured by the effect of an instrument becomes even further blurred in those cases in which the potential force of a treaty is heavily qualified by reservations or when there is a need to wait for ratification and entry into force of that treaty and/or when only few states agree to the terms of that treaty.³⁰³ Soft law's authority in contrast is likely to increase if it is able to secure immediate consensus support among states and

²⁹⁴ Boyle, note 217, 902.

²⁹⁵ Ibid.

²⁹⁶ Chinkin, note 220, 861.

²⁹⁷ Boyle, note 217, 903.

²⁹⁸ Ibid. Chinkin, note 220, 859. On the issue of compliance see for example K. Rausiala/A. Slaughter, "International Law, International Relations and Compliance", in: W. Carlsnaes/T. Risse/B. Simmons, *Handbook of International Relations*, 2002, 538 et seq.

²⁹⁹ Boyle, note 217, 903.

³⁰⁰ On a discussion of this issue with regard to the Convention on the Elimination of All Forms of Discrimination against Women, United Nations, Treaty Series, vol. 1249, 13., 1979, (hereinafter CEDAW) see H. Charlesworth/C. Chinkin, *The Boundaries of International Law. A Feminist Analysis*, 2000, 52 et seq., noting that the Convention on the Elimination of all Forms of Discrimination Against Women has been a widely reserved and frequently violated treaty despite its Treaty status.

³⁰¹ Oviedo Convention, note 5, Articles 5-7, 15-18; UDBHR, note 4, Articles 5 -8. These provisions were, for example, referred to in the case of *Glass v. United Kingdom*, note 730.

³⁰² UDBHR, note 4, Article 2 g. Oviedo Convention, note 5, Article 9.

³⁰³ Boyle, note 217, 906.

other stakeholders so that it becomes immediately valid.³⁰⁴ The UDBHR for example was accepted by all of UNESCO's member states – even if qualified through declarations of vote-, whereas the Oviedo Convention was not signed or ratified by a number of states, including the United Kingdom and Germany. Such signing patterns might even indicate the lesser force of the latter agreement, whereas, in comparison, UNESCO's soft law declarations show immediate support from all states, which also implies some authority at least.

Finally, hard and soft law can, as indicated above, both be influential because states perceive it to be so. In the absence of a reliable international police to enforce the law, much depends upon a commonly shared belief that states' conduct will definitely be constrained by the commitments states have accepted, either by specific consent or by virtue of their membership in a rule regime such as the United Nations. In the interstate community, the belief that *pacta sunt servanda*, that treaties are binding, and not just when they are convenient or advantageous is largely responsible to making these agreements work.³⁰⁵ The same reasoning can be true in the area of soft law. If states perceive to be bound by the terms of the UDBHR then it seems that there will be little difference between the Oviedo Convention and the UDBHR. Both will and are followed because they are perceived to be binding and to entail some sense of obligation not because they come in a certain form.³⁰⁶

Hence quite besides the fact that higher impact and effect do not necessarily attach to hard law only a standard's limited effect and impact does not necessarily mean that the standard in question does not give rise to a legal discourse.

2.2.4. Coming into Existence, Content and Style

A further alternative view on soft law focuses on where and how different types of instruments come into existence as well as on their content and style. Soft law is thereby generally seen as being more readily agreed on and entered into than hard law.³⁰⁷ The requirement of a signature and a certain number of ratifications from states to become binding, as is for example the case with regard to the Oviedo Convention³⁰⁸, thereby certainly requires more of a state than merely accepting a standard in that it asks a state to undertake a positive act to affirm a standard and in

³⁰⁴ Ibid.

³⁰⁵ T. Franck, "The Emerging Right to Democratic Governance", 100 *American Journal of International Law*, 1992, 88, 92, noting that "The freedom of states to bargain away short-term benefits in the expectation of longer-term rewards is kept aloft by the perception that law is not merely a coincidence of self-interest. That a state on the losing end of a WTO arbitration today will comply because it can expect to win a subsequent dispute, and then justifiably expect the losing party to comply in deference to the ongoing practice of compliance. In this pattern of continuing interactions, compliance is almost always the rational choice, in every state's self-interest, because every state has a stake in actualizing the belief that the law, habitually, obligates compliance."

³⁰⁶ Hillgenberg notes that declarations and treaties are in fact complied with to largely the same extent. Hillgenberg, note 216, 502.

³⁰⁷ Chinkin, note 220, 855.

³⁰⁸ See discussion in Chapter IV, 2.1.

that it opens the states' performance to public and often democratic scrutiny whereas no such requirements apply in, for example, the case of the UNESCO instruments. However, while the act of signing and opening up for ratification a document might rightly be said to raise the threshold of a state acceding to an agreement, at least in terms of effectiveness of the document such an act does not necessarily make a difference. First, as was the case with the Oviedo Convention, it might mean that fewer states actually commit to the provisions of the treaty. Secondly, the ratification process often draws out the time until a document becomes effective, whereas the Declaration became effective immediately.

Further, soft law also usually is said to be more prevalent in certain areas, such as environmental law, whereas hard law is seen to regulate 'important' areas, such as economics and trade. Since the area of bioethics is addressed by both types of standards that differentiation, however, does not seem to apply to this area of standard setting. In fact, the Oviedo Convention and the UDBHR are concerned with very similar topics. Merely few issues, such as organ transplantation or concerns for the environment are addressed within either the Convention or the UDBHR only.³⁰⁹ Given the potential range of issues that could have been dealt with under the heading bioethics or biomedicine, the number of similar topics addressed in both documents seems rather remarkable.

A further contrast, so Boyle, is sometimes established between "rules", involving clear and reasonably specific commitments which are supposed to be found in hard law provisions, and "norms" or "principles", which, being more open-textured or general in their content and wording, are conventionally understood to be soft.³¹⁰ However, quite besides the fact that the categories "rules", "principles" and "norms" are not easily demarcated, as they have hazy borders and often considerably overlap³¹¹ both types of instruments in the area of bioethics seem to operate on the same basis in that they are based on similar principles, which are generally seen to be more characteristic of soft law documents.³¹² Moreover, instruments of both the soft and hard law use

³⁰⁹ See Chapter IV, 2.1. and 2.2.

³¹⁰ Boyle, note 216, 906. According to Richard Dworkin principles are distinct from rules. The latter are applicable in an all-or-nothing fashion while principles operate in the dimension of weight and importance. R. Dworkin, "The Models of Rules", 35 *University of Chicago Law Review*, 1967, 12, 14; for a critique see J. Raz, "Legal Principles and the Limits of Law", 81 *The Yale Law Journal*, 1972, 823, 824 and J. Raz, *The Authority of Law: Essays on Law and Morality*, 1979, 14 et seq. For further discussion see Chapter VI, 3.3. below and see Vöneky, *Recht, Moral und Ethik. Grundlagen und Grenzen Demokratischer Legitimation für Ethikgremien*, note 15, Part I.

³¹¹ L. Alexander/K. Kress, "Against Legal Principles", in: A. Marmor (ed.), *Law and Interpretation*, 1995, 279, 280 et seq.; D. Kennedy, "Legal Formality", 2 *Journal of Legal Studies*, 1973, 351, 352. Malanczuk, note 204, 48; one example for such difficulties might be the distinction sometimes drawn between civil and political rights, often classified as rules as they involved "clear and reasonably specific" commitments and social and cultural rights which are often characterised as norms or principles given their open-textured or general character. The distinction has, however, often been shown to be misguided. See International Covenant on Economic, Social and Cultural Rights, E/C.12/1998/24, CESCR General Comment 9, 1998 (hereinafter CESCR General Comment 9).

³¹² Because of this weak wording it is even arguable that the Oviedo Convention, note 5, falls under the label soft law since these "soft" undertakings are hardly normative and cannot be described as creating "rules" in any meaningful sense. That this is probably true of many treaties was recognised by the ICJ in the North Sea Continental Shelf Case when it specified that one of the conditions to be met before a treaty could be regarded as law-making is that it should

similar language and similar expressions, and strength of wording.³¹³ And indeed, with the exception of the provisions on informed consent³¹⁴, overall the language of all instruments might best be described as aspirational in that it speaks of overall goals and long term objectives rather than of strict rules and clear guidelines or of specific, detailed propositions.

Given the similarities between both types of standards in the area of bioethics it seems reasonable to assume that both should be able to give rise to the same type of discourse be that a legal or not legal one.

3. Conclusion: The Legal Character of Instruments in the Area of Bioethics

From all that has been said so far all standards in the area of bioethics to varying degrees and with regard to different aspects can be considered both, hard and soft and thereby conventionally be understood to be of greater or lesser legal relevance and status. On one hand, the UNESCO standards for example are not so legal in the sense that they are not legally binding or enforceable. But also the Oviedo Convention can be considered to be rather soft in that it is binding and enforceable only to a limited extent, in that it is rather weakly worded and in that its effect so far seems to have been as limited or broad as that of the soft law standards in the area. On the other hand, standards are legal to the extent that they are a clear expression of states' intention and there can be no doubt that states, with regard to both the UNESCO standards and the Oviedo Convention, intended to create instruments that go beyond mere moral or political relevance. Secondly, standards in the area of bioethics are legal in the sense that they already have and are likely to further develop some binding force. States already comply with them to some extent or fear that at some point these standards develop legal force. In many cases the instruments already help shape or even set the normative order in the area of bioethics. Moreover, they are legally relevant because courts and states refer to them and take actual guidance from their provisions. States' and courts' perceptions of these instruments therefore indicate that they are or may come to be of legal relevance. The legal nature of the standards also becomes evident when they refer to and endorse a long existent body of legal human rights norms, when they take the form of classical legal instruments such as a treaty, and by means of their wording.

Overall, similarities in terms of form, content, style, impact, effect and relevance across all standards in the area of bioethics, no matter whether they are conventionally considered soft or hard, is noticeable and rather striking. To speak of a legal discourse only in those cases where it builds on hard law, i.e. on the basis of the Oviedo Convention therefore seems somewhat artificial. In the context of this thesis, the soft law standards, in addition to the hard law standards, are then

be so drafted as to be "potentially normative" in character. ICJ, *North Sea Continental Shelf Case* (Judgment), ICJ Rep 1969, 72.

³¹³ See note 275.

³¹⁴ Oviedo Convention, note 5, Articles 5-7, 15-18, UDBHR, note 4, Articles 5 -8.

considered to be legally relevant albeit enforceable and binding only to a limited extent. That is, this thesis treats the soft law standards in the area of bioethics not as a mere expression of political or moral will but as –albeit not legally binding and enforceable - extensions to the traditional sources of international law and therefore as legally relevant. In the case of both the soft and hard law standards in the area of bioethics a legal discourse takes place to the extent that the standards use legal terminology and form, are based on some of the premises that define international law, including that they are made by states and applied in between states, that they are human rights standards, use a language of rights and are based and endorse human rights principles and values. The next chapter will further elaborate on the properties of the type of international legal discourse that takes place in the area of bioethics.

Chapter IV International Legal Standards in the area of Bioethics and their legal and non-legal precursors

This chapter introduces some of the international legal standards that have a more or less direct bearing on questions of bioethical relevance. To that end, this chapter first provides some examples of how international law and the field of bioethics continuously intersect, gives an overview over some of the standards that have a bearing on questions of bioethical relevance and then reflects on whether such questions are already dealt with under general international law.

1. Precursors to Legal Standards Directly Addressed to Issues of Bioethical Relevance

1.1. The Trial at Nuremberg

Despite its origin in and longstanding relation with medical ethics and moral philosophy bioethics is often said to have only properly emerged out of and into a legal context with the so called Nuremberg doctors' trials.³¹⁵

The Nuremberg doctors' trials of 1946, a military tribunal at Nuremberg, opened criminal proceedings against 23 Nazi medical professionals for war crimes and crimes against humanity.³¹⁶ It thereby revealed some of the horrors of Nazi physician's involvement in human experimentation and other cruelties against their patients.³¹⁷ As part of their attempt to establish the rule of law in the face of the outrageous 'medical' practices and unprecedented abuse the judges developed a set of 10 standards setting out 10 fundamental ethical standards based on "principles of the law of nations as they result from the usages established among civilized peoples, from the laws of humanity, and from the dictates of public conscience."³¹⁸

The standards have later come to be known as the Nuremberg Code. Of the 10 principles of this Code, the absolute requirement of informed consent receives the most treatment. According to the Code consent must be voluntary, competent, informed, and comprehending.³¹⁹ The second most important condition promulgated by the code is the need for scientifically-valid research designs

³¹⁵ TMWC, note 56. For background see T. Taylor, *Final Report to the Secretary of the Army on the Nuremberg War Crimes Trials under Control Council Law No. 10*, 1949 and G. Annas/M. Grodin (eds.), *The Nazi Doctors and the Nuremberg Code: Human Rights in Human Experimentation*, 1992.

³¹⁶ Of the 23 Nazi physicians sixteen were found guilty, and seven were hanged. The defendants were held to have acted "in complete disregard of international conventions, the laws and customs of war, the general principles of criminal law as derived from the criminal laws of all civilized nations." Taylor, note 315, 101 and TMWC, note 56, 181-182.

³¹⁷ These crimes included exposure of humans to extremes of temperature, performance of mutilating surgery, and deliberate infection with a variety of lethal pathogens. See M. Marrus, "The Nuremberg Doctors' Trial in Historical Context", 73 *Bulletin of the History of Medicine*, 1999, 106 et seq.

³¹⁸ TMWC, note 56, 182. See also G. Annas, "Protecting Soldiers from Friendly Fire: The Consent Requirement for Using Investigational Drugs and Vaccines in Combat", 24 *American Journal of Law & Medicine*, 1998, 245 et seq.

³¹⁹ TMWC, note 56, 182 et seq.

that have the real potential to produce fruitful results for the good of society.³²⁰ Other fundamental principles include that the experiment must be designed and conducted to minimize the research subject's pain and suffering, that experiments that are likely to result in injury or death to the test subject should not be conducted and that any risk to be applied to the subject must be weighed against the 'humanitarian' importance of the data sought.³²¹

Although the Nuremberg Code never became part of binding international law in that it does not give rise to legal obligation for states to adhere to its provision or in that observance of its provisions could be legally enforced against states³²² it is regularly cited as one point of birth of modern bioethics as well as one foundational cornerstone of modern bioethical thought.³²³ This is so because it was there that bioethics was first approached by a formal, state endorsed and internationally highly visible forum that 'codified' principles of bioethics within an official, widely recognised and internationally applicable document. As a result, the Nuremberg Code has been one source of guidance of many of the modern legal instruments, binding and non-binding, in the area of bioethics.³²⁴ The concept of informed consent featuring so prominently in the Code, today, for example, constitutes a fundamental principle recognised in all bioethical instruments.³²⁵ Also the ethical requirements related to the treatment of patients have clearly left their imprint on all later documents in the area.³²⁶

1.2. Declarations of the World Medical Association

Other prominent, though not legal³²⁷ precursor to current legal instruments in the field of bioethics are the World Medical Association's (hereinafter WMA) Declaration of Geneva³²⁸, adopted in

³²⁰ TMWC, note 56, 181.

³²¹ Ibid.

³²² This statement applies to the ethical codes arising out of the TMWC, note 56, not the judgment delivered by the court. For a profound discussion of the terms "legal", "soft" and "hard law" see chapter V below.

³²³ See for example Plomer, note 64, 1; and G. Annas, "American Bioethics after Nuremberg: Pragmatism, Human Rights and Politics", University Lecture, Boston University of 26 October 2005, at: <http://www.umin.jp/supercourse/lecture/lec30701/lecture.pdf> (last visited 27.04.2012) and Report on the Possibility of Elaborating a Universal Instrument on Bioethics, note 128, para 5.

³²⁴ Plomer, note 64, 1-2.

³²⁵ Cf. for example the provisions on informed consent in the Oviedo Convention, note 5, Chapter II, and Articles 6 – 8 in the UDBHR, note 4, as well as provisions mandating respect for human rights and dignity in Article 3 UDBHR, note 4, and Article 1 Oviedo Convention, note 5.

³²⁶ Cf. for example Chapter V, and Articles 6 – 8 in the UDBHR, note 4. See also B. Brody, *The Ethics of Biomedical Research. An International Perspective*, 1998, 31 et seq.

³²⁷ See discussion of soft and hard law below in Chapter III, 1.2. For the purpose of this thesis all standards that have been issued by states yet remain legally non binding and legally unenforceable are referred to as soft law. Legally enforceable and binding standards that are covered by the provisions of the Vienna Convention, note 206, and that have been issued by the states are referred to as hard law. Accordingly, the Nuremberg Code may be considered to constitute soft law as it has been elaborated by states and comes in a legal format. The standards by the World Medical Association, as guidelines that have not been developed by states, however, do not, according to the definition used in this thesis, constitute soft law. World Medical Association, Declaration of Geneva of 11 September 1948, reprinted in 1 World Medical Association Bulletin, 1949, 34 set seq. (hereinafter Geneva Declaration).

September 1948 and the Helsinki Declaration on Ethical Principles for Medical Research Involving Human Subjects (hereinafter Helsinki Declaration) adopted in 1964.³²⁹ The principles enshrined in the Helsinki Declaration, with some limitations require among other things, that research on humans should only be performed by qualified individuals and that the potential benefits of the experiment be balanced against the risks to the research subject.³³⁰ Since its initial adoption in 1964, the Declaration of Helsinki has been amended five times, most recently in 2000.³³¹ As it stands today, it provides 16 basic principles governing medical research involving human subjects and further five principles governing medical research combined with medical care.

Although WMA standards are legally nonbinding and legally unenforceable³³² the principles set out in the Declarations have contributed to the shaping of modern bioethical thought and legal standards in the area of bioethics.³³³ They have done so because they, together with the Nuremberg Code, were the first to establish basic ethical principles and procedures in many areas of bioethical relevance in a codified and internationally relevant text.³³⁴ They also reaffirmed once more the connection between bioethics and human rights, thereby linking the field of bioethics even more closely to a legal context.³³⁵

1.3. International Human Rights Standards

As will be further explored over the next sections, chapters and throughout this thesis international human rights standards, in particular the Universal Declaration of Human Rights (hereinafter

³²⁸ The Geneva Declaration, note 205, has sometimes been depicted as a modern restatement of the Hippocratic Oath; see K. King, "A Proposal for the Effective International Regulation of Biomedical Research Involving Human Subjects", 34 *Stanford Journal of International Law*, 1998, 163, 179.

³²⁹ World Medical Association, Declaration of Helsinki of 8 June 1964, reprinted in 8 *World Medical Journal*, 1964, 281 et seq. (hereinafter Helsinki Declaration). For background see Brody, "The Ethics of Biomedical Research. An International Perspective", note 326, 34 et seq.

³³⁰ One significant change between the Nuremberg Code, see above under 1.1., and the Helsinki Declaration, note 329, is that the latter permits, under certain circumstances, research on persons unable to consent, which was precluded by the former.

³³¹ Notes of clarification were added to para 29 of the Helsinki Declaration, note 329, and to para 30 of the Declaration in 2004. The 2004 version is the official one. See World Medical Association Ethics Unit on the Declaration of Helsinki, at: <http://www.wma.net/e/ethicsunit/helsinki.htm> (last visited 27.04.2012).

³³² See discussion of soft and hard law below in Chapter III, 1.

³³³ U. Schmidt/A. Frewer (eds.), *History and Theory of Human Experimentation: The Declaration of Helsinki and Modern Medical Ethics*, 2007, 3 et seq.

³³⁴ See for example the 1993 Council for International Organization of Medical Sciences (hereinafter CIOMS) International Ethical Guidelines for Biomedical Research that affirm that the "Declaration of Helsinki... is the fundamental document in the field of ethics in biomedical research and has had considerable influence on the formulation of international, regional and national legislation and codes of conduct" Cited in: D. Human/S. Fluss, *The World Medical Association's Declaration of Helsinki: Historical and contemporary perspectives*, 2001, at:

http://www.wma.net/e/ethicsunit/pdf/draft_historical_contemporary_perspectives.pdf (last accessed 27.04.2012), noting the Declaration's influence on a variety of international standards in the area of bioethics, including some of those developed by the World Health Organization (hereinafter WHO), The Joint United Nations Programme on HIV/AIDS (hereinafter UNAIDS) and the European Union.

³³⁵ Human/Fluss, note 334, 8.

UDHR)³³⁶, have been most influential on current legal approaches to the area of bioethics and generally bioethical thought. In fact, UNESCO's International Bioethics Committee (hereinafter IBC)³³⁷ claims that modern bioethics is “indisputably founded on the pedestal of the values enshrined in the Universal Declaration of Human Rights.”³³⁸

The promotion of human rights as an aim is mentioned in the Charter of the United Nations (hereinafter UN Charter) and it is one of the purposes of the United Nations (hereinafter UN) as such.³³⁹ The importance attached to human rights was later given legal expression in the UDHR which was adopted in 1948 by the United Nations General Assembly and which sets forth the inalienable rights and fundamental freedoms of each and every human being without regard to his race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status.³⁴⁰ It found further recognition in the adoption of two International Covenants, one on Civil and Political Rights (hereinafter ICCPR) and on Economic, Social and Cultural Rights (hereinafter ICESCR).³⁴¹ Many of these standards' provisions could be interpreted as having some bearing on issues of bioethical relevance. The right to life, liberty and security of persons, the right not to be held in slavery and freedom from torture as well as the principle not to be discriminated against could be relevant to discussions around such issues as medical research on human research subjects, organ transplantation or access to essential medicines.³⁴² Also particularly relevant to the context of bioethics is Article 25 of the UDHR which proclaims the right to “a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services”³⁴³ which has subsequently been enshrined in several other human rights standards.³⁴⁴ Taken together, a growing body of international human rights treaties and non binding standards detail the obligation of states to respect, protect and fulfil human rights, many of which can be interpreted as having meaning also in the area of bioethics.

³³⁶ UDHR, note 270.

³³⁷ See below, Chapter IV, 2.2 and Vöney, Recht, Moral und Ethik. Grundlagen und Grenzen Demokratischer Legitimation für Ethikgremien, note 15, Chapter 6 II.

³³⁸ Report on the Possibility of Elaborating a Universal Instrument on Bioethics, note 128, para 5.

³³⁹ UN Charter, note 208.

³⁴⁰ UDHR, note 270, Article 2.

³⁴¹ International Covenant on Civil and Political Rights, UN Doc.A/6316, 1966 (hereinafter ICCPR) and International Covenant on Economic, Social and Cultural Rights, UN Doc.A/6316, 1966 (hereinafter ICESCR).

³⁴² ICCPR, note 314, Articles 3 to 5. 'Medical' research, as revealed by the TMWC, note 56, has already been used in a way that violates the right to be free from torture and the right to life.

³⁴³ UDHR, note 270, Article 25. This right was also articulated and defined in the 1946 Constitution of the World Health Organization, defining health in its preamble as "a complete physical, mental and social wellbeing" Constitution of the World Health Organization, 1946, Preamble.

³⁴⁴ Under the ICESCR, note 341, Article 12 states have an obligation to secure individual rights in relation to health and attainable health standards. See also for example Article 24 of the Convention of the Right of the Child, Doc. A/RES/44/25, 1990; ILO Convention no. 169, 1989, Article 25, concerning indigenous and tribal people in independent countries guaranteeing a right to health for indigenous and tribal people. At the European level the Council of Europe's Convention for the Protection of Human Rights and Fundamental Freedoms, ETS 5, 1950, in Article 10, and the Council of Europe's European Social Charter, ETS 163 (revised), 1996, in Article 11, have equally over the years defined and established a right to health.

That is so even though traditional interpretations, by, for example, governments of these rights and their scope have been rather narrow. With regard to the right to life and the right to health, which so far, for example, has not been interpreted to include a right to access to essential medicines, Holger Hestermeyer argues that

“a distinction between a 'right to life' and 'life' is ... artificialalso, there is no reason why a lack of food or medical services should be less significant for the right to life than insufficient penal laws on murder. To be effective the right to life has to extend to the basic conditions of life, the components necessary for survival, even if that part of the right is to some extent coextensive with economic, social and cultural rights.”³⁴⁵

Thus, the fact that so far the legal human right to life, as for example stated in Article 6 of the ICCPR³⁴⁶, has been narrowly interpreted does not mean that the right to life is not relevant to bioethical debates nor that it could not be taken as the basis of future legal discussions in the area. In any event, however, the sheer existence of human rights that are meant to safeguard individuals' well being and to protect them against abuses by the state has clearly provided the ferment and stepping stone from which the more recent human rights standards in the area of bioethics could at all develop. The discussion of health, health related, environmental and of other questions arising in the life sciences within a human rights framework, for example, certainly has had an influence on that issues of bioethical relevance are acceptably dealt with in human rights frameworks.

1.4. Conclusion

Several international agreements and standards had or have a strong bearing on the development of contemporary standards in the area of bioethics. The first two standards that were mentioned in this context, the Nuremberg Code and the Helsinki Declaration of the WMA, are legally non binding and non enforceable standards that, as will be seen below, have nevertheless clearly helped shaping current standards in the area of bioethics. They have done so by being among the first internationally relevant text that codified standards in the area of bioethics and by linking them to a context of human rights and human rights principles. Human rights law in contrast, being in some cases legally binding and enforceable treaty law and in some cases non legally binding and non enforceable expressions of states' intention, has been most influential to the development of current standards in the area of bioethics, mostly so by giving issues in the area of bioethics a conceptual framework within which these issue can be addressed.

³⁴⁵ H. Hestermeyer, *Human Rights and the WTO. The Case of Patents and Access to Medicines*, 2007, 116.

³⁴⁶ ICCPR, note 314. See also UDHR, note 270, Article 3.

2. Contemporary Instruments in the Area of Bioethics

In the following some of the most relevant international legal standards in the area of bioethics will be discussed. This chapter will start with a discussion of the standards of the Council of Europe as these standards to date constitute the only legally binding and enforceable instruments in the area. It will then move on to discuss some of UNESCO's legally non-binding and non-enforceable soft law standards addressed to the area of bioethics.

2.1. The Council of Europe Instruments in the Area of Bioethics

The Council of Europe is one of various international organisations that have come to concern themselves directly with questions of bioethics. Founded in 1949, the Council of Europe seeks “to achieve a greater unity between its members for the purpose of safeguarding and realising the ideals and principles which are their common heritage and facilitating their economic and social progress. This aim shall be pursued through the organs of the Council ... and in the maintenance and further realisation of human rights and fundamental freedoms and other reference texts on the protection of individuals.”³⁴⁷ It has 47 member countries and five observer countries, including the United States, Canada and Japan.³⁴⁸ The Council's primary aims are to protect human rights, pluralist democracy and the rule of law, to promote awareness and encourage the development of Europe's cultural identity and diversity and to find common solutions to the challenges facing European society, particularly discrimination against minorities, xenophobia, intolerance, bioethics and cloning, terrorism, trafficking in human beings, organised crime and corruption, cybercrime, violence against children. The Council moreover seeks to consolidate democratic stability in Europe by backing political, legislative and constitutional reform.³⁴⁹

Over the last 20 years the Council of Europe has also increasingly addressed itself to bioethical issues.³⁵⁰ Its motivation to do so stems from the recognition that “biological and medical research has produced spectacular advances in the health field, but [that] it also raises questions concerning a number of fundamental values, such as the individual, the family, health, private life, human rights and human dignity.”³⁵¹ Where the Council has addressed issues of bioethical relevance it has done so with a particular view to “protect the individual's dignity and fundamental rights with regard to the application of ordinary medicine and new medical techniques.”³⁵² According to its own mission statement it thereby seeks to “strike a balance between freedom of research and

³⁴⁷ Statute of the Council of Europe, ETS No.1, 1949, Article 1.

³⁴⁸ See List of Member States of the Council of Europe, at: http://www.coe.int/T/E/Com/About_Coe/Member_states/default.asp. (last visited 27.04.2012).

³⁴⁹ See Council of Europe in Brief, at: <http://www.coe.int/t/dg3/healthbioethic/> (last visited 14.12.2012). For background see F. Benoît-Rohmer/H. Klebes, *Council of Europe Law*, 2005.

³⁵⁰ See Council of Europe's Ethics section at: http://www.coe.int/t/e/legal_affairs/legal_co-operation/Bioethics/ (last visited 14.12.2012).

³⁵¹ C. Tofan, *Human Rights and Biomedicine*, 2008, 1.

³⁵² See Council of Europe's Ethics section, note 350.

protection of persons, while fostering reflection and public discussion, ensuring respect for fundamental values, and arbitrating between different viewpoints and interests by drawing up principles and legal standards which reflect these values.”³⁵³

To facilitate its work in the area of bioethics the Council has set up an Ad hoc Committee of experts on Bioethics (hereinafter CAHBI) which became in 1992 the Steering Committee on Bioethics (hereinafter CDBI)³⁵⁴. Its task are (i) “to study the set of problems posed for law, ethics and human rights by progress in the biomedical sciences; (ii) to help harmonising the policies of member States as far as possible and, if necessary, framing appropriate legal instruments; and (iii) to co-operate with other steering committees and ad hoc committees in the implementation of the Projects involving several fields of activity.”³⁵⁵ The work of CAHBI, and then of the CDBI, has led to the adoption of several Recommendations of the Committee of Ministers³⁵⁶ in the area of bioethics and to the elaboration of the European Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (hereinafter Oviedo Convention)³⁵⁷, the first and so far only international treaty in this field. The Oviedo Convention is also special in that it is one of only two international instruments that have so far attempted to approach bioethics in a comprehensive manner, seeking to address a variety of bioethically relevant issues within one coherent approach and under the head of one instrument.

2.1.1. Convention for the Protection of Human Rights and the Dignity of the Human Being with Regard to the Application of Biology and Medicine

The Oviedo Convention was adopted on November 19, 1996 by the Council of Ministers of the Council of Europe and opened for signature on April 4, 1997 in Oviedo.³⁵⁸ It took effect on December 1, 1999 with the 5 necessary ratifications.³⁵⁹ It has since been ratified by 21 European states as well as it has been signed by further 13 states. Notably the Convention has not been signed by a number of countries, including Austria, Belgium, Germany, the United Kingdom and

³⁵³ Ibid.

³⁵⁴ Council of Europe, Information Document Concerning the CDBI, INF, 2007. For a discussion of competencies, working procedures and the role of CDBI in constituting legitimate outcomes in normative processes see Vöneky, Recht, Moral und Ethik. Grundlagen und Grenzen Demokratischer Legitimation für Ethikgremien, note 15, Chapter 6, II, 2.

³⁵⁵ "Terms of References" for CDB, at: Council of Europe, Information document concerning the CDBI, note 354.

³⁵⁶ A list of Resolutions and Recommendations of the Committee of Ministers in the field of bioethics is contained in Council of Europe Compendium of Texts of the Council of Europe on Bioethical Matters, CDBI/INF, 2005, Vol.1.

³⁵⁷ Oviedo Convention, note 5. As background to the Convention and its additional protocols see generally E. Doppelfeld, "Das Menschenrechtsübereinkommen zur Biomedizin: Entstehungsgeschichte und Regelungsinhalt", in: J. Taupitz (ed.), *The Convention on Human Rights and Biomedicine – A Suitable Model for World Wide Regulation*, 2002, 15, 19-20.

³⁵⁸ Oviedo Convention, note 5.

³⁵⁹ Including the ratification of 4 member States of the Council of Europe. See Article 33, para 3 of the Oviedo Convention, note 5.

Russia.³⁶⁰ The Convention is open to signature from non-member states of the Council of Europe³⁶¹. So far, it is the only international treaty in the field of bioethics.³⁶²

The Convention was drafted in an attempt to design an instrument that establishes a common European minimum level of protection concerning the application of biology and medicine.³⁶³ To this purpose the Convention sets out prohibitions against the misuse of biological and medical advances and deals with a variety of issues including access to healthcare, consent requirements, privacy, protection of the human genome, organ transplantation, and rules concerning scientific research. As evidenced by its title, the Convention on Human Rights and Biomedicine thereby aims to fit into the framework of European human rights law. It should be noted that the Oviedo Convention does not use the term bioethics. Although the word bioethics was first to be included in its title, eventually it was repelled from the document. This was done so as it was felt that the term bioethics was not clear enough, not even to specialists and thus might lead to confusion³⁶⁴. While the documents' subject matter makes it fair to subsume the document's discussion under the heading "bioethics", it must be noted that the choice of the word biomedicine was deliberate and that this implies a different focus than the use of the much broader term bioethics.³⁶⁵

Chapter I of the Convention first of all enshrines the dignity and identity of all human beings³⁶⁶ and stresses the supremacy of the interests and welfare of the human being over the sole interests of society and science.³⁶⁷ It further states that Parties, taking into account health needs and available resources, shall take appropriate measures to provide equitable access to healthcare of appropriate quality.³⁶⁸ Finally, Article 4 stresses the important role of professional obligations and standards. Chapter I thereby reflects the most basic concepts of the Convention. The entire Convention and its Protocols have to be read and interpreted in the light of these first principles.³⁶⁹

Chapter II is among the most detailed of the Convention. It specifies the obligation to obtain free and informed consent to any medical intervention from persons concerned.³⁷⁰ Article 6 allows medical treatment on a person unable to consent, such as a minor or a person with a mental

³⁶⁰ Chart of Signatories to the Oviedo Convention, note 5, at: <http://conventions.coe.int/Treaty/Commun/ChercheSig.asp?NT=164&CM=8&DF=3/4/2008&CL=ENG> (last visited 27.04.2012).

³⁶¹ Upon invitation any non-member State of the Council of Europe may accede to the Convention. See Article 34, para 1 of the Oviedo Convention, note 5.

³⁶² See Chapter III, 2.2.

³⁶³ S. Pridan-Frank, "Human-Genomics: A Challenge to the Rules of the Game of International Law", 40 *Columbia Journal of Transnational Law*, 2002, 619, 643; on the development and background to the Convention see also N. Lenoir, "Bioethics, Constitutions and Human Rights", 172 *Diogenes*, 1995, 11 et seq. and Doppelfeld, note 357, 19-25.

³⁶⁴ Council of Europe Steering Committee on Bioethics, Preparatory work on the document, CDBI/Inf, 2000, 1, 6.

³⁶⁵ See note 226.

³⁶⁶ Oviedo Convention, note 5, Article 1.

³⁶⁷ *Ibid.*, Article 2.

³⁶⁸ *Ibid.*, Article 3.

³⁶⁹ See also J. Dute, "The Leading Principles of the Convention on Human Rights and Biomedicine", in: J. Gevers/E. Hondius/J. Hubben (eds.), *Health Law, Human Rights and the Biomedicine Convention. Essays in Honour of Henriette Roscam Abbing*, 2005, 3, 8.

³⁷⁰ Oviedo Convention, note 5, Article 5.

disorder, only “for his or her direct benefit.”³⁷¹ In such cases an intervention may only be carried out with the authorisation of that person's legal representative or appropriate authority.³⁷² A person who has a mental disorder may be subjected, without his or her consent, to an intervention aimed at treating his or her mental disorder only where, without such treatment, serious harm is likely to result to his or her health.³⁷³

The issue of informed consent also features in the fifth Chapter, which is also again more detailed than many of the Convention's other chapters. It addresses the issue of “scientific research” and enshrines the principle of freedom of research.³⁷⁴ But it also states several conditions that have to be met for research to take place. These include the need to obtain the potential research subject's free and informed consent.³⁷⁵ Articles 17 and 18 lay down general rules, as well as special provisions regarding persons not able to consent to research and embryos in vitro.³⁷⁶ A person not able to give consent may be the subject of research only if it has the potential to produce real and direct benefit to the person's health, if the research cannot be carried out on individuals capable of giving consent, if the legal representative consents, and if the person involved does not object. Exceptionally, however, the requirement of direct benefit to the subject may be lifted if the research “has the aim of contributing ... to the ultimate attainment of results capable of conferring benefit to the person concerned or to other persons in the same age category or afflicted with the same disease or disorder or having the same condition .”³⁷⁷

The other chapters of the Convention address various further themes of the bioethical debate. Chapter III enshrines rights to privacy and to information concerning one's health, stipulating that everyone has the right to respect for his or her private life in relation to information about his or her health and that everyone is entitled to know (or to reject) any information collected about his or her health.³⁷⁸ Chapter IV deals with the human genome, prohibiting “any form of discrimination against a person on grounds of his or her genetic heritage”³⁷⁹ as well as “the use of medical techniques to enable selection of a future child's sex.”³⁸⁰ Furthermore, article 12 prescribes that

³⁷¹ Ibid., Article 6 para 1.

³⁷² Ibid., Article 6 para 2; for further discussion see M. Trigilio, “The Convention on Human Rights and Biomedicine: Allowing Medical Treatment and Research without Consent on Persons Unable to Give Informed Consent”, 22 *Suffolk Transnational Law Review*, 1999, 641 et seq.

³⁷³ Oviedo Convention, note 5, Article 7.

³⁷⁴ Ibid., Article 15.

³⁷⁵ Ibid., Article 16, clause iv.

³⁷⁶ The basic requirements for research on humans, pursuant to Article 16, are lack of alternative research methods, proportionality of benefits and risks, approval by an independent ethical review body, and documented informed consent.

³⁷⁷ Ibid., Article 17, para 2. With regard to research on embryos in vitro the Convention in Article 18 stipulates that where the law allows for such research, “it shall ensure the adequate protection of the embryo” and prohibits the creation of human embryos for research purposes.

³⁷⁸ Ibid., Article 10.

³⁷⁹ Ibid., Article 11.

³⁸⁰ Ibid., Article 14.

genetic testing may be performed for health care purposes or for scientific research only.³⁸¹ The seventh chapter deals with organ and tissue removal from living donors for transplantation purposes³⁸², with the prohibition of financial gain³⁸³ and with the adequate disposal of a part of the human body.³⁸⁴ Chapter X advocates the promotion of a public debate and consultation on the issues addressed within the Convention.³⁸⁵

The Convention so far is the only legally-binding and enforceable international text in the area of bioethics. Chapter VIII thus deals with possible infringements of the provisions of the Convention, providing that states should have in place appropriate judicial protection to prevent or to put a stop to an unlawful infringement of the rights and principles set forth in the Convention and the possibility to compensation for those who suffered undue damage.³⁸⁶ Article 25 foresees the possibility of sanctions against states to be applied in the event of infringement of the provisions contained in the Convention. Furthermore, the European Court of Human Rights may be asked to give advisory opinions on legal questions connected with the interpretation of the Convention.³⁸⁷

Overall, the Convention has been designed to serve as framework Convention only. Chapter XII therefore foresees the possibility of concluding further protocols that clarify and specify issues at

³⁸¹ The strict character of the prohibition against discrimination on genetic grounds is highlighted by the fact that signatories to the Convention cannot restrict the exercise of the rights protected by Articles 11 and 12 of the Oviedo Convention, note 5.

³⁸² Ibid., Article 19, holding that tissue transplantation from a living person may be carried out solely for therapeutic benefit and that the person must have given his free and informed consent. The Convention is limited to a discussion of organ transplantation as regards living donors. Article 20 makes special provisions for people unable to consent, allowing only for the removal of regenerative tissue from such a person provided that there is no compatible donor available who has the capacity to consent; that the recipient is a brother or sister of the donor; that the donation must have the potential to be life-saving for the recipient; that the authorisation has been given specifically and in writing, in accordance with the law and with the approval of a competent body; and that the potential donor concerned does not object.

³⁸³ Ibid., Article 21.

³⁸⁴ Ibid., Article 22.

³⁸⁵ Ibid., Article 28.

³⁸⁶ Ibid., Articles 23 to 25. However, Article 26 under certain conditions and with regard to certain rights and protective provisions allows for the restriction of rights in the Oviedo Convention, note 5, maintaining that 1 "no restrictions shall be placed on the exercise of the rights and protective provisions contained in the Convention other than such as are prescribed by law and are necessary in a democratic society in the interest of public safety, for the prevention of crime, for the protection of public health or for the protection of the rights and freedoms of others." And 2 holds that "The restrictions contemplated in the preceding paragraph may not be placed on Articles 11, 13, 14, 16, 17, 19, 20 and 21." This is notwithstanding the fact that "none of the provisions of this Convention shall be interpreted as limiting or otherwise affecting the possibility for a Party to grant a wider measure of protection with regard to the application of biology and medicine than is stipulated in this Convention." Ibid., Article 27. These exceptions are similar to those set out in Article 29 of the UDHR, note 214, although it is worth noting that in the Oviedo Convention the very broad aim of general welfare in society has been replaced by the more specific one of protecting public health. It should also be pointed out that the patient's health is not mentioned as one of the potential reasons for an exception to be made. To avoid any misuse of this concept, the drafters of the text preferred to mention it only in the specific provisions. See R. Andorno, "Biomedicine and International Human Rights Law: In Search of a Global Consensus", 80 *Bulletin of the World Health Organization*, 2002, 959 et seq.

³⁸⁷ Oviedo Convention, note 5, Article 29.

stake³⁸⁸. To date four such additional protocols have been concluded.³⁸⁹ They will be briefly discussed in the following sections.

2.1.2. Additional Protocols

The four additional protocols to the Oviedo Convention build on the principles embodied in the Convention. Only states that have signed the Oviedo Convention may also sign the Protocols.³⁹⁰ The provisions of the Protocol then must be regarded as additional articles to the Convention. The Oviedo Convention's provisions apply accordingly.³⁹¹

2.1.2.1. Additional Protocols to the Oviedo Convention with regard to the Application of Biology and Medicine on the Prohibition of Cloning Human Beings

The Additional Protocol to the Oviedo Convention on the prohibition of cloning human beings was signed in Paris on 12/02/1998 and came into force on 1/3/2001 by the necessary five ratifications including four member states of the Council of Europe.³⁹² Until now, 16 states have ratified and an additional 15 have signed the Protocol. Notably the Protocol has not been signed by a number of countries, including Austria, Belgium, Germany, Ireland, the United Kingdom and Russia.³⁹³ Like the Oviedo Convention it is legally binding and legally enforceable for those states that adhere to it.³⁹⁴

The Protocol remedies the Oviedo Convention's lack of any specific provision with regard to the cloning of human beings.³⁹⁵ Article 1 para 1 prohibits “any intervention seeking to create a human being genetically identical to another human being, whether living or dead.” The expression “human being genetically identical to another human being” is thereby defined as a human being

³⁸⁸ Ibid., Article 31.

³⁸⁹ Additional Protocol concerning Transplantation of Organs and Tissues of Human Origin, note 31; Additional Protocol on Genetic Testing, note 31.

³⁹⁰ Article 31 of the Oviedo Convention, note 5.

³⁹¹ Article 3 of the Additional Protocol on the Prohibition of Cloning Human Beings, note 31; Article 30 of the Additional Protocol concerning Transplantation of Organs and Tissues of Human Origin, note 31; Article 36 of the Additional Protocol concerning Biomedical Research, note 31; and Article 21 of the Additional Protocol on Genetic Testing, note 31.

³⁹² Additional Protocol on the Prohibition of Cloning Human Beings, note 31, Article 5.

³⁹³ Chart of Signatories to the Additional Protocol on the Prohibition of Cloning Human Beings, note 31, at: <http://conventions.coe.int/Treaty/Commun/ChercheSig.asp?NT=168&CM=8&DF=3/4/2008&CL=ENG>. (last visited 27.04.2012).

³⁹⁴ See Chapter III, 2.1.

³⁹⁵ The Oviedo Convention, note 5, in Article 18, para 1 merely ensures the protection of the embryo in vitro in the framework of research and Article 18 para 2 prohibits the creation of embryos for research purposes. However, it does not prohibit the cloning of human beings as such. See L. Honnefelder, "Das Menschenrechtsübereinkommen zur Biomedizin des Europarats", in: W. Barz/A. Hülster/K. Kraemer/M. Lange (eds.), *Umwelt und Europa*, 1999, 159 et seq.

sharing with another the same nuclear gene set.³⁹⁶ Beyond that, however, the Protocol does not provide a definition of the term “human being”.³⁹⁷ The exact scope of the prohibition of cloning of human beings can thus only be assessed by referring to domestic law. The Government of the Kingdom of the Netherlands has, for example, already declared in relation to Article 1 of the Protocol, “that it interprets the term “human being” as referring exclusively to a human individual, i.e. a human being who has been born.”³⁹⁸ According to this definition only the practice of reproductive cloning that would result in the birth of a human being genetically identical to another human being is banned. Therapeutic cloning processes that e.g. merely clone embryonic stem cells for later uses would still be allowed.

Despite this definitional loophole the protocol has and can generally been applauded for providing a complete, unequivocal and unambiguous ban on human cloning, which is simple to understand and therefore easy to administer. On the other hand it must be noted that a complete ban might in fact be premature. For example, could embryonic stem cells regularly be produced without the destruction of embryos it might also be ethically justifiable to clone such cells.³⁹⁹ Moreover, the cloning debate as led in the present context misses one crucial point of the debate. This is the need to explicitly confirm the human rights of cloned humans.⁴⁰⁰ While it seems most people believe that clones are automatically bestowed with such rights, there may be others who disagree. Overall it seems that the protocol has not been the last word on the issue of human cloning.

2.1.2.2. The Additional Protocol to the Convention on Human Rights and Biomedicine, on Transplantation of Organs and Tissues of Human Origin

The Additional Protocol to the Convention on Human Rights and Biomedicine, on Transplantation of Organs and Tissues of Human Origin was opened for signature to the Signatories to the Oviedo Convention, in Strasbourg, on 24 January 2002.⁴⁰¹ It entered into force on 1 May 2006. To date it has been ratified by 12 countries and an additional 8 have signed it. Notably the Protocol has not

³⁹⁶ Article 1 para 2 of the Additional Protocol on the Prohibition of Cloning Human Beings, note 31.

³⁹⁷ According to the Explanatory Report on the Additional Protocol on the Prohibition of Cloning Human Beings, note 31, ETS No. 168, at: <http://conventions.coe.int/Treaty/en/Reports/Html/168.htm> (last visited 27.04.2012), para 6, the term aims to clarify that the cloning of cells as a technique and the use of embryonic stem cells in cloning techniques lie not within the scope of the Protocol. The delimitation, however, of the latter – in particular with regard to the cloning of totipotent (undifferentiated) embryonic stem cells – and the cloning of human beings can only be drawn by defining the exact evolutionary stadium of human life in which a human being emerges.

³⁹⁸ Cf. Statement by the Netherlands in "List of declarations made with respect to ETS No.168", at: <http://conventions.coe.int/Treaty/Commun/ListeDeclarations.asp?NT=168&CM=8&DF=3/4/2008&CL=ENG&VL=1> (last visited 27.04.2012).

³⁹⁹ N. Somekh, "The European Total Ban on Human Cloning: An analysis of the Council of Europe's Actions in Prohibiting Human Cloning", 17 *Boston University International Law Journal*, 1999, 397, 410, arguing that instead of solely curbing cloning experiments, stringent laws may thwart potential life-enhancing research altogether.

⁴⁰⁰ A. Zelony, "Don't Throw the Baby Out with the Bathwater: Why a Ban on Human Cloning Might be a Threat to Human Rights", 27 *Loyola of Los Angeles International and Comparative Law Review*, 2005, 541, 554; see generally B. Knoppers, "Human dignity: In Danger of Banality? The Case of Cloning", 35 *Case Western Reserve Journal of International Law*, 2003, 385 et seq.

⁴⁰¹ Additional Protocol concerning Transplantation of Organs and Tissues of Human Origin, note 31.

been signed by a number of countries, including Austria, Belgium, Denmark, France, Germany, Norway, Poland, Sweden, the United Kingdom and Russia.⁴⁰² It is legally binding and legally enforceable for those states that adhere to it.⁴⁰³

In contrast to the Oviedo Convention the Additional Protocol is not only concerned with living donors but also regulates the removal of organs⁴⁰⁴ and tissues⁴⁰⁵ from deceased persons or the implantation of organs or tissue from such persons.⁴⁰⁶ The Protocol makes explicit in Article 1 that “Parties to this Protocol shall protect the dignity and identity of everyone and guarantee, without discrimination, respect for his or her integrity and other rights and fundamental freedoms with regard to transplantation of organs and tissues of human origin.” It then goes on to specify general principles, such as equitable access to transplantation services for patients, transparent rules for organ allocation, health and safety standards, the prohibition of financial gain by donors, and the need for donors, recipients, health professionals and the public to be properly informed, the prohibition of financial gain, confidentiality, and sanctions and compensation.⁴⁰⁷ It also contains specific provisions covering the removal of organs from living and deceased persons.

As regards living donors transplantations should only be carried out for the therapeutic benefit of the recipient, after a risk assessment for the donor has been undertaken⁴⁰⁸, where there is no suitable organ or tissue available from a deceased person and where no other alternative therapeutic method of comparable effectiveness is available.⁴⁰⁹ The prior, free and informed consent of the donor is necessary.⁴¹⁰ Organs and tissue may not be removed from a person unable to consent.⁴¹¹ Under very limited condition, however, the removal of regenerative tissue from a person who does not have the capacity to consent may be carried out.⁴¹²

⁴⁰² Chart of Signatories to the Additional Protocol concerning Transplantation of Organs and Tissues of Human Origin, note 31, at: <http://conventions.coe.int/Treaty/Commun/ChercheSig.asp?NT=186&CM=&DF=&CL=ENG> (last visited 14.12.2012).

⁴⁰³ See Chapter III, 2.1.

⁴⁰⁴ The Explanatory Report to the Additional Protocol concerning Transplantation of Organs and Tissues of Human Origin, note 31, defines organ in the following: traditionally described as part of a human body consisting of a structured arrangement of tissues which, if wholly removed, cannot be replicated by the body. Explanatory Report on the Additional Protocol concerning Transplantation of Organs and Tissues of Human Origin, note 31, ETS No.186, 2002, para 28, at: <http://conventions.coe.int/Treaty/en/Reports/Html/186.htm> (last visited 27.04.2012).

⁴⁰⁵ Ibid.; the Explanatory report defines tissue as all constituent parts of the human body, including surgical residues, but excluding organs, blood, blood products as well as reproductive tissue such as sperm, eggs and embryos.

⁴⁰⁶ Chapter III and IV of the Additional Protocol concerning Transplantation of Organs and Tissues of Human Origin, note 31.

⁴⁰⁷ Ibid., Articles 3-8.

⁴⁰⁸ Ibid., Article 11.

⁴⁰⁹ Ibid., Article 9.

⁴¹⁰ Ibid., Article 13.

⁴¹¹ Ibid., Article 14 para 1.

⁴¹² Ibid., Article 14 para 2, specifying that the following conditions have to be met: (i) there is no compatible donor available who has the capacity to consent; (ii) the recipient is a brother or sister of the donor; (iii) the donation has the potential to be life-saving for the recipient; (iv) the authorisation of his or her representative or an authority or a person or body provided for by law has been given specifically and in writing and with the approval of the competent body; (v) the potential donor concerned does not object.

As regards deceased persons, organs or tissues shall not be removed unless the person has been certified as dead⁴¹³ by law and unless consent or authorisation required by law has been obtained. The removal shall not be carried out if the deceased person had objected to it.⁴¹⁴

It can be debated whether the protocol is clear on the consent requirements regarding the removal of organs from the body of a deceased person. It is for example not entirely clear whether or not opt-out systems, where consent to the removal of organs is presumed until a person has specifically withdrawn his or her consent to such a procedure, are compatible with the Protocol.⁴¹⁵ Herman Nys notes that this uncertainty “creates a lot of confusion...[that] will not contribute to the wished harmonization of the rules governing the removal of organs and tissue throughout Europe.”⁴¹⁶ Overall, however, the document so far seems to have remained rather uncontroversial.⁴¹⁷

2.1.2.3. The Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research

The Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research was opened for signature on 25 January 2005⁴¹⁸ and entered into force on 1 September 2007, after 5 ratifications.⁴¹⁹ To date the Protocol has been ratified by 6 states and signed by 16 states.⁴²⁰ It is legally binding and legally enforceable for those states that adhere to it.⁴²¹

The Protocol covers the full range of research activities in the health field involving interventions on human beings but excludes from its scope research on embryos in vitro or on foetuses and embryos in vivo.⁴²² Chapter II contains general provisions, affirming the primacy of the human being participating in research over the sole interest of science or society.⁴²³ It also enshrines the

⁴¹³ Ibid., Article 16. For a discussion of a definition of the term "death" or "dead" see Deutscher Ethikrat, Stellungnahme zum Transplantationsgesetz, of 4 May 2007, 16 et seq.

⁴¹⁴ Ibid., Article 17.

⁴¹⁵ H. Nys, "Organ Transplantation", in: J. Gevers/E. Hondius/J. Hubben (eds.), *Health Law, Human Rights and the Biomedicine Convention. Essays in Honour of Henriette Roscam Abbing*, 2005, 219, 226 et seq.

⁴¹⁶ Ibid., 229-230.

⁴¹⁷ Overall, the topic has not featured in academic, political and legal debate as prominently as for example the issue of human cloning or biomedical research on human beings. According to some scholars this is mostly so because it does not strictly preclude the regulation of organ transplantations by means of an opting-out system. See H. Nys, "European Biolaw in the Making. The Example of the Rules Governing the Removal of Organs from Deceased Persons in the EU Member States", in: C. Gastmans/K. Dierickx/H. Nys/P. Schotsmans (eds.), *New Pathways for European Bioethics*, 2007, 160, 161.

⁴¹⁸ See Article 25 of the Additional Protocol concerning Biomedical Research, note 31.

⁴¹⁹ Chart of Signatories to the Additional Protocol concerning Biomedical Research, note 31, at: <http://conventions.coe.int/Treaty/Commun/ChercheSig.asp?NT=195&CM=8&DF=3/5/2008&CL=ENG>. (last visited 27.04.2012).

⁴²⁰ Ibid., notably the Protocol has not been signed by a number of countries, including Austria, Belgium, Germany, Ireland, the United Kingdom and Russia.

⁴²¹ See Chapter III, 2.1.

⁴²² Additional Protocol concerning Biomedical Research, note 31, Article 2.

⁴²³ Ibid., Article 3.

freedom of research⁴²⁴, stipulating that risk and burden to participants must be limited,⁴²⁵ and mandating the approval by a competent body after independent examination of its scientific merit as well as professional standards of obligations.⁴²⁶

Chapter III mandates the use of independent ethics committees to examine the potential research's ethical acceptability.⁴²⁷ Chapter IV deals with information and consent laying out the requirements for free, informed, express, specific and documented consent to participation in research.⁴²⁸ Article 15 and 16 deal with special provisions concerning those unable to consent, thereby basically following the provisions set out in Chapter V of the Oviedo Convention.⁴²⁹

Issues of confidentiality and the right to information are dealt with in Chapter VIII, enshrining in Article 25 the confidentiality of any information of a personal nature collected during biomedical research and giving participants the right to know any information collected on their health. Research on women during pregnancy and breastfeeding, persons in emergency situations, and prisoners is subject to additional requirements.⁴³⁰ Article 23 of the Additional Protocol requires that research does not “delay nor deprive participants of medically necessary preventive, diagnostic or therapeutic procedures” and that members of control groups shall be assured of proven medical methods. Still, placebo studies are permissible if no effective methods exist, or if withdrawal or withholding of such methods only present an acceptable risk or burden. Article 29 of the Additional Protocol extends its applicability to research conducted or sponsored by persons within the jurisdiction of a member state but carried out in a state not party to the Protocol. Chapter X concerns infringement of the provisions of the Protocol and holds that parties shall provide appropriate judicial protection to prevent or to put a stop to an unlawful infringement of the rights or principles set forth in the Protocol and for the possibility of compensation for damage and sanctions.⁴³¹

Overall the Protocol has been assessed positively for seeking to strike a balance between freedom of research and the safeguarding of fundamental rights in the field of biomedical research.⁴³² It has also been positively noted that until today, the Additional Protocol in conjunction with the Oviedo Convention constitutes the most explicit and demanding source of international law pertaining to

⁴²⁴ Ibid., Article 4.

⁴²⁵ Ibid., Article 6.

⁴²⁶ Ibid., Articles 7 and 8.

⁴²⁷ Ibid., Article 9.

⁴²⁸ Ibid., Article 14.

⁴²⁹ Ibid., Article 15 para 2; the requirement of consent may only be waived if research is of direct benefit to the person concerned or if the research has the aim of contributing to the ultimate attainment of results capable of conferring benefit to the person concerned or to other persons in the same age category or afflicted with the same disease or disorder or having the same condition and if the research entails only minimal risk and minimal burden for the individual concerned.

⁴³⁰ Ibid., Articles 18 and 19.

⁴³¹ Ibid., Articles 31 and 32.

⁴³² M. Schott, "Medical Research on Humans: Regulation in Switzerland, the European Union, and the United States", 60 *Food Drug Law Journal*, 2005, 45, 51.

research on humans, containing the most developed and comprehensive international code of protective provisions that is available in the field.⁴³³

2.1.2.4. The Additional Protocol to the Convention on Human Rights and Biomedicine concerning Genetic Testing for Health Purposes

The Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes was opened for signature on 27 November 2008.⁴³⁴ It will enter into force on the condition that 5 states, including 4 member states, ratify the protocol.⁴³⁵ To date the Protocol has been ratified by 1 state and signed by 4 further states.⁴³⁶

The Protocol sets out ethical and legal provisions to be applied to genetic testing carried out for health purposes. It includes principles about information concerning human genetics and its testing, informed consent, the advice necessary concerning genetic information and the quality of services. Chapter I defines the object and scope of the Protocol, clarifying that Member States shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms⁴³⁷ with regard to genetic tests⁴³⁸ carried out for health purposes.⁴³⁹ Article 2 makes it clear that the protocol does not apply to genetic tests carried out on the human embryo or foetus and to those carried out for research purposes.⁴⁴⁰ Chapter II sets out general provisions, including that the welfare of the human being shall prevail over the sole interest of society or science,⁴⁴¹ and prohibiting discrimination and stigmatisation on the grounds of genetic heritage or characteristics.⁴⁴²

Chapter III of the Additional Protocol concerns the quality of genetic services, demanding of Member States to ensure that genetic services are of appropriate quality, in particular that genetic

⁴³³ Ibid.

⁴³⁴ Additional Protocol on Genetic Testing, note 31.

⁴³⁵ Chart of Signatories to the Additional Protocol on Genetic Testing, note 31, at: <http://conventions.coe.int/Treaty/Commun/ChercheSig.asp?NT=195&CM=8&DF=3/5/2008&CL=ENG>. (last visited 27.04.2012).

⁴³⁶ Ibid. To date the protocol has been ratified by Slovenia and signed by Moldova, Malta, Iceland and Finland.

⁴³⁷ Additional Protocol on Genetic Testing, note 31, Article 1.

⁴³⁸ Ibid. Genetic tests, in Article 1, are defined as tests that involve the analysis of biological samples of human origin and that aim specifically to identify the genetic characteristics of a person which are inherited or acquired during early prenatal development.

⁴³⁹ Ibid., Article 2, 1. The Additional Protocol is thus narrower in scope than the Declaration on Human Genetic Data, note 4, discussed under 2.3.2 below in this chapter, which in Article 5 declares that human genetic data and human proteomic data may be collected, processed, used and stored for the purposes of (i) diagnosis and health care...; (ii) medical and other scientific research...; (iii) forensic medicine and civil, criminal and other legal proceedings, (iv) or any other purpose consistent with the Universal Declaration on the Human Genome, note 4, and the international law of human rights.

⁴⁴⁰ Ibid., Article 2, 2. It is also limited in its application to chromosomal analysis, DNA or RNA analysis and functionally equivalent procedures.

⁴⁴¹ Ibid., Article 3.

⁴⁴² Ibid., Article 4.

tests meet generally accepted criteria of scientific validity and clinical validity; that laboratories are subject to regular monitoring; and that persons providing genetic services are appropriately qualified.⁴⁴³ Article 6 further demands that clinical utility of a genetic test should be an essential criterion for deciding to offer this test to a person or a group of persons while Article 7 asks for that genetic tests are performed under individualized medical supervision.

Chapter IV deals with questions of genetic counseling and informed consent. Article 8 states that the person undergoing a test shall be provided with prior appropriate information in particular on the purpose and the nature of the test and that for predictive tests,⁴⁴⁴ appropriate genetic counseling should be made available. Article 9 holds that a genetic test may only be carried out if the person concerned has given his or her free and informed consent. Genetic tests on persons unable to consent may only be carried out for that person's direct benefit and if authorization from the entity responsible for this person has been obtained and after that entity has been provided with appropriate prior information. Wishes relating to a genetic test expressed previously by an adult at a time where he or she had capacity to consent shall be taken into account.⁴⁴⁵

In the case of minors a genetic test shall be deferred until that person has come of age unless that delay would be detrimental to his or her health or well-being.⁴⁴⁶ If such a test is undertaken the authorization of the entity responsible for the minor has to give his or her authorisation, however, the opinion of the minor shall be taken into consideration as an increasingly determining factor in proportion to his or her age and degree of maturity.⁴⁴⁷

Chapter VI deals with the specific case of genetic tests on persons unable to consent being carried out for the benefit of family members. Here, Article 13 provides that exceptionally, and by derogation from the provisions of Article 6, paragraph 1, of the Oviedo Convention and of Article 10 of the Additional Protocol on Genetic testing, a genetic test may be legally carried out, for the benefit of family members, on a person who does not have the capacity to consent, if certain conditions are met, including that the purpose of the test is to allow the family member(s) concerned to obtain a preventive, diagnostic or therapeutic benefit that has been independently evaluated as important for their health, or to allow them to make an informed choice with respect to procreation⁴⁴⁸; the benefit envisaged cannot be obtained without carrying out this test⁴⁴⁹; the

⁴⁴³ Ibid., Article 5.

⁴⁴⁴ Ibid. According to Article 8.2 "tests concerned" are tests of a monogenic disease; tests serving to detect a genetic predisposition or genetic susceptibility to a disease; tests serving to identify the subject as a healthy carrier of a gene responsible for a disease. For background information see Direct-to-Consumer Genetic Testing Kits, Harvard Women's Health Watch, September 2010, at: http://www.health.harvard.edu/newsletters/Harvard_Womens_Health_Watch/2010/September/direct-to-consumer-genetic-testing-kits (last visited 27.04.2012).

⁴⁴⁵ Ibid., Article 12 (2).

⁴⁴⁶ Ibid., Article 10.

⁴⁴⁷ Ibid., Article 12 (1).

⁴⁴⁸ Ibid., Article 13 a.

⁴⁴⁹ Ibid., Article 13 b.

risk and burden of the intervention are minimal for the person who is undergoing the test⁴⁵⁰; the expected benefit has been independently evaluated as substantially outweighing the risk for private life that may arise from the collection, processing or communication of the results of the test⁴⁵¹ and authorisation by the appropriate responsible entity has been given.⁴⁵²

Article 14 provides that tests on biological materials when it is not possible to contact the person concerned and where that person has not expressly opposed such a test may be carried out in accordance with the principle of proportionality, where the expected benefit cannot be otherwise obtained and where the test cannot be deferred. Tests on deceased persons for the benefit of a family member may also be carried out if the consent or appropriate authorisation required by law has been obtained.⁴⁵³

Chapter VII ensures respect for private life and right to information, stating in Article 16 that everyone has the right to respect for his or her private life, in particular to the protection of his or her personal data derived from a genetic test and that everyone undergoing a genetic test is entitled to know and not to know any information collected about his or her health derived from this test.⁴⁵⁴ Biological samples obtained through tests have to be used and stored in a secure and the confidential manner.⁴⁵⁵

Chapter VIII is concerned with genetic screening programmes for health purposes. Such programmes may only be implemented if it has been approved by the competent body, following an independent evaluation of its ethical acceptability and fulfillment of certain specific conditions, including that the programme is recognized for its health relevance for the whole population or section of population concerned; that the scientific validity and effectiveness of the programme have been established.⁴⁵⁶ Finally, Article 20 lies down that the public shall have appropriate access to objective general information on genetic tests, including their nature and the potential implications of their results.

⁴⁵⁰ Ibid., Article 13 c.

⁴⁵¹ Ibid., Article 13 d.

⁴⁵² Ibid., Article 13 e. Article 13 f in addition stipulates that the person not able to consent shall, in proportion to his or her capacity to understand and degree of maturity, take part in the authorisation procedure. The test shall not be carried out if this person objects to it.

⁴⁵³ Ibid., Article 15.

⁴⁵⁴ Ibid., Article 16 (4) however allows for that in exceptional cases, restrictions may be placed by law on the just stated provision in the interests of the person concerned.

⁴⁵⁵ Ibid., Article 17. A similar provision can be found in the Declaration on Human Genetic Data, note 4, discussed in 2.3.2 in the same chapter, which states in Article 14 that data which can be connected to an individual person should not be revealed to employers, insurance companies and educational institutions (or to families) without the explicit consent of the patient.

⁴⁵⁶ Ibid., Article 18. Article 18 c to e also hold that appropriate preventive or treatment measures in respect of the disease or disorder which is the subject of the screening, are available to the persons concerned; appropriate measures are provided to ensure equitable access to the programme; and the programme provides measures to adequately inform the population or section of population concerned of the existence, purposes and means of accessing the screening programme as well as the voluntary nature of participation in it.

Overall the Protocol has been noted positively for dealing, for the first time at the international level, with directly accessible genetic tests for which a commercial offer has been or could develop in future.⁴⁵⁷ It has also been noted as an effort to counter the lack of a coherent regulatory landscape in Europe when it comes to genetic testing.⁴⁵⁸ On the other hand, the lack of support for the Oviedo Convention and for the protocol from such countries as the United Kingdom and Germany has been said to considerably weaken the protocol's impact.⁴⁵⁹ Moreover, it has been submitted that it may take several years before the additional protocol enters into force while the field of genetic services provision, blossoming now in unprecedented ways, might warrant a more immediate legal regulation.⁴⁶⁰ Finally, it has been criticized that it is not quite clear what is being regulated by this additional protocol. According to the scope of this protocol, it should apply "to tests, which are carried out for health purposes, involving analysis of biological samples of human origin and aiming specifically to identify the genetic characteristics of a person which are inherited or acquired during early prenatal development."⁴⁶¹ However, as Nys remarks, "some direct-to-consumer companies make a distinction between services that directly affect healthcare decision making (which might fall under the additional protocol) and making health-related claims (which might not fall under the additional protocol)".⁴⁶² For example, so Nys, the genome scanning company 23andMe has been recorded to argue that the "genetic information provided...about potential health conditions should not be used to estimate your overall risk of future disease" and that it is not "intended to be medical advice."⁴⁶³ Here and in analogous cases it is not quite clear whether the protocol applies.⁴⁶⁴

2.1.3. First Conclusions with regard to the standards set by the Council of Europe

In summarizing these first introductory notes on the Oviedo Convention and its Additional Protocols the following can be ascertained. The Oviedo Convention and its Protocol so far are the only legally-binding and enforceable international legal instrument in the area of bioethics. That is, the Convention and its Protocols are legally binding and enforceable treaty law with regard to those states that have signed up to them.⁴⁶⁵ Yet, it should also be noted that the Oviedo Convention is

⁴⁵⁷ World Health Organisation, Ethics and Health Unit Newsletter, 2009, 4, at:

http://www.jointcentreforbioethics.ca/rss/news/documents/WHO_spring2009.pdf (last visited 27.04.2012)

⁴⁵⁸ P. Borry, "Europe to Ban Direct-to-Consumer Genetic Tests?", 26 *Nature Biotechnology*, 2008, 736, 737.

⁴⁵⁹ Ibid.

⁴⁶⁰ Ibid.

⁴⁶¹ Additional Protocol on Genetic Testing, note 31, Article 2.

⁴⁶² H. Nys, "European Regulatory Issues Related to Quality in Provision of Genetic Service", in: U. Kristofferson/J. Cassiman/J. Schmidtke (eds.), *Quality Issues in Clinical Genetic Services*, 2010, 41, 44.

⁴⁶³ Genome Scanning Company 23andMe, "Consent document", at: <https://www.23andme.com/about/consent/?version=1.3> (last visited 27.04.2012). See also R. Sandroff, "Direct-to-Consumer Genetic Tests and the Right to Know", 40 *Hastings Center Report*, 2010, 24 et seq.

⁴⁶⁴ Nys, note 462, 45.

⁴⁶⁵ See Chapter III, 2.1.

mostly limited in scope to the countries that are members of the Council of Europe and its observatory states. The Convention therefore cannot claim to set universal or global standards in the area of bioethics but it does so in a geographically very limited scope. Furthermore, it must also be noted that the above discussed instruments have not been ratified by a number of countries, including most notably Germany, the United Kingdom and Russia. The fact that these countries have not signed the Convention considerably weakens the Convention's potential impact and standing. It also means that the Convention does not embody a true European, let alone global consensus on questions of bioethical interest. Rather, important questions, such as for example the question of the admissibility of medical research on persons not able to give informed consent, remain contested and not resolved through the Convention.

It is further worth noting that the Oviedo Convention has been designed to serve as framework Convention only. The Convention thus merely seeks to establish a common European minimum level of protection concerning the application of biology and medicine, while it is left to states parties to arrange more extensive protection.⁴⁶⁶ It thus does not aim to give a detailed bioethical roadmap of action. The advantage to this is that many states were able to agree to the Convention even though it dealt with often critical and highly contested questions. Yet the price to pay was to forego clear and precise regulations for often rather vague and minimalistic standards. Moreover, as the example of Germany and the United Kingdom illustrate, even minimum standards can go too far for certain states and thus do not guarantee universal ratification.

Because of its framework and minimum standard setting character Chapter XII of the Convention explicitly foresees the possibility of concluding further protocols that clarify and more specifically formulate certain issues at stake.⁴⁶⁷ To date four such additional protocols have been concluded with regard to the issue of human cloning, on transplantation of organs and tissues of human origin, on biomedical research and, though not yet entered into force, on genetic testing for health purposes. The four additional protocols to the Oviedo Convention build on the principles embodied in the Convention. Only states that have signed the Oviedo Convention may also sign the Protocols.⁴⁶⁸ The provisions of the Protocol then must be regarded as additional articles to the Convention and the Oviedo Convention's provisions apply accordingly.⁴⁶⁹

It is furthermore worth reiterating that the Convention and its Protocols are limited in scope to issues of bioethical interest. To that aim they set out prohibitions against the misuse of biological and medical advances and deal with a variety of issues including access to healthcare, consent requirements, privacy, protection of the human genome, organ transplantation, and scientific

⁴⁶⁶ Oviedo Convention, note 5, Article 27.

⁴⁶⁷ Ibid., Article 31.

⁴⁶⁸ Ibid.

⁴⁶⁹ Additional Protocol on the Prohibition of Cloning Human Beings, note 31, Article 3; Additional Protocol concerning Transplantation of Organs and Tissues of Human Origin, note 31, Article 30; Additional Protocol concerning Biomedical Research, note 31, Article 36; Additional Protocol on Genetic Testing, note 31, Article 21.

research. The Oviedo Convention and its Protocols thereby enshrine a number of bioethical and legal principles and human rights and postulate certain aims that will be discussed in greater detail in the next chapters.

Finally, as evidenced by its title, the Convention on Human Rights and Biomedicine and its Protocols aim to fit into the framework of European and international human rights law. In fact, the Convention is the first multilateral human rights treaty that specifically addresses biomedical concerns. While some of the principles enshrined in the Convention were already included in more general terms in previous international human rights treaties, such as the ICCPR and ICESCR⁴⁷⁰, as briefly discussed above, "this is the first time that these rights have been developed and assembled in one single multilateral binding instrument entirely devoted to biomedical issues"⁴⁷¹. The actual meaning and the wider implications of this will be extensively analysed in the next chapter and, more specifically in chapter VII.

2.2. UNESCO Instruments in the Field of Bioethics

2.2.1. UNESCO

The United Nations Social, Educational and Cultural Organization (hereinafter UNESCO) has been among the first international organisations that explicitly addressed themselves to issues of bioethical relevance. Also, next to the Council of Europe it has been the only international organisation that has attempted to deal with the whole field of bioethics, i.e. biomedicine, within one instrument. The choice of UNESCO as the platform for standard setting in the area of bioethics might not be the most obvious. At first glance, such organisations as the World Health Organisation (hereinafter WHO) may indeed seem much more suitable to deal with bioethics.⁴⁷² However, by virtue of its constitutional objective to promote "collaboration among nations through education, science and culture" as well as its operational experience in the facilitation of cultural exchange and ethical reflection⁴⁷³ it has been given authority by States to negotiate the codification and implementation of international instruments in the area of bioethics.⁴⁷⁴ According

⁴⁷⁰ ICCPR, note 341, and ICESCR, note 341.

⁴⁷¹ R. Andorno, "The Oviedo Convention: A European Legal Framework at the Intersection of Human Rights and Health Law", 2 *Journal of International Biotechnology Law*, 133, 133.

⁴⁷² N. Lenoir, "Comment: Universal Declaration on the Human Genome and Human Rights: The first Legal and Ethical Framework at the Global Level", 30 *Columbia Human Rights Law Review*, 1999, 537, 547. See also Knoppers, note 400, 385.

⁴⁷³ UNESCO Constitution, at: http://portal.unesco.org/en/ev.php-URL_ID=15244&URL_DO=DO_TOPIC&URL_SECTION=201.html (last visited 27.04.2012).

⁴⁷⁴ Lenoir, note 472, 385. Note, however, that UNESCO has been criticized from various sides for taking the lead role in the area of bioethics. See for example W. Landman/U. Schüklenk, "UNESCO 'Declares' Universals on Bioethics and Human Rights - Many Unexpected Universal Truths Unearthed by UN Body", 5 *Developing World Bioethics*, 2005, i, iii, claiming that UNESCO had "overstepped the boundaries of its portfolio within the UN organisation."; see also J. Williams, "UNESCO'S Proposed Declaration on Bioethics and Human Rights - a Bland Compromise", 5 *Developing World Bioethics*, 2005, 210, 211, noting that under certain circumstances UNESCO could encroach on the mandate of the World Health Organization. Nevertheless, in 1993, the Member States explicitly mandated UNESCO to work in the

to UNESCO, the fact that bioethical issues “deeply root in the cultural, philosophical and religious bedrocks of various human communities is [moreover] reason enough for [the Organization], the only one whose fields of competence include the social and human sciences ...[]... to take the lead in this initiative.”⁴⁷⁵

To fulfil its mandate UNESCO has, over the last 30 years, held symposiums on social and cultural changes brought about by scientific progress and has monitored the human rights implications of advances in genetic science.⁴⁷⁶ In 2002 UNESCO further reinforced the importance of this area of work by making ethics one of the five priorities of the Organization.⁴⁷⁷ Over the years UNESCO has demonstrated its standard-setting role in bioethics, mainly through the adoption several major instruments in the area.⁴⁷⁸ To facilitate its work in this area UNESCO had already in 1993 formed the International Bioethics Committee (hereinafter IBC), a group of currently 36 international and independent experts in the fields of medicine, biology, genetics, philosophy, anthropology, law and other human and social sciences to respond to the ethical concerns raised by progress in genetic science and to promote international debate and worldwide dialogue.⁴⁷⁹ The IBC thereby provides one of the few institutionalized global forums directly devoted to bioethical reflection. It meets at least once every year and produces advice, recommendations and reports on specific issues that are adopted by consensus. While the IBC is staffed with independent experts the Intergovernmental Bioethics Committee (hereinafter IGBC), created in 1998 under Article 11 of the Statutes of the IBC, is comprised of 36 representatives of Member States.⁴⁸⁰ Representatives meet at least once every two years to examine the advice and recommendations of the IBC.⁴⁸¹ It informs the IBC of its opinions and submits these opinions along with proposals for follow-up of the IBC's work to the Director-General for transmission to Member States, the Executive Board and the General Conference.⁴⁸²

The following section will first discuss the UNESCO Universal Declaration on Bioethics and Human Rights (hereinafter UDBHR) as the arguably most comprehensive, most important and

area of bioethics. See UNESCO, First Intergovernmental Meeting of Experts Aimed at Finalizing a Draft Declaration on Universal Norms on Bioethics, SHS/EST/05/CONF.203/4, 2005, at 3.

⁴⁷⁵ UNESCO, "Why UNESCO?" at the UNESCO webpage on ethics, at: http://portal.unesco.org/shs/en/ev.php-URL_ID=1883&URL_DO=DO_TOPIC&URL_SECTION=201.html (last visited 27.04.2012).

⁴⁷⁶ Ibid.

⁴⁷⁷ See UNESCO, First Intergovernmental Meeting of Experts Aimed at Finalizing a Draft Declaration on Universal Norms on Bioethics, note 474, at 3.

⁴⁷⁸ Ibid, at 4. For reference to the UNESCO instruments in the area of bioethics see note 22.

⁴⁷⁹ See Statutes of the International Bioethics Committee, note 127. See also Chapter III, 2.2. and Vöneky, Recht, Moral und Ethik. Grundlagen und Grenzen Demokratischer Legitimation für Ethikgremien, note 15, Chapter 6 II.

⁴⁸⁰ The 36 Member States are elected by UNESCO's General Conference taking into account cultural diversity and balanced geographical representation. Members serve for terms of about four years, from the end of the ordinary session of the General Conference in which they are elected until the end of the second subsequent ordinary session. See Article 3, Statutes of the International Bioethics Committee, note 127. See also Vöneky, Recht, Moral und Ethik. Grundlagen und Grenzen Demokratischer Legitimation für Ethikgremien, note 15. Kapitel 6. 2.6.

⁴⁸¹ UNESCO, Webpage of the IGBC, at: http://portal.unesco.org/shs/en/ev.php-URL_ID=1878&URL_DO=DO_TOPIC&URL_SECTION=201.html (last visited 27.04.2012).

⁴⁸² See Articles 11 and 12 of the Statutes of the International Bioethics Committee, note 127.

most recent standard elaborated by UNESCO in the area. The next sections will then respectively discuss in reverse chronological order the International Declaration on Human Genetic Data and the Universal Declaration on the Human Genome and Human Rights.

2.2.2. Universal Declaration on Bioethics and Human Rights

At its 31st session in 2001, the General Conference invited the Director-General to submit “the technical and legal studies undertaken regarding the possibility of elaborating universal norms on bioethics”.⁴⁸³ In October 2005, the General Conference of UNESCO then adopted the Universal Declaration on Bioethics and Human Rights by acclamation.⁴⁸⁴ From the inception of the drafting process, the IBC maintained that the international instrument would not take the form of a treaty but rather a legally nonbinding declaration expressing broad principles.⁴⁸⁵ At the same time, the IBC acknowledged that a declaration could serve as a model for a binding treaty.⁴⁸⁶ To date no such binding treaty has followed however.

The Declaration is divided into six sections, general provisions, principles, application of principles, dissemination and final provisions.

The first section starts by defining the scope of the declaration, providing in Article 1 that the Declaration deals with “ethical issues raised by medicine, life sciences and associated technologies as applied to human beings taking into account their social, legal and environmental dimensions.”⁴⁸⁷ As was the case with the Oviedo Convention here, too, there was some discussion about the term bioethics and about the question of whether or not to use the term at all. That the UDBHR finally settled on the term and this definition must be understood in relation to the Declaration's aim to take a broader approach encompassing also developments that take place outside medicine in society as a whole.

It also makes clear that the declaration is primarily addressed to states but as appropriate also provides guidance to decisions or practices of individuals, groups, communities, institutions and corporations, public and private.⁴⁸⁸ Article two goes on to define the aims of the Declaration, which are, inter alia, to provide a universal framework of principles to guide States in the formulation of their legislation in the area of bioethics, to promote respect for human dignity and to protect

⁴⁸³ See UNESCO, First Intergovernmental Meeting of Experts Aimed at Finalizing a Draft Declaration on Universal Norms on Bioethics, note 474, at 5.

⁴⁸⁴ UNESCO webpage on ethics, at: http://portal.unesco.org/shs/en/ev.php-URL_ID=1883&URL_DO=DO_TOPIC&URL_SECTION=201.html (last visited 27.04.2012).

⁴⁸⁵ It is thus a standard that must be seen as a soft law standard. See discussion in Chapter III, 2.1.

⁴⁸⁶ The tradition of international instruments on human rights is often that these treaties are preceded by declarations which contain guidelines and an invitation to States to follow them. See for examples the Report on the Possibility of Elaborating a Universal Instrument on Bioethics, note 128, paras 43-45.

⁴⁸⁷ See Article 1 para 1 UDBHR, note 4.

⁴⁸⁸ Ibid., Article 1.

human rights, by ensuring respect for the life of human beings, and fundamental freedoms. It also recognizes the importance of freedom of scientific research but stresses the need for such research and developments to occur within the framework of ethical principles. Finally, it aims to promote equitable access to medical and scientific developments as well as the sharing of such knowledge, to foster pluralistic dialogue about bioethical issues and to underline the importance of biodiversity.

In Article 3 to 17 the Declaration mandates respect for several principles. Most prominently, human dignity, human rights and fundamental freedoms are to be fully respected as is the priority of the interests of the individual over the sole interest of science or society.⁴⁸⁹ In applying and advancing scientific knowledge benefits to patients and other affected individuals should be maximized and any possible harm be minimized.⁴⁹⁰ Article 5 requires that the autonomy of persons to make decisions is to be respected. Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned. The informed consent requirements are somewhat weaker in the case of scientific research where the Declaration states that it should (as opposed to is) only be carried out with the prior, free, express and informed consent of the person concerned.⁴⁹¹ The information should be adequate, provided in a comprehensible form and include modalities for withdrawal of consent.

For persons unable to consent Article 7 provides that authorization for research and medical practice should be obtained in accordance with the best interest of the person concerned. Research should only be carried out for his or her direct health benefit and if there is no research alternative of comparable effectiveness with research participants able to consent. Research which does not have potential direct health benefit should only be undertaken with the utmost restraint, exposing the person only to a minimal risk and minimal burden and, only if the research is expected to contribute to the health benefit of other persons in the same category, subject to the conditions prescribed by law and compatible with the protection of the individual's human rights. It is important to note states widely differed with regard to the question of the admissibility of research on subjects unable to consent, pushing some to enter explanations of vote to clarify their interpretation of this issue.⁴⁹² Refusal of such persons to take part in research should be respected. In these provisions the Declaration thus equals roughly the provisions of the Oviedo Convention and its Protocol on biomedical research.⁴⁹³ It is, however, less strongly worded.⁴⁹⁴

Article 8 through 17 set out further principles. Article 8 mandates respect for human vulnerability and personal integrity in applying and advancing scientific knowledge. According to Article 9

⁴⁸⁹ Ibid., Article 3.

⁴⁹⁰ Ibid., Article 4.

⁴⁹¹ Ibid., Article 6 para 2.

⁴⁹² See for example Germany's Explanation of Vote concerning the UDBHR, note 274.

⁴⁹³ Cf. above under 2.1.

⁴⁹⁴ Cf. Article 7 UDBHR, note 4.

privacy and confidentiality of the persons concerned and of their personal information should be respected. Article 10 enshrines the fundamental equality of all human beings in dignity and rights and Article 11 provides that no individual or group should be discriminated against on any grounds. The remaining Articles demand respect for cultural diversity and pluralism⁴⁹⁵, solidarity and cooperation,⁴⁹⁶ restate the importance of achieving the highest attainable standard of health⁴⁹⁷, and call for a sharing of benefits of medical research and knowledge⁴⁹⁸ as well as for the protection of future generations, including the protection of the environment, the biosphere and biodiversity.⁴⁹⁹

Articles 18 through 21 deal with the application of the principles. Decision making should be undertaken in an attitude of professionalism, honesty, integrity and transparency.⁵⁰⁰ There should also be a dialogue between professionals and society as a whole.⁵⁰¹ The establishment of independent, multidisciplinary and pluralist ethics committees is recommended.⁵⁰² Finally, transnational research should be consistent with the principles set out in the Declaration.⁵⁰³

Article 22 makes clear that the Declaration relies on UNESCO, the IBC, the IGBC, and member states to promote and disseminate its principles and procedures in accordance with international human rights law.

Overall the Declaration is most notable for that by its text, UNESCO Member States, for the first time, commit themselves and the international community to respect and apply fundamental principles of bioethics.⁵⁰⁴ It is also notable for that it was a document that was adopted by consensus. However, the UDBHR remains a legally non binding and non enforceable declaration that therefore also does not legally obligate states that have agreed to it.

2.2.3. International Declaration on Human Genetic Data

In view of the complexity and scale of research in genetics, the Director-General of UNESCO in 2001 asked the IBC to examine the possibility of drafting an international instrument on human

⁴⁹⁵ Ibid., Article 12.

⁴⁹⁶ Ibid., Article 13.

⁴⁹⁷ Ibid., Article 14.

⁴⁹⁸ Ibid., Article 15.

⁴⁹⁹ Ibid., Articles 16-17.

⁵⁰⁰ Ibid., Article 18 para 1.

⁵⁰¹ Ibid., Article 18 para 2.

⁵⁰² Ibid., Article 19.

⁵⁰³ Ibid., Article 21.

⁵⁰⁴ H. ten Have, "The Activities of UNESCO in the Area of Ethics", 16 *Kennedy Institute of Ethics Journal*, 2006, 331, 339, and, similarly, A. Asai/S. Oe, "A Valuable Up-to-Date Compendium of Bioethical Knowledge", 5 *Developing World Bioethics*, 2005, 216 et seq.

genetic data.⁵⁰⁵ In 2002 a first draft was sent to Member States of UNESCO, intergovernmental organizations, non-governmental organizations, specialists, professional research associations and many other organizations. As part of this consultation, a Public Hearings Day was held on 28 February 2003 in Monaco, and associations and institutions representing aboriginal groups, the handicapped, doctors and the private sector expressed their views.⁵⁰⁶ A revised version was subsequently adopted unanimously and by acclamation as the International Declaration on Human Genetic Data at UNESCO's 32nd General Conference on 16 October 2003.⁵⁰⁷ The adoption of the Declaration by UNESCO by acclamation should, however, not be confused with universal acceptance. States, such as the United States of America which in 2001 were not a member of UNESCO, have hence also not adopted and are not bound, morally or politically, by the provisions of the Declaration. As the other UNESCO standards the Declaration is legally non-binding and non-enforceable.⁵⁰⁸

The Declaration has 5 parts. In the first section, entitled general provisions, it specifies the Declaration's aims, which are in particular "to ensure the respect of human dignity and protection of human rights and fundamental freedoms in the collection, processing, use and storage of human genetic data, human proteomic data and of the biological samples from which they are derived...[]...in keeping with the requirements of equality, justice and solidarity, while giving due consideration to freedom of thought and expression, including freedom of research."⁵⁰⁹ It thereby undertakes to define the principles that should guide States in formulating their legislation and their policies on these issues.⁵¹⁰

Building on the premise that human genetic data are special and that such data deserves to be treated special,⁵¹¹ the Declaration sets forth a number of limitations and obligations for the collection, processing, use and storage of such data. Art 5 defines that such data may be collected, treated, used and stored for various purposes, including diagnosis and health care, research,

⁵⁰⁵ UNESCO, Webpage of the International Declaration on Human Genetic Data, note 4, at: http://portal.unesco.org/shs/en/ev.php-URL_ID=1882&URL_DO=DO_TOPIC&URL_SECTION=201.html (last visited 16.10.10).

⁵⁰⁶ See IBC Report on the Public Hearings Day of 28 February, SHS/EST/CIB-Gred5/03/01, 2003. On public deliberations in bioethical processes see E. Blacksher/A. Diebel/P. Forest/S. Dorr Goold/J. Abelson, "What Is Public Deliberation?", 42 *Hastings Center Report*, 2012, 14 et seq. and K. O'Doherty/F. Gauvin/C. Grogan/W. Friedman, "Implementing a Public Deliberative Forum", 42 *Hastings Center Report*, 2012, 20 et seq.

⁵⁰⁷ Declaration on Human Genetic Data, note 4.

⁵⁰⁸ See discussion under Chapter V 1.2. and 2.

⁵⁰⁹ Article 1 of the Declaration on Human Genetic Data, note 4.

⁵¹⁰ See UNESCO Press Release No. 2003-81, October 2003.

⁵¹¹ *Ibid.*, Article 3, defining human genetic data as "information about heritable characteristics of individuals obtained by analysis of nucleic acids or by other scientific analysis." According to the declaration, "each individual has a characteristic genetic makeup. Nevertheless, a person's identity should not be reduced to genetic characteristics, since it involves complex educational, environmental and personal factors and emotional, social, spiritual and cultural bonds with others and implies a dimension of freedom."

forensic medicine and criminal proceedings or “any other purpose consistent with Human Rights principles.”⁵¹²

With regard to procedures the Declaration calls for collecting, treating, using and storing data on the basis of transparent and ethically acceptable procedures.⁵¹³ It proposes that independent, multidisciplinary and pluralist ethics committees should be promoted and established at national, regional, local or institutional levels.⁵¹⁴ It also recommends that states should endeavour to foster all forms of ethics education and training as well as encourage information and knowledge dissemination programmes about human genetic data.⁵¹⁵ Every effort should be made to ensure that human genetic data are not used in any discriminate way or in any way that infringes human rights of the individual.⁵¹⁶

In section B the Declaration sets forth more specific limitations and obligations for the collection of genetic data. Informed and free consent should be obtained for the collection of such data.⁵¹⁷ A person not able to consent should as far as possible take part in the authorization procedure of the collection of such data. Persons concerned have the right to decide whether or not to be informed of results.⁵¹⁸ Appropriate genetic counselling should be provided.⁵¹⁹

Part C defines limits of the admissible processing of such data. The privacy and confidentiality of individuals and their genetic data should thereby be protected.⁵²⁰ They, for example, should not be disclosed to third parties, in particular, employers, insurance companies, educational institutions and the family.⁵²¹ The accuracy, reliability, quality and security of these data should also be ensured.⁵²²

The permissible uses of human genetic data is regulated in section D. It limits the purposes of use to those stipulated for in Article 5. Any changes to that should be compatible with the prior, free, informed and express consent of the person concerned or must correspond to an important public

⁵¹² Ibid., specifying that human genetic data and human proteomic data may be collected, processed, used and stored only for the purposes of: (i) diagnosis and health care, including screening and predictive testing; (ii) medical and other scientific research, including epidemiological, especially population-based genetic studies, as well as anthropological or archaeological studies, collectively referred to hereinafter as “medical and scientific research”; (iii) forensic medicine and civil, criminal and other legal proceedings...; (iv) or any other purpose consistent with the Universal Declaration on the Human Genome, note 4, and the international law of human rights. On ethical analysis of some of these topics see Irrgang, note 131, 539.

⁵¹³ Ibid., Article 6 clause a.

⁵¹⁴ Ibid., Article 6 clause b.

⁵¹⁵ Ibid., Article 6 clause c.

⁵¹⁶ Ibid., Article 7.

⁵¹⁷ Ibid., Article 8.

⁵¹⁸ Ibid., Article 10.

⁵¹⁹ Ibid., Article 11.

⁵²⁰ Ibid., Article 14 clause a.

⁵²¹ Ibid., Article 14 clause b.

⁵²² Ibid., Article 14 clause c.

interest reason and be consistent with the international human rights law.⁵²³ The cross-border flow of human genetic data should be supported to foster international medical and scientific cooperation and to ensure fair access to these data.⁵²⁴ Scientific and cultural cooperation, in particular between industrialized and developing countries.⁵²⁵

Section E deals with the storage of human genetic data. Such data should be monitored and stored within a framework that is based on the principles of independence, multidisciplinary, pluralism, non-discrimination, and transparency as well as the other principles set out in the Declaration.⁵²⁶

In the final sections the Declaration recommends that states should endeavour to provide ethics education, training and information.⁵²⁷ Again it relies on UNESCO, the IBC and the IGBC to contribute to the implementation of the Declaration and the dissemination of the principles set out therein.⁵²⁸

Overall the Declaration is important as it provides one of the few international points of reference in the area of collection and use of human genetic data.⁵²⁹ However, it has also been noted that the subject of genetics has regularly been subject to dramatic changes instigated by new findings in the natural sciences.⁵³⁰ As such the Declaration will be in need of frequent adaptations to accommodate the new realities.

2.2.4. Declaration on the Human Genome and Human Rights

In 1997 UNESCO's General Conference unanimously and by acclamation adopted the Universal Declaration on the Human Genome and Human Rights.⁵³¹ The Declaration was subsequently adopted and endorsed by the United Nations General Assembly.⁵³² The Declaration was drafted to anticipate the international social, economic, and political implications of the "Human Genome Project", a worldwide initiative, completed in 2003, to map and sequence the entire chain of human DNA.⁵³³ As the other UNESCO instruments discussed in this section it operates on the bases of broad statements that lay out universal bioethical principles but does not address the

⁵²³ Ibid., Article 16.

⁵²⁴ Ibid., Article 17.

⁵²⁵ Ibid., Articles 18-19.

⁵²⁶ Ibid., Articles 20-21.

⁵²⁷ Ibid., Articles 23-24.

⁵²⁸ Ibid., Article 25.

⁵²⁹ J. Bovenberg, "Towards an International System of Ethics and Governance of Biobanks: A 'Special Status' for Genetic Data?", 15 *Critical Public Health*, 2005, 369, 382.

⁵³⁰ For some examples of these fast paced changes Chapter I, 3.2.

⁵³¹ Universal Declaration on the Human Genome, note 4.

⁵³² Ibid.

⁵³³ A. Taylor, "Globalization and Biotechnology: UNESCO and an International Strategy to Advance Human Rights and Public Health", 25 *American Journal of Law & Medicine*, 1999, 479, 483. See also Report by the Director-General on the Possibility of Drawing Up an International Instrument on the Protection of the Human Genome, UNESCO, Prov. Agenda Item 7.5, at 5-6, UN Doc. 28 C/38, 1995.

details of practices to which such principles might apply.⁵³⁴ Throughout its text it postulates a priority for the respect of human rights, fundamental freedoms and human dignity of individuals over research and research applications.⁵³⁵

It contains seven chapters covering such areas as human rights, human dignity and rights of the persons concerned, including the issue of informed consent and privacy of genetic data; cooperation between industrialized and developing nations, and research on the human genome.

Section A makes clear that the human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity. In a symbolic sense, so the Declaration, it was the heritage of humanity.⁵³⁶ Article 2 repeats that everyone has a right to respect for his or her dignity and for his or her human rights regardless of his or her genetic characteristics.

Section B sets out certain rights of the persons concerned. It stipulates that research on the human genome, as well as treatment or diagnosis thereof should minimize risks and maximize benefits to persons concerned.⁵³⁷ Prior, free and informed consent shall be obtained.⁵³⁸ Research which does not have an expected direct health benefit for a person unable to consent may only be undertaken by way of exception if the research is intended to contribute to the health benefit of other persons in the same age category or with the same genetic condition.⁵³⁹ Article 8 even provides the possibility for reparation for any damage sustained as a direct result of an intervention affecting a person's genome.

Section C provides limitations for research on the human genome. Such research may not prevail over respect for the human rights, fundamental freedoms and human dignity.⁵⁴⁰ Benefits from advances in biology, genetics and medicine, concerning the human genome, shall be made available to all. The Declaration also enshrines freedom of research as long as it is compatible with human rights.⁵⁴¹

Conditions for the exercise of scientific activity are set out in section D. These must be carried out in a manner of meticulousness, caution, intellectual honesty and integrity.⁵⁴² The Declaration recommends the establishment of independent, multidisciplinary and pluralist ethics committees

⁵³⁴ Ibid., 510.

⁵³⁵ See for example Articles 2, 3 and 5 of the Universal Declaration on the Human Genome, note 4.

⁵³⁶ Ibid., Article 1.

⁵³⁷ Ibid., Article 5 clause a.

⁵³⁸ Ibid., Article 5 clause b.

⁵³⁹ Ibid., Article 5 clause e.

⁵⁴⁰ Ibid., Articles 11 and 12.

⁵⁴¹ Ibid., Article 13.

⁵⁴² Ibid., Article 13.

to assess the ethical, legal and social issues raised by research on the human genome and its applications.⁵⁴³

Section E emphasizes the principles of solidarity and international co-operation that should guide the set up, undertaking, and use of findings of international and national research on the human genome.⁵⁴⁴

The Declaration is notable for being the first global and one of the most thorough initiative to address human rights implications with respect to genetic advances for both, research itself and the application of findings. As all instruments in this field it will, however, need to be adapted to new scientific developments.⁵⁴⁵

2.2.5. First conclusions with regard to the UNESCO Instruments in the Field of Bioethics

In conclusion to these first introductory notes to the UNESCO standards in the area of bioethics several things are worth emphasising. First of all, the three UNESCO standards, the UDBHR, the Universal Declaration on the Human Genome and the International Declaration on Human Genetic Data are all legally non binding and legally non enforceable standards. That is, even though states have drafted and agreed to them no state can legally demand of another state to fulfil the provisions set out in the standards and no state can threaten another state with legal action in case of breach of a provision. As such these standards can still develop considerable normative force, however, they must be considered to constitute "soft law" standards, a term whose content and implications will be further explained and analysed above in chapter III. Nevertheless, the UDBHR in particular should be noted for that here for the first time, nearly all States of the international community of states have committed themselves to respect and apply the principles and rights set out in the Declaration.⁵⁴⁶

Furthermore, all three UNESCO standards must be noted for that they explicitly deal with a number of issues of bioethical relevance. While the Declaration on the Human Genome and the Declaration on Human Genetic Data are more focused respectively on genetic research and the protection of the human genome the UDBHR certainly seeks to set a more comprehensive framework for dealing with issues of bioethical interest. Like the Oviedo Convention, discussed above, the UDBHR sets out provisions against the misuse of biological and medical advances and

⁵⁴³ Ibid., Article 16.

⁵⁴⁴ Ibid., Articles 17 to 19.

⁵⁴⁵ S. Marks, "Public Health and International Law: Tying Prometheus Down: The International Law of Human Genetic Manipulation", 3 *Chicago Journal of International Law*, 2002, 115, 120 et seq. and Final Report: Committee of Governmental Experts for the Finalization of a Declaration on the Human Genome, UNESCO, at 1, UN Doc. BIO-97/CONF.201/19, 1997.

⁵⁴⁶ H. Ten Have, "The Universal Declaration on Bioethics and Human Rights", in: 57 *International Social Science Journal*, 2005, 745, 745.

deals with a variety of issues including access to healthcare, consent requirements, privacy and scientific research. Yet it also goes beyond the Convention in including such issues as environmental questions and sustainable development. It moreover goes beyond the Oviedo Convention in that it, to some extent at least, seeks to address also non-state actors.⁵⁴⁷

Thirdly, all standards by UNESCO, in the same way as those by the Council of Europe, enshrine certain bioethical principles and have certain distinctive aims that will be further discussed in the next chapter. Also in parallel to the Council of Europe standards do all UNESCO standards address the issues of bioethical relevance that they are concerned with through a human rights framework. The exact meaning of this and the implications of this will be discussed over the next chapters.

3. Other international Standards concerned with Areas of Bioethics

Besides the Council of Europe and UNESCO a variety of other entities have been concerned with questions of bioethical relevance. Examples include the Guidelines for Good Clinical Practice for Trials on Pharmaceutical Products, adopted by the World Health Organization in 1995⁵⁴⁸, the Guidelines for Good Clinical Practice, adopted by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use in 1996,⁵⁴⁹ various World Health Organisation resolutions on for example the issue of human cloning and the UN Declaration on human cloning (hereinafter Cloning Declaration), adopted in 2005.⁵⁵⁰ The latter will briefly be discussed below.

3.1. The UN Cloning Declaration

The Cloning Declaration resulted from intense discussions over a period of 4 years. In 2001 the General Assembly decided to follow a proposal by France and Germany to prepare an international convention against the reproductive cloning of human beings.⁵⁵¹ The working group and Ad Hoc Committee that was thereafter established met in 2002 to consider the elaboration of a mandate for the negotiation of an international Convention against the reproductive cloning of human beings.⁵⁵² Subsequent negotiations in 2002 and 2003 within the working group, however, soon

⁵⁴⁷ UDBHR, note 4, Article 2.1.

⁵⁴⁸ WHO, Guidelines for Good Clinical Practice for Trials on Pharmaceutical Products, contained in the appendix to the report on the Use of Essential Drugs, TRS 850, Annex 3, 1995, 97-137.

⁵⁴⁹ International Conference on Harmonisation, Guidelines for Good Clinical Practice, CPMP/ICH/135/95, 1996.

⁵⁵⁰ UN Declaration on Human Cloning, note 35.

⁵⁵¹ International Convention Against the Reproductive Cloning of Human Beings, UN Res.56/93, 2001.

⁵⁵² Ibid., as the aim was to achieve a global normative instrument capable of effectively regulating an area of research and its attendant techniques that could have a profound impact on the entire humanity it was generally preferred that the General Assembly be seized of the matter instead of leaving it to other United Nations bodies. See generally M. Arsanjani, "Negotiating the UN Declaration on Human Cloning", 100 *American Journal of International Law*, 2006, 164 et seq.

proofed that consensus on merely the content of a mandate for the negotiation of such a treaty was elusive, with discussions beginning to revolve around mainly two irreconcilable positions.⁵⁵³ One side suggested a ban on reproductive cloning⁵⁵⁴ but would allow member States to make their own decisions on therapeutic cloning.⁵⁵⁵ The counter-proposal recommended a complete ban on both reproductive and therapeutic cloning.⁵⁵⁶ Negotiations were subsequently postponed until 2004. Realizing that states were unlikely to reach an agreement on the issue of human cloning, the General Assembly then decided to establish a Working Group to finalize the text of a non binding declaration on human cloning.⁵⁵⁷ In 2005 the General Assembly adopted the Declaration on Human Cloning by a recorded vote of 84 to 34, with 37 abstentions.⁵⁵⁸

The Declaration calls upon member states to “prohibit all forms of human cloning inasmuch as they are incompatible with human dignity and the protection of human life.”⁵⁵⁹ It furthermore calls upon member states to adopt “all measures necessary to protect adequately human life in the application of life sciences” and “the measures necessary to prohibit the application of genetic engineering techniques that may be contrary to human dignity”.⁵⁶⁰ As an instrument of the soft law the Declaration does not bind Member States, yet urges Member States “to adopt domestic legislation compatible with the Declaration's text.”⁵⁶¹

The wording of the Declaration is ambiguous and reflects the controversies that also dominated the negotiations on the failed treaty. As a result, the Declaration, for one, does not explicitly and unqualifiedly prohibit human cloning, neither for reproductive nor therapeutic purposes. Nations that support a comprehensive ban of all forms of human cloning consequently can thus interpret

⁵⁵³ Arsanjani, "Negotiating the UN Declaration on Human Cloning", note 552, 166 and M. Arsanjani, "The Negotiations on a Treaty on Cloning: Some Reflections", in: R. Wolfrum/S. Vöneky, *Human Dignity and Human Cloning*, 2004, 145 et seq.

⁵⁵⁴ Reproductive cloning aims at the creation of a living human embryo or person with (virtually or 100%) identical genes to those of a currently or previously existing human being. In contrast, therapeutic cloning or cloning for research purposes does not aim to create a whole human organism, but rather to harvest stem cells which can be used to study human development, to treat disease or to generate tissues and organs for transplants. See Achenbach/Clados, note 2. For further discussion see Winnacker, note 96, 55 et seq.

⁵⁵⁵ This side built on a Franco-German proposal and which was subsequently led by Belgium, See International Convention against the Reproductive Cloning of Human Beings, UN, A/C.6/57/WG.1/CRP.1/Rev.1, 2002. This side was also supported by the United Kingdom and many of those States, which were already involved in or at least had the capacity to become engaged in experiments on cloning.

⁵⁵⁶ This side was led by Costa Rica and was supported by the United States as well as by more than 60 other States, see International Convention Against the Reproductive Cloning of Human Beings - Letter dated 2 April 2003 from the Permanent Representative of Costa Rica to the United Nations addressed to the Secretary-General UN, A/58/73, 2003. This position also gained considerable support from many developing states that felt that a Convention on human cloning might divert focus from far more urgent medical and health concerns. Also the Holy See and many Christian countries rejected all aspects of human cloning on the grounds that it, in the case of therapeutic cloning, involved the creation of human beings for the purpose of destroying them and, in the case of reproductive cloning, involved the generation of a child by asexual and agamic means which would impose the image of a donor on the new human being and thus ultimately deny human dignity to the child. See Arsanjani, "Negotiating the UN Declaration on Human Cloning", note 552, 166.

⁵⁵⁷ UN GA decision 59/547, 2004.

⁵⁵⁸ UN Declaration on Human Cloning, note 35.

⁵⁵⁹ Ibid., clause b.

⁵⁶⁰ Ibid., clause a and c.

⁵⁶¹ Ibid., clause e.

the Declaration's provisions so as to call for an absolute prohibition on all forms of human cloning, including therapeutic cloning.⁵⁶² In contrast, states in favour of a ban of reproductive cloning only can generally interpret the Declaration as prohibiting only those cloning processes that they consider contrary to human dignity, i.e. those used for reproductive cloning.⁵⁶³ Moreover, the term 'clone' is not defined, thus providing leeway for those states to engage in therapeutic and even reproductive cloning processes, that define the term 'clone' as applicable to those 100% genetic replicates only where egg and nucleus have been derived from the same female donor.⁵⁶⁴ Also, the Declaration refrains from providing a definition of the controversial terms "human being", "human dignity", and of the moment when a "human life" begins, thus leaving it to member states to decide what might constitute adequate protection measures, at which stage of a human life –however defined- they should apply and which processes might be considered contrary to human dignity.⁵⁶⁵

Given these ambiguities the Declaration has sometimes been demurred as an ineffective and political instrument that confirms absence of rather than actual agreement in the area of human cloning.⁵⁶⁶ Overall, the Declaration's subject matter has made it the subject of much debate among scholars and practitioners. The fact that it has not been able to effectively and clearly regulate even the issue of reproductive human cloning has thereby been met with some bewilderment, given that most of the world's states seem to agree on that proposition. It has also been noted that due to the adoption of the Declaration, the United Nations will no longer formally consider the issue of human cloning regulation until a member state raises the issue again.⁵⁶⁷

3.2. International Forums indirectly concerned with Bioethics: The Example of WTO and the TRIPS agreement

Besides the international bodies that directly address bioethically relevant issues in one or several of their instruments there exist also several international entities that regularly address questions of bioethical relevance, however, without expressly acknowledging to doing so and without elaborating specific instruments on the subject matter. Since these entities often have considerable influence on how issues of bioethical relevance are de facto dealt with these entities and their (indirect) bearings on issues of bioethical relevance deserve mentioning.

⁵⁶² Arsanjani, "Negotiating the UN Declaration on Human Cloning", note 552, 176.

⁵⁶³ Ibid. On the debate on therapeutic cloning in Germany and several other countries and on the question of whether or not the cloning of human beings violates human dignity see Nida-Rümelin, "Bioethik und Menschenwürde: Dokumentation einer Debatte", note 77, 401 et seq.

⁵⁶⁴ J. Kersten, *Das Klonen von Menschen. Eine Verfassungs-, Europa- und Völkerrechtliche Kritik*, 2004, 63.

⁵⁶⁵ But see R. Wolfrum/S. Vöneky, "Who is protected by Human Rights Conventions? Protection of the Embryo vs. Scientific Freedom and Public Health", in: R. Wolfrum/S. Vöneky (eds.), *Human Dignity and Human Cloning*, 2004, 133 et seq.

⁵⁶⁶ Arsanjani, "Negotiating the UN Declaration on Human Cloning", note 552, 177.

⁵⁶⁷ Ibid. See also C. Jarrell, "No Worldwide Consensus: The United Nations Declaration on Human Cloning", 35 *Georgia Journal of International and Comparative Law*, 2006, 205, 231-232.

Bioethics' broad scope thereby translates into that a broad range of international organisations fall into this category. For example, the international Tribunal for the Law of the Sea established by the United Nations Convention on the Law of the Sea addresses bioethically relevant questions when it comes to such issues as extinction of species or pollution of the seas.⁵⁶⁸ One further example to be discussed in more detail in the next section is the World Trade Organisation (WTO) and in particular its' Agreement on Trade Related to Intellectual Property Rights (hereinafter TRIPS agreement).⁵⁶⁹ Another prominent and relevant example is the Convention on Biological Diversity which aims at the conservation of biological diversity, sustainable use of the components of biological diversity, and a fair and equitable sharing of the benefits arising out of the utilization of genetic resources.⁵⁷⁰ Of these, the WTO TRIPS agreement will be exemplarily discussed in the next sections.

3.2.1. The World Trade Organisation

The WTO came into being on January 1, 1995 as the successor to the General Agreement on Tariffs and Trade (hereinafter GATT).⁵⁷¹ GATT was concluded in 1947. Until the WTO was created during the Uruguay discussion round between 1986 and 1994 GATT functioned as a quasi international organization.⁵⁷² WTO then is an international organization that is concerned with liberalizing and facilitating trade. It is also a forum for governments to negotiate trade agreements and a place for them to settle trade disputes in this area.⁵⁷³ In case of trade disputes, the WTO provides a compulsory dispute settlement process where resolution can be reached through bilateral consultations or expert panel rulings. Failure to comply with the rulings may result in the imposition of sanctions by the WTO's dispute settlement body.⁵⁷⁴ WTO as an international organization is not bound by human rights treaties. However, its members are bound in as far as they have signed and ratified the relevant human rights treaties.⁵⁷⁵

⁵⁶⁸ International Maritime Court, Southern Bluefin Cases, *Australia and New Zealand v. Japan*, Cases No. 3 and 4 of 4 August 2000, ILM 38, 2000, 1359; and International Maritime Court, The Mox Plant Case, *Ireland v. United Kingdom*, Case No.10 of 3 December 2001, ILM 41, 2002, 405.

⁵⁶⁹ TRIPS Agreement, note 3.

⁵⁷⁰ Convention on Biological Diversity, 1992, UNEP/Bio.Div./N7-INC5; 31 ILM 818, (CBD) entered into force on 29 December 1993.

⁵⁷¹ GATT, defined in the Multilateral Agreements on Trade in Goods, ILM 33, 1994, 1154, consists of the text of the General Agreement on Tariffs and Trade of 30 October 1947, UNTS 55, 1947, 194; most of the prior existing GATT agreements, other decisions, and several new Understandings. See Multilateral Agreements on Trade in Goods, same note, Article 1. See J. Jackson, "The Uruguay Round and the WTO: New Opportunities for the Bretton Woods System", in: Bretton Woods Commission (ed.), *Bretton Woods: Looking to the Future*, 1994, 219, 220-222.

⁵⁷² The system was developed through a series of trade negotiations, or rounds, held under GATT. The first rounds dealt mainly with tariff reductions but later negotiations included other areas such as anti-dumping and non-tariff measures. The last round, the 1986-1994 Uruguay Round, led to the WTO's creation, See TRIPS Agreement, note 3.

⁵⁷³ WTO, Understanding the WTO, at: http://www.wto.org/english/thewto_e/what_is_e/tif_e/fact1_e.htm (last visited 27.04.2012).

⁵⁷⁴ Ibid.

⁵⁷⁵ Hestermeyer, note 345, 44 et seq.

WTO is concerned with all issues of bioethical relevance as far as they concern trade. It is thus relevant to the international regulation of bioethical issues as far as the trading of such goods as genetic material, technical equipment relevant in the context of biomedical research or the trading with hazardous material etc. is concerned. It is also relevant regarding the issuing patents for concepts and ideas in such areas as life organism or technical and scientific techniques used in several process of bioethical relevance. Another area where WTO is relevant to bioethics is health and safety restrictions on agricultural products.⁵⁷⁶ In one way or another WTO is therefore concerned with many areas of bioethics, although it has never for itself claimed or acknowledged a role in these processes.⁵⁷⁷

3.2.2. The TRIPS Agreements

The TRIPS Agreements establish certain intellectual property rights, including in the area of patent protection, copyrights and trademarks that signatories must provide through domestic legislation.⁵⁷⁸ TRIPS were negotiated as part of the Uruguay Round of the GATT negotiations under the auspices of the WTO. Over one hundred countries signed TRIPS on April 15, 1994.⁵⁷⁹ The Agreement provides for enforcement measures through its use of civil and administrative procedures and remedies. Provisions on criminal procedures are also included.⁵⁸⁰ Additionally, TRIPS provides for dispute settlement between countries. Disputes arising between WTO members in relation to TRIPS are subject to the WTO's compulsory dispute settlement procedures.⁵⁸¹ Ultimately, the violation of TRIPS may result in the suspension of WTO privileges.⁵⁸² The obligations in the TRIPS agreement apply equally to all members.⁵⁸³ Developing countries are,

⁵⁷⁶ Of special relevance to biotechnology are two WTO agreements that came out of the Uruguay Round to encourage the international harmonization of food standards. These are the Agreement on the Application of Sanitary and Phytosanitary Measures (hereinafter SPS), Marrakesh Agreement, note 252, Annex 1A Vol.27, Article 5.6 et seq. and the Measures and the Agreement on Technical Barriers to Trade (hereinafter TBT), Marrakesh Agreement, note 340, Annex 1A Vol.27, Article 7.8 et seq.

⁵⁷⁷ WTO's self-portrayal as an organisation that only focuses on 'technical' issues in the area of trade has, however, come under scrutiny recently. Hestermeyer, note 223, 84 et seq.

⁵⁷⁸ It covers copyright, trademarks, geographical indications, industrial designs, patents, integrated circuit layout, trade secrets, and test data. Patents provide exclusive rights to prevent third parties from "making, using, offering for sale, selling, or importing" any patented product or process. Article 7 and Articles 9 through 40 of the TRIPS Agreement, note 3; see generally M. Smith, "Bringing Developing Countries' Intellectual Property Laws to TRIPS Standards: Hurdles and Pitfalls Facing Vietnam's Efforts to Normalize an Intellectual Property Regime", 31 *Case Western Reserve Journal of International Law*, 1999, 211, 236.

⁵⁷⁹ Chart of Signatories to the TRIPS agreement, note 3, at: http://www.wto.org/english/docs_e/legal_e/ursum_e.htm (last visited 27.04.2012).

⁵⁸⁰ Articles 41 through 48 of the TRIPS Agreement, note 3.

⁵⁸¹ Ibid., Part III.

⁵⁸² J. Berman, "Using the Doctrine of Informed Consent to Improve HIV Vaccine Access in the Post-Trips era", 22 *Wisconsin International Law Journal*, 273 et seq.

⁵⁸³ Smith, note 455, 237.

however, given a grace period of between one to eleven years depending upon the country's economic status to phase in all of TRIPS' standards.⁵⁸⁴

Of particular relevance to the bioethical debate are inter alia those provisions that deal with patent provisions. Under Article 27(1) of TRIPS, “[p]atents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.” Article 70(8) specifically requires members to adopt a procedure for collecting pharmaceutical patent drug applications.⁵⁸⁵ Patents are to run for at least twenty years from the date of patent application collection. However, TRIPS expressly grants member states the right to exclude inventions from patentability under certain conditions.⁵⁸⁶

Some of these possible exclusions have bioethical aspects.⁵⁸⁷ Members of the WTO “may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment”⁵⁸⁸. In particular, “diagnostic, therapeutic and surgical methods for the treatment of humans or animals” and “plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes” may be excluded.⁵⁸⁹

Exceptions, however, must be rather narrowly construed. The term “necessary” does not encompass an exclusion based solely on a domestic law prohibition, i.e. an exclusion may not be made merely because the exploitation is prohibited by the law of a member state.⁵⁹⁰ The jurisprudence of the Court of Justice of the European Communities (hereinafter ECJ) which has been concerned with the terms ordre public and morality⁵⁹¹ and that of GATT⁵⁹², which has been

⁵⁸⁴ Articles 65 and 66 of the TRIPS Agreement, note 3. The original period has expired in 2005. However some of the least developed countries have been granted an extension as regards the grace period. Doha WTO Ministerial Declaration, WT/MIN(01)/DEC/1, 2001.

⁵⁸⁵ Berman, note 582, 275.

⁵⁸⁶ Ibid. TRIPS Agreement, note 3, Article 27 para 3 provides:

Members may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

⁵⁸⁷ WIPO, Intellectual Property and Bioethics - an Overview, consultation draft, available at:

http://www.kipo.ke.wipo.net/export/sites/www/freepublications/en/life_sciences/932/wipo_pub_b932ipb.pdf (last visited 27.04.2012).

⁵⁸⁸ Ibid., Article 27 para 2.

⁵⁸⁹ Ibid.

⁵⁹⁰ Ibid.

⁵⁹¹ The European Court of Justice has, for example, addressed questions relating to derogation from international obligations on the basis of ordre public and morality in for example, ECJ, *Cullet v. Centre Leclerc Case* 231/83, CMLR 2, 1985, 524, thereby recognising that such limitations may only be deemed necessary if the state imposing such measures proves that they “serve a purpose which is in the general interest, and as such... take precedence over the requirements of the free movement of goods, which constitutes one of the fundamental rules of the Community.” Such purpose may not have a mere economic motive. And it may not be applied in a discriminatory way, favouring for example domestic products over those of other states.

concerned with the word 'necessary', further indicate that the scope of admissible exceptions is very limited. The scope of exceptions is highly relevant from an ethical point of view. It, for example, decides whether pharmaceutical companies have the right to hold exclusive access to their products for a set amount of time or whether developing countries may invoke an exception on moral grounds that would allow it to produce generic versions of drugs without paying intellectual property rights.⁵⁹³ It is also relevant to the question of whether or not biotech companies should be allowed to use indigenous people's traditional knowledge in developing and then patenting medical drugs.⁵⁹⁴ Similarly, by allowing a state to exclude from its patent scheme products that, for example, only have been made possible by a wilful destruction of embryonic stem cells so that the biotech firms investing in such research could not recover its costs invested in the research, TRIPS could also considerably impact the proliferation of such research.

The example shows that WTO has considerable influence on how issues of bioethical relevance are resolved at the international level, what kind of research is being promoted and who profits from new developments. WTO's role in these processes is interesting: WTO is inherently about trade liberalization, not about an ethically sensitive regulation of bioethical issues. When dealing with the rules of trade between countries WTO's objective is hence to create a secure trading environment for producers of goods and services mainly through economic liberalization and not about the most commendable ethical outcome.⁵⁹⁵ Moreover, by not making explicit WTO's involvement in questions of bioethical relevance WTO's role in these processes and questions goes largely unnoticed.

3.3. General International Law

To conclude the overview of relevant international legal standards this final section also addresses the question of whether issues of bioethical relevance can also be dealt with under general international law, i.e. other than treaty law or soft legal standards.

Apart from what is enshrined in treaty and non-treaty human rights standards, issues of bioethical relevance can also gain relevance through customary international law.⁵⁹⁶ That is, customary

⁵⁹² On GATT see T. Ackermann, "Disorderly Loopholes: TRIPS Patent Protection, GATT, and the ECJ", 32 *Texas International Law Journal*, 1997, 489, 507 et seq.

⁵⁹³ Berman, note 582, 288.

⁵⁹⁴ See Records of a Hearing before the WTO Ministerial Conference, Serial 106-50 of 2 February 2000, at: http://www.lib.washington.edu/uwill/research101/Images/wto_govpub.pdf (last visited 27.04.2012).

⁵⁹⁵ This will also be discussed in Part III of this thesis.

⁵⁹⁶ On customary international law see *Military and Paramilitary Activities in and against Nicaragua (Nicaragua v. United States)*, Merits, ICJ Reports 14, 1986, para 97; *Continental Shelf (Libya v. Malta)*, ICJ Rep, 1985, para 29; and *Advisory Opinion on the Legality of the Use of Threat or Nuclear Weapons*, ILM 35, 1996, 826. See generally Malanczuk, note 204, 44 et seq. and Cassese, note 203, 135 et seq. There is some debate about the question of whether international customary law also binds states that consistently object to it. Cf. for example P. Weil, "Towards Relative Normativity in International Law", 77 *American Journal of International Law*, 1983, 413, 433 et seq. Yet the rule

international law can be relevant as far as it covers the same norms that international human rights treaties and standards specify. That is so because customary international law can have a separate existence (apart from human rights law), even if it covers the same norms and binds the same state.⁵⁹⁷ The separate existence of a norm under customary international law is for example relevant in those cases where states have not ratified a treaty or merely signed a non-binding standard as customary law binds all states no matter whether they have signed it, unless they have persistently objected to it.⁵⁹⁸ Moreover, as opposed to general treaty law, there is no question of whether or not customary law has to be incorporated into national law – it is immediately binding no matter whether it has or has not been incorporated into national law. Finally, the question of the existence of customary law is relevant as customary law can modify treaty rules.⁵⁹⁹ Thus, if it can be shown that there exist customary international norms with regard to the human rights enshrined in the above discussed standards, these norms must be taken to be binding, no matter whether a state has signed or ratified the relevant human right standard and no matter whether a state has incorporated a norm into its national law. Customary international law can, of course, also be relevant to the extent that it establishes norms that exist in addition to what has been specified in the area of bioethics in human rights standards, for example if it could be shown that there exists a customary international rule regarding the questions of abortion of euthanasia that would then oblige states to apply this norm in their territory irrespective of whether or not there exists a written or other agreement to that extent.

Following the traditional doctrine, the existence of customary international law depends on the fulfilment of two preconditions. One, there has to be an established, widespread, and consistent practice on the part of states.⁶⁰⁰ Secondly, there has to be evidence of an *opinio iuris* as the conviction that such practice reflects, or amounts to, law.⁶⁰¹ Both concepts, consistent state practice and *opinio iuris*, however, are far from being clear in terms of what amounts to either. The content and exact meaning of the affix 'consistent' in the expression 'consistent state practice', for example, has been widely debated as has the question about what and which practices qualify as state

seems to be that state that consistently and timely object to a rule are not bound by it, See *Asylum Case (Columbia v. Peru)*, ICJ Reports 1950, 266, 277 – 278 .

⁵⁹⁷ *Military and Paramilitary Activities in and against Nicaragua (Nicaragua v. United States)*, Merits and Judgment, ICJ Reports 14, 1986, para 178.

⁵⁹⁸ Hestermeyer, note 345, 122. See also T. Meron, *Human Rights and Humanitarian Norms as Customary Norms*, 1991, 3 et seq.

⁵⁹⁹ Hestermeyer, note 345, 122.

⁶⁰⁰ For a discussion of what constitutes state practice see *North Sea Continental Shelf Case (Judgment)*, ICJ Rep, 1969, para 73 and generally A. d'Amato, *The Concept of Custom in International Law*, 1971, 88 et seq.; K. Wolfke, *Custom in Present International Law*, 1993, 41 et seq.; I. Brownlie, *Principles of International Law*, 1982, 26 et seq.

⁶⁰¹ For discussion see the Case of the *SS Lotus (French Republic vs Turkish Republic)*, PCIJ Reports 1927, Ser A, No 10, 18; M. Byers, *Custom, Power and the Power of Rules, International Relations and Customary International Law*, 1999, 135 et seq.

practice. It is also not clear what amounts to proof of opinion juris.⁶⁰² While it seems clear that a state concerned has to feel “that it is conforming to what amounts to a legal obligation”⁶⁰³ it is by no means clear how and through which act such a “feeling” is shown.⁶⁰⁴

Generally with regard to both premises, consistent state practice and opinion juris in the area of human rights, it may be fair to say that there is hardly any other area of law in which so many standards have been developed that consistently reaffirm and cross-reference the principles and norms enshrined in other human rights documents, in particular the UDHR and the Covenants. This indicates that at least on paper there is a 'consistent state practice' and, by means of their formulation as human rights standards, opinion juris with regard to those human rights norms that are enshrined in these standards.⁶⁰⁵ As such an argument can be made that human rights generally can be regarded as norms of customary international law. As far as these norms are relevant to the context of bioethics, briefly discussed above, norms enshrined in these standards could then also be interpreted to be part of customary international law. On the other hand should it be noted that the existence of this dense fabric of human rights texts and standards and states' repeated affirmation of them has in no way hindered states from engaging in often widespread and systematic abuses even of some of the most fundamental human rights, including that of the right to life and to be free from torture.⁶⁰⁶ Actual state actions as opposed to what states say and what they sign in terms of international legal standards thus seem to suggest that there exist no customary norms. Nevertheless, having said all that by now it seems that the overwhelming majority of scholars and states agree that at least some parts of the UDHR and the Covenants constitute customary international law.⁶⁰⁷ The standards in the area of bioethics, to the extent that they replicate these parts enshrined in the UDHR and the Covenants thus could be argued to be customary international law. This would, however, only apply to the extent to which norms replicate those norms in the Bill of Human rights, not to the extent that the standards in the area of bioethics deviate from those standards or establish new human rights. For example, the right to life is generally accepted to constitutes a norm of customary international law⁶⁰⁸, however, a specific adaptation of this right, for

⁶⁰² Malanczuk, note 204, 44-45.

⁶⁰³ *North Sea Continental Shelf Case* (Judgment), ICJ Rep, 1969, para 77.

⁶⁰⁴ The confusion and wide range of opinions with regard to these premises is such that Hestermeyer, for example, concludes with regard to a potential customary norm regarding the question of whether or not the right to health includes such a basic premise as a "right to access to medicine" that "dressing up a concise argument on state practice ... seems preposterous." Hestermeyer, note 345, 124.

⁶⁰⁵ Hestermeyer, note 345, 132.

⁶⁰⁶ Alston/Steiner, note 214, Chapter 1, listing a variety of news articles documenting contemporary gross violations of human rights.

⁶⁰⁷ However, it is not quite clear which parts constitute customary international law, see the debate below in Chapter IV, 3.3. But see for example, A. d'Amato, "Human Rights as Norms of Customary International Law", in: A. d'Amato (ed.), *International Law: Prospect and Processes*, 1987, 123 et seq. Alston/Steiner, note 214, 35. O. Schachter, *International Law in Theory and Practice*, 1991, 334-335.

⁶⁰⁸ See note 287.

example to cover embryos or embryonic stem cells or to grant access to drugs and medicine would not constitute customary international law.

It could further be argued that several human rights that form part of the category of *jus cogens*⁶⁰⁹ can be said to have a bearing on bioethical discussions. A norm qualifies as *jus cogens* if it is a fundamental principle of international law which is accepted by the international community of states as a norm from which no derogation is permitted.⁶¹⁰ As such norms of *jus cogens* always qualify as norms of international customary law while the latter is not confined to the category of *jus cogens*. Acts of torture, for example, no matter whether they take place in a context of medical experiments (and hence in an area relevant to the field of bioethics) or not are prohibited by the fundamental principles of law enshrined in the concept of *jus cogens* as are acts of slavery or genocide. *Jus cogens* is, however, a category of crimes reserved for only the most gross and blatant human rights violations, such as genocide and crimes against humanity, which reflects the importance of these crimes and their universal condemnation.⁶¹¹ To the extent that questions of bioethical relevance mount up to such gravity they may be considered under the law of *jus cogens*. Outside of the category of the gravest human rights violations *jus cogens*, however, cannot offer protection to crimes or offences committed in areas of relevance to bioethics. While certain cases of gross abuse of the doctor-patient/research relationship, such as the above mentioned crimes committed by Nazi physician, may certainly be considered to fall into the area of norms of *jus cogens*, overall it must be doubted whether states, in any near future, would be willing to extend the notion of *jus cogens* to cover for example such conduct as the wilful destruction of embryonic stem cells or euthanasia, under the heading of *jus cogens*. That is partly so because many of the cases in the area of bioethics, which could potentially be linked to the category of *jus cogens* concern those marginal human beings in regard to which it is not clear which level of protection international law awards them. If it is not even clear whether or how general international law or international human rights law applies, it is even less clear so with regard to norms of *jus cogens*. Another reason is

⁶⁰⁹ There is no clear agreement regarding precisely which norms are *jus cogens* nor on how a norm reaches the status of *jus cogens* but it is generally accepted that *jus cogens* includes the prohibition of genocide, piracy, slave trade, torture, racial discrimination and wars of aggression and territorial aggrandizement. The Vienna Convention, note 128, affirmed *jus cogens* as an accepted doctrine in international law. See generally Malanczuk, note 204, 57 and Cassese, note 203, 200. It should be kept in mind that norms of *jus cogens* always form part of customary international law, while customary international law is not always *jus cogens*. For that reason both categories will be treated separately in this thesis.

⁶¹⁰ Under Article 53 of the Vienna Convention, note 218, a *jus cogens* norm is: "a norm accepted and recognized by the international community of States as a whole as a norm from which no derogation is permitted and which can be modified only by a subsequent norm of general international law having the same character."

⁶¹¹ A. Orakhelashvili, *Peremptory Norms in International Law*, 2008, 3 et seq.

certainly states' general unwillingness to expand and thereby potentially dilute the category of *jus cogens*.⁶¹²

Finally, it should be mentioned that international criminal law can be relevant to issues of bioethical interest to the extent that international criminal law provisions cover issues of bioethical relevance. The positive sources of international criminal law, dealing with international crimes committed by individual persons, most importantly war crimes and crimes against humanity, can be found in such a range of standards and statutes as the UN Convention on the Prevention and Punishment of Genocide in 1948⁶¹³, the Statutes of the International Criminal Tribunal for the former Yugoslavia and the International Criminal Tribunal for Rwanda⁶¹⁴ and the Statute of the International Criminal Court.⁶¹⁵ International criminal law deals with the most serious crimes considered of concern to the international community as a whole, including crimes against humanity and war crimes. Unlike the International Court of Justice which has jurisdiction over states, the courts and tribunals dealing with cases of international criminal law have jurisdiction over individuals.⁶¹⁶ To the extent that crimes of humanity or war crimes can be construed to be of relevance to matters of bioethical interest international criminal law may well be relevant to issues of bioethical relevance. Cases and crimes dealing with forced impregnation, forced motherhood, or slavery, as far as relevant to international criminal law, could be relevant to questions of bioethical interest. However, as was the case with norms of *jus cogens*, international criminal law has been developed and hence so far been applied to cases of some of the gravest breaches of international criminal law. For the same reasons as issues of bioethical issues will hardly be dealt with under the norms of *jus cogens* will they then hardly be dealt with under international criminal law.

Concerning the existence of customary international norms outside of long grown and well established human rights norms, such as those of the UDHR and Covenants, it seems highly doubtful whether provisions that are for example enshrined in the Oviedo Convention, the UDBHR or the cloning declaration constitute norms of customary international law by themselves.⁶¹⁷ Given the obvious lack of consistent and harmonic state practice with regard to many issues of bioethical relevance it is difficult to sustain an argument in favour of a customary international law regarding any of these issues. However, some scholars nevertheless argue for the existence of a customary prohibition of for example the cloning of human beings, arguing that *opinio iuris* not state practice

⁶¹² Malanczuk, note 204, 57 and Cassese, note 203, 200.

⁶¹³ Article 6 of the Convention on the Prevention and Punishment of Genocide, 1948, 102 Stat. 3045, 78 U.N.T.S. 277.

⁶¹⁴ Statute of the International Criminal Tribunal for the Former Yugoslavia, S.C. Res. 808, UN SCOR, 48th Sess., 3217th mtg., Annex, UN Doc. S/RES/808, 1993; Statute of the International Criminal Tribunal for Rwanda, S.C. Res. 955, UN SCOR, 49th Sess., 3453d mtg., Annex, UN Doc. S/RES/955, 1994.

⁶¹⁵ Rome Statute of the International Criminal Court, July 17, 1998, 37 I.L.M. 999.

⁶¹⁶ *Ibid.*, Part II on Jurisdiction, admissibility and applicable law.

⁶¹⁷ Cf. for example Achenbach/Clados, note 2.

showed such a rule. The argument is that customary international law is established instantly on a declared universal conviction that something is legal or illegal under existing international law, compatible or incompatible with basic values of the international community or that it is itself a basic value of the international community.⁶¹⁸ According to these scholars, this *opinio iuris* can be deduced from non-binding universal instruments, such as resolutions of the UN General Assembly. On this basis it is argued that universal soft law instruments which label reproductive human cloning as contravening human dignity and human rights such as e.g. the UNESCO Human Genome Declaration, WHA Resolutions 50.37⁶¹⁹, and UN GA Resolution 59/280⁶²⁰, evidence a universal *opinio iuris* which declares the illegality of reproductive human cloning under international law because of its incompatibility with human dignity as a basic value of the international community. Analogous arguments can be made with regard to norms established in, for example, the UNESCO standards in the area of bioethics, for example regarding such issues as stem cell research or informed consent. However, to assume that non-binding instruments, supplemented by one binding instrument such as the Oviedo Convention is prove of states' conviction of the existence of an enforceable customary rule with regard to the norms enshrined in the UDBHR is rather untenable given that states deliberately chose the form of soft law instruments and one regionally confined Convention to deal with issues at stake, which altogether rather supports the view of a lack of consensus among states and hence lack of customary international norms regarding issues dealt with in these standards.⁶²¹ Therefore, it seems that so far at least, customary international law does not offer much with regard to issues of bioethical relevance.

Finally, general principles of international law could be relevant to the area of bioethics to the extent that they enshrine principles relevant to the area. General principles can be derived in a variety of ways, most prominently from the existence of a rule in several municipal laws of states or from general principles of international law.⁶²² In particular, if most states could be shown to endorse basic human rights in their national legislations or, even more specifically, the norms enshrined in the UNESCO standards, that could be taken to show that there are either general

⁶¹⁸ C. Tomuschat, *International Law: Ensuring the Survival of Mankind on the Eve of a New Century*, 1999, 281 et seq. and 333 et seq.

⁶¹⁹ World Health Assembly Resolution 50.37 on Cloning in Human Reproduction, 1997.

⁶²⁰ UNGA Res 59/280, 2005.

⁶²¹ Achenbach/Clados, note 2.

⁶²² Brownlie, note 600, 16 and Malanczuk, note 204, 49. There are various opinions as to what the concept of general principles of international law is intended to refer to. Some writers regard it as an affirmation of natural law concepts, which are deemed to underlie the system of international law and constitute the method for testing the validity of the positive (i.e. man made rule). See e.g. H. Lauterpacht, *Private Law Sources and Analogies of International Law*, 1927, 1. Other writers treat it as a sub-heading under treaty and customary law, incapable of adding anything to these major sources of international law. M. Shaw, *International Law*, 2007, 99, citing M. Tunkin, *Theory of International Law*, 1974, chapter 7. Important principles of international law underpinning many international legal rules are for example that of *pacta sunt servanda*, *estoppel*, that of good faith, *res judicata*, and that violation of engagement involves an obligation to make reparation. Shaw, 100-102.

human rights principles or more specific principles in the area of bioethics that apply to issues of bioethical relevance.⁶²³ The wide acceptance of human rights in national and international standards makes it convincing to accept basic human rights as general principles of international law.⁶²⁴ Again, however, that does not mean that these norms can suddenly be extended to apply to all areas of ethical interest or that they are accepted as general principles by states when tailored specifically to the area of bioethics. The right to life for example, even though it might in some states be interpreted to serve as foundation for a right to access to medicine is far from being enshrined and interpreted as such in all or even most national laws and hence cannot be claimed to lay the basis for a general principle of access to medicine. Rather the opposite seems true: given the diverse range of state opinions and national regulations with regard to matters of bioethical interests no general principles regarding such issues as cloning for therapeutic purposes, stem cell research, abortion, euthanasia etc can be deduced. General principles of international law thus can offer something to bioethical debate to the extent that they enshrine general human rights principles. The specific principles set out in the standards in the area of bioethics or specific interpretations of general human rights principles, however, can not yet be taken to constitute general principles of international law.

4. Conclusion

The preceding chapter has shown that at least from the Nuremberg Doctor's Trial onwards, bioethics and international law have been heavily intertwined. Particularly, the Nuremberg Code, the UDHR and the Helsinki Declarations have done much to provide modern standards in the area of bioethics with their current face.

Moreover, international standards concerned with questions of bioethical interest exist in many areas of international law. Given bioethics' broad scope, in fact, many international legal standards in some way or another deal with questions of bioethical relevance. The standards discussed above can be divided into two groups of standards. One is the group of standards directly addressed to matters of bioethical relevance, including all standards by the Council of Europe and by UNESCO, discussed above, as well as the UN Declaration on Human Cloning. These standards can be distinguished from other standards in that they, in their title and subsequently in their content are clearly addressed to matters of bioethical relevance. All these standards are framed in the language of human rights and endorse similar bioethical principles and aims. Yet they can be distinguished internally in that some of these standards, i.e. all of those issued by the Council of Europe are legally binding and enforceable on its Member States, while the UNESCO standards and the UN

⁶²³ See generally Lauterpacht, note 622, 1. Malanczuk, note 204, 49 et seq. and Brownlie, note 600, 65 et seq.

⁶²⁴ Hestermeyer, note 345, 135.

Cloning Declaration remain legally non enforceable and non binding. The other standards mentioned above, including most prominently the WTO standards must be considered to constitute examples of standards that have a significant bearing on matters of bioethical interest while they are not directly addressed to such matters.

Finally the above chapter showed that customary international law, international criminal law and general principles of international law can be relevant to matters of bioethical interest to the extent that they endorse general human rights norms that can have a bearing on issues of bioethical relevance. However, the specific adaptation of these norms to issues of bioethical relevance is not covered by customary international law, international law and general principle of international law so that little normative force can be derived from these standards when it comes to regulating issues of bioethical interest

Chapter V Aims and Principle of International Legal Standards Directly Addressed to Matters of Bioethical Relevance

As the preceding chapter was more descriptive of standards directly addressed to bioethical interest than analytical this chapter compares and discusses some of the similarities that can be found in all standards directly addressed to questions of bioethical interest. For one, this chapter establishes that all standards directly addressed to questions of bioethical relevance are framed as human rights instruments. That is, all international legal standards directly addressed to issues of bioethical relevance are at their heart human rights standards in that they build on and root in established human rights standards, endorse human rights principles and follow general human rights doctrine. Yet the standards also, while clearly operating within a human rights framework, secondly, endorse several aims and principles that somewhat go beyond traditional human rights doctrine in that their content differs from what has been enshrined in the UDHR and the above mentioned Covenants on Civil and Political and Economic, Social and Cultural Rights. These aims and principles do not contradict human rights provisions or principles, nor override them. Rather they coexist with human rights and, where necessary or possible, supplement them.⁶²⁵ This chapter will explain and further elaborate these two characteristics and their relationship.

1. The Standards as Human Rights Instruments

1.1. A Primer on the Positive Sources of International Human Rights

Most of the positive international human rights standards only came into existence after World War II when the international law regime, among other things, sought to react to the atrocities and genocidal rule of the Nazi regime. It did so by establishing a number of rights that seek to protect individuals from abuse by its government, so called human rights.⁶²⁶

The promotion of human rights as an aim was first enshrined in the UN Charter and it is one of the purposes of the United Nations as such.⁶²⁷ To achieve this purpose the UN Charter and its members⁶²⁸ commit themselves to promote higher living standards, to find solutions to international economic, social and health problems and to universal respect for human rights. The UN Charter also endows the General Assembly and the UN Economic and Social Council

⁶²⁵ With slight variations these aims and principles form a coherent set of aims or principles across a variety of instruments. Hence they will be referred to as 'principles and aims enshrined in the instruments in the area of bioethics' even though they may not feature explicitly in all instruments or not at the same level of prominence. Their overall coherence has prompted some authors to suggest the emergence of 'some basic norms' that constitute the foundational core of an international 'biomedical law'. See, for example, R. Andorno, "First steps in the Development of an International Biolaw", in: C. Gastmans/K. Dierickx/H. Nys/P. Schotmans (eds.), *New Pathways for European Bioethics*, 2007, 121, 134.

⁶²⁶ J. Morsink, *The Universal Declaration of Human Rights*, 1999, 5.

⁶²⁷ UN Charter, note 208, Article 1(3).

⁶²⁸ Ibid., Articles 55- 56.

(hereinafter ECOSOC) with competencies in the human rights field.⁶²⁹ Additionally ECOSOC is required to set up commissions in economic and social fields for the promotion of human rights.⁶³⁰ Even though states according to the Charter are only obliged to promote rather than to abide by human rights and even though the Charter did not specify in detail what was covered by human rights, UN involvement in human rights law has contributed tremendously to that human rights received and continue to receive a prominent space in international forums, negotiations and deliberations as well as to their successful further development as part of the wider field of international law.⁶³¹ The trial and judgement of the international military tribunal at Nuremberg of major war criminals⁶³², expanding individual criminal liability from such crimes as piracy to crimes against humanity and thereby “catapulting individuals onto the international stage” added further fuel to the embryonic international human rights movement.⁶³³

The importance attached to human rights was subsequently given legal expression in the UDHR adopted in 1948 by the United Nations General Assembly, setting forth “the inalienable rights and fundamental freedoms of each and every human being without regard to his race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status.”⁶³⁴ As a resolution of the General Assembly the UDHR is not legally binding. Seeking the recognition of human rights within legally binding instruments, the UN eventually adopted two International Covenants on human rights, one on Civil and Political Rights (hereinafter ICCPR) and one on Economic, Social and Cultural Rights (hereinafter ICESCR).⁶³⁵ The rights enshrined in the former instrument, sometimes referred to as “first generation” human rights, are meant to protect an individual's liberty from undue interference from the state, specifying such rights as the right to life, liberty, freedom from torture, etc. The latter group of rights, sometimes referred to as “second generation” human rights, is meant to promote the social, economic and cultural well-being of the individual. They include such rights as the right to food, health, social security, housing etc.⁶³⁶ The division of rights into two separate Covenants is mostly owed to then political

⁶²⁹ Ibid., Article 62.

⁶³⁰ Ibid., Article 68.

⁶³¹ Hestermeyer, note 345, 81. See generally R. Wolfrum, "The Progressive Development of Human Rights. A Critical Appraisal of Recent UN Efforts", in: J. Jekewitz et al (eds.), *Des Menschen Recht zwischen Freiheit und Verantwortung, Festschrift fuer Karl Josef Pratsch zum 75. Geburtstag*, 1989, 67 et seq.

⁶³² TMWC, note 56.

⁶³³ R. Smith, *International Human Rights*, 2007, 25.

⁶³⁴ UDHR, note 214, Article 2. See also generally Morsink, note 626.

⁶³⁵ ICCPR, note 341, and ICESCR, note 341.

⁶³⁶ The "generational approach" to human rights was introduced by Karl Vasak in 1977 and is still sometimes used. By analogy with the slogan of the French revolution first generation rights have been said to correspond with the theme of *liberte*, second generation rights with that of *egalite*. There is also a 'third generation' of human rights correlated with the theme of *fraternite*. See generally K. Vasak, "Human Rights: A Thirty-Year Struggle: the Sustained Efforts to give Force of Law to the Universal Declaration of Human Rights", 30 *UNESCO Courier*, 1977, 11. and K. Vasak, "For the Third Generation of Human Rights; The Right of Solidarity," *International institute of Human Rights*, 1979, 3, listing the rights correlated to 'egalite' as the right to development, to peace, environment, ownership of common heritage of mankind and right to communication. For further discussion see T. Meron, "On a Hierarchy of International Human Rights", 80 *American Journal of International Law*, 1986, 21 et seq. The distinction has, however, often been shown to be misguided. See for example CESCR General comment 9, note 311.

and ideological rifts between 'West' and 'East'. Socialist countries mostly understood both categories of rights to be on equal footing, yet often claimed that social, economic and cultural rights to be a prerequisite to the enjoyment of civil and political rights. They sought to have both types of rights in one comprehensive human rights document.⁶³⁷ Western states, inspired by the French revolution and the US Bill of Rights, generally preferred civil and political rights, arguing mostly that only civil and political rights were justiciable, could be immediately given effect and required the state to abstain from interfering with individuals whereas social and economic rights required a state to engage in bringing goods to the individual.⁶³⁸ The latter view ultimately prevailed and two distinct Covenants were opened up for signature. Despite numerous resolutions, proclamations and declarations affirming that both sets of rights are universal, indivisible, and interdependent the distinction between them endures with socio economic and cultural rights long being somewhat neglected by states and in negotiations.⁶³⁹ Over recent years ICESCR rights, however, they have received more attention from states as well as from scholars and NGOs.⁶⁴⁰

Since the Covenants numerous additional human rights instruments, binding and non-binding, have come into existence. Some of these cover new subject field, such as sustainable development or the environment, or rights pertaining to different right holders, such as groups. However, the three original documents discussed above, have remained the centrepiece of human rights, reflected in that they are sometimes referred to as the "International Bill of Human Rights".⁶⁴¹ All standards in the International Bill of Human Rights (hereinafter Bill of Human Rights) provide for individual human rights that can be invoked to protect an individual against abuses perpetrated by a state. Generally, obligations are owed erga omnes, i.e. between states that have signed or ratified the instruments, which also means that states are the addressees of these rights and that it is mostly states that can allege a breach of the rights enshrined therein. The UDHR as a non-binding declaration does not dispose over any enforcement mechanisms, although it has been argued that by now most of its provisions forms part of customary international law and as such constitute binding law that and create legal obligations.⁶⁴² The ICCPR and ICESCR in turn, as legally binding treaties undoubtedly create binding obligations on states. They, however, dispose over different enforcement mechanisms. That is, the first Optional Protocol to the ICCPR establishes an

⁶³⁷ Morsink, note 626, 43.

⁶³⁸ Alston/Steiner, note 214, 62.

⁶³⁹ Cf., for example, D. Beetham, "What Future for Economic and Social Rights?", 43 *Political Studies*, 1995, 41 et seq.; H. Shue, *Basic Rights: Subsistence, Affluence and U.S. Foreign Policy*, 1996, 2 and E. Frankel Paul, *Economic Rights*, 1992, x-xi.

⁶⁴⁰ See for example K. Roth, "Defending Economic, Social and Cultural Rights: Practical Issues Faced by an International Human Rights Organization", 26 *Human Rights Quarterly*, 2004, 61, 63 et seq.; Alston/Steiner, note 214, 143; Schachter, *International Law in Theory and Practice*, note 607, 330 and 352 et seq.; D. Kelly, *A Life of One's Own: Individual Rights and the Welfare State*, 1998, 1 and J. Waldron, "A Rights-Based Critique of Constitutional Rights", 13 *Oxford Journal of Legal Studies*, 1993, 18 et seq.

⁶⁴¹ Alston/Steiner, note 214, 60. Office of the High Commissioner of Human Rights, Fact Sheet No2, at: <http://www.ohchr.org/EN/PublicationsResources/Pages/FactSheets.aspx> (last visited 28.12.2009).

⁶⁴² This pertains to such rights as the right to life and liberty, the right not to be subjected to torture and the right to be free from discrimination, however, not generally to the whole document. See discussion under Chapter V, 1.

individual complaints mechanism, allowing individuals, under certain conditions, to complain to the Human Rights Committee about violations of the Covenant.⁶⁴³ The ICESCR to this date disposes over no such mechanism.⁶⁴⁴ Differences between both Covenants are also reflected in the key provision of these instruments, i.e. in their respective Articles 2(1). In the case of the ICCPR it holds that “each State Party to the present Covenant undertakes to respect and to ensure to all individuals within its territory and subject to its jurisdiction the rights recognized in the present Covenant”. Article 2 (1) of the ICESCR, in contrast recognizes that the obligation of state parties stated in that Covenant is subject to the availability of resources (to the maximum of its available resources) and second the obligation is one of progressive realization (with a view to progressive realization), a formulation which has often been interpreted to either provide a lesser degree of obligation or at least has given rise to endless speculations as to the exact meaning and level of obligation enshrined in ICESCR.⁶⁴⁵ In response the Committee on Economic, Social and Cultural Rights (hereinafter CESCR) in various non-binding Comments has subsequently showed that the formulation “progressive realization” is not devoid of meaning and that instead, states have to take steps to the realization of the right in question within reasonable time while using reasonable care in trying to achieve this aim.⁶⁴⁶ General Comment No 3 ICESCR also makes it clear that the Covenant impose obligations with an immediate effect. Having said that, questions around the justiciability of, exact obligations created by and the best way of implementation of ICESCR (and often ICCPR) rights persist.⁶⁴⁷ Also human rights philosophy and jurisprudence generally still pose difficult and largely unresolved conceptual questions, such as the question of whether human rights really impose obligations *erga omnes partes* or how to deal with rights of groups or populations through a framework of individual rights.⁶⁴⁸ Despite these debates, however, human rights have become a firmly established part of the wider field of international law and they are applied to ever more expanding fields of international law.

⁶⁴³ Optional Protocol to the International Covenant on Civil and Political Rights, GA Res 2200A (XXI), 1966.

⁶⁴⁴ In 1996, the Committee on Economic, Social and Cultural Rights (CESCR) submitted a proposal that the ICESCR, note 341, should be supplemented by an Optional Protocol, establishing a system of individual complaints. See Draft Optional Protocol to the International Covenant on Economic, Social and Cultural Rights, Note by the Secretary-General, E/CN.4/1997/105, 1996. To this date, however, no such complaint mechanism has been established and prospects for it seem rather low. See for example M. Scheinin, "The Proposed Optional Protocol to the Covenant on Economic, Social and Cultural Rights: A Blueprint for UN Human Rights Treaty Body Reform—Without Amending the Existing Treaties", 6 *Human Rights Law Review*, 2006, 131 et seq.

⁶⁴⁵ For discussion see for example Alston/Steiner, note 214, 138, Hestermeyer, note 345, 91.

⁶⁴⁶ CESCR General Comment No. 3, "The Nature of States Parties Obligations (Article 2, par.1)", UN Doc. E/1991/23, 1990, para 1-2.; CESCR General Comment No. 14: "The Right to the Highest Attainable Standard of Health (Article 12)", E/C.12/2000/4, 2000, para 4. General comments are non-binding interpretations meant to assist states in their interpretation. ICESCR obligations have thereby been read as demanding more of states than merely to abstain from interfering with those rights. See for example CESCR General Comment No.3 and 9, "The Domestic Application of the Covenant", UN Doc. E/C.9/1997/5, 1998. See also Beetham, note 639, 41 et seq.

⁶⁴⁷ Alston/Steiner, note 214, 299 et seq. B. Roebes, *The Right to Health as a Human Right in International Law*, 1999; A. Chapman/S. Russell (eds.), *Core Obligations: Building a Framework for Economic, Social and Cultural Rights*, 2002.

⁶⁴⁸ Hestermeyer, note 345, 83. Alston/Steiner, note 214, 1523.

1.2. Standards in the Area of Bioethics as Human Rights Standards

Many standards directly addressed to matters of bioethical interest, including the Universal Declaration on Bioethics and Human Rights, the Convention for the Protection of Human Rights and the Dignity of the Human Being with Regard to the Application of Biology and Medicine and the Declaration on the Human Genome and Human Rights make it already in their title clear that they concern not only bioethical issues but also human rights or rather human rights in the area of bioethics.⁶⁴⁹ However, the titles say little about the actual relationship between bioethics and human rights within these standards.⁶⁵⁰ For example, the connector “and” between Bioethics and Human Rights or between the Human Genome and Human Rights in the titles of the UDBHR and the Declaration on the Human Genome respectively leaves it open to speculation whether and/or to what extent bioethics and human rights are similar, the same or just two random areas of interests that are bound together in a Declaration.⁶⁵¹ This relationship will be further explored throughout this chapter.

In addition to references in the title, all international legal standards directly concerned with questions of bioethical relevance make explicit reference in their Recitals to a number of international human rights instruments, including the UDHR⁶⁵², the ICCPR and ICESCR⁶⁵³ and on the regional level, the Convention for the Protection of Human Rights and Fundamental Freedoms⁶⁵⁴ and the European Social Charter⁶⁵⁵. For example Recital 1 of the International Declaration on Human Genetic Data, Recital 2 of the Universal Declaration on the Human Genome and Human Rights and Recital 5 of the UDBHR specifically recall the UDHR and the Covenants as 'guiding standards'.⁶⁵⁶ Also the Oviedo Convention and its additional protocols refer to these human rights standards at similarly prominent places.⁶⁵⁷

Furthermore, all instruments directly addressing questions of bioethical relevance refer to human rights in their provisions. For example, Article 2 (c) of the UDBHR specifies the Declaration's aims as “to promote respect for human dignity and protect human rights, by ensuring respect for the life of human beings, and fundamental freedoms, consistent with international human rights law”. Article 3 (1) states: “Human dignity, human rights and fundamental freedoms are to be fully

⁶⁴⁹ UDBHR, note 4; Declaration on Human Genetic Data, note 4; Universal Declaration on the Human Genome, note 4.

⁶⁵⁰ H. Schmidt, "Bioethics, Human Rights and Universalisation: a Troubled Relationship? Observations on UNESCO's Universal Declaration on Bioethics and Human Rights", in: S. Vöneky/M. Clados/J. Achenbach/C. Hagedorn, *Legitimation Ethischer Entscheidungen im Recht Interdisziplinäre Untersuchungen, Beiträge zum Ausländischen Recht und Völkerrecht*, 2008, 254, 257.

⁶⁵¹ Ibid. See also discussion below under 3.

⁶⁵² UDHR, note 214.

⁶⁵³ ICCPR, note 219, and ICESCR, note 219.

⁶⁵⁴ Council of Europe Convention for the Protection of Human Rights, note 344.

⁶⁵⁵ European Social Charter, note 344.

⁶⁵⁶ UDBHR, note 4; Declaration on Human Genetic Data, note 4; Universal Declaration on the Human Genome, note 4.

⁶⁵⁷ Oviedo Convention, note 5. The Convention refers to the UDHR, note 214, in Recital 2 and to the Council of Europe Convention for the Protection of Human Rights, note 344, in Recital 3 and to the European Social Charter, note 222, in Recital 4.

respected.” Overall, twelve of the UDBHR's 28 articles refer to human rights generally.⁶⁵⁸ Similarly, Article 1 of the Declaration on Human Genetic Data reads as follows “The aims of this Declaration are to ensure the respect of human dignity and the protection of human rights and fundamental freedoms in the collection, processing use and storage of human genetic data....” Overall, 13 of its provisions refer to human rights.⁶⁵⁹ In the case of the Declaration on the Human Genome eight articles refer to human rights.⁶⁶⁰ Merely the Oviedo Convention, apart from its title, does not mention the term 'human rights' itself in its provisions. As will be discussed in more detail below it does, however, refer to specific human rights, including the right to privacy or the right to bodily integrity and makes frequent references to the core principle of human rights doctrine, that of human dignity.⁶⁶¹ The high frequency by which reference to human rights takes place and the prominence allocated to the protection of human rights as a major aim of all instruments make it clear that the link between the legal standards in the field of bioethics and human rights is everything but a coincidence. Rather, the former are clearly meant to build on and extend the existing human rights body and thought and to ensure human rights' protection in the field of bioethics.

A further indication for that the standards specifically addressed to the matters of bioethical relevance are at their heart human rights standards is their repeated reference and the importance attached to the concept of human dignity.⁶⁶² Human dignity has always been a most important concept to human rights discourses and the concept is deeply embedded in modern human rights thinking. It should be noted, however, that the concept of human dignity when used in

⁶⁵⁸ UDBHR, note 4, Articles 2 (c) and (d) – Aims; 3 – Human dignity and human rights; 5 – Autonomy and individual responsibility; 6 – Consent; 7 – Persons without the capacity to consent; 9 – Privacy and confidentiality; 10 – Equality, justice and equity; 11 – Non-discrimination and non-stigmatization; 12 – Respect for cultural diversity and pluralism; 22 – Role of States; 27 – Limitations on the application of the principles; 28 – Denial of acts contrary to human rights, fundamental freedoms and human dignity.

⁶⁵⁹ Declaration on Human Genetic Data, note 4, Articles 1 – Aims and Scope, 5 – Purpose, 6 - Procedures, 7 – non-discrimination and stigmatization, 8 – consent, 12 – Collection of biological samples for forensic medicine or in civil, criminal and other legal proceedings, 14 – Privacy and confidentiality, 16 – Change of purpose, 21 – Destruction, 22 – Cross-matching, 23 – Implementation, 26 – Follow-up action by UNESCO, 27 – Denial of acts contrary to human rights, fundamental freedoms and human dignity.

⁶⁶⁰ Universal Declaration on the Human Genome, note 4, Article 6 for example declares that "no one shall be subjected to discrimination based on genetic characteristics that is intended to infringe or had the effect of infringing human rights, fundamental freedom and human dignity." Article 10 of the same Declaration reads that "no research[.]...should prevail over respect for human rights, fundamental freedoms and human dignity...". In addition see Articles 2, 5 to 7, 9 to 12, 25.

⁶⁶¹ For example Article 3 on equitable access to health care of the Oviedo Convention, note 5, reflects Article 25 of the UDHR, note 214, and Article 12 of the ICESCR, note 219. Article 10 on privacy in the Oviedo Convention, note 5, reflects Article 12 of the UDHR, note 214, and Article 17 of the ICCPR, note 219.

⁶⁶² Universal Declaration on the Human Genome, note 4, refers to the concept in the Preamble and in Articles 1,2,6,10,11,12,15,21,24. The Declaration on Human Genetic Data, note 4, refers to the concept in the Preamble, and in Articles 1, 7, 26,27. The UDBHR, note 4, refers to the concept in the Preamble and in Articles 2,3,10,11,12,28; the Oviedo Convention, note 5, refers to the concept in the Preamble and in Article 1. Instruments relating to biomedicine or bioethics emphasize the notion of human dignity in a very powerful way, possibly even stronger than the roles assigned to human dignity in the founding international instruments of human rights. D. Beylveld/R. Brownsword, *Human Dignity in Bioethics and Biolaw*, 2001, 11. See also R. Andorno, "Human Dignity, and the UNESCO Declaration on the Human Genome", in: J. Gunning/S. Holm, *Ethics, Law, and Society*, 2002, 73 et seq.

international legal texts, is more of an ethical than a legal principle.⁶⁶³ That is, in contrast to for example the legal guarantee that human dignity receives in Article 1 of the Grundgesetz for the German Federal Republic (German Constitution),⁶⁶⁴ on the international level, the legal status of the concept of human dignity remains the subject of some debate. One of the first documents mentioning the concept is the Charter of the United Nations stating in its second preambular paragraph that the Peoples of the United Nations are determined “to reaffirm faith in fundamental human rights, in the dignity and worth of human person”.⁶⁶⁵ Here, human dignity is portrayed as one of the primary ends of the United Nations and as one of the foundations of the international legal order. The concept of human dignity is further mentioned prominently in Article 1 of the UDHR⁶⁶⁶ which states that “All human beings are born free and equal in dignity and rights”. Yet, the UDHR is a non legally non binding and non enforceable document and the UN Charter is formally binding only in regard to its operative part; it is not formally binding in regard to its Preamble. Moreover, when explicitly used in legally binding and enforceable international human rights standards, such as the ICESCR or ICCPR, the concept of human dignity is always used in a more specific way, i.e. connected with a certain right. For example the prohibition of torture is justified by reference to the concept of human dignity. In respect to these more specific formulations human dignity can be said to have been transformed into a legal right yet apart from these specific formulations it must be considered to be an ethical concept enshrined in international human rights standards.⁶⁶⁷ Nevertheless, the frequent references to the concept in the standards in the area of bioethics show that these standards deliberately seek to embed themselves in human rights thought and traditions.

In the standards, human dignity is named explicitly in the title of the Oviedo Convention, in its preamble and in its Article 1, specifying the purpose of the Convention as - among others - protecting the dignity and identity of all human beings.⁶⁶⁸ Also the UDBHR puts the promotion of respect for human dignity as one of its aims listed in Article 2 as well as on the top of the list of principles it endorses in Articles 3 - 17.⁶⁶⁹ The Declaration on the Human Genome again titles Section A of its provisions with “human dignity and the human genome”, making it clear in Article

⁶⁶³ Cf. N. Petersen, "Human Dignity, International Protection", in: R. Wolfrum (ed.), *The Max Planck Encyclopedia of Public International Law*, 2008, online edition, [www.mpepil.com] (last visited 27.04.2012) and Wolfrum/Vöneky, note 565, 137.

⁶⁶⁴ Basic Law for the Federal Republic of Germany (Grundgesetz, GG) of 23 May 1949. As this provision belongs to the few norms of the German constitution which cannot be subject to change, it is a powerful instrument that must be taken into consideration even when reviewing constitutional amendments. Moreover, it can be invoked in courts.

⁶⁶⁵ UN Charter, note 208, Preamble.

⁶⁶⁶ UDHR, note 270, in its Preamble even starts with the emphasis on human dignity. It reads: "Whereas recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family is the foundation for freedom, justice and peace in the world."

⁶⁶⁷ ICCPR, note 341, Article 10 and ICESCR, note 341, Article 13.

⁶⁶⁸ In the Oviedo Convention, note 5, the term dignity is also mentioned in Recital 10. While it receives no further explicit mentioning in the Convention the concept's importance is still obvious given that it is the overall purpose of the Convention to protect the dignity of the human being and that all Articles beyond Article 1 must be interpreted as either furthering the overall purpose of the Convention or at least as being in conformity with that aim.

⁶⁶⁹ UDBHR, note 4, Articles 2 and 3 as well as Articles 10 to 12, 28.

1 that the “human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity” and in Article 2 that “everyone has the right to respect for their dignity...”. Besides its very general meaning as the norm to which virtually all provisions in the area of bioethics must relate⁶⁷⁰ human dignity also serves more specific functions throughout the instruments. It is cited as a limit to stigmatization and discrimination of human beings and as an obstacle to genetic reductionism and to genetic discrimination⁶⁷¹, as a limit to charges of cultural relativists⁶⁷², against abuse of human subjects in the area of human research and experimentation,⁶⁷³ and it is mentioned as a barrier to human cloning⁶⁷⁴ and to germ line intervention.⁶⁷⁵ While it is difficult to define the concept of human dignity – a topic that will be discussed below –, its' obviously important role in the area of bioethics cannot be easily dismissed for its lack of clarity and the vagueness of the concept. Moreover, even though the concept, as has just been discussed, is more an ethical than a legal principle, it nevertheless is a core principle of both, human rights discourses and of the standards in the area of bioethics and as such ties the standards to a human rights discourse.

The standards directly addressed to matters of bioethical interest also refer to and reformulate several specific human rights and human rights principles in that they refer to civil and political and economic and social rights as well as to overarching human rights principles. In the category of civil and political rights one may find within the UDBHR references and reformulations of several civil and political rights that have been specified in the UDHR, the ICCPR and the Convention for the Protection of Human Rights and Fundamental Freedoms. These include the right to life⁶⁷⁶, right to liberty and security⁶⁷⁷, the right not to be subjected to torture or to cruel, inhuman or degrading treatment or punishment, i.e. the right not to be subjected to scientific or medical experimentation⁶⁷⁸, the right to privacy⁶⁷⁹, and the right to freedom of expression, opinion and

⁶⁷⁰ So stated for example in Article 28 of the UDBHR, note 4.

⁶⁷¹ E.g. Article 11 UDBHR, note 4; Universal Declaration on the Human Genome, note 4, Article 6.

⁶⁷² E.g. Article 12 UDBHR, note 4.

⁶⁷³ Universal Declaration on the Human Genome, note 4, Articles 15 and 21; Declaration on Human Genetic Data, note 4, Article 10.

⁶⁷⁴ Universal Declaration on the Human Genome, note 4, Article 11.

⁶⁷⁵ Ibid., Article 24.

⁶⁷⁶ UDHR, note 270, Article 3; ICCPR, note 341, Article 6; Europe Council of Europe Convention for the Protection of Human Rights, note 344, Article 2; reflected in the UDBHR, note 4, for example, in Article 1 (c).

⁶⁷⁷ ICCPR, note 341, Article 9; UDHR, note 270, Article 3; Europe Council of Europe Convention for the Protection of Human Rights, note 344, Article 5; reflected in the UDBHR, note 4, for example, in Article 1 (c) and 3 (2).

⁶⁷⁸ UDHR, note 270, Article 5; ICCPR, note 341, Article 7 (No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation); Council of Europe Convention for the Protection of Human Rights, note 344, Article 3; reflected in the UDBHR, note 4, for example, in Articles 1 and 3.

⁶⁷⁹ UDHR, note 270, Article 12; ICCPR, note 341, Article 17; Council of Europe Convention for the Protection of Human Rights, note 344, Article 8; also reflected in the UDBHR's, note 4, Article 9, in the Universal Declaration on the Human Genome, note 4, Article 7, in the Declaration on Human Genetic Data, note 4, Article 14 and in the Oviedo Convention, note 5, Article 10. On the right to privacy see ICCPR General Comment No. 16, Article 17 (Right to Privacy), 1988, 21.

thought.⁶⁸⁰ The right to life, liberty and security is for example reflected by the UDBHR's Article 2 c which states that one of the aims of the declaration is to “promote respect for human dignity....by ensuring respect for the life of human beings”. It is arguably also generally reflected by such provisions as Article 2 of the Oviedo Convention which makes it clear that the “interest and welfare of the human being shall prevail over the sole interest of society or science”, by Article 16 which deals with the protection of persons undergoing research and by the UDBHR's Article 4 which specifies that “in applying and advancing scientific knowledge, medical practice and associated technologies, direct and indirect benefits to patients, research participants and other affected individuals should be maximised and any possible harm ...minimised”. Freedom of scientific research⁶⁸¹ reflects and restates the human right to freedom of expression and thought.

The UNESCO instruments also refer to a range of established social, economic and cultural rights such as Articles 22 and 25 of the UDHR⁶⁸² which as Schmidt points out

"emphasise the importance of food, clothing, housing, medical care and social services for acceptable standards of living, as well as social security provisions relating to unemployment, sickness, disability, old age or other lack of livelihood due to circumstances that are beyond people's individual control. The relevance of international cooperation is stressed in this regard."⁶⁸³

Several of the provisions of the UDBHR relate to this and specify in more detail the precise meaning and implications of these rights.⁶⁸⁴ Recitals 19 and 21 and Article 13 of the UDBHR, for example, emphasize "the concepts of solidarity and social responsibility and stress the need for international cooperation".⁶⁸⁵ Article 15, entitled 'Sharing of benefits', declares for example that “benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries.”⁶⁸⁶ And Article 2 (f) of the UDBHR seeks “to promote equitable access to medical, scientific and technological developments as well as the greatest possible flow and the rapid sharing of

⁶⁸⁰ UDHR, note 270, Article 19; ICCPR, note 341, Article: 19; Council of Europe Convention for the Protection of Human Rights, note 344, Articles 9 and 10; reflected in the UDBHR, note 4, for example, in Article 1 (d).

⁶⁸¹ ICCPR, note 341, Article 19 is usually construed so as to guarantee a right to scientific freedom. This is reflected in the Universal Declaration on the Human Genome, note 4, Article 12 (b); in the UDBHR, note 4, Article 2 (d); and in the Oviedo Convention, note 5, Article 15.

⁶⁸² UDHR, note 270, also to be found in ICESCR, note 341, Articles 7 and 11.

⁶⁸³ Schmidt, "Bioethics, Human Rights and Universalisation: a Troubled Relationship? Observations on UNESCO's Universal Declaration on Bioethics and Human Rights", note 650, 254, 257. See in particular Article 14 of the UDBHR, note 4, on social responsibility and health, which holds that 1. The promotion of health and social development for their people is a central purpose of governments that all sectors of society share and that 2. Taking into account that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition [].

⁶⁸⁴ Schmidt, "Bioethics, Human Rights and Universalisation: a Troubled Relationship? Observations on UNESCO's Universal Declaration on Bioethics and Human Rights", note 650, 267.

⁶⁸⁵ Ibid. in particular with respect to “the special needs of developing countries, indigenous communities and vulnerable populations”. On the subject of solidarity and cooperation see also Explanatory Memorandum, note 8, para 74, at: <http://unesdoc.unesco.org/images/0013/001390/139024e.pdf> (last visited 27.04.2012).

⁶⁸⁶ The UDBHR, note 4, also states that externally sponsored research projects should be reviewed both in the sponsoring country and the country where research takes place, and appeals to states to take measures to combat bioterrorism and illicit traffic in organs, tissues, samples, and genetic resources and materials. UDBHR, note 4, Articles 19 a and 21.

knowledge concerning those developments and the sharing of benefits, with particular attention to the needs of developing countries". The Oviedo Convention does not so much stress international cooperation. It does, however, also echo several social and economic rights enshrined for example in Articles 11 to 14 of the European Social Charter which stress the right to enjoy the highest possible standard of health attainable, the right to social security, the right to social and medical assistance and the right to benefit from social welfare services. Article 3 on equitable access to health care for example dictates that "parties, taking into account health needs and available resources, shall take appropriate measures with a view to providing, within their jurisdiction, equitable access to health care of appropriate quality." Thus, social and economic rights as much as civil and political human rights often form the background and soil from which the provisions in the presently examined standards emerged.

Finally all standards operate on the basis of certain general human rights principles. These principles include most prominently the principles of non-discrimination⁶⁸⁷, equality and respect for the autonomy of the human being.⁶⁸⁸ In the UDBHR, for example, the principle of equality and non-discrimination clearly features in Article 2 f which states the aims of the Declaration as "to promote equitable access to medical, scientific and technological developments..." The principle of autonomy again can be found in Article 3 declaring that the interest and welfare of the individual should have priority over the sole interest of science or society and Article 5 which mandates respect for autonomous decisions of individuals as well as in the provisions on informed consent in Article 6 and 7.⁶⁸⁹ The principle that the basic conditions to lead an autonomous life have to be met is reflected in the instruments' recognition of socio economic rights, discussed above.

The majority of the provisions of the standards in the area of bioethics are thus at the very least inspired by established human rights norms or principles. They usually, however, also go beyond the established human rights norms in that they "are not mere rehearsals of these norms, nor are they reducible to them."⁶⁹⁰ Instead they further develop and specify human rights norms and principles by adapting them to the context of bioethics. As such they are not new human rights but either a more detailed restatement or an advancement or adaptation of existing human rights and human rights principles.

⁶⁸⁷ In the UDHR, note 270, this principle is for example reflected in Articles 1 and 2 but also in such provisions as Article 7. In the ICCPR, note 341, see for example Articles 4, 20, 22, 24.

⁶⁸⁸ In the UDHR, note 270, this principle is named in Articles 7 and 23. In the ICCPR, note 341, this principle is, for example, reflected in Articles 7 to 9, holding respectively that no one may be submitted to torture, or slavery and that everyone has the right to liberty of the person.

⁶⁸⁹ In the Oviedo Convention, note 5, the principle of non-discrimination is for example reflected in Articles 1 and 11. The principle of autonomy in all articles on informed consent, for example, Articles 16 - 17.

⁶⁹⁰ Schmidt, "Bioethics, Human Rights and Universalisation: a Troubled Relationship? Observations on UNESCO's Universal Declaration on Bioethics and Human Rights", note 650, 257.

2. Aims and Bioethical Principles in the Standards Directly Addressed to Matters of Bioethical Interest

2.1. Aims of the Standards

All standards directly addressed to matters of bioethical interest endorse a number of aims. A first aim that features in all standards directly addressed to issues of bioethical relevance is to promote respect for human dignity and to protect human rights in the area of relevance to the standards. Consistency with other international human rights standards is thereby to be ensured. The Oviedo Convention formulates this objective in its Article 1 which states that "Parties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine." Each party is thereby asked to take in its internal law the necessary measures to give effect to the provisions of the Convention.⁶⁹¹ The UDBHR again in Article 1 (c) states that it aims "to promote respect for human dignity and protect human rights, by ensuring respect for the life of human beings, and fundamental freedoms, consistent with international human rights law".⁶⁹² This aim generally reasserts the human rights character of all standards and makes it clear that the primary function and aim of all standards in the area is to protect human rights and human dignity, however, with a special focus on those issues and concerns that arise in the area of bioethics.

One further objective stated in most standards is "to provide a universal framework of principles and procedures to guide States in the formulation of their legislation, policies or other instruments in the field of bioethics."⁶⁹³ The UDBHR is even more ambitious, aiming not only to provide such a framework for states but also, where appropriate, to "individuals, groups, communities, institutions and corporations, public and private."⁶⁹⁴ While the Oviedo Convention does not specify this aim in its provisions the Council of Europe gateway to bioethics and biomedicine states that "the Convention....provides a framework for the protection of human rights and human dignity by establishing fundamental principles applicable to daily medicine as well as to new technologies in the fields of biology and medicine."⁶⁹⁵ Implicitly it therefore also aims to provide guidance to

⁶⁹¹ Oviedo Convention, note 5. Similarly, Article 2 dealing with the primacy of the human being states that "the interests and welfare of the human being shall prevail over the sole interest of society or science."

⁶⁹² Likewise in the other standards: Article 2 (a) of the Universal Declaration on the Human Genome, note 4, holding that "everyone has a right to respect for their dignity and for their rights regardless of their genetic characteristics." And in the Declaration on Human Genetic Data, note 4, Article 1 a, refers to the aims and scope of the declaration as "to ensure the respect of human dignity and protection of human rights and fundamental freedoms in the collection, processing, use and storage of human genetic data..." and that (b) "any collection, processing, use and storage of human genetic data, human proteomic data and biological samples shall be consistent with the international law of human rights."

⁶⁹³ UDBHR, note 4, Article 2 a.

⁶⁹⁴ Ibid.

⁶⁹⁵ See Bioethics Gateway of the Council of Europe, at: http://www.coe.int/t/dg3/healthbioethic/default_en.asp (last visited 27.04.2012).

signatories of the Convention and to serve as an overall framework for dealing with issues.⁶⁹⁶ This aim mirrors states' concern for a coherent and human rights based approach to matters of bioethical interest. The standards are meant to provide such a uniform and human rights based framework approach that provides some minimum agreement between states in the sense of that human rights have to be protected when issues of bioethical relevance are addressed.

Next, all standards in one way or another aim to foster multidisciplinary and pluralistic dialogue among all stakeholders. The Oviedo Convention in Chapter X entitled 'Public debate' stipulates that "parties to this Convention shall see to it that the fundamental questions raised by the developments of biology and medicine are the subject of appropriate public discussion in the light, in particular, of relevant medical, social, economic, ethical and legal implications, and that their possible application is made the subject of appropriate consultation." The UDBHR in Article 2 e states that it is one aim of the Declaration "to foster multidisciplinary and pluralistic dialogue about bioethical issues between all stakeholders and within society as a whole".⁶⁹⁷ The 2003 Declaration in Article 24 entitled "ethics education, training and information" holds that "in order to promote the principles set out in this Declaration, States should endeavour to foster all forms of ethics education and training at all levels as well as to encourage information and knowledge dissemination programmes about human genetic data. These measures should aim at specific audiences, in particular researchers and members of ethics committees, or be addressed to the public at large." This aim pays recognition to the fact that many issues of bioethical relevance concern many fundamental questions that have a bearing on the broader public and should be discussed at all levels of society. The public should not lose sight of the sometimes highly technical debate involved in scientific research and technical application involved in issues of bioethical relevance while the technical or research oriented side in the debate should not lose sight of what the broader public opines with respect to these issues and these issues' ethical implications.⁶⁹⁸ That seems to also be the consideration with regard to another aim of the standards, that of the establishing of national or international ethics Committees. The Oviedo Convention does not specifically address the need for states to set up ethics committees and instead specifies in Article 32 the responsibilities of the CDBI. It should however be noted that

⁶⁹⁶ Likewise the Universal Declaration on the Human Genome, note 4, does specify in Article 1 b the same with regard to actions in the area of "collection, processing, use and storage of human genetic data, human proteomic data and biological samples"; and the Declaration on Human Genetic Data, note 4, in Article 1 (a) states that "the aims of this Declaration are: ... to set out the principles which should guide States in the formulation of their legislation and their policies on these issues [in the collection, processing, use and storage of human genetic data, human proteomic data and of the biological samples from which they are derived]; and to form the basis for guidelines of good practices in these areas for the institutions and individuals concerned."

⁶⁹⁷ Likewise the Universal Declaration on the Human Genome, note 4, holds under 'F' referring to the promotion of the principles set out in the Declaration that "states should take appropriate measures to promote the principles set out in the Declaration, through education and relevant means, inter alia through the conduct of research and training in interdisciplinary fields and through the promotion of education in bioethics, at all levels, in particular for those responsible for science policies."

⁶⁹⁸ Andorno, "First Steps in the Development of an International Biolaw", note 625, 128.

most member states of the Council have ethics committees in place⁶⁹⁹ and that it has given rise to the European Conference of National Ethics Committees (COMETH) which has it as its aim to help countries wishing to set up national ethics committees in doing so.⁷⁰⁰ The UDBHR in Article 19 entitled 'Ethics committees' states that "independent, multidisciplinary and pluralist ethics committees should be established, promoted and supported at the appropriate level."⁷⁰¹ In addition to fostering exchange at all levels of society and between the science community and the broader public, here the rationale is also to have a body of independent experts or advisors that can help governments in formulating legislation.⁷⁰² Moreover, the need to establish independent multidisciplinary and pluralist ethics committees also results from the increasing complexities in bioethical research and research applications.⁷⁰³ By establishing such institutions it is hoped that they can help establish national rules in the area of bioethics, that they are helpful in detecting and representing various public sentiments about issues of bioethical relevance, that they help arriving at common regulations in these areas and that they help to establish a process of how to deal with questions in the area of bioethics generally.⁷⁰⁴ Moreover, these bodies also create a forum for international exchange, which might help to liken approaches on a global level.⁷⁰⁵

Fourthly, standards, in the words of the UDBHR, provide that states should "promote equitable access to medical, scientific and technological developments as well as the greatest possible flow and the rapid sharing of knowledge concerning those developments and the sharing of benefits, with particular attention to the needs of developing countries."⁷⁰⁶ The Oviedo Convention focuses on this requirement to health care in stipulating in Article 3 - dealing with equitable access to health care - that "parties, taking into account health needs and available resources, shall take appropriate measures with a view to providing, within their jurisdiction, equitable access to health care of appropriate quality."⁷⁰⁷ This aim or principle reflects considerations of justice, also

⁶⁹⁹ WHO, National Bioethics Committees in the European Region, at: <http://www.who.int/ethics/committees/euro/en/index.html> (last visited 27.04.2012). On Ethics Committees in a variety of countries see also Vöneky, *Recht, Moral und Ethik. Grundlagen und Grenzen Demokratischer Legitimation für Ethikgremien*, note 15, Chapter 6.

⁷⁰⁰ Conference of National Ethics Committees, Article 2 b appendix to Resolution COMETH 11, 4th meeting, 1998, at: http://www.coe.int/t/dg3/healthbioethic/cometh/default_en.asp (last visited 27.04.2012).

⁷⁰¹ See also the Declaration on Human Genetic Data, note 4, Article 24 and Universal Declaration on the Human Genome, note 4, Article 16.

⁷⁰² On democratic legitimacy of such Committees see Vöneky, *Recht, Moral und Ethik. Grundlagen und Grenzen Demokratischer Legitimation für Ethikgremien*, note 15, in particular Chapter 9.

⁷⁰³ Universal Declaration on the Human Genome, note 4, Article 16; Declaration on Human Genetic Data, note 4, Article 6 (b); UDBHR, note 4, Article 19; Oviedo Convention, note 5, Article 16 (iii).

⁷⁰⁴ See for example para 2 of the Gesetz zur Einrichtung des Deutschen Ethikrats (Ethikratgesetz - EthRG), 16 July 2007 (BGBl. I S. 1385), and Terms of Reference of the Irish Council for Bioethics, at: <http://www.bioethics.ie/uploads/docs/AbouttheCouncil.pdf> (last visited 27.04.2012).

⁷⁰⁵ See Vöneky, *Recht, Moral und Ethik. Grundlagen und Grenzen Demokratischer Legitimation für Ethikgremien*, note 15, on functions and on how ethics committees work, chapters 5-6.

⁷⁰⁶ UDBHR, note 4, Article 2 f.

⁷⁰⁷ The Universal Declaration on the Human Genome, note 4, states the principle of equitable access to medical development in Article 12 in that (a) "benefits from advances in biology, genetics and medicine, concerning the human genome, shall be made available to all, with due regard for the dignity and human rights of each individual." The Declaration on Human Genetic Data, note 4, implicitly upholds this principle in Article 19 entitled- sharing of benefits-

enshrined in the UN, i.e. of a fair distribution of goods within and across societies. Governments are under the responsibility to create such conditions.⁷⁰⁸ They therefore have to ensure minimal standards of health care and in case of scarce goods, fair mechanisms to allocate these scarce resources.⁷⁰⁹

All standards moreover in some way or another aim at enhancing regional or international cooperation. The Oviedo Convention though it does not explicitly stipulate that in its operative clauses in recital 13 “stresses the need for international co-operation so that all humanity may enjoy the benefits of biology and medicine”. The UDBHR holds that dialogue should be enhanced within and across societies and nations. That is to be achieved through transfer or exchange of relevant knowledge within and between nations.⁷¹⁰ International cooperation and development is one fundamental aim of the UN and as such it is only consistent that it also receives recognition in the standards.⁷¹¹ The need for justice in transnational research as a principle in the instruments reflects the trend that also biomedical research is becoming increasingly globalised and hence that the results of such research should also benefit and contribute to the well-being of the whole world. The danger is that if benefits are only reserved for developed countries then that is likely to even further widen the gap between them and the developing countries. In theory therefore, “solidarity among human beings and international cooperation towards that end are to be encouraged”.⁷¹²

Finally, the UDBHR states in Article 1 (g) that it aims “to safeguard and promote the interests of the present and future generations.” The theme is repeated in Article 1 (h) in which the declaration holds that it aims “to underline the importance of biodiversity and its conservation as a common concern of humankind.” The Declaration on the Human Genome repeats this theme in Article 1 which holds that “the human genome underlies the fundamental unity of all members of the human family... In a symbolic sense, it is the heritage of humanity.”⁷¹³ The Oviedo Convention in

it says that “...benefits resulting from the use of human genetic data, human proteomic data or biological samples collected for medical and scientific research should be shared with the society as a whole and the international community. In giving effect to this principle, benefits may take any of the following forms....(ii) access to medical care”.

⁷⁰⁸ UN Charter, note 208, Chapter IX.

⁷⁰⁹ It is plausible to understand the requirements that this principle entails for governments as one that – like the correlated human right to health as enshrined Article 12 ICESCR, note 341, has to be fulfilled progressively, according to limits and possibilities of each government. See ICESCR Article 2.1 and CESCR General Comment 14, “The right to the highest attainable standard of health (Article 12)”, E/C.12/2000/4, 2000. The principles of equitable access to health care, in particular access to appropriate medical care and essential medicines can be found in the Universal Declaration on the Human Genome, note 4, Article 12; UDBHR, note 4, Articles 10,14; Oviedo Convention, note 5, Article 3.

⁷¹⁰ See also Universal Declaration on the Human Genome, note 4, Articles 17 to 19; Declaration on Human Genetic Data, note 4, Articles 18 to 19; UDBHR, note 4, Articles 13, 14, 16.

⁷¹¹ UN Charter, note 208, Chapter IX.

⁷¹² UDBHR, note 4, Article 13. Article 24 of the UDBHR again stresses that “States should foster international dissemination of scientific information and encourage the free flow and sharing of scientific and technological knowledge”.

⁷¹³ See also Declaration on Human Genetic Data, note 4, which expresses concern for the interest of future generations in recognizing in Recital 6 “that human genetic data have a special status on account of their sensitive nature since they can be predictive of genetic predispositions concerning individuals and that the power of predictability can be stronger than assessed at the time of deriving the data; they may have a significant impact on the family, including offspring, extending over generations, and in some instances on the whole group; they may contain information the significance of

Recital 12 affirms “that progress in biology and medicine should be used for the benefit of present and future generations.” This is probably the most vaguely and ambitiously worded aim stated in the standards. It also breaks with the traditional human rights language of individual rights in that it takes a future generation as beneficent. As an aim or principle it owes its existence to recent growing awareness of the destructive powers at the hands of the present generations and a growing sense of responsibility towards future generations.⁷¹⁴ The notion pertains not only to the environment but also to the identity of humankind itself, which, according to some, could be damaged by practices like reproductive cloning or germline intervention. Arguments, such as those advanced by the philosopher Habermas for example suggest that we do not have the right to pre-determine the characteristics of future generations, as they should be free to develop their potentialities without being biologically conditioned by current particular conceptions of good and bad.⁷¹⁵ The standards aim to address such concerns and to ensure that they are being dealt with within a human rights framework

2.2. Principles enshrined in the Standards

Certain principles are endorsed across all or at least most standards. These principles are at the very least ethical principles in that they seek to provide justifications for moral behaviour or provide criteria according to which acts are morally justifiable yet in that they cannot by themselves be invoked in a court as a legal principle that gives rise to a legal right. It is arguable, however, that some of the principles discussed below, also constitute legal principles.⁷¹⁶ As was seen above general legal principles in international law can most prominently be derived from the existence of a rule in several municipal laws of states or from general principles of international law.⁷¹⁷ In particular, if most states can be shown to have enshrined the bioethical principles in their national legislation or if it can be shown that these principles are in fact legal principles under international law that could be taken to show that these principles are also legal principles.⁷¹⁸ As will be argued below this might be the case when it comes to such principles as the principle of freedom of scientific research, that in one form or another, has found legal recognition in international legal

which is not necessarily known at the time of the collection of biological samples; and they may have cultural significance for persons or groups". It also repeats this theme in Article 4 which reads that (a) "human genetic data have a special status because: ... (ii) they may have a significant impact on the family, including offspring, extending over generations, and in some instances on the whole group to which the person concerned belongs."

⁷¹⁴ See for example Universal Declaration on the Human Genome, note 4, Article 1; UDBHR, note 4, Articles 16 and 17; Oviedo Convention, note 5, Preamble.

⁷¹⁵ Andorno, "Biomedicine and International Human Rights Law: In Search of a Global Consensus", note 386.

⁷¹⁶ The major difference between legal and ethical principles being that a legal principle is a source of law itself while an ethical principle can inform that source but is not a source itself. For in-depth discussion of the concept of principles and rights see below in Chapter III, 3.

⁷¹⁷ See Chapter IV, section 3.3.

⁷¹⁸ See generally Lauterpacht, note 622. Malanczuk, note 204, 49 et seq.

text and in many municipal laws around the world.⁷¹⁹ However, for the most part the bioethical principles enshrined in the standards cannot be said to be reflected enough in either international or municipal law for them to have gained legal status. That does not mean that these principles are irrelevant to legal analysis, as will be discussed in more detail in the next section.⁷²⁰ In fact, ethical principles always to some extent inform legal principles and legal decision making and vice versa.⁷²¹ Nor does it mean that ethical principles cannot be transformed into legal principles, for example, if they become part of customary international law or receive wide recognition in binding international or municipal laws. Yet for the present context, unless stated otherwise the below listed principles are considered to be more ethical than legal principles.

The important role assigned to the ethical concept of human dignity in international legal standards in the area of bioethics, not only as a general principle to which all other principles and norms have to relate but as a barrier to many types of conduct specified in the standards, has already been mentioned in the previous sections and will be discussed further below.⁷²²

A second principle is that of the “primacy of the human being over the sole interest of science and society” which is usually given a prominent position in the standards as it is a direct corollary to the principle to safeguard human dignity. The UDBHR in Article 3 (2) entitled Human Dignity and Human Rights, for example, holds that “the interests and welfare of the individual should have priority over the sole interest of science or society.”⁷²³ Similarly, the Oviedo Convention holds in Article 2 that “the interests and welfare of the human being shall prevail over the sole interest of society or science.” This principle echoes the Kantian injunction that individuals should not be instrumentalised, in this case, for the sole benefit of science or society.⁷²⁴ It is also a provision that specifically is directed against certain utilitarian perspectives that could justify the

⁷¹⁹ See for example Article 5 Abs. 3 [1] of the Grundgesetzes (GG), note 541; Article 44 of the Spanish Constitution of 31 October 1978. In the United Kingdom it is protected by that the United Kingdom incorporated the European Convention on Human Rights, note 222, and the guarantee of freedom of expression it contains in Article 10, into its domestic law under the Human Rights Act in 1998. Freedom of speech is protected by Article 40.6.1 of the Irish constitution, etc. See generally D. McGoldrick/T. Donnel, "Hate Speech Laws: Consistency with National and International Human Rights Law", 18 *Legal Studies*, 1998, 458 et seq. See also European Court of Human Rights, *Jersiled v. Denmark*, Series A, No. A928, 1994, and *Faurisson v. France*, Communication No. 550/1993, 1993; Human Rights Committee, Views of the Committee, UN Doc. A/52/40, 1999, Vol. II, at 84 et seq.

⁷²⁰ On Principles see Chapter VI, 2.2.1.

⁷²¹ Vöneky, Recht, Moral und Ethik. Grundlagen und Grenzen Demokratischer Legitimation für Ethikgremien, note 15, Chapter 3 II et seq., citing para 6 Abs. 4 Nr. 2 Stammzellgesetz - StZG, note 19, as one example of a legal standard that explicitly incorporates ethical considerations. See also Vöneky, Recht, Moral und Ethik. Grundlagen und Grenzen Demokratischer Legitimation für Ethikgremien, note 15, chapter 3 III with regard to a discussion of the mutual interdependence of ethical, moral and legal norms in Germany.

⁷²² See Chapter VI, 2.2.2. and Chapter VII, 2.

⁷²³ Universal Declaration on the Human Genome, note 4, Article 10; UDBHR, note 4. Article 3(2); Oviedo Convention, note 5, Article 2. See also Helsinki Declaration, note 207, Article 5 providing that "... in medical research on human subjects, considerations related to the well-being of the human subject should take precedence over the interests of science and society".

⁷²⁴ Immanuel Kant's concept of human dignity, is to some extent elaborated in: I. Kant, *Grundlegung zur Metaphysik der Sitten*, 1785, 4:431; cf. 4:432. See discussion below in Chapter VI, 2.2.2.

instrumentalization of the few or individual for the sake or benefit of the many.⁷²⁵ That this is, however, not an absolute proposition is suggested by this principle's wording which states that human beings take primacy merely over the sole interest of science and society. Thus, while the human being in principle is accorded primacy over the sole interest of science or society, the general interest of society or science may prevail under certain circumstances.

A third principle prominently featuring in the legal instruments is that of respect for the autonomy of patients and research subjects and its direct corollary, the requirement of informed consent for any intervention in the area of biomedical research or treatment.⁷²⁶ Patients and research subjects insofar as they are competent adults must be treated as autonomous agents and therefore must be accorded the right to make decisions about medical interventions carried out on themselves, without any kind of coercion or deception. Obviously, for this principle to work it is a prerequisite that sufficient and understandable information is provided. This principle has been transformed into one of the most fundamental and most clearly specified provisions enshrined in the legal instruments in the area of bioethics, making it one of the core and most widely accepted principles of ethical and legal debates in the field, to be discussed in detail below.⁷²⁷ This principle is correlated with a further one, the principle that everyone should have the right to know his or her diagnosis or health information⁷²⁸ and it is reflected in many other provisions of the standards, including the principle to protect those unable to consent.⁷²⁹ This principle responds to more traditional models of the doctor-patient-relationship, which were rather paternalistic in that the physician often exerted absolute discretion about treatment options and with regards to whether and what about to inform the patient.⁷³⁰ Over the last decades these assumptions were then replaced with models that stressed the autonomy and self-responsibility of competent patients so that patients could be involved in the decisions concerning their treatment.⁷³¹ Since it is only through adequate information that they are in a position to give informed consent or participate informedly in the decision on their treatment options they also need to have the right to know, i.e. they need to be granted access to their health information, including diagnosis and genetic data.

⁷²⁵ Two often cited utilitarians, Jeremy Bentham and John Stuart Mill, roughly identified the good with pleasure. Good ought to be maximized, in the sense of bringing about 'the greatest amount of good for the greatest number'. See for example, Bentham, note 79, and Mill, note 79. On a critical view see Nida-Rümelin, *Kritik des Konsequentialismus*, note 79.

⁷²⁶ Universal Declaration on the Human Genome, note 4, Article 5 (b); Declaration on Human Genetic Data, note 4, Article 8 (a); UDBHR, note 4, Article 5, 6. Oviedo Convention, note 5, Article 5; ICCPR, note 341, Article 7. This principle has already been enshrined in the ICCPR, however, only with regard to biomedical research and not clinical practices.

⁷²⁷ See Chapter VII, 5.

⁷²⁸ Universal Declaration on the Human Genome, note 4, Article 5; Declaration on Human Genetic Data, note 4, Article 10; Oviedo Convention, note 5, Article 10 (2).

⁷²⁹ Universal Declaration on the Human Genome, note 4, Article 5 (a) and (b); Declaration on Human Genetic Data, note 4, Article 8 (b); 2005: Article 7; Oviedo Convention, note 5: Articles 6,7, and Articles 17-18. Universal Declaration on the Human Genome, note 4.

⁷³⁰ D. Rothman, *Strangers at the Bedside: A History at how Law and Bioethics Transformed Medical Decision Making*, 1992, 1-2.

⁷³¹ *Ibid.*

Fourth, and in the same spirit, the standards endorse a principle of special protection for those unable to consent as research subjects. This principle applies to those who lack the capacity to consent, which usually includes children and people with mental disabilities.⁷³² These groups of persons are considered particularly vulnerable as they depend on the decisions others take for them. It is therefore necessary to specify the conditions under which an intervention may be carried out on these people in order to ensure their protection.⁷³³ Besides minors, mentally incapacitated and the deceased also other groups of people can at times be considered particularly vulnerable and hence in need of special protection. People with certain physical disabilities, pregnant women or economically disadvantaged people may be socially disadvantaged to an extent that they deserve special protection. Extra protection and safeguards have therefore to be added to prevent harmful abuse, particularly in the area of biomedical research. Because of the potential harm for persons unable to consent this principle has been subject to wide discussions during the elaboration of the standards.

A further principle endorsed in most instruments is that biomedical activities should not harm patients and research subjects and, if possible, improve their health condition.⁷³⁴ This principle, also often stated in medical ethics as *primum non nocere*, and today often referred to as the dual concept of beneficence and non-maleficence, has long been a widely respected injunction of medical ethics. It can for example already be found in the Hippocratic Oath,⁷³⁵ commonly dated to around 400 BC. As such, and because of its rather vague and principled approach that avoids absolute and hierarchical specifications of this principle it has remained little contested and generally intact.⁷³⁶

⁷³² Explanatory Report Council of Europe European Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine DIR/JUR, 1997, 5 paras. 41 and 50.

⁷³³ Ibid., paras 41 and 42.

⁷³⁴ Universal Declaration on the Human Genome, note 4, Article 5; UDBHR, note 4, Article 4; and to a lesser extent in the Oviedo Convention, note 5, Article 4 but see the Explanatory report to the Council of Europe European Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine DIR/JUR, note 609, para 32, which holds that it is the essential task of the doctor not only to heal patients but also to take the proper steps to protect health and relieve pain.

⁷³⁵ The modern translation of the Oath states: "Into whatever homes I go, I will enter them for the benefit of the sick, For original Text see: National Institute of Health at: http://www.nlm.nih.gov/hmd/greek/greek_oath.html (last visited 27.04.2012).

⁷³⁶ Andorno, "First Steps in the Development of an International Biolaw", note 625, 128, noting that with new advances in medical technology it might sometimes no longer be easy to demarcate clearly harm from benefit. In cases of 'end of life care' it, for example, sometimes seems impossible to tell whether life-prolonging measures provide more benefit or more pain to comatose patients. Here the principle remains intact but further and adapted definitions of what constitutes harm and benefit are necessary. Secondly, it is noteworthy that the legal instruments in the area of bioethics tend to restate this principle as a risk-benefit balance, specifying for example that "research, [and] treatment ... shall only be undertaken after rigorous and prior assessment of the potential risks and benefits". Such a rephrasing of the principle might be problematic to the extent "that these principles have a deeper meaning that goes far beyond a mere calculation of interests. For example, care or responsibility towards a patient might not be adequately measured by a numerical risk benefit analysis. In some cases responsibility might even be discouraged if the risk benefit analysis is taken to be the basis of decisions and no longer a physician's responsibility. Finally, in cases where it is not clear what constitutes harm and what benefit a simple benefit-risk analysis might prove useless or beside the point. See also H. Schmidt/J. Kreis, "Lessons from Abroad", 39 *Hastings Center Report*, 2009, 20 et seq.

The next principle that needs mentioning is that of freedom of scientific research.⁷³⁷ Freedom of scientific research is “one of the highest expressions of human capacities and the principle pays recognition to the fact that this freedom is one of the main guarantors of human health and welfare as it can propel progress and development.”⁷³⁸ The correlated right has already been enshrined in one of the most basic civil and political right, the human right to freedom of thought, speech and expression.⁷³⁹ Because it is also enshrined in international treaty law such as the ICCPR and European Convention on Human Rights and in many municipal laws as well as it has been frequently been referred to in courts this principle can be said to constitute a legal principle.⁷⁴⁰

A further principle enshrined across the instruments in the area of bioethics is the protection of confidentiality of medical data.⁷⁴¹ The duty of confidentiality is essential to foster trust in the doctor-patient relationship and as such again an old injunction of medical ethics that can already be found in the Hippocratic Oath.⁷⁴² With the advent of modern means of communications, electronic data collection and storage special safeguards for the preservation of the confidentiality of data have come in order. Such measures might include encoding of data, limited access to the data, use of passwords, etc. Moreover, through modern means of data collection and processing the range of possible use of this data has been much increased. It therefore seems that there is a need to clearly identify what kind of research should be undertaken and what data needs collecting for that.⁷⁴³

The next principle worth mentioning as it is endorsed in all instruments is that of non-discrimination and non-stigmatization.⁷⁴⁴ This includes a prohibition of stigmatization on the basis of health status, particularly as regards genetic status but also when it comes to the allocation of scarce resources and access to health care. This issue has recently received considerable attention with fear of genetic discrimination, that is of the abuse of genetic information to discriminate

⁷³⁷ Universal Declaration on the Human Genome, note 4, Article 12 (b); UDBHR, note 4, Article 2 (d); Oviedo Convention, note 5, Article 15.

⁷³⁸ Andorno, "First Steps in the Development of an International Biolaw", note 625, 128.

⁷³⁹ Cf. UDHR, note 270, Article 19 stating that - everyone has the right to freedom of opinion and expression; this right includes freedom to hold opinions without interference and to seek, receive and impart information and ideas through any media and regardless of frontiers. See also ICCPR, note 314, Article 19 (2); Council of Europe Convention for the Protection of Human Rights, note 344, Article 10.

⁷⁴⁰ See note 93.

⁷⁴¹ Universal Declaration on the Human Genome, note 4, Article 7; Declaration on Human Genetic Data, note 4, Article 14; UDBHR, note 4, Article 9; Oviedo Convention, note 5, Article 10 (1).

⁷⁴² The Oath, note 735, states: Whatever I see or hear in the lives of my patients, whether in connection with my professional practice or not, which ought not to be spoken of outside, I will keep secret, as considering all such things to be private.

⁷⁴³ See some of the recent scandals in the United Kingdom and Germany, e.g. T. Brake, "Loss of Data Discs Emphasises the Need to Widen the Debate on Identity Fraud", December 2007, at: <http://www.libdems.org.uk/home/loss-of-data-discs-emphasises-the-need-to-widen-the-debate-on-identity-fraud-159583> (last visited 12.09.09). K. Weber/U. Bittner/A Manzeschke/E. Rother/F. Quack/K. Dengler/H. Fangerau, "Taking Patient Privacy and Autonomy More Seriously: Why an Orwellian Account Is Not Sufficient", 12 *American Journal of Bioethics*, 2012, 51 et seq.

⁷⁴⁴ Universal Declaration on the Human Genome, note 4, Article 6; Declaration on Human Genetic Data, note 4, Article 7 (a); Oviedo Convention, note 5, Article 11.

against people in health insurance, employment or other field, being on the rise.⁷⁴⁵ The principle clearly roots in the broader human rights principles of equality and non-discrimination enshrined in the UDHR, ICCPR and ICESCR.⁷⁴⁶

Non-commercialisation of the human body and its parts reflects two notions.⁷⁴⁷ For one, it follows from “an ethical and legal axiom according to which human organs and tissue should be regarded as gifts and not as mere commodities.”⁷⁴⁸ Secondly, the principle has been in place to prevent the exploitation of economically disadvantaged people who might readily part with one of their organs for remuneration. Since it must be doubted that such an act could ever be based on a truly informed and autonomous decision abusive practices could easily be established. Such abusive practices in turn could amount to an objectification of a human person. As such prohibition of the sale of human body part is grounded in the conviction that even if informed consent has been obtained such acts “would diminish human dignity and our sense of solidarity.”⁷⁴⁹

Finally, a clear and rather unequivocal prohibition of reproductive human cloning for reproductive reasons is endorsed both, in the Oviedo Convention and in the Additional Protocol on human cloning and in the Declaration on the Human Genome.⁷⁵⁰ However, it is noteworthy that this principle has not been further endorsed through the General Assembly in the form of a Convention, as discussed above. The fact that states could not agree on a complete ban on human reproductive cloning suggests that they may in fact want to leave the door ajar to such experiments even though the majority of states seem to consider cloning, at least if undertaken for reproductive purposes, to constitute a repulsive practice.

3. The Relationship between Human Rights and Bioethical Principles

All bioethical principles discussed above have been incorporated and hence become principles enshrined in international human rights instruments. The acquaintance of this new form also somewhat changes or transforms certain aspects of the character of these principles. First of all they are no longer addressed primarily to doctors and physicians but to states and their agencies, and only exceptionally to the broader public. States thereby, to varying degrees at least, owe it to

⁷⁴⁵ See for example the arguments and discussions surrounding the Additional Protocol on Genetic Testing in C. Eng/J. Vijg, "Genetic Testing: The Problems and the Promise", 15 *Nature Biotechnology*, 1997, 422 et seq. P. Billings et al, "Discrimination as a Consequence of Genetic Testing", 50 *American Journal of Human Genetics*, 1992, 476 et seq.

⁷⁴⁶ UDHR, note 270, Article 7, ICCPR, note 341, Article 2, ICESCR, note 341, Article 2.

⁷⁴⁷ Universal Declaration on the Human Genome, note 4, Article 4, Oviedo Convention, note 5, Article 21, Additional Protocol concerning Transplantation of Organs and Tissues of Human Origin, note 31, Articles 21, 22.

⁷⁴⁸ Andorno, "First Steps in the Development of an International Biolaw", note 625, 134. See generally also R. Titmuss, *The Gift Relationship: From Human Blood to Social Policy*, 1970.

⁷⁴⁹ Andorno, "First Steps in the Development of an International Biolaw", note 625, 135.

⁷⁵⁰ Universal Declaration on the Human Genome, note 4, Articles 11, 24; Oviedo Convention, note 5, Article 13, Additional Protocol on the Prohibition of Cloning Human Beings, note 31, Article 1. and not so unequivocally in the UN Declaration on Human Cloning, note 35.

other states to ensure within their area the application of these principles.⁷⁵¹ Secondly, the principles at the very least have entered the realm of political discussions and negotiations on international legal and/or policy standards.

This transformation seems also to have been in the mind of the IBC that elaborated the UDBHR. The explanatory memorandum for the fifth draft of the UDBHR comments on the relationship between bioethics and human rights as follows:

“...A most important achievement of the draft declaration is that it anchors the principles that it espouses firmly in the rules governing human dignity, human rights and fundamental freedoms. Bioethics has hitherto developed substantially along two broad streams. One of these, present since the ancient times, derives from reflections on medical practice and on the conduct of medical professionals. The other, conceptualized in more recent times, has drawn upon the developing international human rights law. One of the important achievements of the declaration is that it seeks to unit these two streams. It clearly aims to establish the conformity of bioethics with international human rights law.”⁷⁵²

The description shows that “a picture of bioethics that did not include human rights would be an incomplete one”⁷⁵³ today. The first stream, described as being centred around the activity of “reflection” on medical practices and hence constituting medical ethics, meets a second stream, that of bioethics, which has “drawn upon the developing international human rights law”.⁷⁵⁴ It seems thereby that the IBC considers one stream to approach matters from an ethical, and the other from a more legal perspective.⁷⁵⁵ Based on this proposition Harald Schmidt, reflecting on the relationship between bioethical principles and human rights convincingly summarises their relationship as follows:

“... it is plausible to view the general relationship between bioethics and human rights as a complementary one. On this view, academic bioethics - in the various disciplines that contribute to this field, which is in itself an inter-disciplinary one - legitimately addresses many of the same questions as the human rights branch, whether in the context of academic research, jurisprudence, politics, the setting out of human rights policy standards or grass roots activism. I take this overlap to be unproblematic as long as one is clear about the scope and limitations of the respective approaches. Accordingly, while both streams have a clear and robust theoretical element, with distinct methodologies and normative frameworks to draw on, the human rights stream is closer to the sphere of politics and jurisprudence, and thus to the actual implementation of normative provisions, whether at a national or global level. The role of bioethics is primarily to provide input into the process

⁷⁵¹ For example, states that have signed up to the Oviedo Convention, note 5, are obliged by the Convention's provisions.

⁷⁵² On the subject of solidarity and cooperation see also Explanatory Memorandum, note 8, para 12, see also para 125: “It is this harmonization of bioethical principles and human rights norms that constitutes a major achievement of the declaration”.

⁷⁵³ Schmidt, “Bioethics, Human Rights and Universalisation: a Troubled Relationship? Observations on UNESCO's Universal Declaration on Bioethics and Human Rights”, note 650, 277.

⁷⁵⁴ Ibid., 278.

⁷⁵⁵ Ibid. see also T. Faunce, “Will International Human Rights Subsume Medical Ethics? Intersections in the UNESCO Universal UDBHR”, 31 *Journal of Medical Ethics*, 2005, 173 et seq.

of establishing legal norms generated at the human rights level, and to give constructive criticism on the appropriateness of norms once they have been established.”⁷⁵⁶

Norms and principles enshrined in the instruments in the area of bioethics therefore are human rights norms and principles to the extent that they root in and built on human rights doctrine and thought and or to the extent that they reformulate and adapt these provisions. Human rights thought and principles provide the framework in the sense that the human rights framework determines the interpretation of the single provisions, i.e. how they are to be operationalized, how they relate to other norms of international law and what effect they have.⁷⁵⁷ The part of “bioethics” and the bioethical body of thought must be understood as the part that fills this framework with specific content.⁷⁵⁸ Bioethical principles thereby fill in the gaps in case established human rights norms and principles do not cover a specific factual situation of bioethical relevance. The relationship is thus indeed a complementary one, albeit it seems that human rights are dominating in that they provide the framework and hence set certain limits for bioethical principles to be filled and operationalised within this framework. For example, a bioethical principle that would completely undermine the principle of freedom of expression or one that would suggest that the sole interest of society should trump individual interests would be incompatible with human rights framework and hence would be inconceivable in a standard. In the literature it has, however, been noted that bioethical principles sometimes deviate from a classical human rights approach to matters at hand as the former approach less aims at the protection of fundamental freedoms than it is about the endorsement of ethical principles that can, under certain circumstances seek to curb the fundamental freedoms encapsulated in human rights.⁷⁵⁹ For example the Deutsche Ethikrat in its commentaries did not so much press for the value of scientific freedom then for an ethically balanced approach to such questions as whether or not the import of embryonic stem cells should be allowed and whether or not the cloning of human beings for therapeutic purposes should be allowed.⁷⁶⁰ An ethical discourse, that arrives at its conclusions on the basis of 'good but not purely legal reasons' and that, in a pluralistic society, necessarily takes a mediating role, is thereby juxtaposed to a human rights discourse that is fundamentally about the protection of freedoms and can thereby come to very different conclusions about how a certain topic should be regulated. This certainly holds true for discourses at the national level and it might be arguable that certain ethical principles, such as the principle that the cloning of human beings for therapeutic purposes is

⁷⁵⁶ Schmidt, "Bioethics, Human Rights and Universalisation: a Troubled Relationship? Observations on UNESCO's Universal Declaration on Bioethics and Human Rights", note 650, 279.

⁷⁵⁷ This relationship is exemplified by the title of the UDBHR, note 4, which is on Bioethics and Human Rights. The and thereby simply shows that the Declaration is about both bioethical thought expressed as bioethical principles and about human rights. The relationship between human rights and bioethics in the UDBHR is thereby such that the bioethical principles are being dealt with through a human rights framework. Bioethical principles provide the content, human rights the framework within which bioethical concerns are being addressed.

⁷⁵⁸ But see J. Arras/E. Fenton, "Bioethics and Human Rights: Access to Health-Related Goods", 39 *Hastings Center Report*, 2009, 27 et seq.

⁷⁵⁹ Vöneky, *Recht, Moral und Ethik. Grundlagen und Grenzen Demokratischer Legitimation für Ethikgremien*, note 15, Chapter 7, I 3 -4, and II and Chapter 8 III.

⁷⁶⁰ Ibid. Chapter 7, I 3. On background and different ethical positions see Nida-Rümelin, "Bioethik und Menschenwürde: Dokumentation einer Debatte", note 77, 401 et seq.

against the human dignity of human beings, at the international level can be construed as somewhat limiting fundamental freedoms, such as the freedom to expression.⁷⁶¹ It should, however, also be noted that human rights, while the protection of fundamental freedoms has always been a core *raison d'être* for their existence, they, because they had to be a common ground for all nations and cultures also always had to be eclectic and flexible enough to accommodate different views on how far the protection of fundamental freedoms should be stretched and in how far other considerations should be given priority.⁷⁶² With the exception of the Additional Protocol on Human Cloning, discussed above in chapter 3, no international standard in the area of bioethics endorses an unequivocal prohibition of human cloning for therapeutic or reproductive purposes, thus leaving it to national interpretations to decide whether to give priority to a right of freedom of expression or to an ethical principle that prohibits the cloning of human beings for therapeutic or reproductive purposes.⁷⁶³ At the international level it therefore seems justified to speak of a complementary discourse in which bioethical principles flesh out and fill in gaps in human rights standards without too starkly undermining the fundamental freedoms set out within the standards.⁷⁶⁴

4. Conclusion

In essence all standards that are directly addressed to issues of bioethical relevance are human rights standards at their core. That is, they refer to human rights in their title, refer to human rights standards throughout their texts and endorse and are based on human rights principles. They are bioethical to the extent that their objectives are directed towards and that their content deals with questions of bioethical interest and to the extent they endorse bioethical principles within the human rights framework. As could be seen above most of the principles discussed above are rather long grown ethical principles that have developed from the general medical ethics or bioethical body of thought. The general bioethical principles enshrined in the instruments continue to exist and to inform legal norms and principles in the area of bioethics. Most bioethical principles, in theory at least, constitute absolute statements. In practice, however, these principles are often rather flexible and relative principles.

⁷⁶¹ Ibid. Chapter 7, I 3 -4.

⁷⁶² The debate regarding scientific freedom and hate speech in the US for example shows that fundamental rights always have to allow for ethical considerations that might curb fundamental freedoms. McGoldrick/O'Donnell, note 719, 458 et seq.

⁷⁶³ See discussion under Chapter IV, 3.1.

⁷⁶⁴ For different viewpoints see A. Rose, "Questioning the Universality of Medical Ethics: Dilemmas Raised Performing Surgery around the Globe", 41 *Hastings Center Report*, 2011, 18 et seq.; P. Singer, *Practical Ethics*, 2011; President's Council (ed.), *Human Dignity and Bioethics*, 2008; T. Metz, "African and Western Moral Theories in a Bioethical Context", 10 *Developing World Bioethics*, 2009, 49 et seq.; E. Ermann, *Human Rights do not Make Global Democracy*, 2011; G. Kao, *Grounding Human Rights in a Pluralist World*, 2011; I. Westra, *Human Rights: The Commons and the Collective*, 2011; G. Kateb, *Human Dignity*, 2011; R. Hare, *Moral Thinking*, 1981; J. Rachels/S. Rachels, *The Elements of Moral Philosophy*, 2012, in particular Chapters 7 and 8.

The bioethical principles are thereby “anchored” in human rights. At the same time, are they not mere rehearsals of abstract human rights norms. Rather, they infuse human rights with past and contemporary controversies in bioethics, thereby illustrating again the above-asserted complementarities of human rights and bioethics.

Part III:

**The Analysis of the Implications of Discussing issues of Bioethical
relevance in this Epistemological Approach to Bioethics**

Chapter VI Roots, Narrative and Episteme of Human Rights Standards

Having established in the previous chapters that the standards in the area of bioethics are at their core human rights standards and having further established that in this thesis these standards are considered legal and hence can give rise to a legal discourse of some sort this chapter aims to provide a better understanding of the properties of this legal discourse. That is, this chapter inquires into the character and nature of the episteme or structure giving concepts of the human rights discourse that takes place in the area of bioethics. To that purpose this chapter first discusses the context from which and into which human rights emerged, i.e. it discusses some of the socio-historical background to and the philosophical roots of human rights. Analysing the history and roots of the standards is helpful in explaining why their episteme was formed in the way it has. It also to some extent is helpful in explaining how the structure giving concepts or grid-points that together form these standards' episteme are charged, i.e. what their context is, what they mean and how they must be read or interpreted, a discussion that is undertaken in the second part of this chapter.

1. Philosophical Roots of Human Rights

There are divergent views as to the philosophical roots and origins of human rights. In particular, scholars differ widely on the question of whether or not these roots are universal, i.e. on whether they can be found in all philosophical, religious or cultural traditions around the world.

One prominent view thereby is to argue that most of the concerns dealt with in the UDHR and other human rights instruments had long been recognised within varying conceptions of human dignity which again are an integral part of all of the world's major religious and cultural traditions.⁷⁶⁵ On this view states' practice of human rights in the pre-UN era was not only limited to Western States. Rather, it is argued that "all societies cross-culturally and historically manifest conceptions of human rights."⁷⁶⁶ To contend that "the concept of human rights is basically a

⁷⁶⁵ See for example, S. Subedi, "Are the Principles of Human Rights "Western" Ideas? An Analysis of the Claim of the "Asian" Concept of Human Rights from the Perspectives of Hinduism", 13 *Western School of Law California Western International Law Journal*, 1999; 45 et seq.; J. Cobbah, "African Values and the Human Rights Debate", 9 *Human Rights Quarterly*, 1987, 309 et seq. and A. An-Na'Im, "Human Rights in the Muslim World", 3 *Harvard Human Rights Journal*, 1990, 13 et seq. See also J. Nida-Rümelin, "Gibt es ein Menschenrecht? Der Philosoph Julian Nida-Rümelin im Gespräch", Philosophie und Religion - Philosophie und Ethik - Goethe-Institut, at: <http://www.goethe.de/ges/phi/eth/de6294965.htm> (last visited 27.04.2012), arguing that certain specific human rights exist independently of the cultural traditions in which a human being lives and arguing that the reason for their existence is self-evident.

⁷⁶⁶ J. Donnelly, *Universal Human Rights in Theory and Practice*, 2002, 71, though ultimately dismissing the argument and J. Donnelly, "The Relative Universality of Human Rights", 29 *Human Rights Quarterly*, 2007, 281 et seq. Some authors, for example, argue that contemporary human rights doctrines merely replicate 1400 year old Islamic ideas, see Sultanhussein Tabandeh of Gunabad, *A Muslim Commentary on the Universal Declaration of Human Rights*, 1970, 85. Others, such as Dunstan Wai, hold that "traditional African attitudes, beliefs, institutions and experiences, sustained the view that certain rights should be

Western concept is to ignore the practices of other great ancient civilisations of the world.”⁷⁶⁷

Closely related is often an understanding of human rights as arising from universal basic human needs⁷⁶⁸ or entitlements to fulfil a person's capabilities.⁷⁶⁹ Human rights in this perspective are the answer to being human, they logically stem from humans' humanness and correlated human needs and as such can be found everywhere at all times.⁷⁷⁰

Another group of scholars makes strong linkages between the actual coming into existence of human rights, i.e. between the moral consensus achieved in the Universal Declaration of Human Rights, and the atrocities of the 2nd World War.⁷⁷¹ According to this view it is the “shared outrage” in the face of these atrocities and “the need to reaffirm each and everyone's individual rights after their violation during the war”⁷⁷² that explains why the Declaration has found such widespread support from so many delegations from so many different backgrounds.⁷⁷³

upheld against alleged necessities of state" cited in F. Snyder/S. Sathirathai, *Third World Attitudes Towards International Law: An Introduction*, 1987, 343.

⁷⁶⁷ Subedi, note 765, 45, maintaining that the absence of sufficient literature 'unearthing and analysing' the practices of ancient States of Asia, Africa, and other parts of the world and the lack of reliable study on the subject is thereby cited as part of the reason for the subsequently rather 'ignorant' perception that human rights have their origin only in Christian Western civilisation.

⁷⁶⁸ See for example E. Kamenka, "Human Rights, People's Rights", in: J. Crawford (ed.), *The Rights of People*, 1988, 125, 127. But see discussion below in chapter VII, 4.2.1.

⁷⁶⁹ Martha Nussbaum arguing that all world citizen are entitled to being able to live out a decent minimum level of specific capabilities, such as Life (being able to live to the end of a human life of normal length; not dying prematurely, or before one's life is so reduced as to be not worth living); Bodily Health (being able to have good health, including reproductive health; to be adequately nourished; to have adequate shelter) Bodily Integrity (being able to move freely from place to place; to be secure against violent assault, including sexual assault and domestic violence; having opportunities for sexual satisfaction and for choice in matters of reproduction), etc. For a brief introduction to the capabilities approach and how it relates to human rights see M. Nussbaum, "Human Rights and Human Capabilities", 20 *Harvard Human Rights Journal*, 2007, 20 et seq. See also A. Sen, *Development as Freedom*, 1999, 13 et seq. And see discussion below in chapter VII, 4.2.1.

⁷⁷⁰ There is considerable debate as to what constitutes "humanness" and human needs, how humanness is being constituted and to what entitlements this status then leads. Cf. for example M. Nussbaum, *Sex and Social Justice*, 2000, who, following an Aristotelian approach, and arguing at 57 that all, just by being human, are of equal dignity and worth, no matter where they are situated in society, and that the primary source of this worth is a power of moral choice within them, a power that consists in the ability to plan a life in accordance with one's own evaluation of ends." To this idea is linked one more, that at 70 "the moral equality of persons gives them a fair claim to certain types of treatment at the hands of society and politics. . . . [T]his treatment must do two . . . things [:] respect and promote the liberty of choice, and ... respect and promote the equal worth of persons as choosers." Nussbaum's view holds that "the core of rational and moral personhood is something all human beings share, shaped though it may be in different ways by their differing social circumstances... . Matthias Mahlmann again argues that the human mind is furnished with a distinct capacity for moral judgement which makes a human being a human being. M. Mahlmann, *Elemente einer Ethischen Grundrechtstheorie*, 2008, 94. See also René Descartes' reflections on res cogitans and his analysis of the existence of innate ideas. R. Descartes, *The Philosophical Writings of Descartes*, 1985, 303 et seq. and Noam Chomsky's idea on a "Universal Grammar", N. Chomsky, *Knowledge of Language, its Nature, Origin and Use*, 1986 and N. Chomsky, *The Minimalist Programme*, 2002. On reflexion of what constitutes a human being from the perspective of 'Humanismus' see J. Nida-Rümelin, "Humanismus", in: D. Ganten/V. Gerhardt/J. Heilinger/J. Nida-Rümelin (eds.), *Was ist der Mensch? (Humanprojekt)*, 2008, 11, 11-18.

⁷⁷¹ See for example Morsink, note 626, 5; Wolfrum/Vöneky, note 565, 137.

⁷⁷² Morsink, note 626, 36, citing delegate Lakhshimi Menon from India.

⁷⁷³ Ibid., 28.

Other scholars again dismiss the idea of universal roots, arguing that this idea confuses 'ontological and functional equivalents of human rights', which are inherently present in every culture, with the specific concept of human rights, which is unique to the Western⁷⁷⁴ liberal⁷⁷⁵ tradition.⁷⁷⁶ These scholars moreover argue that while human dignity, as the major concept underlying and driving human rights philosophy, is an age old concept that can be found in all cultures at all times, the specific notion of human dignity as used in a human rights context stems principally from liberal, enlightenment traditions of thought.⁷⁷⁷ Thus, while Buddhism, Islam and Confucianism, for example, may very well provide viable perspectives on human dignity, these specific conceptions of human dignity differ from other perspectives used, including from that underlying human rights. Since the conceptualisation of human dignity differs also the "particular social practice that aims to realize a distinctive substantive conception of human dignity"⁷⁷⁸ differs. Human rights, constituting one specific such social practice, consequently differ from other social practices. Donnelly, therefore concludes that

"most non-Western cultural and political traditions lack not only the practice of human rights but the very concept. As a matter of historical fact, the concept of human rights is an artefact of modern Western civilisation."⁷⁷⁹

In much the same way detects Onua Yasuaki for example several compelling 'substantive and psychological factors'⁷⁸⁰ that give rise to theories of human rights' universal origin. On the whole, however, he equally dismisses this notion since "those mechanisms that protected the interest of the people ... may be characterised as the ontological or functional equivalents of human rights but not as human rights per se."⁷⁸¹

⁷⁷⁴ Although the term is ambiguous in that there is no one Western culture the term will nevertheless be used here in order to demarcate the more powerful economically developed countries, which in many cases are culturally of European origin. These mainly include Western Europe, The USA, Canada and some countries from South America. For a further discussion see for example: Alston/Steiner, note 214, pp.387 ff. or T. Inoue, "Liberal Democracy and Asian Orientalism", in: D. Bell/J. Bauer (eds.), *The East Asia Challenge For Human Rights*, 1999, 27 et seq.

⁷⁷⁵ Liberalism is not one monolithic tradition. The very term liberal has assumed different meanings from the liberal economics associated with a laissez-faire attitude to contemporary associations of liberalism with a more active and engaged state or liberal philosophers such as Ronald Dworkin or John Rawls. Being aware of the fact that these ongoing transformation caution against inclusive and dogmatic comparisons between human rights and liberalism this thesis nevertheless continues to use the term in order to refer to a general broad trend or tradition, as discussed in the next section, bearing, however, in mind that this thesis cannot provide more than a scant overview of some of the notions relevant to the idea of liberalism. For discussion of liberalism see J. Nida-Rümelin/W. Vossenkuhl (eds.), *Ethische und Politische Freiheit*, 1998, in particular Part I and II, 3 – 279.

⁷⁷⁶ Donnelly, *Universal Human Rights in Theory and Practice*, note 766, 13. See also Association of American Anthropologists, "Statement on Human Rights", 49 *American Anthropologist* 4, 1947, 539.

⁷⁷⁷ See for example O. Yasuaki, "Toward an Intercivilisational Approach to Human Rights", in: D. Bell/J. Bauer (eds.), *The East Asia Challenge For Human Rights*, 1999, 109.

⁷⁷⁸ J. Donnelly, "Human Rights and Human Dignity: An Analytical Critique of Non-Western Conceptions of Human Rights", 76 *American Political Science Review*, 1982, 303, 303.

⁷⁷⁹ Donnelly, "Human Rights and Human Dignity: An Analytical Critique of Non-Western Conceptions of Human Rights", note 766, 302. and M. Franck, "Is Personal Freedom a Western Value?", 91 *American Journal of International Law*, 1997, 593 et seq.

⁷⁸⁰ Yasuaki, note 777, 108 et seq.

⁷⁸¹ *Ibid.* pp. 109.

This thesis, as will be further explained in the next sections, upholds that concepts of human dignity as well as ontological and functional equivalents of human rights can be found in all cultures at all times. Nevertheless, it also recognises that human rights as rights were not born into a vacuum but that some of the specific characteristics of human rights as enshrined in international human rights standards in many ways inhere in a certain tradition of thought and in a certain *nomos*⁷⁸², to be explained over the next section. The claim made here is not that human rights are not or cannot become universal or that the idea of human rights and human dignity is a specific 'Western' concept. Yet it is upheld that human rights as enshrined in many international standards, with their specific understanding of human dignity, use of legal concepts and language, emphasis on the individual and his or her autonomy as well as intricate relationship with the state can be indebted and often have been influenced by certain liberal, and enlightened traditions of thought which again to some extent defines the content, meaning, scope, fundamental notions and application of today's human rights. Understanding the roots and *nomos* of human rights will then be helpful to better understand the meaning and scope of the presently examined human rights discourse. Hence it is worthwhile to elaborate on the traditions that gave rise to human rights and to thereby bring human rights and human rights' episteme into context.

1.1. The Idea of Liberalism

Liberalism is conventionally said to root in the experience of the Wars of Religion that swept Europe during the 16th and 17th century and to have emerged "in response to the growth of the modern nation-states, which centralize governmental functions and claim sole authority to exercise coercive power within their boundaries."⁷⁸³ Today liberalism comes in many differing philosophical variations and institutional manifestations.⁷⁸⁴ Yet its foundation still is that of tolerance – albeit in differing conceptualisations - and that of two other bases captured by Locke's famous claim that men are born in a state of perfect freedom and a state of equality. Locke maintained that in order

“to properly understand political power and trace its origins, we must consider the state that all people are in naturally. That is a state of perfect freedom of acting and disposing of their own possessions and persons as they think fit within the bounds of the law of nature. People in this state do not have to ask permission to act or depend on the will of others to arrange matters on their behalf. The natural state is also one of equality in which all power and jurisdiction is reciprocal and no one has more than another. It is evident that all human beings – as creatures belonging to the same species and rank and born indiscriminately with all the same natural advantages and faculties – are equal amongst themselves. They have no relationship of subordination or subjection unless God (the lord

⁷⁸² On the term *nomos* see Cover, "Nomos and Narrative", note 38, 95 set seq.

⁷⁸³ Entry on liberalism in: Audi, note 9, 502 et seq.

⁷⁸⁴ See for example, R. Nozick, *Anarchy, State and Utopia*, 1974; W. Kymlicka, *Liberalism, Community and Culture*, 1989.

and master of them all) had clearly set one person above another and conferred on him an undoubted right to dominion and sovereignty.”⁷⁸⁵

Much like in Locke's reasoning liberal theories generally build on the tenet that all human beings are fundamentally equal as much as they are individuals and free and that they are entitled to equal individual liberty. In one way or another these theories' aim is to promote social outcomes that are, as far as possible, the result of free individual choices – as long as the choice of one person does respect the equal freedom and rights of others. The ideal of freedom and equality, to the largest possible extent, has to be preserved even after the formation of the state. The state is thus only legitimate to the extent that the individual voluntarily trades his or her liberty away in exchange for the state's guarantee of a good social order. The state may only exercise coercion in order to ensure the maintenance of basic liberal ideas.⁷⁸⁶ Yet a state's coercive order must not build on the superiority of one substantive conception of the good life for human beings. Rather, people are generally free to choose what values to pursue in their lives provided that they pursue them within the limits of an equal liberty that respects equal limits on individual entitlements.⁷⁸⁷ Liberalism thus does generally not seek to resolve conflicts emanating from different values, but to provide a 'neutral' framework within which everyone can live up to his values. A liberal modern government, as Dworkin summarises, for example,

“must treat those whom it governs with concern, that is, as human beings who are capable of suffering and frustration, and with respect, that is, as human beings who are capable of forming and acting on intelligent conceptions of how their lives should be lived. Government must not only treat people with concern and respect, but with equal concern and respect. It must not distribute goods or opportunities un-equally on the ground that some citizens are entitled to more because they are worthy of more concern. It must not constrain liberty on the ground that one citizen's conception of the good life . . . is nobler or superior to another's.”⁷⁸⁸

Liberalism, then, "generally consists in the structuring of individual interactions in society on the basis of a set of rights or entitlements that require human beings to respect each other's liberty and equality to the greatest extent possible".⁷⁸⁹ These rights or entitlements do not have to be expressed as natural or human rights.⁷⁹⁰ However human rights, at least in their current form, have been born from and into liberal traditions and, at least their origins cannot be separated from

⁷⁸⁵ J. Locke, *Two Treatises On Government*, 1689, Chapter II, section 4.

⁷⁸⁶ See for example, Nozick, note 784, 26 (the Nightwatchman state of classical liberal theory, limited to protecting all citizens against violence, theft, and fraud, and to the enforcement of contracts...). See also W. Kymlicka, "Liberal Complacency", in: M. Nussbaum (et al., eds.), *Is Multiculturalism Bad for Women?*, 1999, 31, 31 -34, taking a slightly broader view of the powers of the state in arguing that minorities should for example be granted certain protection by the state. In any event it is noticeable that the modern, territorial nation state, to some extent, is important in liberal thought, because it alone has the power to subject differing groups with different value conceptions to the same law and to monopolise use of force.

⁷⁸⁷ J. Charvet/E. Kaczynska-Nay, *Liberal Project and Human Rights: The Theory and Practice of a New World Order*, 2008, 2.

⁷⁸⁸ R. Dworkin, *Taking Rights Seriously*, 1987, 227.

⁷⁸⁹ Charvet/Kaczynska-Nay, note 787, 2.

⁷⁹⁰ There are liberal theories that defend the adoption of such relevant principles on the grounds that societies so organised will achieve a greater sum of utility or happiness than any alternative models. Charvet/Kaczynska-Nay, note 787, 3.

the liberal project of ensuring respect of individual's liberty, equality and autonomy by means of rights, usually within the context of a nation state. Human rights and thereby the standards in the area of bioethics, standing in the tradition of liberal thought, are built on and emphasise liberal values, which, as will be shown further below, again impacts the way issues of bioethical relevance are approached and dealt with.

1.2. Enlightenment

A second strand that clearly left its imprint on contemporary human rights doctrine might best be referred to by the broad term 'enlightenment'.⁷⁹¹ That movement and its equivalents in other European languages, denotes an intellectual movement which is characterised by certain doctrines or ideas which to some extent are similar to that of liberalism. Of course, as is the case with 'liberalism' and any other grand philosophical idea, it must be noted at the outset that

“no single idea, belief or practice unites all of the writers associated with Enlightenment thought; no one meaning informed even the banners under which dispute was sustained; no one definition embraces the ways in which the most self-consciously used terms were employed – terms such as 'science', 'republic', 'scepticism', 'Christian', 'atheist'. This does not render such labels useless, because they function as maps, simultaneously reflecting and requiring interpretation. No one map, and no single label, can represent everything that could be represented; each must be drawn up on a certain scale, and all can be misread. An analogy with maps was popular among writers of the time who were keen to signal the challenges of interpreting unfamiliar contexts”⁷⁹²

Bearing these inevitable limitations in mind this thesis will in the following attempt to sketch out some of the propositions that are commonly associated with enlightenment thought. For one, the scientific and intellectual achievements of the 16th, 17th and 18th century, including for example the expansion of the print culture, discoveries and inventions in a variety of disciplines such as astronomy, chemistry, mathematics and biology as well as the general popularization of science for example by means of a promotion of the value of scientific education, encouraged a belief in a scientifically discernible natural order and paved the way for growing confidence in human reason. Reason hence came to be regarded as man's central capacity as it enabled men to think and to discern information.⁷⁹³

Since all men (and on some accounts women) at all times were understood as having the same capacity to exercise reason they, secondly, were also considered to be fundamentally equal. It follows that they should hence be granted equality before the law and equal freedom of expression

⁷⁹¹ I. Kant, *Beantwortung der Frage: Was ist Aufklärung?*, 1784, 1, defining enlightenment as "man's release from his self-incurred tutelage. Tutelage is man's inability to make use of his understanding without direction from another. Self-incurred is this tutelage when its cause lies not in lack of reason but in lack of resolution and courage to use it without direction from another. Sapere aude! "Have courage to use your own reason!" - that is the motto of enlightenment". See also J. Israel, *Enlightenment Contested: Philosophy, Modernity, and the Emancipation of Man 1670-1752*, 2006, 43.

⁷⁹² M. Fitzpatrick, *The Enlightenment World*, 2004, 3.

⁷⁹³ C. Kirwan, "Enlightenment Philosophy", in: T. Honderich (ed.), *Oxford Companion to Philosophy*, 2005, 225, 252-253.

and thought. Tolerance had to be extended to other creeds and ways of life and local prejudice and customs, which owed their existence not to the exercise of reason but to authority were to be devalued.⁷⁹⁴ Overall, non-rational aspects of human nature were to be played down. Education, for example, according to many enlightenment thinkers should impart knowledge rather than mould feelings or develop character.⁷⁹⁵ Much of enlightenment philosophy is therefore characterised by its atheistic or agnostic, anti-theological and anticlerical character, by its rejection of authority and advocating for intellectual and moral autonomy and self-reliance.⁷⁹⁶

Thirdly, acting rationally was understood to imply acting correctly or good. Therefore, men, by nature, was seen to be rational and good⁷⁹⁷ and both, an individual and humanity as a whole, were understood as being able to progress to perfection by means of using their capacity to reason.⁷⁹⁸ Many parts of Immanuel Kant's philosophy, including his concepts of autonomy and human dignity illustrate this strand of thought. For example, autonomy, according to Kant, is the duty of each man to live according to rules that he himself sees fit for himself and everyone else⁷⁹⁹, i.e. autonomy is the self-imposition of rationally identified laws. Laws that are rationally identified are necessarily good or correct laws. That is so because all good and correct moral requirements or rules are based on standards of rationality (categorical imperatives), i.e. because all good and correct moral requirements or rules can be identified by a rational mind and only rules that have been identified in that way are then, according to Kant, justified and those that must be self-imposed. Immorality involves a violation of these standards of rationality and is thereby irrational.⁸⁰⁰ Because acting rationally is acting morally and thereby is acting correctly or good humans have the ability (and the duty) to arrive at morally good decisions and thereby to progress to good ends.⁸⁰¹

⁷⁹⁴ Ibid., 252-253.

⁷⁹⁵ Ibid.

⁷⁹⁶ Kirwan, note 793, 253.

⁷⁹⁷ On Kant's view of a 'radical evil' in human nature, that, however, can also be overcome see S. Grimm, "Kant's Argument for Radical Evil", 10 *European Journal of Philosophy*, 2002, 160, 169.

⁷⁹⁸ Kirwan, note 793, 254. See also J. Bury, *The Idea of Progress*, 1920 and I. Kant, *A Renewed Attempt to Answer the Question: Is the Human Race Continually Improving?*, 1798 and I. Kant, *Zum ewigen Frieden*, 1795. Of course Enlightenment inspired ideas of progress were by no means universal or unambiguous. See for example Fitzpatrick, note 792, at 189, citing Voltaire and Hume as being rather hesitant with regard to the idea of progress.

⁷⁹⁹ Kant, *Grundlegung zur Metaphysik der Sitten*, note 724, 4:431; cf. 4:432. Kant's project in the *Grundlegung zur Metaphysik der Sitten* is "the search for and establishment of the supreme principle of morality" (Ibid., 4:392). The Formulas of Universal Law are "Act only in accordance with that maxim through which you at the same time can will that it become a universal law" (4:421; cf. 4:402); And the variant "So act, as if the maxim of your action were to become through your will a universal law of nature" (4:421; cf. 4:436). Second formulation: "So act that you use humanity, as much in your own person as in the person of every other, always at the same time as an end and never merely as a means" (4:429; cf. 4:436) and the third formula (of autonomy) "the idea of the will of every rational being as a will giving universal law" (4:431; cf. 4:432). For background see J. Nida-Rümelin, *Politische Philosophie der Gegenwart*, 2009, 138 et seq.

⁸⁰⁰ R. Johnson, "Kant's Moral Philosophy", in: E. Zalta (ed.), *Stanford Encyclopedia of Philosophy*, Summer 2010 Edition, at: <http://plato.stanford.edu/archives/sum2010/entries/kant-moral> (last visited 27.04.2012), introduction.

⁸⁰¹ G. Bird, *A Companion to Kant*, 2008, 366. O. Sensen, *Kant on Human Dignity*, 2011, 45 et seq.

Men's status as free rational agents who are the source of the authority of the moral laws that bind themselves is also the source of Kant's concept of humans' dignity. The freedom of the individual to exercise his or her own innate capacity for rational thought, for thinking for him or herself, is, for Kant, every human beings' vocation, and it is also a key to enlightenment.⁸⁰² The human dignity of each human being is best promoted by their progressive development into autonomous rational human beings capable of "forgoing the tutelage incurred by unexamined dogma or authority" for such development is the proper destination of human nature.⁸⁰³ Dignity then stems from human beings' ability to reason and to thereby form moral decisions, i.e. to constitute ends.⁸⁰⁴ As human beings are capable to form such moral decisions, i.e. because they can distinguish between right and wrong at all and thereby constitute ends, they have dignity.⁸⁰⁵ It follows for Kant that human beings in themselves or in others must never be treated as a means only but always as an end in themselves. Dignity demands that they are not to be instrumentalised for whatever reason.⁸⁰⁶ In his *Metaphysik* Kant further elaborates this concept of dignity and the respect that is owed to human's dignity

"Every human being has a legitimate claim to respect from his fellow human beings and is in turn bound to respect every other. Humanity itself is a dignity; for a human being cannot be used merely as a means by any human being . . . but must always be used at the same time as an end. It is just in this that his dignity (personality) consists, by which he raises himself above all other beings in the world that are not human beings and yet can be used, and so over all things. But just as he cannot give himself away for any price (this would conflict with his duty of self-esteem), so neither can he act contrary to the equally necessary self-esteem of others, as human beings, that is, he is under obligation to acknowledge, in a practical way, the dignity of humanity in every other human being. Hence there rests on him a duty regarding the respect that must be shown to every other human being."⁸⁰⁷

Kant's concept of human dignity, in particular the idea that human beings are priceless and that they may not be instrumentalised, is frequently invoked in discussions of bioethical interest and it seems that many prevailing contemporary views concerning patient "autonomy", informed consent and with regard to what ought or what ought not to be done in the name of patients' human dignity are informed by Kant's philosophy.⁸⁰⁸ Since his ideas are so intricately linked with the enlightenment project itself it seems then also that contemporary debates in the area of bioethics are indebted to enlightenment thought.

⁸⁰² Kant, *Beantwortung der Frage: Was ist Aufklärung?*, note 791.

⁸⁰³ Fitzpatrick, note 792, 649.

⁸⁰⁴ Kant, *Beantwortung der Frage: Was ist Aufklärung?*, note 791.

⁸⁰⁵ Kant, *Grundlegung zur Metaphysik der Sitten*, note 724, 4:434-435.

⁸⁰⁶ That is, "act that you use humanity, whether in your own person or in the person of any other, always at the same time as an end, never merely as a means", Kant, *Grundlegung zur Metaphysik der Sitten*, note 724, 4:429.

⁸⁰⁷ Kant, *Grundlegung zur Metaphysik der Sitten*, note 724, 6:462.

⁸⁰⁸ S. Shell, "Kant's Concept of Human Dignity as a Resource for Bioethics", in: *Human Dignity and Bioethics: Essays Commissioned by the President's Council on Bioethics*, at: http://www.bioethics.gov/reports/human_dignity/chapter13.html#endnote4 (last visited 27.04.2012).

To summarise, enlightenment philosophers were generally united in their optimism or belief in the powers of reason to yield knowledge about the natural, including the human, world and by their commitment to reason as the main basis and source of authority and dignity, as well as to equality and respect for every individual's freedom to exercise reason and autonomy to follow what reason demands to do. A good human society, accordingly, is to be based on the fundamental values of personal liberty, equality, and freedom of thought and expression.⁸⁰⁹ As will be seen throughout this and the following chapter, human rights, standing in that tradition of enlightenment thought, emphasise many of the values and endorse many of the ideas connected with the enlightenment tradition of thought, including the values of equality and autonomy. As such also the standards in the area of bioethics endorse certain values, which again have a bearing on how issues of bioethical relevance are perceived of and dealt with.

1.3. Socio-Historical Developments and the Emergence of the Modern Nation State

Occurring parallel to and in conjunction with the above mentioned developments and equally influential on the development of a liberal, enlightenment world view and the idea of human rights were the development of the modern European state as well as several socio-historical changes in European (Western) society.⁸¹⁰ Particularly the above mentioned experiences of religious strife in Europe, the technological and scientific revolutionary developments as well as changes, generally referred to as those of 'modernization', including the formation of the nation state, migration, urbanization and industrialisation deserve mentioning.⁸¹¹ The religious strife, in particular the 30 years of war in Europe between 1618 and 1648 brought a level of destruction that to some extent led to the dissolution of religion as the foundation of society. It also made it clear that tolerance of different creeds and beliefs was paramount to any peaceful society.⁸¹² Technical and scientific developments in addition fostered a belief in man's capacity to reason and to progress.⁸¹³ By questioning established authority in their respective fields both these developments also helped bring along the emergence of a new vision of the individual's relationship to god, society, and the state. That is, the individual was seen as capable to reasoning and thereby to question established religious or otherwise inspired modes of explanation, which in turn allowed him or her to reconfigure his or her relationship with the entities that embodied these authorities.⁸¹⁴ Modernisations also furthered this trend by for example replacing the all-encompassing moral

⁸⁰⁹ Israel, note 791, 14.

⁸¹⁰ No account, particularly this brief account here can do justice to the topic at hand, i.e. the development of the modern nation state as well as of scientific and technological.

⁸¹¹ Of course, many more themes and topics could be included in this list, for example capitalism. See for example J. Hall, "Classical Liberalism and the Modern State", 116 *Daedalus* 3, 1987, 95 et seq.

⁸¹² See above under 1.1. in the same chapter.

⁸¹³ See above under 1.1. and 1.2. in the same chapter.

⁸¹⁴ See Held/McGrew/Goldblatt/Perraton, note 61, 3.

whole of traditional society by a much more segmented social order.⁸¹⁵ A strong workforce that was capable of claiming rights and entitlements emerged.⁸¹⁶ More complex divisions of labour resulted in changes in class structure, particularly the rise of a working class.⁸¹⁷ The individual was suddenly not merely separable from the community and his or her traditional social roles or class, but specially valued precisely as a distinctive, discrete individual. No longer could persons thus be reduced to their roles, to parts of the community. Rather, they were now separate individuals, possessing special worth and dignity precisely as individuals.⁸¹⁸

In this environment or because of this environment the modern state emerged, originally as a guarantor of an individual's rights against all-encompassing rights of kings, emperors and religious authority and as guarantor of a territorially confined order, in which resources and benefits were to be spread more evenly than the 'favouritism' of aristocratic elites. Soon, however, also the state threatened the individual citizen as it grew in power and as new elites emerged.⁸¹⁹ To forestall encroachments "freemen" began to demand that they indeed be free. Such demands eventually also took the form of arguments for universal natural rights, to be discussed below, as well as it reinforced a belief in the ideal of the equality of all men. In the new socially mobile society in which entrance to and exit from the bourgeois class was less predictable, a new set of privileges could not readily be reserved for a new elite defined by birth or some similar characteristic. Rather, "in order that some (the bourgeoisie) might be able to exercise these new rights, they had to be guaranteed for all."⁸²⁰ Thus, natural (or human) rights came to be articulated primarily as claims of any individual against the state.

In practice, of course, all these structural changes remain incompletely realized even today, are ongoing or have been restricted to a small segment of the population or society.⁸²¹ Nevertheless, as will be seen below human rights, emerging from this background, clearly have a special reference to the state, individualism and individual autonomy, for states' equal concern and respect for its population, which other traditions of thought might lack or emphasis less strongly.

1.4. Natural Rights

Against the backdrop of the liberal and enlightenment ideas and their socio-historical background, various scholars such as Hugo Grotius, Samuel Pufendorf and Locke developed theories of natural

⁸¹⁵ Alston/Steiner, note 214, 406.

⁸¹⁶ B. Wittrock, "Early Modernities: Varieties and Transitions", 127 *Daedalus*, 1998, 12 et seq.

⁸¹⁷ Ibid., 13.

⁸¹⁸ Ibid.

⁸¹⁹ E. Keene, *Beyond the Anarchical Society: Grotius, Colonialism and Order in World Politics*, 2002, 15

⁸²⁰ M. Ishay (ed.), *The Human Rights Reader: Major Political Essays, Speeches, and Documents*, 2007, 406.

⁸²¹ R. Howard/J. Donnelly, "Human Dignity, Human Rights and Political Regimes", 80 *American Political Sciences Review*, 1986, 801 et seq.

rights.⁸²² Natural rights theorists generally hold that there are universally applicable general rules or principles of conduct for human beings which have overriding moral authority. They command human beings and states to respect the rights arising from these rules in all their practices and associations. These rights or principles are claimed to derive from such sources as God, a state of nature or from some essential human quality or capability that necessitate the existence of such rights.⁸²³ Locke, one of the most prominent natural law theorists, for example, argued that certain rights self-evidently pertain to the individual.⁸²⁴ That is, these rights were derived from reason and hence from a source that was held to be rationally self-evident. Prehistoric humans in their above mentioned original “state of nature,” i.e. before humans began forming complex societies enjoyed certain “natural rights” which humans could discover through reason.⁸²⁵ Natural rights, maybe most prominently, obligated that “no one ought to harm another in his life, health, liberty or possessions.”⁸²⁶ Because of their self-evident and 'natural' character these rights then laid the rationale of certain inalienable 'human rights' that are attached to and derive from human being's innate qualities and capabilities.⁸²⁷

Hugo Grotius, widely credited with being one of the founding fathers of international law, similarly set forth a theory of natural laws and laws of nations. His treatise is about how the law of nature should affect the law of nations, how international law must serve as the foundation for universal human freedom.⁸²⁸ To Grotius "human law, like God's law, must be just. As God's creatures humans are endowed with the capacity of reason and blessed with the opportunity of sharing the gift of life."⁸²⁹ Natural law is “the dictate of right reason” necessary to human's rational and social nature.⁸³⁰ The system of rights and duties that flows necessarily from our essential nature as rational creatures living together in society is a just one.⁸³¹ Natural rights must both be respected and realized “irrespective of the inclinations of individual nation-states” as “the dictate of right reason” applies at all times to everyone, everywhere.⁸³²

⁸²² For an overview of natural law and its main proponents see Freeman, note 237, 89-139 and K. Haakonssen, *Grotius, Pufendorf and Modern Natural Law*, 1999. For influential contemporary approaches to or theories on natural law see Finnis, note 237; L. Fuller, *The Morality of Law*, 1969. See also S. Pufendorf, *The Law of Nature and of Nations*, 1674, at: <http://www.constitution.org/puf/puf-law.htm> (last visited 27.04.2012), arguing that justice and the law of nations derive from natural law.

⁸²³ Freeman, note 237, 90.

⁸²⁴ Locke, note 785, para 4 - 5.

⁸²⁵ *Ibid.*, para 6, 7.

⁸²⁶ *Ibid.*, para 6.

⁸²⁷ One practical applications of this rationale may be found in the English, American and French revolution in 1688, 1776 and 1789 respectively where the rhetoric of natural rights played a key role in the struggles against political absolutism. See B. Weston, "Human Rights", 6 *Human Rights Quarterly*, 1984, 257, 257-258.

⁸²⁸ J. Bacchus, "Groping toward Grotius: The WTO and the International Rule of Law", 44 *Harvard International Law Journal*, 2003, 533 et seq.; H. Grotius, *On the Law of War and Peace*, 1814. Book 1 at X, at: <http://www.constitution.org/gro/djbp.htm> (last visited 27.04.2012).

⁸²⁹ Bacchus, note 828, 534.

⁸³⁰ *Ibid.*

⁸³¹ *Ibid.*

⁸³² *Ibid.*, 536.

Natural rights theories therefore generally come with certain characteristics. For one, they usually hold that natural rights are discernible by reason. Because of their foundation in reason or some human essential qualities or generally in 'humanness', natural rights are seen to be universally valid and independent from time and social or historical culture. They moreover generally ground in the idea of human beings' special status or worth, which the natural rights are to protect. Next, because natural rights ground in humanness and humans' special features and status, they must be accessible by every human being equally and they have the purpose of preserving, to varying degrees, human beings' humanness and capacities.⁸³³ Good and natural is often associated with the nature of human beings, a concept to which God or another authority outside of the human being is often only of secondary importance.⁸³⁴ Another important feature is that an individual's rights, such as the protection of life and private property, are usually understood to constitute an essential aspect of individual autonomy against the state.⁸³⁵ Since only the exercise of these rights can protect the individual against arbitrary incursion by the powerful state and because the aim is to prevent the state from interfering with a human being's capacity to exercise autonomy and to reason,

“the list of [natural] rights comprised rather what have been termed negative freedoms, than positive liberty, that is, the freedoms that protect the individual from any outside invasion rather than the freedom of the individual or group to achieve its purposes or ideals”⁸³⁶

Finally, natural rights are usually individual rights that each individual may invoke and even enforce against the state and society. They presuppose an autonomous individual who can and is willing to form autonomous decisions. Most of these characteristics of natural rights, as will be seen below, are well reflected in modern human rights thought and doctrine.

2. Human Rights Law Today

2.1. *The Nomos of Modern Human Rights Law*

Of course, human rights by the time of their coming into existence were no longer tied to liberal, enlightenment traditions or natural law theories in their classical senses. Nor is today's human rights agenda or body of thought solely informed by liberal and enlightenment traditions of thought nor have human rights and their concepts ever been uncontested even in these liberal and enlightenment traditions of thought.⁸³⁷ Instead, human rights, by the time of their coming into

⁸³³ Weston, note 827, 259.

⁸³⁴ W. George, "Grotius, Theology, and International Law: Overcoming Textbook Bias", 14 *Journal of Land, Resources and Environmental Law*, 2000, 605 et seq.

⁸³⁵ New Encyclopedia Britannica, 'Entry on Natural Law', at: www.britannica.com (last visited 27.04.2012).

⁸³⁶ D. Sidorsky, "Contemporary Reinterpretations of the Concept of Human Rights", in: D. Sidorsky (ed.), *Essays on Human Rights*, 1979, 89 et seq.

⁸³⁷ See for example J. Bentham, *Critique of the Doctrine of Inalienable, Natural Rights, Anarchical Fallacies*, vol. 2, 1843, dismissing the idea of "the preservation of the natural and imprescriptible rights of man" with: "More confusion --

existence and ever since, were informed and are constantly further developed and extended through a variety of influences which can hardly be tied to a single monolithic body of thought. However, the influence of the liberal and enlightenment perspective has been a factor in the constitution and development of human rights, a factor that is still evident in several ways. Koskenniemi expresses this idea of the legacy of historical roots in the following way:

"I have not met an international lawyer who would have said: "Look, here is my liberal theory of politics. The international law which I teach is based on that theory."... And yet, I know of no modern international lawyer who would not have accepted some central tenet in it. Obviously this is not a matter of conscious political choice...[...]the case appears that if one tries to engage in the sort of debate about international legality which international lawyers undertake, then one is bound to accept an international legal liberalism. Self-determination, independence, consent and most notably the idea of a Rule of law, are all liberal themes. These themes create distinctively liberal problems: How to guarantee that states are not coerced by law imposed from above? How to maintain the objectivity of law? How to delimit off a "private" realm of sovereignty over domestic jurisdiction while allowing international action to enforce collective preferences or human rights? How to guarantee state "freedom" while providing the conditions for international "order"? These are all distinctly liberal problems..."⁸³⁸

According to this view modern human rights law reflects liberal and enlightenment traditions and has inherited many of their strands of thought and the conceptual riddles associated with it. What, according to Koskenniemi, makes it sometimes difficult to understand these traditions as materially controlling is that they usually claim to merely constitute a neutral framework within which substantive political choices can be made as opposed to a grand theory themselves.⁸³⁹ Yet, the liberal enlightenment worldview certainly has an impact on how and whether at all human rights emerged and on the way they are framed. It does so by providing the soil, and the philosophical and intellectual ferment and background from and into which human rights developed and often continue to do so. That is, these traditions form the *nomos* or normative universe of human rights in that they are part and parcel of the narratives, epics and stories that found and inform human rights, often also in their contemporary forms. Robert Cover, reflecting on the normative universe of human rights and their implication for general human rights jurisprudence, provides an example for how the founding story or epic, as part of human rights'

more nonsense, -- and the nonsense, as usual, dangerous nonsense. The words can scarcely be said to have a meaning..." and E. Burke, *Reflections on the Revolution in France*, 1790, which is highly critical of the philosophical foundations that brought about the Revolution, casting for example doubt on the "use of discussing a man's abstract right to food or medicine... The question is upon the method of procuring and administering them."

⁸³⁸ M. Koskenniemi, *From Apology to Utopia*, note 245, 5. Of course this is not to be understood as a factual account of human rights but as a means to show that human rights are indebted to certain ideas. Arguing along similar lines see also Weston, note 827, 262; Alston/Steiner, note 214, 472 et seq.; Freeman, note 237, 136; J. Gray (ed.), "Max Horkheimer: The Way They See and Hear Is Inseparable from the Social Life Process", in: J. Gray, *Enlightenment's Wake: Politics and Culture at the Close of the Modern Age*, 1999, 200 arguing that ours are "Ours are enlightenment cultures not by positive conviction but by default."

⁸³⁹ Koskenniemi, *From Apology to Utopia*, note 245, 5-6. One such way in which liberal thought for example controls without seeming to control is through the often discussed divide between a public and private sphere in law. The division of law in a public sphere, in which law is enacted and behaviour controlled by the state and a private sphere which is left to the private person to exercise his or her autonomy rests on a distinction between private and public spheres which is owed to liberal distinction between a public sphere in which the state has a role and a private sphere in which it has not. C. Chinkin, "A Critique of the Public/Private Dimension", 10 *European Journal of International Law*, 1999, 387 et seq.

*nomos*⁸⁴⁰, first of all, is heavily indebted to liberal and enlightenment tradition of thought and, secondly, lives on and impacts contemporary human rights thought.⁸⁴¹ According to him the myth that founds and underlies human rights is one of

“...social contract. The myth postulates free and independent if highly vulnerable beings who voluntarily trade a portion of their autonomy for a measure of collective security. The myth makes the collective arrangement the product of individual choice and thus secondary to the individual... “Rights” is the fundamental category because it is the normative category that most nearly approximates that which is the source of the legitimacy of everything else. Rights are traded for collective security. But some rights are retained, and ...[]... are inalienable.”⁸⁴²

Oversimplified, the story that founds and then informs human rights, according to Cover, presupposes a state of nature in which there exist individuals who are free and dispose over unlimited rights.⁸⁴³ In this setting the individual is the first and fundamental unit, and rights locate him as an individual separate and apart from every other individual, society and the state.⁸⁴⁴ Only through each individual's choice and free consent to trade some of his or her rights away, i.e. through a social contract, can there be a legitimate limitation of the rights of the individual. Yet, even then some of these original rights, so called human rights, are retained by the individual.

⁸⁴⁰ Cover, “*Nomos and Narrative*”, note 38, 95, 95 set seq. Law, according to Cover, is not to be conceived of as a system of rules and interpretations or a set of institutions but as a normative world, i.e. a *nomos*, in which legal rules and institutions interact with other cultural forces in the production of legal meaning. Ibid, at 145. That is, “no set of legal institutions exists apart from the narratives that locate it and give it meaning” – as “for every constitution there is an epic, for each decalogue a scripture.” Ibid. at 146. Of course it must be noted at the outset that narrative and founding stories cannot ‘explain’ human rights. They are not ‘real’ in the way historically discernible facts are ‘real’. Instead they are myths and stories that embed law and form part of ‘law’s universe’, that attempt to explain why human rights have come into existence in the way they have, why they are important and what their purpose is, yet they remain pieces of the larger picture that together ‘explains’ human rights, not the complete picture itself. Moreover, narratives, like discourses, are always contested by other narratives and there always exist different and sometimes competing narratives that seek to embed and ‘explain’ human rights. Ibid. 146. Nevertheless, narrative, in the form of popular, academic or other accounts, can provide some insight in the context and structure of the subject that it describes and thereby help embed and ultimately better understand it. The power of narratives in constituting and shaping understandings, views, ideas and ideals and their thereby very real impact on for example attitude and behaviour of people, groups, cultures, societies and governments has been widely researched. On narrative in a legal context see for example H. Arendt, *Eichmann in Jerusalem*, 1970; M. Osiel, *Mass Atrocity, Collective Memory, and the Law*, 1999; R. West, *Narrative, Authority and the Law*, 2004; D. Manderson, “Formalism and Narrative in Law and Medicine: The Debate over Medical Marijuana Use”, 29 *Journal of Drug Issues*, 1999, 121 et seq. In a medical context see S. Krippner/M. Bova/L. Gray (eds.), *Healing Stories: The Use of Narrative in Counselling and Psychotherapy*, 2007.

⁸⁴¹ R. Cover, “Obligation: A Jewish Jurisprudence of the Social Order”, 5 *Journal of Law and Religion*, 1987, 65 et seq.

⁸⁴² Cover, “Obligation: A Jewish Jurisprudence of the Social Order”, note 841, 66. Of course this is not to suggest that all or even most theories that are founded upon rights are “individualistic” or “atomistic.” Nor does this mean to suggest that with a starting point of “rights” and social contract one must get to a certain end. Thomas Hobbes, John Locke and Jean-Jaques Rousseau have all to some extent been part of this tradition yet they have arrived at different conceptions of states, their legitimate powers and individuals in the sense that they found more collective as well as more individualistic answers to the questions they posed. However, so Cover, even the collectively-oriented answers are arrived at by way of a theory that derives the authority of the collective from the individual. Cf. for example T. Hobbes, *Leviathan*, 1660, at: <http://oregonstate.edu/instruct/phl302/texts/hobbes/leviathan-contents.html> (last visited 27.04.2012), chapter XIII and XVIII.

⁸⁴³ Cover, “Obligation: A Jewish Jurisprudence of the Social Order”, note 841, 65 et seq. Similarly, for example Nussbaum, Amrtya Sen and John Rawls postulate an idea of social contract. See for example, M. Nussbaum, “Beyond the Social Contract: Capabilities and Global Justice”, The Tanner Lectures on Human Values, Delivered at Australian National University, Canberra, November 12 and 13, 2002 and at Clare Hall, University of Cambridge, March 5 and 6, 2003. Sen, Development as Freedom, note 769, 52 et seq.; and J. Rawls, *A Theory of Justice*, 1975.

⁸⁴⁴ Cover, “Obligation: A Jewish Jurisprudence of the Social Order”, note 841, 66 et seq.

These rights then are meant to guarantee a good order or society. In the human rights epic, it is mostly left to the state, as the product or end result of the social contract, to be the guarantor of these rights and to thereby establish a good moral order.⁸⁴⁵ The narrative of human rights thus constructs a particular vision of the human being as a free and autonomous human being who is capable and willing to form his or her decisions individually and who voluntarily trades some of his freedoms away in exchange for being part of society. It also postulates a particular ideal of a good society or good order and the means by which to achieve this good order – i.e. one that is based on each and everyone's enjoyment of and access to human rights within a state that acts to guarantee each and everyone's enjoyment of and access to human rights.

Cover contrasts this myth and the way it constructs the individual, the state and a good order with the myth that defines the Jewish jurisprudence of 'mitzvah',⁸⁴⁶ which, according to him, is a fundamentally different one though it is functionally equivalent to human rights.⁸⁴⁷ In contrast to the contract based theory that founds human rights the myth that founds the Jewish concept of 'mitzvah' is essentially one of heteronomy and not autonomy. It is the 'myth of Sinai' which gives meaning to the word 'mitzvah' which is

“a collective - indeed, a corporate – experience. The experience at Sinai is not chosen. The events give forth the words which are commandments... All law was given at Sinai and therefore all law is related back to the ultimate heteronomous event in which we were chosen...”⁸⁴⁸

In the myth that founds the concept and jurisprudence of mitzvah the autonomy and individuality of each and everyone consequently is of lesser importance than in a human rights context. The individual's consent to whether or not a jurisprudence of mitzvah is to be established is in fact irrelevant as it is God who chooses the collective people of the Jews no matter an individual's consent.⁸⁴⁹ Also the means and concepts used to establish a good order significantly differ from that based on the establishment of the “rule” of human rights. There are no rights that an individual retains and that he or she is at liberty to invoke against a state. Thinking of the Jewish concept of mitzvah in terms of rights is generally amiss as there is no choice as to whether or not an individual accepts a jurisprudence of mitzvah. Moreover, the state is largely irrelevant to the concept of mitzvah as responsibilities are owed to God and not to the state. The founding stories or myths underlying human rights and mitzvah and their implications for the respective core concepts of human rights and mitzvah thus contrast in several important ways. They, for example, rather markedly differ with regard to the status of the individual, as concerns questions of free choice or

⁸⁴⁵ See for example J. Slaughter, *Human Rights, Inc.: The World Novel, Narrative Form, and International Law*, 2008, 1 et seq..

⁸⁴⁶ According to Cover the "word mitzvah literally means "commandment", it is not a right - and "it has a general meaning closer to "incumbent obligation."" Mitzvah thus is fundamentally a concept of duty not of entitlement. In fact, Cover concludes "in Jewish law an entitlement without an obligation is a sad, almost pathetic thing." Cover, "Obligation: A Jewish Jurisprudence of the Social Order", note 841, 145.

⁸⁴⁷ Ibid., 146

⁸⁴⁸ Ibid.

⁸⁴⁹ Ibid.

autonomy of the human being, on the question of the means by which a good or legitimate order is to be realized and the relevance and role of the individual and state in securing this order. To some extent then the founding story of social contract reflects many of the abovementioned liberal and enlightenment tenets and core principles, including that of autonomy, individual rights and the state as the protector of these rights.

In summary, liberal, enlightenment and natural law traditions of thought thus had and have a significant impact on the ideas and ideals that inform human rights, on the range of concepts that are relevant in the field, on the content of human rights concepts and the methodology used by human rights to resolve the issues it tackles. That is, human rights self evidently pertain to each individual. They are viewed as (morally) prior to and above society and the state. They emphasise a person's autonomy, equality, individuality and dignity and are linked to human beings' innate capacity to reason i.e. to human beings humanness. They are rights, not duties and, at least when first conceived of within the UDHR, they were mainly negative rights, i.e. rights that restrict rather than incite the state to act.⁸⁵⁰ The state has a duty to protect them, it is the guarantor of a good order.

In terms of epistemological concepts (grid points) that constitute a human rights discourse it may then be fair to say that any such discourse is based on the following structure giving concepts. First, it is based on the idea and concept of individual rights or legal entitlements that self-evidently pertain to each and everyone equally. Secondly, it is based on the idea and concept of that each everyone has human dignity simply qua being human and that this dignity must be or is best to be protected through the aforementioned individual rights. Third, any such discourse is about the idea and concept of a nation state as main guarantor and threat to human rights. Fourth, it is somehow linked to the idea and concept of universality as all human rights, if they have to have to be valid for everyone i.e. if they can be identified by the rational mind and inhere in the human being, must apply to everyone equally and must be the same for everyone everywhere. Finally any such discourse is about the idea and concept of autonomy which, as the natural birth right of each and every person, has to be protected in a human rights discourse. The following section will explain the idea and concept of each of these structure giving points as relevant to a human rights discourse.

2.2. Episteme of the Standards in the Area of Bioethics

So far it has been established why and how the just identified epistemological concepts came to be important to human rights discourses. This section then focuses on how these epistemological concepts are charged in a modern human rights discourse, i.e. how they are conventionally

⁸⁵⁰ See discussion under Chapter IV, 1.3.

understood or interpreted in a modern human rights discourse. It will thereby be seen that while these concepts are still to some extent wedded to and informed by the traditions that gave birth to them they have obviously also been extended and developed since. The following sections therefore discuss the nature, meaning and scope of each of these concepts as far as is relevant to a contemporary human rights discourse.

2.2.1. Human Rights as Rights or Principles

One characteristic and structure giving concept to any human rights discourse and to the discourse that takes place in the area of bioethics is that the standards are couched in a language of rights. With regard to the standards directly addressed to matters of bioethical interest it must, however, first be discussed to what extent these provisions are at all rights and/or to what extent they are principles and what the concept of a right entails.

In definitional terms, a right, according to the Oxford dictionary of law, is (1) a title to or an interest in any property (2) any other interest or privilege recognised and protected by law (3) freedom to exercise any power conferred by law. Rights can thus denote several meanings. They can be a claim to something (e.g. to property), a liberty to do something (e.g. to move or to seek employment), or a power to do something (e.g. to destroy property or to make certain decisions).⁸⁵¹ Principles, are hardly defined in legal dictionaries, at least not without the affix of “general principles of international law”.⁸⁵² If used in legal texts principles are often taken to be general moral ideals or ideas, sometimes legally codified, that help make decisions in that they can help form and direct a decision. They are “a reason that argues in one direction but does not necessitate a particular decision ... all that is meant when we say that a particular principle is a principle of our law, is that the principle is one which officials must take into account if it is relevant as a consideration inclining in one direction or another.”⁸⁵³

From this short reflection on the nature of principles and rights it can be inferred that one distinction between rights and principles then is that human rights have right holders – a person or agency having a particular right who has the freedom to invoke that right. Principles in contrast have no holder as such who could invoke a principle in courts. They form the background to decisions but are not attached to one specific person or entity.⁸⁵⁴ Next, human rights, at least to the extent that they form part of the non-derogable core of human rights as enshrined in such

⁸⁵¹ E. Martin (ed.), *Oxford Dictionary of Law*, 2002, 56.

⁸⁵² See also B. Cheng, *General Principles of Law as Applied by International Tribunals*, 1951 and Malanczuk, note 204, 48 - 49.

⁸⁵³ Dworkin, *The Models of Rules*, note 310, 26.

⁸⁵⁴ *Ibid.*

international legal standards as the ICCPR or to the extent that they form part of non-derogable international customary law must offer the same standard of protection for all those being under the jurisdiction of a state that has signed up to the standard.⁸⁵⁵ Principles in contrast can apply differently to different entities for example, when a principle in equity seeks to balance differences in bargaining power. To have a human right to x (e.g. the right to have my autonomy respected or the right to not to be abused as research subject in dangerous experiments) moreover asserts that the state has a duty not to prevent the right-holder from x (i.e. to respect his or her autonomy and not to abuse him or her as a research subject in dangerous experiments).⁸⁵⁶ That is, the addressee of human rights, including of those in the area of bioethics, are mostly states and it is states that have clear duties that correlate the right.⁸⁵⁷ Principles, in contrast, can be addressed to states but can also be general considerations such as principles of equity which are not necessarily addressed to one entity or can obligate various entities. In any event, principles do not necessarily correlate a clear duty on the part of the state or any other stakeholder but can be of a more general nature, such as that *pacta sunt servanda*.⁸⁵⁸ Next, to have a human right to x implies a person is entitled to x. It is owed to the bearer of the right. If x is threatened or denied a human right-holder is “authorized to make special claims that ordinarily trump utility, social policy, and other moral or political grounds for action”.⁸⁵⁹ That is, human rights can – to some extent at least- be enforced, no matter if there are good reasons for why they should not be enforced. Principles in contrast are more often statements that suggest that it is desirable, good or right in a moral or legal sense that someone enjoys what the principle entails. While it might be right or good in a moral or legal sense that these principles are observed, they usually cannot, standing by themselves be enforced. Endorsing this principle is not owed to anyone, it does not trump other considerations. In the words of Dworkin, principles are to be distinguished from rules (rights) “in the character of the discretion they give⁸⁶⁰, for while rules are applicable in a all or nothing fashion, principles allow for discretion.⁸⁶¹ Moreover, according to Dworkin, principles can conflict with each other, whereas if rules conflict with each other, a superior rule has to be established determining which rules is to be given priority.⁸⁶² Finally, rights only apply to certain injuries whereas principles can be much broader in scope. In the case of human rights that means that besides the requirement for a human right to be violated by a state or state agent human rights only cover certain areas of misconduct.

⁸⁵⁵ Non-derogable rights are set out in the ICCPR, note 219, in Article 4, (2) which holds that “no derogation from articles 6, 7, 8 (paragraphs 1 and 2), 11, 15, 16 and 18 may be made under this provision”.

⁸⁵⁶ J. Waldron, “Rights”, in: R. Goodin./P. Pettit, *A Companion to Contemporary Political Philosophy*, 1995, 575, 575.

⁸⁵⁷ H. Steiner, “The Youth of Rights”, 104 *Harvard Law Review*, 1999, 929, 929. The only exception might be the UDBHR that seeks to give guidance to non-state actors, see UDBHR, note 4, Article 2. However while it seeks “to provide a universal framework of principles and procedures to guide States in the formulation of their legislation, policies or other instruments in the field of bioethics” it merely wants to “to guide the actions of individuals, groups, communities, institutions and corporations, public and private” which is a weaker form of obligation than that formulated in relation to states.

⁸⁵⁸ Malanczuk, note 204, 45.

⁸⁵⁹ Dworkin, *Taking Rights Seriously*, note 788, xi.

⁸⁶⁰ Dworkin, “The Models of Rule”, note 310, 24.

⁸⁶¹ *Ibid.*, 26.

⁸⁶² *Ibid.*, 29. He also argues that a principle can change over time, a rule remains the same or is discharged altogether.

Principles in contrast can be much broader than rights and can hence in theory be applied to a wider variety of circumstances.

In short, the term 'rights' usually refers to a legally enforceable set of expectations as to how others, most obviously the state, should behave towards rights bearers. These expectations may take the form of limitations on, and/or requirements of, the behaviour of others. Rights bearers have to be entities legally considered to possess 'personality' – that is, legally deemed to be autonomous moral agents – and therefore capable of taking decisions and accepting responsibilities, as in the case of adult persons, trade unions, corporations, or states.⁸⁶³ Principles in contrast are much broader, have no clear addressee or holder and cannot be enforced in court. Their content is broader defined and they can be breached without giving rise to any obligation to set someone right.

In practice however, these distinctions between rights and principles cannot be easily maintained and they are often blurred, particularly when used in a human rights context.⁸⁶⁴ That is so because the term rights, particularly when used in a human rights context is “chameleon-like”⁸⁶⁵ in the sense of that it can describe a variety of legal relationships. In the provisions enshrined in the Bill of Human Rights and most of the more recent human rights standards rights can for example be formulated as positive rights such as “everyone's right to for example life and liberty or security”⁸⁶⁶, formulated negatively such as “no one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment”⁸⁶⁷ or neither be framed as a positive nor as a negative right at all. Article 10 of the ICESCR, for example, reads that “States Parties to the present Covenant recognize that: 1. The widest possible protection and assistance should be accorded to the family, which is the natural and fundamental group unit of society, particularly for its establishment and while it is responsible for the care and education of dependent children. Marriage must be entered into with the free consent of the intending spouses.”⁸⁶⁸ Similarly vague formulations can be found in more recent human rights standards, such as the UN Declaration on Social Progress and Development which uses formulations, such as “social progress and development require the full utilization of human resources, including, in particular: (a) The encouragement of creative initiative under conditions of enlightened public opinion....”⁸⁶⁹ or as the Declaration of Commitment on HIV/Aids which in para 42 holds that states “encourage and support local and national organizations to expand and strengthen regional partnerships,

⁸⁶³ A. Woodiwiss, *Human Rights*, 2005, xi.

⁸⁶⁴ N. MacCormick, *Legal Reasoning and Legal Theory*, 2008, arguing that the differences between rules and principles can be over-emphasised. And Alexander/Kress, note 311 , 292- 300. See also the concept of principles as used in Rawls, *A Theory of Justice*, note 843, 10 et seq. and generally Shaw, note 622, 247 and J. Waldron, *Theories of Rights*, 1984.

⁸⁶⁵ J. Shestack, “The Jurisprudence of Human Rights”, in: T. Meron (ed.), *Human Rights in International Law*, 1986, 69, 70.

⁸⁶⁶ ICCPR, note 341, Article 6.

⁸⁶⁷ Ibid., Article 7.

⁸⁶⁸ See for example Alston/Steiner, note 214, 345.

⁸⁶⁹ UN Declaration on Social Progress and Development, proclaimed by GA Res 2542 (XXIV), 1969, Article 5.

coalitions and networks.”⁸⁷⁰ In all these instances rights can imply different meanings and commitments. Some, for example, are intended as immediately enforceable binding commitments, others merely as specifying a possible future. Particularly many of the social, cultural and economic rights can be used and often have been interpreted in the latter sense of specifying a future possibility yet are still being referred to as rights.⁸⁷¹ If used in this sense there, however, hardly seems a difference to the concept of principle which is also usually taken so as not to create an immediately enforceable binding commitment. On the other hand some of the principles endorsed in the presently examined standards, for example, those referring to informed consent could be seen as to give rise to justiciable, and immediately binding commitments or at least as being as close to doing so as a right to health that is to be progressively realised.⁸⁷² Next, sometimes a human right has a clear rights-bearer such as the autonomous individual who has a right to life and liberty. However, some human rights are more difficult to assign to an autonomous individual or specific rights holder. With regard to the right to self-determination or many rights in the area of environmental law, for example, as Waldron points out, there has been a movement to recognize and to enforce group claims to self-determination or to for example a sustainable environment as a basic human right.⁸⁷³ Groups, however, are not easily defined so that at least in relation to those rights there is not a clear right holder. Moreover it is not quite clear how a group's right to sustainable environment distinguishes from a principle formulating a group's claim to sustainable environment. In both cases it is not clear who may invoke that right or principle and how it may or must be operationalised in a judicial systems or how it may be enforced. In the same way it is difficult to assign a clear rights bearer to a right to transnational cooperation or benefit sharing in the area of bioethics. It is for example, not clear how an individual could invoke this right and in what form and to what extent it is owed to him or her. Moreover, even though human rights in principle are addressed to the state while principles are not necessarily solely addressed to the state it is sometimes difficult to see how some human rights can be meaningful without a variety of stakeholders, including but not limited to the state, observing them.⁸⁷⁴ For example the right of future generations to sustainable development requires everyone to act upon this right.⁸⁷⁵ Next,

⁸⁷⁰ UN Declaration of Commitment on HIV/AIDS, adopted by GA, GA Res S-26/2, 2001.

⁸⁷¹ For general discussion see Alston/Steiner, note 214, 345. But see also B. Simma/S. van Bennigson, "Wirtschaftliche, Soziale, Kulturelle Rechte im Voelkerrecht", in: J. Baur/K. Hopt/K. Mailaender (eds.), *Festschrift fuer Ernst Steinsdorff zum 70. Geburtstag*, 1990, 1477, arguing that the ICESCR is justiciable but does not grant individual rights; and B. Simma, "The implementation of the International Covenant on Economic and Social and Cultural Rights", in: F. Matscher (ed.), *Die Durchsetzung Wirtschaftlicher und Sozialer Grundrechte*, 1991, 75 et seq.; E. Riedel, "New Readings to the State Reporting Procedures: Practical Ways to Operationalise Economic, Social and Cultural Rights - the Example of the Right to Health", in: S. von Schorlemer, *Praxishandbuch UNO, Die Vereinten Nationen im Lichte Globaler Herausforderungen*, 2003, 345 et seq.

⁸⁷² A. Eide, "Economic, Social and Cultural Rights as Human Rights", in: A. Eide/C. Krause/A. Rosas, *Economic, Social and Cultural Rights: A Textbook*, 2001, 9, 10; E. Vierdag, "The Legal Nature of the Rights Granted by the International Covenant on Economic, Social and Cultural Rights", 9 *Netherlands Yearbook of International Law*, 1978, 69, 103.

⁸⁷³ Waldron, Rights, note 856.

⁸⁷⁴ J. Feinberg, "Duties, Rights and Claims", 3 *American Philosophy Quarterly*, 1966, 137.

⁸⁷⁵ R. Andorno, "Global Bioethics at UNESCO: In Defence of the Universal Declaration on Bioethics and Human Rights", 33 *Journal of Medical Ethics*, 2007, 150, 155.

human rights also, in many ways, much like in the case of principles, are value driven or based on broad moral and ethical principles. While other considerations certainly played into the establishment of international human rights standards at some level these standards were and are inspired by a desire to promote certain broad moral values and ideals, namely that human beings are endowed with certain inalienable rights which are to be protected at the international level by an international standard.⁸⁷⁶ That, however, is exactly a quality that was previously assigned to principles only. Finally, both rights and principles can conflict with other rights or principles. The right to health can as much conflict with a right to religious freedom without one of these rights necessarily having to be abrogated as the principle that freedom of religion should be observed can conflict with the principle that everyone's health should be insured.

Assessing the provisions of the standards in the area of bioethics against what has just been laid out in terms of rights and principles it should first be noted that only few of the provisions in these standards are formulated as 'positive' rights of individuals. In fact, merely the Oviedo Convention formulates positive rights by using, for example, in Article 10 such formulations as (1) "everyone has the right to respect for private life in relation to information about his or her health" and that (2) "everyone is entitled to know any information collected about his or her health." Negative rights arguably are created by a range of provisions in the Oviedo Convention as well as through UDBHR's Article 6 on consent which reads that "any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information" or through the International Declaration on Human Genetic Data which in its Article 13 states that "no one should be denied access to his or her own genetic data or proteomic data unless such data are irretrievably unlinked to that person as the identifiable source or unless domestic law limits such access in the interest of public health, public order or national security." Most of the Oviedo Convention's Articles can be taken to formulate rights negatively.⁸⁷⁷ The majority of the provisions of the UNESCO standards, however, do not seem to create any specific rights, negatively or positively formulated, at all.⁸⁷⁸

It may, however, be fair to correlate the positive and negative rights formulated in the standards directly addressed to matters of bioethical interest with those formulated in the ICCPR and ICESCR and therefore to assume that these provisions are meant to create some sort of rights. At least in the case of the Oviedo Convention, which creates binding obligations on states, this seems mostly justified. That view is also supported by that Article 26 of the Oviedo Convention holds that "no restrictions shall be placed on the exercise of the rights and protective provisions contained in this Convention" and by that article 1 states that "Parties to this Convention shall protect the

⁸⁷⁶ Cf. Cassese, note 203, 376-7. For alternative opinions see for example Alston/Steiner, note 214, 421 et seq.

⁸⁷⁷ Oviedo Convention, note 5, for example through Article 5 which states that "an intervention in the health field may only be carried out after the person concerned has given free and informed consent to it."

⁸⁷⁸ The UDBHR's, note 4 Article 12, for example, reads that "the importance of cultural diversity and pluralism should be given due regard. However, such considerations are not to be invoked to infringe upon human dignity, human rights and fundamental freedoms, nor upon the principles set out in this Declaration, nor to limit their scope."

dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine.” It thus seems that with regard to the Oviedo Convention there is an understanding that it creates some individual rights. The same cannot, however, be assumed with regard to the provisions of the UNESCO standards or the UN Cloning Declaration. Here it seems that the standards did not so much aim to create individual rights than to lay down guiding principles that might give rise to rights now or in the future. For the perspective that standards lay down individual rights speaks that these standards refer to themselves as human rights standards, that they are referred to as such by OHCHR⁸⁷⁹, and that they endorse, extend and strengthen, as discussed above, existing human rights by reformulating, adapting and construing existing human rights to apply to a new context, that of bioethics. As such they at least anchor their provisions in a rights based philosophy. Moreover, with regard to some of the principles enshrined in the standards, such as those on autonomy and consent, it is hard to see who should be the beneficent if not the individual who is entitled to have his or her autonomy respected. This at least seems to show that there is some recognition that the provisions in the standards could at some point be transformed into or already may be giving rise to individual rights. Moreover, other Human Rights Conventions such as the Convention on the Elimination of All Forms of Discrimination against Women or those non-binding standards mentioned above, use similarly worded provisions.⁸⁸⁰ Most importantly, however, it is the aim of all the standards directly addressed to the area of bioethics to protect human rights and human dignity in the respective specific areas covered.

On the other hand, for the perspective that these provisions are principles speaks their rather vague formulation and the fact that they themselves refer to the provisions they specify as “principles”. In this thesis it will therefore be assumed that the UNESCO standards in the area of bioethics do not create rights per se but are, with the limited exceptions mentioned above, meant to lay down principles that may be the stepping stone to rights or can give rise to rights but are not rights themselves.

Nevertheless, for the purpose of this thesis differences between principles and rights will be assumed to be of little relevance overall. That is, to the purpose of this thesis principles and rights that are inscribed in the standards seem conceptually close enough and their implications similar enough that both these concepts' implications will then be discussed under the same headings in the next chapter. That is, in the following chapter this thesis will only where absolutely necessary draw a distinction between implications following from a use of rights and those following from a use of principles and otherwise deal with implications of both under the same headings.

⁸⁷⁹ See list of standards referred to as human rights standards at: <http://www2.ohchr.org/english/law/index.htm#instruments> (last visited 27.04.2012).

⁸⁸⁰ CEDAW, note 300, in Article 6 for example states that “States Parties shall take all appropriate measures, including legislation, to suppress all forms of traffic in women and exploitation of prostitution of women.” Here a right is created even though the right itself is not directly so formulated.

2.2.2. Human Dignity and Human Rights

The second grid point that is of fundamental importance to and constitutive of a human rights discourse, including the one in the area of bioethics, is the centrality of the concept of human dignity. Human dignity is a cornerstone and one *raison d'être* for human rights. In the area of bioethics, human dignity was identified as the ethical principle to which virtually all provisions in the area of bioethics must relate as well as it occupied more specific functions throughout the instruments in the area of bioethics, such as a barrier to human cloning⁸⁸¹ and to germ line intervention.⁸⁸²

However, while, as discussed above, the principle is well enshrined as a mostly ethical principle in international law⁸⁸³ and even though the notion of human dignity is at the heart of the several major international human rights instruments, it is as Andorno notes "never explicitly defined by them, other than making it clear that dignity is "inherent... to all members of the human family"⁸⁸⁴ i.e. that it is inseparable from the human condition."⁸⁸⁵ Moreover, it is usually understood that all human beings are "free and equal in dignity;"⁸⁸⁶ that "human rights derive from the inherent dignity of the human person"⁸⁸⁷ and that recognition of the inherent dignity "of all members of the human family is the foundation of freedom, justice, and peace in the world."⁸⁸⁸ The source of dignity thus seems to be every human beings' 'humanness' and respect for that dignity can lead to a well ordered, free and just society. Yet human rights standards generally do not specify what humanness is or how it comes about, i.e. whether it stems from human's ability to reason or from a divine or transcendental source, whether it just is and who exactly qualifies as a member of the 'human family'. It is worth noting in addition that from the wording of human rights standards it is not quite clear whether the concept of human dignity is an absolute one. That is, if used in a human rights context, human dignity is sometimes specifically targeted as a concept or quality that needs to be protected and sometimes as a quality or concept the respect of which is worth supporting. For example, article 22 of the UDHR states that "everyone, as a member of society, has the right to social security and is entitled to realization, through national effort and international co-operation and in accordance with the organization and resources of each State, of the economic, social and

⁸⁸¹ Universal Declaration on the Human Genome, note 4, Article 11.

⁸⁸² Ibid., Article 24.

⁸⁸³ See discussion in Chapter IV, 1.3.

⁸⁸⁴ UDHR, note 270, Preamble.

⁸⁸⁵ R. Andorno, "Human Dignity and Human Rights as a Common Ground for a Global Bioethics", 34 *The Journal of Medicine and Philosophy*, 2009, 195 et seq.

⁸⁸⁶ Ibid. See also Universal Declaration on the Human Genome, note 4, Article 1.

⁸⁸⁷ ICCPR, note 341; and ICESCR, note 341, Preambles. While the concept of human dignity has always been of special significance to the area of human rights it seems, if possible, to have gained even more prominence in the context of bioethics. That is, many of the recent articles that deal with human dignity and half of the books recently published on the concept of human dignity are somehow related to bioethics. Andorno, "Global bioethics at UNESCO: In Defence of the Universal Declaration on Bioethics and Human Rights", note 875, 155.

⁸⁸⁸ UDHR, note 270, Preamble.

cultural rights indispensable for his dignity and the free development of his personality." Here the achievement of certain rights is indispensable for the enjoyment of dignity, i.e. it seems that dignity is dependent on the achievement and observance of these rights. Similarly, Article 11 of the UDBHR holds that "no individual or group should be discriminated against or stigmatized on any grounds, in violation of human dignity, human rights and fundamental freedoms". On the other hand, other articles stress the importance of ensuring respect for human dignity. Article 10 UDBHR holds for example that the fundamental equality of all human beings in dignity and rights is to be respected so that they are treated justly and equitably.⁸⁸⁹ Thus, the notion of dignity is used in at least two senses or at two levels in human rights provisions, as something that deserves or has to be protected in itself and as something the respect for which is to be furthered and protected by standards.

While human dignity is an important concept in many religions, as well as in moral and political philosophy and can therefore have many different meanings and connotations in a human rights context human dignity is usually tied to three claims which together form the "basic minimum content" of the concept of human dignity.⁸⁹⁰ For one, the concept contains an ontological claim about the intrinsic worth of the human person. That is, it is claimed that every human being possesses an intrinsic worth, merely by being human and that human beings, by virtue of their fundamental equality not in terms of actual achievement but capacity and potential possess dignity equally.⁸⁹¹ That dignity, moreover, cannot be lost or discharged, enhanced or diminished, taken away or bestowed upon someone else as a function of achievement, class, gender, religious affiliation etc. It is worth noting that the ontological claim is frequently related back to Kant's concept of human dignity, discussed above. Based on that understanding human dignity, when used in a human rights context is usually portrayed as a secular concept that stems from human beings' innate capability to exert reason, and humans' duty and ability to act morally and to constitute ends. However, that is not an authoritative interpretation of the foundation of human dignity and the notion of human dignity can and is claimed by for example various religious groups and movements. Nevertheless, while the ontological claim does not clearly state how or why it is that human dignity exists it still shows that this conceptualisation of human dignity differs from other possible conceptualisations of the concept that tie dignity to for example social status, achievement or gender, give it a communitarian notion in the sense that dignity is something that only a member of a certain community, such as a certain cast or group, obtains, or that construe it so that it admits of degree, etc.

The second claim that human dignity comes with when used in a human rights context is that it contains a relational claim about how others should treat human beings in view of their inherent

⁸⁸⁹ See H. Schmidt, "Whose Dignity? Resolving Ambiguities in the Scope of "Human Dignity" in the Universal Declaration on Bioethics and Human Rights", 33 *Journal of Medical Ethics*, 2007, 578 et seq.

⁸⁹⁰ C. McCrudden, "Human Dignity and Judicial Interpretation of Human Rights", 19 *European Journal of International Law*, 2008, 655, 657.

⁸⁹¹ *Ibid.*, 658-659.

value.⁸⁹² That is, the intrinsic worth of every human being is to be "recognized and respected by others, and some forms of treatment by others are inconsistent with, or required by, respect for this intrinsic worth."⁸⁹³ Since all human beings are the bearer of human dignity equally they for example must be treated equally and without discrimination of any kind.⁸⁹⁴ Again this conceptualisation can differ from other traditions which require differential treatment depending on for example gender, class, status, association with certain groups, etc.

Finally, the third element of human dignity in a human rights context is supplied by the human rights framework itself and concerns the relationship between the state and the individual.⁸⁹⁵ The idea is that the state exists for the good of persons and not vice-versa and that the state has to ensure that each human being can access and enjoy his or her human rights, conducive to his or her human dignity.⁸⁹⁶ Again this claim sets the concept of human dignity as used in a human rights context apart from the way it is construed in other contexts. As mentioned above, the state has little role to play in relation to the concept of human dignity as advanced for example through a jurisprudence of mitzvah.

To summarise, human dignity when used in a human rights context thus carries a somewhat specific meaning, which is probably best described by that it comes with an ontological and relational claim and a special understanding of the state and its role in relationship to the individual.⁸⁹⁷ Yet, even while it seems that these three basic cores of human dignity when used in a human rights context are generally accepted among scholars, politicians and the wider public, the concept is still far from being clear. That is, scholars still differ in terms of "their understanding of what the intrinsic worth of the individual human being consists in (ontological claim) and who it applies to or what its foundation is, in their understanding of what forms of treatment are inconsistent with the inherent worth of the human being (relational claim), and in their understanding of what the detailed implications of accepting the ontological and relational claims are for the role of the state vis-à-vis the individual, beyond the core idea that the individual does not exist for the state."⁸⁹⁸ In other words, there nevertheless "appears to be no consensus, politically, [legally] or philosophically, on how any of the three claims that make up the core of the concept are best understood nor is there any final agreement regarding the foundation of dignity."⁸⁹⁹

⁸⁹² Ibid., 659.

⁸⁹³ Ibid., 672.

⁸⁹⁴ See also R. Dillon, "Respect", in: E. Zalta (ed.), *Stanford Encyclopedia of Philosophy*, Fall 2010 Edition, at: <http://plato.stanford.edu/archives/fall2010/entries/respect/>. (last visited 27.04.2012).

⁸⁹⁵ McCrudden, Human Dignity and Judicial Interpretation of Human Rights, note 890, 672.

⁸⁹⁶ Ibid.

⁸⁹⁷ Ibid., 659.

⁸⁹⁸ Ibid.

⁸⁹⁹ Ibid.

2.2.3. The Sovereign States

A further grid point essential to any human rights discourse is, as has been mentioned at various points before, human rights' connection with state authority. Human rights usually only exist in relation to a state or supranational entities such as the European Union and only to a very limited extent in relation to private actors. In the words of Thomas Pogge "to engage human rights, conduct must be in some sense official."⁹⁰⁰ This dictum is somewhat changing with the introduction of soft law, such as the UDBHR that addresses itself also to non-state actors.⁹⁰¹ However, it should be noted that the UDBHR merely seeks to give guidance to non state actors, it does not bind them nor is it in fact properly addressed to non-state actors in the sense that it called specifically on them in the preamble or title. It is also difficult to see how the vague reference to "guidance" as stated in Article 2 of the UDBHR could be construed to give rise to any obligations. The term guidance in fact implies that it is up to the individual non-state actor to follow up or not on that guidance. Therefore, as long as it is unclear to what extent non-state actors are addressed, obliged and how obligations on non-state actors are to be operationalised this thesis will assume that standards in the area of bioethics are still mainly addressed to states and obligate, if at all, only states.

The connection with the state is reflected in the standards in the area of bioethics in several ways. For one, they are primarily addressed to states, bind states and require or allow states to act in certain ways. The Oviedo Convention starts off by making it clear that it is "the member States of the Council of Europe, the other States and the European Community which are signatories here to [i.e. to the Convention]". Only states can sign and ratify the Convention and it can only entry into force between states.⁹⁰² Moreover, only states can at the time of signature specify the territory or territories to which the Convention shall apply⁹⁰³, make reservations⁹⁰⁴, denounce the Convention⁹⁰⁵ and only states are to be notified by the Secretary General of the Council of Europe of any further state that has signed⁹⁰⁶, ratified, accepted, approved or acceded to⁹⁰⁷ the Convention, of the date of entry into force of the Convention⁹⁰⁸, of any amendment or Protocol adopted and of the date on which such an amendment or Protocol enters into force⁹⁰⁹, of any declaration⁹¹⁰, reservation or withdrawal of reservation made by any signatory⁹¹¹ or of any other

⁹⁰⁰ T. Pogge, "The International Significance of Human Rights," 4 *Journal of Ethics*, 2000, 45, 47.

⁹⁰¹ Article 2, UDBHR, note 4.

⁹⁰² Oviedo Convention, note 5, Article 33.

⁹⁰³ Ibid., Article 35.

⁹⁰⁴ Ibid., Article 36.

⁹⁰⁵ Ibid., Article 37.

⁹⁰⁶ Ibid., Article 38 a.

⁹⁰⁷ Ibid., Article 38 b.

⁹⁰⁸ Ibid., Article 38 c.

⁹⁰⁹ Ibid., Article 38 d.

⁹¹⁰ Ibid., Article 38 e.

⁹¹¹ Ibid., Article 38 f.

act, notification or communication relating to this Convention.⁹¹² Also the UDBHR, as was just discussed, is primarily addressed to states.⁹¹³

Standards in the area of bioethics and everywhere else also nearly only create obligations for states. Article 1 of the Oviedo Convention for example holds that “parties [that is states] to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine.” Similarly, chapter VIII of the Oviedo Convention makes it clear that it is states that shall provide appropriate judicial protection to prevent or to put a stop to an unlawful infringement of the rights and principles set forth in the Convention⁹¹⁴, compensate for undue damage,⁹¹⁵ provide for sanctions⁹¹⁶, that may restrict the exercise of the rights enshrined in the Convention⁹¹⁷, grant a wider measure of protection with regard to the application of biology and medicine than is stipulated in the Convention⁹¹⁸ and that should ensure that the fundamental questions raised by the developments of biology and medicine are the subject of appropriate public discussion.⁹¹⁹ In the same way does UDBHR's Article 22, defining the role of states, for example, hold that, it is (1) “[s]tates [that] should take all appropriate measures, whether of a legislative, administrative or other character, to give effect to the principles set out in this Declaration in accordance with international human rights law.” Only “[s]tates should encourage the establishment of independent, multidisciplinary and pluralist ethics committees...”⁹²⁰, it is “[s]tates [that] should foster international dissemination of scientific information and encourage the free flow and sharing of scientific and technological knowledge⁹²¹ and “[s]tates [that] should promote cultural and scientific cooperation and enter into bilateral and multilateral agreements enabling developing countries to build up their capacity to participate in generating and sharing scientific knowledge.”⁹²² In effect, only states therefore have legitimate roles in the negotiations leading up to the conclusion of standards at the international level, and only they have a role in their implementation or any further dealings with it.⁹²³

It was briefly discussed above how the emergence of the modern nation state intersected with the development of human rights. Yet, some further reflection regarding the concept, meaning, scope and use of the term “state” is clearly warranted in order to understand this concept's implications

⁹¹² Ibid., Article 38 g.

⁹¹³ UDBHR, note 4, Article 1. Only as far as appropriate and relevant it is meant to also provide guidance (not rules) to decisions or practices of individuals, groups, communities, institutions and corporations, public and private.

⁹¹⁴ Oviedo Convention, note 5, Article 23.

⁹¹⁵ Ibid., Article 24.

⁹¹⁶ Ibid., Article 25.

⁹¹⁷ Ibid., Article 26.

⁹¹⁸ Ibid., Article 27.

⁹¹⁹ Ibid., Article 28.

⁹²⁰ UDBHR, note 4, Art 22 (2) and Article 23.

⁹²¹ Ibid., Article 24 (1).

⁹²² Ibid., Article 24 (2).

⁹²³ Ibid., Article 27.

for the presently examined discourse. Most significantly maybe states when referred to in international human rights standards and international law generally are considered to be sovereign states, i.e. the “supreme authority within a territory” and the sole legitimate actor on the world stage.⁹²⁴ Sovereignty thereby, though never quite clearly defined, constitutes one fundamental cornerstone of international law. The concept is enshrined within the United Nations Charter⁹²⁵, particularly in Article 2.1, which states that the United Nations is “based on the principle of the sovereign equality of all its Members”, in Article 2.4, which states that “members shall refrain in their international relations from the threat or use of force against the territorial integrity or political independence of any State” and in Article 2.7, which prevents the UN from intervening in the domestic affairs of states. The UN General Assembly's 1970 Declaration on Principles of International Law concerning Friendly Relations and Co-operation among States⁹²⁶ further elaborates a list of 'elements' that comprise sovereign equality, amongst which are included the notions that all 'States are juridically equal', that the 'territorial integrity and political independence [of all states] are inviolable', and that a state has a right to determine its own 'political, social, economic and cultural systems'.⁹²⁷ In addition 'no state or group of states has the right to intervene, directly or indirectly, for any reason whatever, in the internal or external affairs of any other state.'⁹²⁸ Sovereign states thus at least pro forma are equal in terms of status and rights, and they have no higher authority above them. That is, there exists no sovereign state that could enforce international law provisions on other states or demand obedience from them.⁹²⁹

Of course, the here portrayed ideal notion of an egalitarian community of equally sovereign states with equal powers has never been an adequate representation of reality nor, was it ever meant to be one. Existing hierarchies between states were clearly reflected in international law at all times of its existence. Some “states” were or are, for example, a priori excluded from the community by not being recognised at all or only to some extent as a sovereign state.⁹³⁰ Some were or are classified as “rogue” states and thereby stripped of some of their sovereign privileges, such as territorial sovereignty.⁹³¹ Also, the set up of certain UN organs or agencies such as the UN Security Council pays tribute to hierarchies among states, for example by granting certain states permanent veto

⁹²⁴ Ibid.

⁹²⁵ UN Charter, note 208, Article 1(3).

⁹²⁶ UN Declaration on the Principles of International Law Concerning Friendly Relations and Cooperation Among States in Accordance with the Charter of the UN Res.2625 (XXV), 1970.

⁹²⁷ D. French. "A Reappraisal of Sovereignty in the Light of Global Environmental Concerns", 9 *Legal Studies*, 2001, 376 et seq.

⁹²⁸ Ibid.

⁹²⁹ Malanczuk, note 204, 75 et seq. Sovereignty thus in fact constitutes a modern notion of supreme political and legal authority within a territory, generally embodied in the modern nation state. Traditional legal theory holds that the state is the primary actor on the international stage and that each state possesses equal sovereign powers. A sovereign is "a person of international law [which] should possess the following qualifications: (a) a permanent population; (b) a defined territory; (c) government; and (d) the capacity to enter into relations with the other States. See the Montevideo Convention on the Rights and Duties of States, 165 LNTS 19, 1933. See also Alston/Steiner, note 214, 575 et seq.

⁹³⁰ A. Anghie, *Imperialism, Sovereignty, and the Making of International Law*, 2005; and M. Koskenniemi, *The Gentle Civilizer of Nations: The Rise and Fall of International Law 1870-1960*, 2004, 98 et seq.

⁹³¹ See generally G. Simpson, *Great Powers and Outlaw States: Unequal Sovereigns in the International Legal Order*, 2004.

rights or more voting powers than others.⁹³² Moreover, the principle of sovereignty itself has never been an absolute one in that it has been continuously challenged from various sides. Over the years, human rights law, for example, often has helped to carve out inroads into the principle of sovereignty.⁹³³ That is so because in contrast to international law generally, which mostly aims at regulating the relations between and the distribution of power among states human rights reach broad areas of everyday life within states that are vital to the internal distribution of political power. The promotion of human rights concern, including with regard to such questions as how states organise their prisons, how and which criminal law provisions apply under what circumstances, whether citizens have access to judicial remedies, housing, health etc., have then played into question the legitimate scope for states to use their sovereign privileges and to make important decisions on the character of their domestic law free from interference by other states.⁹³⁴ The observance of human rights to some extent at least also seems to play a role in the very conception of statehood as there has been some indication that states nowadays require some guarantee of respect for human rights before bestowing recognition by other states.⁹³⁵ Other potential venues for a clash between human rights and the principle of sovereignty lie in the right to self-determination which contests the principle of state sovereignty by threatening the territorial integrity of sovereign states.⁹³⁶ In any event, as international human rights aspirations grow, and as human rights law becomes ever more critical of and hence more distanced from and powerful in relation to states' behaviour, the potential for conflict between the human rights movement and the principle of sovereignty have certainly grown.⁹³⁷ On the other hand it may not be forgotten that human rights still are addressed mostly to states and that states in turn are the only guarantor of human rights. The tensions between human rights and the concept of sovereignty as well as the implications of obliging sovereign states to protect human rights, as far as reflected and relevant to the bioethical debate, will be discussed in the next chapter.

⁹³² Ibid., 62 et seq.

⁹³³ O. Schachter, "The Decline of the Nation-State and its Implications for International Law", 36 *Columbia Journal of Transnational Law*, 1997, 7 et seq.; and generally Alston/Steiner, note 214, 534 et seq.

⁹³⁴ Ishay, note 820, 2-4. Other ways in which human rights and the principle of state sovereignty can clash is the interplay between art 2 (7) and Articles 55-56 of the UN Charter, note 208, on the one hand, and, on the other, actions by the Security Council in response to a threat to international peace and security or in cases of humanitarian intervention, such as in Kosovo in 1999.

⁹³⁵ See e.g. the guidelines formulated by the European Community for the recognition of new states formed out of break up of the former USSR and Yugoslavia, which make recognition dependent upon a commitment to the rule of law, democracy and a guarantee of minority rights. EC Guidelines for the Recognition of New states in Europe and the former Soviet Union, EC, 1991.

⁹³⁶ R. McCorquodale, *Self-Determination in International Law*, 2000, 2 et seq.

⁹³⁷ Alston/Steiner, note 214, 930, citing Kofi Annan as stating that "by enhancing individual sovereignty by a 'renowned consciousness of the right of every individual to control his or her destiny human rights have certainly made states more vulnerable to internal pressure'. Speech of Kofi Annan at the UN General Assembly's 'general debate' 1999. G. Fox, "Globalization at the Margins: Strengthening the State", 7 *Indiana Journal of Global Legal Studies*, 1999, 35 et seq.

2.2.4. Universality in the Context of the Standards

One further important concept in human rights discourses is human rights' implicitly and sometimes explicitly voiced aspiration to universal validity. That is, human rights exist at several intersecting levels. For one, they have a legal dimension. Human rights are constituted by being enshrined in national constitutions as well as in international declarations, covenants, and treaties. At this level, human rights standards are not universally applicable or valid. With the exception of norms of *jus cogens* they formally and legally only bind those states that have signed up to them and only to the extent that a state actually accepts the standard as a binding standard, i.e. to the extent that it has not qualified its commitment by entering explanations or clarifications with regard to its interpretation of provisions, or, if admissible, derogates from the provisions.⁹³⁸ While it has been argued that human rights standards are nevertheless de facto universally valid as "almost all states have signed at least one of the "six major human rights treaties"⁹³⁹, it has also been submitted that a significant number of states have not adhered to many of these treaties and are therefore neither bound by the respective treaty obligations nor entitled to invoke those obligations against parties of the treaty. A claim to universal validity thus cannot be based on the contention that most states have signed one or several human rights standards. It can also not easily be based on another contention, namely that human rights, in particular the UDHR, had become part of international customary law which consequently binds all states even if they had not formally consented to it.⁹⁴⁰ That is so because apart from certain norms enshrined in international standards, such as the right to life, the right to be free from slavery and torture and the prohibition of discrimination and genocide which all arguably have become customary international law and/or part of *jus cogens*, it seems that neither governments nor courts have accepted for example the whole UDHR as an instrument with obligatory force. That is also not changed by the fact that governments sometimes refer to the UDHR in condemning certain acts and thereby "rhetorically rely on the UDHR as a touchstone of legality and/or frequently laud the UDHR's principles as standards to be achieved by all."⁹⁴¹ Hence, while a limited number of specific human rights can be said to form part of international customary law and hence could be said to be universally obligatory on all states that statement certainly does not hold true for the whole body of human rights.⁹⁴²

⁹³⁸ See discussion above Chapter IV, 1.3 and Chapter V.

⁹³⁹ These include the ICESCR, note 341, ICCPR, note 341, The International Convention on the Elimination of All Forms of Racial Discrimination, UN Treaty Series, vol. 660, 1965, 195; CEDAW, note 300; The Convention Against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment, UN Treaty Series, vol. 1465, 1984, 85; and the Convention on the Rights of the Child, UN Treaty Series, vol. 1577, 1989, 3. As Ann Bayefsky writes, "Every UN member state is a party to one or more of the six major human rights treaties. 80% of states have ratified four or more." A. Bayefsky, *The UN Human Rights Treaty System: Universality at the Crossroads*, 2001, 86.

⁹⁴⁰ See discussion in Chapter IV, 3.3.

⁹⁴¹ Schachter, *International Law in Theory and Practice*, note 607, 85 et seq. and 92 et seq.

⁹⁴² The ICCPR, note 341, in Part 2 (Articles 2 – 5) for example merely obliges parties to legislate where necessary to give effect to the rights recognized in the Covenant, and to provide an effective legal remedy for any violation of those rights. Similarly, Article 1 of the Oviedo Convention, note 5, specifies that "Each Party shall take in its internal law the necessary measures to give effect to the provisions of this Convention." It can thereby generally be assumed that a

It has also sometimes been suggested that the UN Charter contained a legal obligation to promote universal respect for and observance of human rights.⁹⁴³ Proponents of this idea usually cite the Preamble of the UN Charter which states the spirit of the Charter as, *inter alia*, reaffirming "... faith in fundamental human rights, in the dignity and worth of the human person, in the equal rights of men and women and of nations large and small ..." and article 1 (3) of the Charter which holds that human rights are "for all without distinction".⁹⁴⁴ They further content that the Charter legally commits the United Nations and all Member States in Article 55 (3) to promote "universal respect for, and observance of, human rights and fundamental freedoms" and in Article 56 pledges Member States to take actions to achieve certain ends of the Charter, including human rights. They also cite Arts 62 and 68 that mandate that the Economic and Social Council takes steps towards promoting human rights.⁹⁴⁵ However, as the just stated provisions are very general and abstract in nature, as they lack a specific definition of the concept of human rights they have have been argued to fail to "impose any positive legal obligation to observe or promote the universal validity of human rights on Members States."⁹⁴⁶ Yet even if the obligatory force of in particular Arts 55 and 56 of the UN Charter is dismissed, these Articles and the Preamble of the Charter still powerfully connect human rights with ideas and ideals of universal applicability of human rights.

This connection, even if legally irrelevant is even more pronounced in the context of international human rights standards themselves. In the Universal Declaration of Human Rights an aspiration to universal applicability, for example, is literally written into the title of the Declaration. The text of the UDHR further recognizes that all human beings are "free and equal in dignity"⁹⁴⁷, and that recognition of the inherent dignity "of all members of the human family is the foundation of freedom, justice, and peace in the world."⁹⁴⁸ The UDHR is moreover proclaimed as a "common standard of achievement for all peoples and all nations" and hence at some level clearly aims to set standards applicable to all peoples and nations.⁹⁴⁹ The ICCPR again, for example, proclaims in its first two recitals that "recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family is the foundation of freedom, justice and peace in the world" and recognises "that these [human] rights derive from the inherent dignity of the human person"⁹⁵⁰,

country ratifying a UN human rights treaty agrees to respect and implement within domestic law the rights the treaty covers. It also agrees to accept and respond to international scrutiny and criticism of its compliance. This is a significant, if non-coercive, form of accountability. A ratifying country does not agree to make the human rights norm "self-executing" - that is, directly enforceable in domestic courts. That often requires implementing legislation.

⁹⁴³ Schachter, *International Law in Theory and Practice*, note 607, 85.

⁹⁴⁴ UN Charter, note 208, Article 1(3).

⁹⁴⁵ This requirement forms the legal basis for the establishment of the Office of the United Nations High Commissioner for Human Rights. In addition, UN Charter, note 196, Article 76 (c) also states one of the objectives of the United Nations trusteeship system as to "encourage respect for human rights."

⁹⁴⁶ Princeton Articles Series, "Human Rights Under International Law", available at:

<http://www.princeton.edu/~lawjourn/Spring98/ding.html> (last visited 27.04.2012). See also Schachter, *International Law in Theory and Practice*, note 607, 85 et seq. and 92 et seq.

⁹⁴⁷ UDHR, note 270, Article 1.

⁹⁴⁸ *Ibid.*, Preamble.

⁹⁴⁹ *Ibid.*, Preamble.

⁹⁵⁰ See Preamble of ICCPR, note 341, and ICESCR, note 341.

statements that cannot meaningfully be construed without linking the ICCPR to a notion of universal rights of all members of the human family. Finally, the Vienna Declaration and numerous other declarations by states have confirmed that “the universal nature” of all human rights and fundamental freedoms is “beyond question”.⁹⁵¹

It can thus be submitted that while human rights standards are not legally universally applicable, they at least invoke ideals of universal applicability in their titles and provisions, are often written in a universalist spirit and are often intertwined with a philosophical, ethical or political claim to universal validity. That is for one so because human rights standards cannot be completely separated from the traditions, philosophical underpinnings and the *nomos* that gave rise to them and because these traditions and roots, as discussed above, often inscribe into human rights some form of universal applicability.⁹⁵² This is also so because legal human rights cannot be completely separated from their existence in a political dimension, where their proclaimed universality is sometimes used to bolster political claims about the correct or legitimate behaviour of states.⁹⁵³ Particularly soft law instruments that, as discussed above, can be more aspirationally worded than hard law instruments and that, exactly because they remain legally non-binding and non-enforceable, are sometimes very much akin to political statements seem to lend themselves more easily to such a use and perception.⁹⁵⁴ That this does not always remain political rhetoric but that soft law instruments can have or can mature into some legal commitment was discussed above. To the extent that international legal standards in the area of bioethics reflect and incorporate ethical or political aspirations to universal validity that might at some point develop into legal commitments and to the extent that these aspirations trigger debates as to the justification, meaning, scope and validity of these aspirations, these debates are then also relevant to the present context.

In fact, in the standards in the area of bioethics references to the term universal abound. Two of the standards dealing directly with questions of bioethical interest, the Universal Declaration on the Human Genome and Human Rights and the Universal Declaration on Bioethics and Human Rights declare their universal aspirations in their respective title. The explanatory memorandum to the UDBHR also makes it clear that the Declaration is about developing “universally applicable ethical guidelines within a context of cultural pluralism inherent in bioethics. This involves the identification and promotion of universally shared values...”⁹⁵⁵ Similarly, the same document

⁹⁵¹ Vienna Declaration and Programme of Action, A/CONF.157/23, 1992, Article 1.

⁹⁵² See above under 1 and 2 in this chapter.

⁹⁵³ Rawls, for example, claims that human rights define where legitimate toleration of other countries ends. He says that human rights “specify limits to a regime’s internal autonomy” and that “their fulfillment is sufficient to exclude justified and forceful intervention by other peoples, for example, by diplomatic and economic sanctions, or in grave cases by military force”. J. Rawls, *The Law of Peoples*, 1999, 79-80. On the relationship between rights, ethics and morality see D. v.d. Pfordten, “Rechtsethik”, in: J. Nida-Rümelin, *Angewandte Ethik. Die Bereichsethiken und ihre theoretische Fundierung. Ein Handbuch*, 2005, 201 et seq.

⁹⁵⁴ See e.g. the UDHR, note 270.

⁹⁵⁵ Explanatory Memorandum, note 8, para 74.

explains that the IBC was given the task to submit a report on “the technical and legal studies undertaken regarding the possibility of elaborating universal norms on bioethics” and the Director-General was invited to continue preparatory work on a declaration on universal norms on bioethics.”⁹⁵⁶ With regard to the use of the term universal in the title of the Declaration the report then remarks at 10 that

“During the consultations with intergovernmental organisations, non-governmental organisations, National Bioethics Committees as well as the written consultations with the Member States, it has been pointed out frequently that the adjective 'universal' before the term 'declaration' would be more appropriate. The word 'universal' refers not merely to the general applicability of the norms but also emphasizes the global recognition of bioethical principles. Every culture, even those most critical of technological advances, must develop a response - be it supportive or controlling – to the emergence of new technologies, including biotechnology...”⁹⁵⁷

The norms enshrined in the UDBHR are thus meant to be generally applicable. By analogy it may be assumed that similar considerations have preceded the inclusion of the word universal in the Universal Declaration on Human Rights and the Human Genome. Further references to the term universal can moreover be found in various provisions of the standards in the area of bioethics. The UDBHR for example in Recital 3 recognizes that ethical issues raised by the rapid advances in science and their technological applications should be examined with due respect to the dignity of the human person and universal respect for, and observance of, human rights and fundamental freedoms; in Recital 4 it resolves that it is “necessary and timely for the international community to state universal principles that will provide a foundation for humanity's response to the ever-increasing dilemmas and controversies that science and technology present for humankind and for the environment”⁹⁵⁸. It also uses the term universal in Article 2, specifying the aims of the declaration as among others (a) to provide a universal framework of principles and procedures.

Moreover, all standards in the area of bioethics, even if they do not indicate so in their title or directly use the term universal in their provisions speak in somewhat universalist tones when they claim the same rights for 'everyone', for example that 'everyone' has the right to respect for private life in relation to information about his or her health⁹⁵⁹ or that “everyone has a right to respect for their dignity and for their rights regardless of their genetic characteristics.”⁹⁶⁰ Also, an argument can be made that by using the concept of human dignity as a guiding principle, which itself is generally construed as adhering equally and intrinsically to all members of the human family and which as such invokes notions of universal applicability the standards too, to some extent, must be connected with aspirations to universal validity. Moreover, some of the statements enshrined in the standards simply do not seem to make much sense if they do not at some level imply that they are

⁹⁵⁶ Ibid. at 5-6.

⁹⁵⁷ Ibid, at 10.

⁹⁵⁸ See Schmidt, “Whose Dignity? Resolving Ambiguities in the Scope of “Human Dignity” in the Universal Declaration on Bioethics and Human Rights”, note 889, 578.

⁹⁵⁹ Oviedo Convention, note 5, Article 10 para 2.

⁹⁶⁰ The Universal Declaration on the Human Genome, note 4, article 2.

linked with everyone's intrinsic dignity and that they inhere in every human being, that human rights therefore should be for all people at all times, in short, that human rights at some level are meant to be universal.

Finally, it must be acknowledged that states deliberately chose to incorporate into the text of standards references to the concept of universality, for example, when choosing the title of the UDBHR. If that is assumed it can also be assumed that the term has some meaning and that, as was stated in the explanatory memorandum, the expectation was to set out universal or generally applicable norms. In the following chapter it will be clarified and assessed what is actually meant and entailed by when declarations refer to the concept of universality, and what implications of doing so are for bioethical debate.

2.2.5. Autonomy

Respect for human beings' autonomy is one further central tenet and constituting concept of human rights doctrine. As stated by Karl Klare, "the dominant understanding of the human rights project is to erect barriers between the individual and the state, so as to protect human autonomy and self-determination from being violated or crushed by governmental power."⁹⁶¹

Autonomy indeed features prominently in several provisions of all standards in the area of bioethics. In the UDBHR it is explicitly mentioned in Article 5 - Autonomy and individual responsibility – which holds that “the autonomy of persons to make decisions, while taking responsibility for those decisions and respecting the autonomy of others, is to be respected. For persons who are not capable of exercising autonomy, special measures are to be taken to protect their rights and interests.” In all other standards dealing directly with bioethics the principle of autonomy also receives a prominent place mostly through the clauses dealing with informed consent, discussed above as well as through those dealing with privacy and confidentiality. The international declaration on the Human Genome for example specifies in Article 14 that “(a) States should endeavour to protect the privacy of individuals and the confidentiality of human genetic data linked to an identifiable person, family or, where appropriate, group, in accordance with domestic law consistent with the international law of human rights. Valuing each individual's autonomy also means that (b) Human genetic data, human proteomic data and biological samples linked to an identifiable person should not be disclosed or made accessible to third parties, in particular, employers, insurance companies, educational institutions and the family.”

The principle of respect for autonomy and its common expression as or in the process of obtaining informed consent deserves some further elaboration. In the literature on bioethics autonomy is

⁹⁶¹ M. Mutua, "Human Rights and Powerlessness: Pathologies of Choice and Substance", 56 *Buffalo Law Review*, 2008, 1027, citing at 1027 K. Klare, "Legal Theory and Democratic Reconstruction: Reflections of 1989", 25 *University of British Columbia Law Review*, 1991, 69, 97.

commonly construed to mean that patients have a right to make decisions about their medical care without their health care providers trying to influence the decision.⁹⁶² That is, the latter should sufficiently educate patients, use his or her training, knowledge and experience to provide patients with facts about the diagnosis and about the prognoses without treatment and with alternative treatment but may not make decisions for patients.⁹⁶³ In other words, to act autonomously in the area of bioethics and health care means that one has to have the liberty, possibility and the capacity to act and make moral choices independently and in accordance with the individual's beliefs, maxims and principles and without controlling influences that would mitigate against a free and voluntary act.⁹⁶⁴ Respect involves not only refraining from interfering with others' choices, but sometimes entails providing them with the necessary conditions and opportunities for exercising autonomy - in that sense autonomy is often equated with informed consent. A patient's autonomy is only limited where the principle of autonomy can or does result in harm to others. The explanatory memorandum on the previous draft of the UDBHR echoes these considerations:

Respect for personal autonomy is strongly linked to and, according to certain interpretations, derives from the notion of human dignity. It is directly derived from binding international human rights law. Individuals cannot be instrumentalised and treated merely as means to a scientific end; they should be granted the authority to make autonomous decisions in all aspects of their lives where their decisions do no harm to others. Respect for autonomy involves not just a respectful attitude but also respectful action. However, autonomy, in this interpretation, is not simply an invested right. It also has the dimension of responsibility towards others. Article 9 [of the UDBHR] reflects the right of each person to make individual decisions, whilst at the same time respecting the autonomy of others. Some experts wanted to reinforce the emphasis on responsibility by including in Article 9 reference to the duty to take such responsibility. However that formulation seemed to be too forceful and might indicate a possible erroneous interpretation of autonomy which is not a synonym of 'freedom' or 'liberty'. Autonomy refers to the concept of acting in accordance with voluntarily accepted principles but it does not liberate the individual from taking responsibility for his or her actions.⁹⁶⁵

In the area of human rights the absolute need to preserve and protect human beings' autonomy is usually taken to be one fundamental cornerstone of human rights philosophy and theory.⁹⁶⁶ Yet, while there are many differences in human rights scholars' understanding of what and how autonomy is exactly constituted, how it exactly relates to persons, moral obligations and responsibilities and what social policies or laws it justifies or necessitates, most of these scholars, nevertheless, also seem to agree on three accounts. For one, autonomy and the need to protect it,

⁹⁶² J. Childress, "The Place of Autonomy in Bioethics", 20 *Hastings Center Report*, 1990, 12, 12. K. Möller, "Two Conceptions of Positive Liberty", in: 29 *Oxford Journal of Legal Studies*, 2009, 757 et seq. F. Miller/A. Wertheimer (eds.), *The Ethics of Consent: Theory and Practice*, 2009 and P. Candilis/C. Lidz, "Advances in Informed Consent", in: F. Miller/A. Wertheimer (eds.), *The Ethics of Consent: Theory and Practice*, 2009, 329 et seq.

⁹⁶³ C. Schneider, *The Practice of Autonomy*, 1998, 3.

⁹⁶⁴ See J. Nida-Rümelin, "Autonomie und Würde Angesichts des Eigenen Todes", Beitrag zur Tagung Sterbehilfe. Recht auf Leidfreies Leben? an der FU Berlin, November 23 and 24, 2007, 12. See also Beyleveld/Brownsword, note 662, 4.

⁹⁶⁵ Explanatory Memorandum, note 8, 60- 61.

⁹⁶⁶ Schneider, *The Practice of Autonomy*, note 963, 3. D. Weissstüb/G. Diaz Pintos, *Autonomy and Human Rights in Health Care: An International Perspective*, 2008, 2.

generally is rooted in human beings' unique capacity to reason, "their capacity to decide upon, to revise, and rationally to pursue a conception of the good."⁹⁶⁷

A second shared characteristic of how the concept of autonomy is used in a human rights context, is that it is in one way or another about 'self-government' and freedom from manipulative influence.⁹⁶⁸ It aims, to varying degrees to give a person some control over his or her "physical integrity, liberty, expression, religious and moral beliefs, private and family life, property, personal data and more."⁹⁶⁹ Individual autonomy thus implies the capacity to exercise one's capacity to reason and to live according to motives that are taken to be one's own i.e. not the product of manipulative or distorting external forces.⁹⁷⁰ It is the "capacity to be selfdetermining, to be in control of one's own life."⁹⁷¹ As such accounts of autonomy contrast with those of "heteronomous" theories that for example credit the state, society, a deity or institutions, with the capacity to determine an individual's desires and choices and to obstruct his or her ability to follow through with these choices and desires.⁹⁷²

Thirdly, autonomy in the context of human rights is usually relational, in that autonomy is located in the relationship between the state and its citizen. It moulds this relationship by making conduct of the state impermissible or incompatible with the autonomy of the person. In particular, the state has to ensure that an individual is freedom from paternalistic interference by the state. For example "the prohibition of certain religions on the ground that they are religiously wrong or misguided or an insult to God would be a violation of autonomy."⁹⁷³

Yet, while in one way or another many human rights scholars agree on these three properties of the concept of autonomy in a human rights context they nevertheless to this date argue about what autonomy exactly implies and which conduct it necessitates. It will be seen below how and to what extent framing issues of bioethical relevance by reference to the concept of autonomy has implications for the bioethical debate.

⁹⁶⁷ Möller, note 962, 759 and Nida-Rümelin, "Autonomie und Würde Angesichts des Eigenen Todes", Beitrag zur Tagung Sterbehilfe. Recht auf Leidfreies Leben? an der FU Berlin, note 964. In one form or another it thereby replicates and extends the above described Kantian idea of autonomy. J. Christman, "Informed Consent", in: E. Zalta (ed.), *Stanford Encyclopedia of Philosophy*, Summer 2010 Edition, at: <http://plato.stanford.edu/contents.html> (last visited 10.12.09), arguing that "it should, however, be noted that this concept of autonomy is a rather modern development. That is, "putting moral weight on an individual's ability to govern herself, independent of her place in a metaphysical order or her role in social structures and political institutions is very much the product of the Enlightenment humanism of which contemporary liberal political philosophy is an offshoot."

⁹⁶⁸ Dworkin, *Taking Rights Seriously*, note 788, 61 et seq.

⁹⁶⁹ Möller, note 962, 759, showing how autonomy is reflected in national constitutions.

⁹⁷⁰ Schneider, *The Practice of Autonomy*, note 963, 3.

⁹⁷¹ R. Norman, "Autonomy", in: T. Honderich (ed.), *Oxford Companion to Philosophy*, 2005, 72 et seq. On the relationship between consciousness, autonomy and freedom see in particular J. Nida-Rümelin, "Bewusstsein und Freiheit", in: D. Ganten/V. Gerhardt/J. Nida-Rümelin (eds.), *Funktionen des Bewusstseins*, 2008, 177 et seq.

⁹⁷² *Ibid.*, 73.

⁹⁷³ Möller, note 962, 762 et seq.

3. Conclusion

In summary, the liberal, enlightenment and natural law traditions of thought have a significant impact on the ideas and ideals that constitute and inform human rights, on the structure giving concepts that are relevant in the field and on their content. These traditions, thus, to a large extent, provide the context and background into which human rights and in their extension the standards in the area of bioethics were born and against which they are set to work. Without knowing and understanding this fabric or *nomos* many concepts used in human rights jurisprudence remain fragmented and/or unclear. As such these traditions form an integral part of human rights jurisprudence.

The way this plays out is that standards in the area of bioethics as human rights standards are rights or principle based standards, that they endorse human rights values, including that of human dignity and individual's autonomy that they include notions of universal validity, that they operate within the confinement of state sovereignty, and that they firmly endorse the value of the individual's autonomy. Implications of framing bioethical debates in this discourse will be discussed in the next section.

Chapter VII Impact on the Area of Bioethics

This chapter discusses implications of leading bioethical debates in a human rights discourse. In particular it discusses how leading bioethical debates through the prism of the five epistemological grid points identified and characterised in the previous chapters impacts bioethical debates. For each of these grid-points it shows how the structuring of bioethical debates along or within these grid points has several implications for the way these debates are constructed and conceived of as well as for how possible solutions to questions raised in that context are answered or resolved.

1. Human Rights in the Area of Bioethics as Rights or Principles

It was explained above how human rights, standing in the liberal, enlightenment and natural rights tradition, became rights and legal principles and how these concepts are charged. In this section some of the implications of employing a jurisprudence of rights or principles as an approach to matters of bioethical relevance will be explored.

1.1. Focusing and Developing the Debate through Rights and Principles

Referring to bioethically relevant issues through a framework of human rights, in their specifications as rights or principles, first of all can and has helped broadening and sharpening the focus of fledgling and then evolving bioethical debates. It can and has, secondly, also provided tools through which problems or dilemmas of bioethical relevance can and have been successfully resolved. That is, using a language of human rights or principles can help prioritise certain concerns and show ways of how such concerns can be meaningfully addressed.⁹⁷⁴

In terms of shaping and focusing the debate Daniel Sperling, for example, notes how rights discourses have been used to conceptualise and deal with traditional concerns in the doctor patient relationship. Tort cases, for example, promoted the idea of the integrity of the human body, implying that no individual should be touched, let alone treated without prior consent.⁹⁷⁵ Any unapproved appropriating of the body was regarded as battery and breach of duty of care.⁹⁷⁶ Gradually these cases established and developed the right of and requirement of consent which not only protected patients from unwanted touching but also empowered them by furnishing them

⁹⁷⁴ See generally Glendon, note 21, 1- 13, summarising some of the advantages of employing a rights based approach to social questions.

⁹⁷⁵ D. Sperling, "A Rights-Based Relationship and its Troubling Implications", in: M. Freeman (ed.), *Law and Bioethics*, 2008, 52, 56. See also for example R. Fox, *The Sociology of Bioethics*, 1989, 224, arguing that as movements that were inspired by legal or normative notions of equality and freedom "from its outset the value and belief questions with which it [bioethics] had been preoccupied have run parallel to those with which the society had been grappling more broadly."

⁹⁷⁶ Ibid.

with the right to autonomy and self-determination.⁹⁷⁷ Similarly, the law and its discourse expanded the right to and requirement of consent to include the obligation to provide patients with sufficient knowledge about treatment, risks, and alternatives so that the giving of consent was not only to be free but also informed.⁹⁷⁸ Case law and advance directive also established the right to refuse treatment including life sustaining treatment and more generally to participate actively in medical decisions.⁹⁷⁹ Overall, resorting to a language of rights thus has been particularly helpful to further develop those cases in the area of bioethics that involve professional misconduct or mistreatment of vulnerable persons or of groups, such as people of certain ethnicity or class.

In the same vein can and have rights discourses also been successfully used as a way of broadening out the traditional focus of bioethics on the doctor-patient relationship to include, for example, wider social discriminatory practices and newly arising challenges posed by new technologies or economic degradation. The civil rights and feminist movements of the 1950s through to the 1970s, for example, during which individuals and civil rights organizations challenged discriminatory practices such as the discrimination of black Americans and which campaigned for, inter alia, achieving equal rights of women in areas such as reproductive rights, domestic violence, maternity leave, equal pay, sexual harassment, and sexual violence, did much to stimulate and direct early debates in the area of bioethics.⁹⁸⁰ Tina Stevens for example notes that

“...just when courts were defining an expanded right to privacy the bioethicists were emphasizing the principle of autonomy, ... Just when movements on behalf of a variety of minorities were advancing their claims the bioethicists were defending another group that appeared powerless – patients. All these advocates were siding with the individual against constituted authority; in their powerlessness patients seemed at one with women, inmates, homosexuals, tenants in public housing, welfare recipients, and students, who were all attempting to limit the discretionary authority of professionals.”⁹⁸¹

In addition to providing a framework for these debates a language of human rights can also do much to empower those in “need of a voice.”⁹⁸² That is, (human) rights are not “some abstract, inchoate good but defined, particular claims listed in international instruments.”⁹⁸³ A holder of a right may choose to press claims against a trespasser or to not to pursue the matter. To have a right to something means that this right can at some level be asserted and even be enforced - even if a majority within any given society does not comply or agree with the principles that are established

⁹⁷⁷ Sperling, note 975, 57.

⁹⁷⁸ Ibid.

⁹⁷⁹ Ibid.

⁹⁸⁰ See C. Carson, “Civil Rights Movement”, in: L. Levy/K. Karst/J. West (eds.), *Encyclopedia of the American Constitution*, 1992, 35, 35.

⁹⁸¹ M. Stevens, “History and Bioethics”, in: F. Miller/J. Fletcher/J. Humber (eds.), *The Nature and Prospect of Bioethics*, 2003, 179, 181 et seq.

⁹⁸² C. Chinkin, “The Hunger Trap: Women, Food, and Self-Determination”, 1993 *Michigan Journal of International Law*, 1993, 262, 264 and C. Chinkin, “Rape and Sexual Abuse of Women in International Law”, 5 *European Journal of International Law*, 1994, 326 et seq.

⁹⁸³ L. Henkin, *Age of Rights*, 1990, 19. W. Hohfeld/W. Cook, *Fundamental Legal Conceptions: As Applied in Judicial Reasoning*, 2000.

by that right or with the content of that right itself.⁹⁸⁴ That these empowering qualities of rights are well known and well understood is also evidenced by that many political movements at the international level want to see their main concerns categorized as matters of human rights, arguably also because this allows them to publicize, promote, and legitimate their concerns in a manner that is accepted, respected, and well understood by other actors.⁹⁸⁵ As Mr Hang Chhaya notes "aggrieved groups around the world thus have routinely portrayed themselves as victims of human rights abuses. Physically and mentally disabled people, indigenous peoples, AIDS patients, and many others have attempted to protect and promote their interests by advancing new human rights before the United Nations and other international bodies."⁹⁸⁶ The power and success of rights thereby is not only due to international currency and a sense of empowerment on behalf of those who invoke them but also due to their high visibility and practicality. Rights can be invoked in courts and can deal with very real life situations on a practical as opposed to a theoretical level. This quality makes them also particularly relevant to the fostering of a broader public debate on issues which in turn often enhances rights' popularity and thereby their acceptance by people and states as a legitimate framework for dealing with issues of bioethical relevance.⁹⁸⁷ Menikoff in that respect, for example, observes that if one was to ask "the average [American] person to tell you something about bioethics...likely as not, the response will include a reference to Karen Ann Quinlan, Nancy Cruzan or Baby M"⁹⁸⁸, i.e. to cases that involved a language of rights. These rights' application thus can provide a face to bioethics as well as offer a well-probed and hands on methodology on how to resolve bioethical problems that enjoys wide acceptance.

Overall human rights thus can do much to conceptualise and to further develop bioethical debates in certain areas, particularly where professional misconduct or mistreatment of vulnerable persons is concerned or where discrimination or unfair treatment of certain groups of people are involved. Their empowering qualities also make them an attractive means particularly for disadvantaged groups to voice their concerns. Their wide visibility and widely acknowledged status as a framework within which sometimes difficult and contested queries can be addressed moreover

⁹⁸⁴ Henkin, note 983, 20. and Schachter, *International Law in Theory and Practice*, note 607, 12.

⁹⁸⁵ J. Nickel, "Human Rights", in: E. Zalta (ed.), *Stanford Encyclopedia of Philosophy*, Fall 2010 Edition, at: <http://plato.stanford.edu/archives/fall2010/entries/rights-human/>. (last visited 27.04.2012).

⁹⁸⁶ See Statement by Mr Hang Chhaya, Chairman of Cambodian Human Rights Action Committee (CHRAC) and Executive Director of the Khmer Institute for Democracy (KID), Report from the EU-Cambodia Civil Society Seminar on human Rights and the role of civil society and human rights defenders, Phnom Penh, 31 August - 1 September 2010, at: http://www.eeas.europa.eu/delegations/cambodia/more_info/events/index_en.htm (last visited 27.04.2012). The list of newly 'invented' human rights includes for example a right to clean water and lesbian, transgender human rights. B. Clifford (ed.), *The International Struggle for New Human Rights*, 2008, 1-12.

⁹⁸⁷ Dworkin, *Taking Rights Seriously*, note 788, 227, chapter 7 and 12.

⁹⁸⁸ J. Menikoff, *Law and Bioethics: An Introduction*, 2002, 1, noting also at 3 that because rights are usually the means of choice when it comes to discussing bioethically relevant issues in courts they are by many understood as being well "equipped for the cleaner business of analysis and reasoning." See also G. Smith, *Law and Bioethics: Intersections along the Mortal Coil*, 2012.

render rights highly relevant to issues of bioethical interest where some form of practical and highly visible solution is required.⁹⁸⁹

1.2. Rigidity and Simplicity of Rights

Yet, while a rights discourse thus can certainly help broadening, shaping and advancing bioethical debates in particular areas it can also limit such debates in several ways. One problem commonly associated with a rights discourse is that it often is seen to have a rigid, absolutist and simplistic character which is held to make rights inapt to adequately deal with some of the complex problems involved in bioethics.⁹⁹⁰

The argument is that rights neither admit of compromise nor allow room for competing considerations and that they offer 'simple formulas' that cannot realistically resolve the complex and intricate problems at stake. Cass Sunstein illustrates this point by pointing out that rights

“rooted in nineteenth-century ideas of absolute sovereignty over property, ... are said to be ill-adapted to what we usually need, that is, a careful discussion of trade-offs and competing concerns. If rights are ... “trumps,” they are for that very reason harmful to the difficult process of accommodating different goals and considerations in resolving such thorny problems as abortion, the environment, and plant closings.”⁹⁹¹

Rights, for example, hardly allow the state or other respective addressees of a right to form decisions about when to endorse that right. The process of

“a person claiming a right- for example, a handicapped person claiming that all buildings should be accessible to people who use wheelchairs - may not ...[]... allow a process of balancing in which we judge, for example, whether accessibility for wheelchairs really makes sense in light of the relevant costs and benefits.”⁹⁹²

In the context of the area of bioethics this means that conceiving of bioethically relevant issues, such as standards of patient care, genetic research or sustainable development under a framework of rights might be problematic as the correlated rights can be somewhat too rigid, narrow, or simplistic to offer realistic solutions to the underlying complex problems.⁹⁹³ For example, a right to informed consent that is taken to be the basis for the decision of whether or not a medical treatment is applied leaves out a host of considerations, including emotions, such as fear or shame on the part of the person seeking treatment and/or his or her family, questions

⁹⁸⁹ D. Rothman, *Strangers at the Bedside: A History at how Law and Bioethics Transformed Medical Decision Making*, 1992, 245, for example, argues that the rights context helped bioethics to ban paternalism. And Sperling, note 975, 56, argues that only through the emergence of a rights driven context in the area of bioethics there was also the possibility for consent as a right and rejection of paternalism.

⁹⁹⁰ C. Sunstein, "Rights and their Critics", 70 *Notre Dame Law Review*, 1995, 727, 730.

⁹⁹¹ *Ibid.*, 730. Cf. also Dworkin, *Taking Rights Seriously*, note 788, xi, arguing that "individual rights are political trumps held by individuals."

⁹⁹² Sunstein, note 990, 730.

⁹⁹³ For some examples see e.g. R. Ashcroft, "The Troubled Relationship Between Bioethics and Human Rights", in: M. Freeman (ed.), *Law and Bioethics*, 2008, 31 et seq.

of religious belief, family arrangements, financial aspects, social networks etc,⁹⁹⁴ that the distinct focus of the right to informed consent simply cannot grasp.

Moreover, because rights, such as the right to the best available treatment, apply to all human beings in the same 'rigid' way, rights can sometimes not make a distinction when for example allocating scarce resources between a person with dependents, a person with a self-induced ailment, such as liver failure due to consistent alcohol abuse, or a 99 or 20 years old. Of course, non-discrimination among human beings is one of the big achievements of human rights – yet the question of whether there may be cases in which a differentiated treatment is in order can only be asked with some difficulty under a (human) rights framework.

Another side-effect is that the rights specified in the area of bioethics can be somewhat simplistic catch-it all statements.⁹⁹⁵ While acknowledging that the problems taken up under the rubric of a right to health for example are real and serious, including such a broad array of issues as inequalities in life expectancy, access to clean water, access to medicines and so on, the notion that all of these different problems can be coherently framed under a single overarching right to health seems somewhat misplaced.⁹⁹⁶ Many of these concerns involve rather complex interplays of a variety of factors. For example, access to medicine depends on inter alia such a wide range of factors as logistics, research and development capacity, innovation capacity, governments' budgeting and spending in the area of health care, national health plans and policies, gender conceptions, infrastructure, health education etc. To address all of these concerns under the heading of for example the Oviedo Convention's Article 3 on "equitable access to health care" thus seems somewhat simplistic.

Finally, international human rights law, like any discipline, is also a system that to some extent will need to keep its coherence.⁹⁹⁷ Hence the law might not as readily and flexibly accept innovative approaches to regulating the area of bioethics even if doing so flies in the face of "better" justice or better reason, because it might have to endorse a certain rule or value, such as autonomy, for want of coherence.⁹⁹⁸ In these instances law must give up some of its sensitivity, precision and possibly the ideal of justice.⁹⁹⁹

⁹⁹⁴ Sunstein, note 990, 730, arguing that these issues typically call up a range of issues about networks of relationships, between individuals and the state, between individuals and families, between individuals and localities" which a right might not be able to adequately reflect.

⁹⁹⁵ Here rights approaches often have to subsume a variety of cases under one rule without being able to cater for the vast variety of specific and particular complexities of single cases. Schneider, "Bioethics in the Language of the Law", note 21, 18. See also M. Meyer, "Against One-Size-Fits-All Research Ethics", 40 *Hastings Center Report*, 2010, 10 et seq.

⁹⁹⁶ Ashcroft, *The Troubled Relationship Between Bioethics and Human Rights*, note 993, 41:

⁹⁹⁷ Schneider, "Bioethics in the Language of the Law", note 21, 16.

⁹⁹⁸ See for example below under the section 5.4. mandatory autonomy.

⁹⁹⁹ Schneider, "Bioethics in the Language of the Law", note 21, 16.

1.3. The Indeterminacy of Rights of and Principles

Another point of note is that rights and principles, taking the form of general propositions, are - to some extent - indeterminate.¹⁰⁰⁰ One obvious example is Article 16 of the UDBHR¹⁰⁰¹ which deals with the protection of future generations and which reads “the impact of life sciences on future generations, including on their genetic constitution, should be given due regard.” Just standing by itself this proposition is certainly too indeterminate and broad to adequately deal with the vast area of potential issues involved in a possible right, duty or responsibility of humankind towards future generations. Stated like it is, the clause, for example, neither specifies who exactly is the right-bearer in this context nor what action is required to honour this right, what action would violate that right or who the addressee of this right is.

Yet also more recognised and more regularly invoked human rights, such as the right to equitable access to health care¹⁰⁰² or the right to privacy¹⁰⁰³, need to be concretised in order to have meaning. Standing by itself, the right to equitable access to health care says, for example, nothing about whether different types of health care insurances within a country are acceptable or prohibited, whether health care infrastructure across a country may differ, for example, between rural and urban areas and on whether or not regionally diversified types of trainings for doctors are permissible. Similarly, the right to freedom of scientific research¹⁰⁰⁴, without supplemental work, remains unspecific. It, for example, does not clarify which and whether at all limits to the exercise of that right exist, whether commercial trade with ethically contested goods that are necessary for that research, such as e.g. embryonic stem cells is allowed, permissible or even mandatory and whether the state is obligated to support all or only selectively chosen research projects and if so on which basis such decisions have to be made.¹⁰⁰⁵ Rights thus have to be specified in order to have concrete meaning. As will be discussed in more detail below these specifications, however, depend on premises not contained within the announcement of the right itself and thus regularly include political, ethical, and religious considerations.¹⁰⁰⁶ That is problematic to the extent that rights thereby run the risk of being hijacked by political or other power struggles which could lower their acceptance in a society and hence their capacity to regulate conflict.¹⁰⁰⁷

¹⁰⁰⁰ Sunstein, note 990, 735. See also, O. Holmes (ed.), "Codes and the Arrangement of the Law", in: O. Holmes, *Formative Essays*, 1984, 77 et seq.

¹⁰⁰¹ UDBHR, note 4.

¹⁰⁰² Oviedo Convention, note 5, Article 3.

¹⁰⁰³ For example ICCPR, note 341, Article 17.

¹⁰⁰⁴ See discussion above in Chapter V, 2.2.

¹⁰⁰⁵ Ibid.

¹⁰⁰⁶ See below under 1.4.

¹⁰⁰⁷ Koskeniemi, *From Apology to Utopia*, note 245, 7, albeit referring to international law as a whole and not only to rights, for example notes that the system of international law has a structural bias, wherein it favours some outcomes or distributive choices over others, especially showing a bias against the South or the Third World.

1.4. Conflicting Rights and Principles

A further corollary of using a (human) rights' discourse can be that rights conflict with other rights of the same category. That is, formally there is no hierarchy between different human rights and hence no objective or rather no incontestable, clear-cut way of judging whether one or the other right supersedes in case of conflict.

For example, as Michael Selgelid points out "the promotion of one person's autonomy can conflict with the autonomy or well being of others"¹⁰⁰⁸ – and it can also often conflict with the principle of equality.¹⁰⁰⁹ Articles 5¹⁰¹⁰ and 6¹⁰¹¹ of the UDBHR both appeal to the importance of individual autonomy. Both of these principles, however, can conflict with Article 4 of the UDBHR which holds that: in applying and advancing scientific knowledge and medical practice, direct and indirect benefits to patients, research participants and other affected individuals should be maximized and any possible harm to such individuals should be minimized.¹⁰¹² Applying these provisions to the question of whether or not it is permissible to use genetic technologies to 'enhance' the quality of life, for example by eliminating a gene which makes it likely that a person will develop a certain form of cancer or by enhancing perceived attractiveness of a person through the elimination or correction of certain genes, conflicting interpretations can ensue.¹⁰¹³ Article 5 apparently, on the one hand, grants freedom to those who would use genetic technologies to enhance their quality of life. The practice of genetic enhancement by the rich, however, so Selgelid could be interpreted to conflict with Article 4 as it could harm others who would be "competitively disadvantaged because they cannot afford enhancement oriented technologies"¹⁰¹⁴. The advancement of enhancement orientated genetic technologies could moreover "conflict with Article 4 if the profitability of developing them draws industry resources away from more fruitful technological directions, such as antibiotic and vaccine development."¹⁰¹⁵

Many more such potentially conflicting examples can be construed. Yet in no case do the standards help resolving this general problem of how to deal with conflicting rights. That is, none of the standards in the area of bioethics provides an answer as to how the rights enshrined in them should be ranked or what should be done in case they conflict with each other. The problem is of course, that there can be "more than one justifiable ordering or understanding of them [rights]" and the ranking of decisions depends upon such contingencies as the specific information and

¹⁰⁰⁸ M. Selgelid, "Universal Norms and Conflicting Values", 5 *Developing World Bioethics Volume*, 2005, 267 et seq.

¹⁰⁰⁹ Ibid.

¹⁰¹⁰ UDBHR, note 4, stating that: "the autonomy of persons to make decisions, while taking responsibility for those decisions and respecting the autonomy of others, is to be respected"

¹⁰¹¹ Ibid., stating that: "any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information."

¹⁰¹² Ibid. Selgelid, note 1008, 268

¹⁰¹³ Ibid, 268.

¹⁰¹⁴ Ibid.

¹⁰¹⁵ Ibid.

circumstances involved in each case.¹⁰¹⁶ In the absence of clear guidance from the standards on how to resolve conflict such decisions will then likely be made based on premises that again will be found outside of the wording of the standards' provisions and hence might replicate structural inequalities underlying the rights.¹⁰¹⁷ Another potential result is that standards are conceived of as incoherent. Ashcroft rather harshly notes

"If principles are, on the face of it, in contradistinction, how far should we construe them as mutually consistent? Or do we take the interpretative work here as a question of balancing principles which are taken to be in tension rather than in logical contradiction? Or do we instead convict the statements in the text as in actual contradistinction, and a sign of poor drafting? Bioethicists are inclined I think to the last approach whereas human rights advocates, especially those with legal training would prefer the more charitable construction approaches."¹⁰¹⁸

No matter how this question is resolved it shows that principles and rights are far from providing clear guidance as to how rights or principles are to be construed or how they are to be resolved in case they conflict, which can limit their utility.

1.5. Structural Inequalities Underlying Rights and Principles

Another concern about using a framework of human rights thus, as already alluded to in the previous sections, is then that rights are often unable to take account of structural inequalities underlying a right. This is problematic to the extent that these inequalities can substantially impact the exercise of the right itself.¹⁰¹⁹

That is, even though the UDBHR, for example, "asserts the 'fundamental equality of all human beings in dignity and rights' and insists that 'the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition', it does not explicitly recognize structural inequities of power and wealth"¹⁰²⁰ that may thwart the equal dignity and rights to many. Mary Rawlinson, for example, notes that

¹⁰¹⁶ Ibid.

¹⁰¹⁷ See discussion below under 1.4.

¹⁰¹⁸ Ashcroft, "The Troubled Relationship Between Bioethics and Human Rights", note 993, 34.

¹⁰¹⁹ See for example M. Rawlinson/A. Donchin, "The Quest for Universality: Reflections on the Universal Declaration on Bioethics and Human Rights", 5 *Developing World Bioethics*, 2005, 258 et seq., noting at 258 that an important theme in recent feminist bioethics scholarship is recognition that contemporary ethical urgencies tend to arise in relations that are unequal: doctor/patient, teacher/student, parent/child, boss/worker, or between the politically and economically powerful and those who are poorer, weaker, and disenfranchised. On structural inequalities generally see for example N. Nzegwu, "Recovering Igbo Traditions: A Case for Indigenous Women's Organizations", in: M. Nussbaum/J. Glover (eds.), *Women, Culture and Development: A Study of Human Capabilities*, 1995, 444 et seq. and R. Parker, "The Global HIV/AIDS Pandemic, Structural Inequalities, and the Politics of International Health", 92 *American Journal of Public Health*, 2002, 343, 343 et seq.

¹⁰²⁰ Rawlinson/Donchin, note 1019, 262

“a person who cannot vote or drive in her own country or who is condemned by her village council to be raped in order to settle a dispute among men or whose children die of dysentery in the twenty-first century is not 'fundamentally equal'. Nor are the many women around the world whose lives are disrupted when multinational companies and technically oriented development projects irresponsibly impose changes that deprive their local economies of traditional markets and other resources required to meet subsistence needs and sustain their culture. Without recognition of structural (as opposed to merely accidental) inequity, UNESCO's invocation of rights [in the UDBHR] is so abstract as to be incompatible with its avowed intention.”¹⁰²¹

Thus a right to equal access to health care might be implicitly invalidated by societal structures which favour medical treatment of boys over girls or which allocate more and better nutritional resources to boys over girls. The face-value neutrality of a language of rights then sometimes merely disguises systemic or structural inequalities in any given society which the right does nothing to address as the right remains silent on the question of the impact of structural inequalities on the health of populations, as well as on the question of the necessity of social transformations and redistributions of power in addressing the underlying structural inequalities.¹⁰²²

It should also be noted that structural inequalities not only thwart rights that exist but are reflected in even more basic terms. That is, they play a role with regard to such questions as which issues are considered pressing issues at all within any society or at the international level and which hence are formulated as rights or principles at all, who the addressee of a human right is and how or whether they are to be enforced in case of a breach. For example, whether or not rights of indigenous groups with respect to natural resources are considered legitimate concerns for the international community of states to deal with is as much a question of power as is the question of whether or not domestic abuse of women is considered a violation of a human right as is the question of how much technology transfer in the area of bioethics should take place between developed and developing nations. Similarly, a country can have exceptionally high income inequality, inadequate provision for higher education, no medical infrastructure, lack public health emergency plans or refuse to provide training for physicians and yet no human right is breached. The question of whether or not these instances are considered a violation of a human right at all is a question of power which is not addressed by the right itself.

1.6. The Lack of Telos of Rights

One further problem sometimes associated with rights is that they are – to some extent at least – indifferent to the ends they procure. In other words “the rights system is indifferent to ends and in its indifference can claim systemic coherence without making any strong claims about the fullness

¹⁰²¹ Ibid. See also generally H. Brody, *The Future of Bioethics*, 2009.

¹⁰²² Ibid.

or vanity of the ends it permits.”¹⁰²³ That is, as long as each individual can exercise his or her right a system based on rights has no self-evident *telos*, overall moral aim or control of or interest in the ends it produces. Applied to the area of bioethics that means that standards merely seek to ensure that human beings have access to rights, such as the right to give informed consent or to highest attainable health care standards. Yet apart from setting conditions under which the ideal of highest attainable health care may or may not be invoked by individuals, i.e. apart from providing individuals or the right holder with the however distant opportunity to invoke a right, rights do nothing to actually endorse the aim, i.e. to endorse the aim of the highest attainable health care standard itself. Doctors in that sense might feel less responsible for their patients' overall wellbeing, as his or her responsibility formally does not extend beyond ensuring that his or her patient makes a free and informed decision.

This is related to a similar concern more specifically expressed by Alasdair MacIntyre and which is that rights simply lack the words or conceptual clarity to do what they are meant to do. In MacIntyre's word

“traditional European society inherited from the Greeks and from Christianity a moral vocabulary in which to judge an action good was to judge it to be the action of a good man, and to judge a man good was to judge him as manifesting dispositions (virtues) which enabled him to play a certain kind of role in a certain kind of social life ... But the breakup of the traditional forms of social life which was produced by the rise of individualism, begotten partly by Protestantism and capitalism, made the reality of social life so different from the norms implied in the traditional vocabulary that all the links between duty and happiness were gradually broken. The consequence was a redefinition of moral terms. Happiness is no longer defined in terms of satisfactions which are understood in the light of the criteria governing a form of social life; it is defined in terms of individual psychology. Since such a psychology does not yet exist, it has to be invented. Hence the whole apparatus of appetites, passions, inclinations, principles [such as rights], which is found in every eighteenth century moral philosopher.”¹⁰²⁴

The lack of *telos* of rights in this understanding is a consequence of the moral structures that emerged from the Enlightenment. Enlightenment and post-Enlightenment moral philosophers 'failed' because they, among others, abandoned the Aristotelian concept of teleology, which in one way or another relied on the idea that human life had a proper natural purpose, and that human beings could not reach this natural purpose without practicing their virtues.¹⁰²⁵ Enlightenment, however, by rejecting teleology also in ethics and morality, and by focusing purely on reason

¹⁰²³ Cover, "Obligation: A Jewish Jurisprudence of the Social Order", note 841, 69. See also Nida-Rümelin, "Wert des Lebens", note 66, arguing at 394 that "eine Ethik der Rechte kann daher in höherem Masse als teleologische Konzeptionen die Frage des Erstrebenswerten offenlassen und sich auf eine Abgrenzung derjenigen individuellen Freiheitsspielräume beschränken, die für die autonome Lebensgestaltung notwendig sind." See also A. MacIntyre, *After Virtue*, 1967, discussed below and generally Jonas, note 109.

¹⁰²⁴ MacIntyre, note 1023, 161. For a short background on MacIntyre see W. Kersting, "MacIntyre", in: J. Nida-Rümelin/E. Özmen (eds.), *Philosophie der Gegenwart in Einzeldarstellungen*, 2007, 413 et seq.

¹⁰²⁵ However, see Nussbaum, *Sex and Social Justice*, note 770, 57 et seq. following an Aristotelian approach as well as Sen, *Development as Freedom*, note 769, 52 et seq.

rendered ethics a 'body of empty knowledge devoid of its central content and context.'¹⁰²⁶ Basing their moral and ethical understanding on this incomplete framework, Enlightenment and post-Enlightenment thinkers, according to McIntyre lack a framework within which they can assess what a good act is. Instead McIntyre argues an ethics of virtue can provide meaning to human acts and deeds as it always comes with a teleological understanding of how humans should act.¹⁰²⁷

This overall critique is of some relevance in the present context. For example, treating someone with a placebo, if done with the honest intention to help, might be less deplorable, while it might be more so if the aim is simply to cut costs. Similarly, someone disclosing patient information to a third person, if undertaken with the honest intent to bring about some better form of treatment, for example, will seem less deplorable than if the same act is undertaken for financial gain, such as disclosure of information to a health insurance company. In these cases, being a good person is not necessarily about following or enforcing formal rules, a consideration that human rights cannot take into account. Instead, human rights, because they need to be to some extent at least coherent and their application predictable must be mostly blind to such considerations. Moreover, given the complexity of cases that are and can be dealt with by reference to rights and the infinite personal circumstances involved in cases of bioethical interest there is indeed an argument to be made in favour of an approach that deals with each of these cases on a case-by-case basis and individual level. What is right in one circumstance or for one person does not necessarily have to be right for another person and it does not even have to be right for the same person at all times and places.

1.7. The Fostering of Negative Human Traits through Rights

A further related problem sometimes associated with rights is that they are said to foster highly undesirable characteristics in humans, including lack of responsibility, selfishness and indifference to others.

It is held that "a culture of rights encourages a form of selfishness and an unwillingness to compromise that are incompatible with citizenship."¹⁰²⁸ The argument is that rights "posit selfish, isolated individuals who assert what is theirs, rather than participating in communal life."¹⁰²⁹ Where rights are laid down, so the argument, people no longer refer to their own sense of responsibility to people in need.¹⁰³⁰ A preoccupation with legal remedies – as William Sage puts it – moreover "is likely to lead to compliance with the law – nothing less, but certainly nothing

¹⁰²⁶ J. Schneewind, "Virtue, Narrative, and Community", in: 79 *Journal of Philosophy*, 1982, 653, 653 et seq.

¹⁰²⁷ Ibid.

¹⁰²⁸ Sunstein, note 990, 66, referring to the American legal system.

¹⁰²⁹ Ibid., 67.

¹⁰³⁰ R. Shep Melnick, *Between the Lines: Interpreting Welfare Rights*, 1994, 281, citing then President Bill Clinton, Address Before the National Baptist Convention, on 9 September 1994, describing a "crisis of values" and a "lack of individual responsibility".

more.”¹⁰³¹ Similarly, Arras concludes that “as medical ethics collapsed into law and rights ...[this] drove another nail into the coffin of medical ethics, and self-responsibility of the medical profession.”¹⁰³²

This position has several famous proponents. Jeremy Bentham for example regarded the idea that rights could be the starting point for political morality as “pernicious nonsense.”¹⁰³³ Similarly Marx claimed that none of the “so-called rights of man goes beyond egoistic man,...an individual withdrawn behind his private interests and whims and separated from the community.”¹⁰³⁴ More recently the critique has been continued by such authors as Kirsten Sellars who claims that “idealist championing human rights have done more to benefit themselves than their supposed beneficiaries”¹⁰³⁵ and Mary Ann Glendon who, while not so much criticising the concept of rights per se, still argues that the way a right is often interpreted results in that is abused by individualistic and selfish humans.¹⁰³⁶

It indeed seems that a language of individual rights might be less well-equipped to describe certain experiences, for example, what is involved in cases that concern groups or communities. A language of individual rights, for example, seems somewhat misplaced or inapt when dealing with a right, duty or responsibility to engage in sustainable development of present humankind towards future generations. It is not immediately obvious why the concern of sustainable development should at all be addressed under an individual right to sustainable development.¹⁰³⁷ Similarly a right to informed consent might be unduly individualistic in cases where the individual decision actually affects a range of people such as family members or friends.¹⁰³⁸ Yet whether it in fact promotes selfish behaviour in people may be doubted. For one, human beings and human activity never take place in complete isolation from its surroundings and hence it may be doubted whether a person really disregards family or community wishes only because he or she has a right to do so. To the contrary it seems that even if law exists in certain fields, people often reject the due process rights offered to them by law when it e.g. comes to resolving personal matters in close relationships.¹⁰³⁹ Also the contraposition, i.e. the idea that more community oriented societies necessarily result and foster less selfish behaviour cannot be sustained. Quite apart from the question of how to measure the degree of selfishness in any given society it is not clear whether more altruistic societies exist because they do not endorse a jurisprudence of rights. Moreover, to

¹⁰³¹ M. Sage, "The Lawyerization of Medicine", 26 *Journal of Health Politics, Policy and Law*, 2001, 1179, 1182.

¹⁰³² J. Arras/T. Murray, "In Defence of Clinical Bioethics", 8 *Journal of Medical Ethics*, 1982, 122, 124.

¹⁰³³ See Waldron, Theory of Rights, note 864, 1, citing J. Bentham, *Anarchical Fallacies*, 1824, 491.

¹⁰³⁴ K. Marx, "On the Jewish Question", in: K. Marx (ed.), *Selected Writings*, 1977, 54 et seq.

¹⁰³⁵ K. Sellars, *The Rise and Rise of Human Rights*, 2007, 2.

¹⁰³⁶ Glendon, note 21, 1, 10 and 56 et seq.

¹⁰³⁷ See also generally W. Parment, *Populations, Public Health, and the Law*, 2009, who advocates for a new vision for how courts should move past antiquated notions of individual versus communal interests.

¹⁰³⁸ Note however, that the UDBHR, note 4, and some other human rights standards as discussed above seeks to deviate from the language of strictly individualism by for example acknowledging that certain groups might need special assistance, Article 15 1 and Article 8. Yet it is not clear how groups might claim the rights enshrined in the UDBHR.

¹⁰³⁹ L. McClain, "Rights and Irresponsibility", 43 *Duke Law Journal*, 1994, 989 et seq.

say that rights instigate selfish behaviour seems somewhat simplistic. Rights, among many other functions, often constitute functional answers to a felt need to regulate human behaviour, they are not necessarily the source of this behaviour.

1.8. Excessive Use of Rights and Legal Talk

Much has been written about the excessiveness of rights and how everything is “rights talk” nowadays. The critique thereby seems to be that an overuse of rights might dilute their success and power and/or renders them meaningless.

Indeed, as briefly mentioned above, the language of rights is very present in international legal texts as well as in political movement and debate. Human rights, no matter the frequency of their violation, remain the 'currency' of international relations and many international legal negotiations and, for the reasons discussed in the first sub-section of this section, one of the favourite choices of groups or individuals to advance their concerns at the international level. Yet because human rights are so frequently invoked, linking bioethics with human rights can carry some negative implications as well. First of all, it could be that rights' “proliferation” renders human rights a victim of their own success.¹⁰⁴⁰ Too many human rights might dilute the invocation of a human right in single instances. It might also be that the 'brand' human rights becomes less powerful the wider it is spread and the more concerns are framed as human rights issues.¹⁰⁴¹ The continuing pressure to expand the list of human rights to include new areas, including that of bioethics, also might weaken efforts to protect traditional human rights concerns in the area such as the rather long established human right to life or health.¹⁰⁴² Here it is argued that human rights should focus on their core business of defending certain basic civil liberties of human beings.

Besides uncertainty as to the effectiveness of human rights if overused one further possible result of the inflationary use of rights is the devaluation of human rights caused by producing too much “bad human rights currency”.¹⁰⁴³ That is, if human rights, despite them being enshrined in international human rights standards, are consistently abused by governments or if they are implemented according to widely disparaging standards across states they might lose credibility and as such force of argument.¹⁰⁴⁴

¹⁰⁴⁰ With regard to the the European Court of Human Rights and the way it is being overwhelmed by the sheer number of submitted cases see R. Wolfrum/U. Deutsch (eds.), *The European Court of Human Rights Overwhelmed by Applications: Problems and Possible Solutions*, 2009.

¹⁰⁴¹ U. Baxi, "Too Many or too Few Human Rights", 1 *Human Rights Law Review*, 2001, 1 et seq.

¹⁰⁴² D. Feldman, "The Contribution of Human Rights to Improving Public Health", 120 *Public Health*, 61 et seq.

¹⁰⁴³ Nickel, note 985.

¹⁰⁴⁴ Asai/Oe, note 504, 216 et seq.

1.9. Conclusion

Using a framework of rights thus comes with several implications, including that human rights provide for a long established, well recognised and highly successful language within which ethical problems can and have successfully been addressed. Yet despite rights' many successes rights can also be problematic to the extent that rights can be rigid, simplistic and indeterminate and thereby prone to overlook structural inequalities. Their general lack of *telos* might inhibit their relevancy for the area of bioethics and their overuse might limit their effectiveness to achieve the very aims it wanted to reach.

2. Human Dignity

The second grid point identified above in thinking about bioethics within a human rights framework was that of human dignity. That is, the standards in the area of bioethics are tied to and are based on the philosophical concept and ideal of human dignity.

2.1. Fostering of Consensus and Justification of the Human Rights Project

It should first of all be noted that the use of the concept of human dignity as a central concept in the standards examined in this thesis and hence in the presently examined discourse, because of its high level of generality, has been one of the major reasons for or at least has been a most important factor in achieving a successful outcome in the negotiations leading to the instruments in the area of bioethics.¹⁰⁴⁵ As it was necessary to persuade states of vastly different ideological point of view that the declarations and the Convention in the area are consistent with their conceptions of a good order or with their conception of what it takes to lead a dignified life in the area of bioethics a vague conceptualisation of human dignity was and is much more likely to secure support from all states than a narrow definition¹⁰⁴⁶. That is so because in the end everyone can agree that human dignity is central, even if not why or how.¹⁰⁴⁷ Human dignity in that sense, in the same way as human rights per se provides for one language in which problems in the area of bioethics can be discussed and addressed while it at the same time allows states to infuse the concept with a meaning that is in accordance with their respective national sense of morality. For example, states came to vastly differing conclusions with regard to the question of whether or not it is compatible with respect for

¹⁰⁴⁵ Wolfrum/Vöneky, Human Dignity and Human Cloning, note 565, 133, making a similar statement with regard to the UN Declaration on Human Cloning, note 35.

¹⁰⁴⁶ McCrudden, note 890, 657.

¹⁰⁴⁷ Ibid. See also Schmidt, "Whose Dignity? Resolving Ambiguities in the Scope of "Human Dignity" in the Universal Declaration on Bioethics and Human Rights", note 889, 579, arguing that "in the absence of further guidance (as regards the term human dignity in the text), one could therefore assume that different accentuations in meaning are thought to be necessary, justified and helpful."

human dignity to engage in stem cell research, or whether to allow for research to be carried out on persons unable to consent.¹⁰⁴⁸

The concept of human dignity also provides a robust justification for the human rights project. If human dignity is important everywhere and human rights are the means by which human dignity is to be safeguarded then human dignity can provide the concept that can rally enough support from states to actually agree on substantive provisions and to provide support to human rights at any time and place.¹⁰⁴⁹

The concept of human dignity thus has an important mediating and reconciliatory function that is sometimes essential to reaching agreement among states in the area of bioethics.

2.2. The Definition of Dignity

Yet framing issues of bioethical interest by reference to the concept of human dignity also comes with certain drawbacks. As was discussed above, the term human dignity as used in a human rights context is not devoid of meaning. Yet outside of confined cases¹⁰⁵⁰ there is little guidance with regard to the meaning and scope of the term dignity. That is, the minimum definition of human dignity provided in the previous chapter, by no means forecloses further debate as to the exact meaning or scope of the concept. Even if the three claims specified above are accepted by scholars, scholars still differ in terms of their understanding of what the intrinsic worth of the individual human being consists in and who it applies to (ontological claim), "in their understanding of what forms of treatment are inconsistent with the inherent worth of the human being (relational claim), and in their understanding of what the implications of accepting the ontological and relational claims are for the role of the state vis-à-vis the individual, beyond the core idea that the individual does not exist for the state."¹⁰⁵¹ In other words, there exists no consensus, politically or philosophically, on how any of the three claims that make up the core of the concept are best understood.¹⁰⁵² In the words of Marmot

“many find the idea of putting dignity at the centre of global health convincing and appealing. “But what is dignity? How would we know if we were doing it? Is dignity, like beauty, in the eyes of the beholder, or is it a property of the individual? Can you have dignity, for example, regardless of how authority treats you? If we cannot define dignity

¹⁰⁴⁸ For background see UNESCO, General Conference, 33rd Session, Draft Report of Commission III, 33 C/83. Paris: Unesco, 2005:Annex II, 2–3. Schmidt, "Whose Dignity? Resolving Ambiguities in the Scope of "Human Dignity" in the Universal Declaration on Bioethics and Human Rights", note 889, 579.

¹⁰⁴⁹ Nickel, note 985.

¹⁰⁵⁰ See discussion above in Chapter V, 1.2.

¹⁰⁵¹ McCrudden, note 890, 658.

¹⁰⁵² Ibid.

precisely, we will have trouble measuring it. If we cannot measure it, how will we know if we are achieving it?"¹⁰⁵³

The following sub-sections elaborate some of the difficulties that stem from the lack of a clear definition of the concept of human dignity.

2.2.1. Uncertainties as Regards the Bearer of Human Dignity

One difficulty with the concept of human dignity as used in a human rights context is that it is rather difficult to make out who exactly is or, rather, who is not the bearer of that dignity.¹⁰⁵⁴ That is so because particularly in the context of bioethics it has been rather difficult to determine who does and who does not qualify as a human being. For example, standards in the area of bioethics do not define whether an embryo at any stage in its existence, a foetus of three or one of nine months, a deceased, a brain dead person or all or none of these qualify as a 'human being' and whether they are or are not hence the bearer of human dignity.¹⁰⁵⁵ Since only a human beings' dignity is, however, protected according to international legal standards, the lack of definition also means uncertainty as regards the very subjects of this protection.

Also long established international human rights standards do little to remove confusion regarding the question of who qualifies as human. That is so because many of the standards use different terms to refer to 'human beings' i.e. to bearers of human dignity. While the UDHR, for example, holds in Article 1 that "all human beings are born free and equal in dignity and rights", the ICCPR in its Recital 2 refers to the "recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family" and the ICESCR in Recital 3 recognises the rights specified in the Covenant derive from the inherent dignity of the human person. The UDBHR again in Article 2 (c) aims "to promote respect for human dignity and protect human rights, by ensuring respect for the life of human beings. It uses the term 'dignity' eight more times, six times of which in connection with the term human, yet as Schmidt points out "dignity is also related twice to "persons", once to "the life of human beings" and once to "all human beings".¹⁰⁵⁶ In addition, there is one reference to the dignity of "individuals."¹⁰⁵⁷ The Oviedo Convention in turn in its title makes

¹⁰⁵³ M. Marmot, "Dignity and Inequality", 364 *The Lancet*, 1019, 1020.

¹⁰⁵⁴ See Nida-Rümelin, "Bioethik und Menschenwürde: Dokumentation einer Debatte", note 77, 401 et seq., where various different opinions are expressed with regard to whether or not an embryo is the bearer of human dignity. See also generally Schmidt, "Whose Dignity? Resolving Ambiguities in the Scope of "Human Dignity" in the Universal Declaration on Bioethics and Human Rights", note 889; and J. Nida-Rümelin, "Menschenwürde und Selbstachtung", in: J. Nida-Rümelin (ed.), *Philosophie und Lebensform*, 2009, 236, 255 et seq. See also W. Vossenkuhl, *Ecce Homo! Menschenbild-Menschenbilder*, 2009. J. Seidel, *Schon Mensch oder Noch Nicht?*, 2010.

¹⁰⁵⁵ Cf. for example, N. Cantor, *After We Die: The Life and Times of the Human Cadaver*, 2010 and C. McCrudden, "Human Dignity and Judicial Interpretation of Human Rights", 19 *European Journal of International Law*, 2008, 655 et seq.

¹⁰⁵⁶ Schmidt, "Whose Dignity? Resolving Ambiguities in the Scope of "Human Dignity" in the Universal Declaration on Bioethics and Human Rights", note 889, 578. UDBHR, note 4, Articles 3 and 28 and Recitals.

¹⁰⁵⁷ Schmidt, "Whose Dignity? Resolving Ambiguities in the Scope of "Human Dignity" in the Universal Declaration on Bioethics and Human Rights", note 889, 578. UDBHR, note 4, Articles 3.

it clear that it is about the protection of human rights and dignity of the human being.¹⁰⁵⁸ It also mentions dignity in relation to the term individual.¹⁰⁵⁹ Generally it must be noted that no international human rights standard so far has provided an authoritative definition of what constitutes a human being¹⁰⁶⁰ in the same way as no biological or philosophical strand or dictionary so far has provided an authoritative definition of what it means to be human. To the contrary the question of what is and what is not a human being, what its characteristics and properties are have been endlessly debated among biologists and philosophers.¹⁰⁶¹

Commenting on the somewhat confusing use of terminology across human rights standards Harald Schmidt then notes that

“at one end of the spectrum, there are “all human beings” (or “the life of human beings”): although these terms may have metaphysical–vitalistic undercurrents, they are primarily biological concepts that can be understood to refer to humans in all stages of development, from the newly merged DNA that can be found in a fertilised egg, to infants, to children, to physically and mentally healthy women and men, to those with disabilities, to older people, as well as to patients in a state of brain death, and, in principle, even to corpses of recently deceased persons. All of these are forms of human life, or human beings at different stages of capacity or development. Then there is the reference to “human person”, which is primarily a legal or philosophical term, often used to refer to human beings with specific capacities, or qualities—these terms can be coextensive with biological definitions but they may also relate to a more narrow range of instantiations of humans. And there is the somewhat vaguer, albeit quantitatively most frequent, concept of human dignity: the adjectival construction suggests that dignity relates to humanity, although it is not clear whether this is humanity in the biological sense, or in the philosophical or legal sense.”¹⁰⁶²

Also the explanatory memorandum to a previous draft of the UDBHR eschews the question of who or what exactly is the bearer of human dignity. In para 21 it states that

“Bioethics applies to human beings and their relationship with the biosphere. While the notion of 'person' is defined in domestic law, human beings frequently appear in international documents and more recently in legal instruments related to bioethics. The two notions are often regarded as synonymous....”¹⁰⁶³

¹⁰⁵⁸ Oviedo Convention, note 5, Title.

¹⁰⁵⁹ Oviedo Convention, note 5, Recital 17.

¹⁰⁶⁰ While the UDHR, note 270, refers to all human beings who are born that limitation was dropped in the ICCPR, note 341, and ICESCR, note 341.

¹⁰⁶¹ See Chapter VI, 2.2. For a discussion of different possible elements of a definition of a human being see also Heilinger, *Unterwegs zum Neuen Menschen?*, note 11, 234 et seq. See also C. Illies, “Biologie statt Philosophie?”, in: D. Ganten/V. Gerhardt/J. Heilinger/J. Nida-Rümelin (eds.), *Evolution in Natur und Kultur*, 2010, 15 et seq. Discussing how and whether theories of evolution can explain what it means to be a human being and how culture comes about. And Nida-Rümelin, “Die Anthropologische als Normativ-Ethische Frage”, note 111, 197, arguing that “Den Menschen gibt es nicht, es gibt eine Vielfalt von Kulturen und Gemeinschaften, die untereinander zuwenig gemeinsam haben, als dass man „essentialistisch“ festlegen könnte, was das Charakteristische des Menschen sei”.

¹⁰⁶² Schmidt, “Whose Dignity? Resolving Ambiguities in the Scope of “Human Dignity” in the Universal Declaration on Bioethics and Human Rights”, note 889, 280.

¹⁰⁶³ Explanatory Memorandum, note 8, para 2, 60 and 74.

Yet the report does, however, not go on to elaborate on who or what kind of life forms are included in the term 'human beings'.¹⁰⁶⁴ While definitional quandary about who does and who does not constitute a human being and who hence is and who is not a bearer of human dignity might be less relevant and hence in lesser need of specification when it comes to deciding whether the torturing of any man or women is in accordance with his or her dignity, it is crucial in the area of bioethics, where the question of the dignity of the human being often arises exactly with regard to those 'marginal' beings or life forms that are either not yet born, deceased, not purely human, such as hybrid stem cells, or might have lost some of the biological or philosophical attributes sometimes connected with humanness, such as the ability to reason, think and express wishes or act. For all these beings the question of who or what comes under the protection of human dignity have very real implications. A definition which, for example, excludes embryos from having human dignity might allow for a framework in which IVF and stem cell research are perfectly permissible. In reverse a definition which grants embryos equal dignity as born human persons will have to place some or complete restrictions on embryonic stem cell research. Similar implications arise in the cases of for example human cloning, genetic research or organ transplantation of deceased people, etc. Moreover, history has shown time and again that such terms as 'human being' can come to be interpreted in ways that from today's vantage point might seem inconceivable, such as the exclusion of witches, sorcerers or slaves from the category of human being or as the definition of certain races or ethnic groups as less or not yet fully evolved human beings.¹⁰⁶⁵ Yet to think of this as a distant and irreversible part of humankind's past history is certainly naïve too.¹⁰⁶⁶ Hence, while remaining silent on the question of an exact definition of who is the bearer of human dignity provides for the much needed leeway for states to construe their national regulations according to their internal values and ideals, doing so also comes at the price of considerable uncertainty as to what it is that is protected and at the risk of that human dignity might be construed in a way that that is harmful to some human beings or life forms.

2.2.2. Actions in Conformity with Human Dignity

One further problem with an overtly vague definition of the concept of dignity is that it can be endlessly debated what treatment is and what is not in accordance with the dignity of the human being.

¹⁰⁶⁴ States made, however, various submissions regarding the meaning of the concept of human dignity. Schmidt, "Whose Dignity? Resolving Ambiguities in the Scope of "Human Dignity" in the Universal Declaration on Bioethics and Human Rights", note 889, 280. See also Nida-Rümelin, "Bioethik und Menschenwürde: Dokumentation einer Debatte", note 77, 401 et seq. on the debate of human dignity and cloning.

¹⁰⁶⁵ Beyleveld/Brownsword, note 662, 19-20

¹⁰⁶⁶ For some more modern forms of this phenomenon see Fact Sheet 1 of the UN World Conference on Racism, 2001, at: <http://www.un.org/WCAR/e-kit/fact1.htm> (last visited 27.04.2012).

To obtain some sense of the uses of dignity in recent debates in the area of bioethics Ashcroft, for example, point to all of the following examples that have been argued to be contrary to human dignity: "organ sales from living "donors", seeking patent rights over human genes, making animal–human chimeras, obliging someone to live in abject poverty, pornography, torture, sex selection by pre-implantation genetic diagnosis, death in irremediable physical or psychological suffering, abandonment to senility in a nursing home and prolonged proceedings of court cases."¹⁰⁶⁷ Even conflicting meanings can be inferred from the term dignity as Mohammed Bedjaoui points out:

... 'human dignity'. It is an expression which seems simple: one immediately apprehends its prospective import, if not its exact meaning. But, paradoxically, it is also an expression full of fragility, for in the name of the same argument of 'human dignity' some refute the legitimacy of euthanasia, whilst others claim it as the ultimate right of those who wish to 'die in dignity'!¹⁰⁶⁸

The breadth of actions that can be justified by reference to human dignity and the fact that sometimes even conflicting meanings can be derived from it then undermines the concept in several ways.¹⁰⁶⁹ It for example unduly broadens the concept of human dignity beyond meaningful limits. If all the above stated claims are to be discussed under the broad theme of human dignity, if all can claim to be in accordance with human dignity, then it seems that the term human dignity is too unspecific as to be of much meaning at all. In the same way as pro and anti assisted suicide arguments can and are framed under the heading of human dignity so can be the selection of embryos during IVF treatment which do or do not carry certain genetic disorders may be construed as being in accordance or against a life worth of dignity. Because of these uncertainties regarding the scope and meaning of human dignity the concept in fact can become an empty formula, used to patch over and disguise states' actual disagreement on substantive issues at hand. This has arguably been the case with regard to the UN cloning declaration, discussed above, which sets a limit to human cloning by prohibiting "all forms of human cloning inasmuch as they are incompatible with human dignity and the protection of human life" as well as it prohibits any genetic engineering techniques "that may be contrary to human dignity."¹⁰⁷⁰ However, stated like this, these provisions leave it first of all unclear whether the cloning of a human being for reproductive purposes or for therapeutic purposes or both or neither violates human dignity. It

¹⁰⁶⁷ Ashcroft, "The Troubled Relationship Between Bioethics and Human Rights", note 993, 35. See also H. Biggs, *Euthanasia, Death with Dignity and the Law*, 2001, x; Beyleveld/Bownsword, note 662, 25, discussing the case of the French dwarfs; C. Schneider (ed.), *Law at the End of Life The Supreme Court and Assisted Suicide*, 2000, 125 et seq.; J. Frowein/M. Hartwig, *Völkerrecht - Menschenrechte - Verfassungsfragen Deutschlands und Europas*, 2004, 311, discussing the case of *Bock v. Germany*, 159 Eur Ct. Hr. R., 1989, 36-37. See also Nida-Rümelin, "Bioethik und Menschenwürde: Dokumentation einer Debatte", note 77, 242, linking the concept of human dignity with self-esteem (Selbstachtung) and an humiliation (Demütigung).

¹⁰⁶⁸ M. Bedjaoui, "Address Before the International Bioethics Committee of UNESCO", 1995, 1 UN ESCOR International Bioethics Committee, UN Doc. DRG.96/WS/8, 1995, 137, 144. On the question of euthanasia, assisted suicide and general worth of human life see in particular also J. Nida-Rümelin, "Autonomie und Würde", in: J. Nida-Rümelin, *Philosophie und Lebensform*, , 2009, 222 et seq.

¹⁰⁶⁹ Ashcroft, "The Troubled Relationship Between Bioethics and Human Rights", note 993, 34.

¹⁰⁷⁰ UN Declaration on Human Cloning, note 35.

also leaves it unclear whether it is actually the human dignity of the potential clone or of the person that has been cloned or of both or none that is in question.¹⁰⁷¹ Taken together, despite its 'immediate appeal', any reference to the concept of human dignity in bioethical debates then does provide little actual guidance with regard to the question of what is and what is not in conformity with a protection of human dignity.

2.2.3. The State and Dignity

It is furthermore not clear what role the state has as regards human dignity. As one major addressee of human rights standards, including those in the area of bioethics, it falls mostly on states to safeguard human dignity.¹⁰⁷² Yet, non-state actors have the capacity and have often been engaged in actions that, if performed by a state official, would very likely have qualified as torture.¹⁰⁷³ It is not immediately self-evident why the state should be considered a major threat to human dignity if non state actors not only have the capacity but have also been shown to use this capacity to engage in activity that arguably fulfils most of the definitional requirements of torture.

Secondly, even if human dignity only gains meaning in relation to the state it is still far from being clear what a state has to or can do to enable a human being to live a dignified life. Apart from the fact that the exact meaning of the statement "the individual does not exist for the sake of the state" is far from being clear, the antithesis, i.e. the claim that the state exists for the sake of the individual human being is also rather vague and difficult to be engendered with meaning. In German constitution, as seen above, human dignity is generally seen as an absolute limit to state action and treated as a legal principle."¹⁰⁷⁴ Yet it is also clear that "what human dignity requires may depend on the context."¹⁰⁷⁵ Moreover, the special status that the concept of human dignity has been given in the German Constitution is unparalleled in the world and certainly has not been replicated in international law.¹⁰⁷⁶ Nevertheless, this suggests that at least at some national levels and at the level of the European Union there are certain minimum standards of political treatment that a state must observe in order to preserve human dignity. The use of coercion, physical or psychological for example is usually cited to be "as striking an

¹⁰⁷¹ For a further discussion of human dignity in relation to human cloning see also H. Putnam, "Cloning people", in: J. Burley (ed), *The Genetic Revolution and Human Rights*, 1999, 1 et seq.

¹⁰⁷² Even if human dignity as an ethical concept could be said to be addressed to all human beings, as used in the standards it is still mostly addressed to states.

¹⁰⁷³ See for example the "Bhopal case". E. Broughton "The Bhopal Disaster and its Aftermath: A Review", 4 *Environmental Health*, 2005, 1 et seq.

¹⁰⁷⁴ Petersen, note 663.

¹⁰⁷⁵ J. Frowein, "The Concept of Human Dignity", in: D. Kretzmer/E. Klein (eds.), *Human Rights Discourse*, 2002, 121, 124.

¹⁰⁷⁶ Petersen, note 663.

affront to the dignity of the person as physical abuse or mental torture"¹⁰⁷⁷. Yet different definitions exist regarding the question of what exactly qualifies as torture or physical or psychological coercion.¹⁰⁷⁸ States, for example, differ widely with regard to the question of whether human beings who are unable to consent may be subjected to biomedical research.¹⁰⁷⁹ Human dignity therefore might set an absolute limit to state action but that limit must not be the same in every state and it is not clear what this limit really is. It is even less clear what it is - beyond the absolute limit-setting function - that the protection of human dignity requires a state to do. For many scholars respect for the dignity and worth of all persons, and for their individual choices, leads for example, broadly speaking, to a strong emphasis on the will and consent of the single patient.¹⁰⁸⁰ They take it to mean that states have to ensure that paternalistic behaviour of doctors is outlawed as it is incompatible with the due respect for the dignity of the person and that they have to ensure that doctors may not use coercion to impose decisions and attitudes on those subject to their treatment or to extend their authority into areas of human life that are essentially personal and familial.¹⁰⁸¹ Yet again, that is not an authoritative statement on how states have to behave in order to be in accordance with the human rights standards and in fact actual state practice shows that there is no international agreement regarding the exact scope and meaning or level of protections that flow from any of the provisions in the standards.

The absence so far of uniform national approaches to many questions of bioethical interest, including for example with regard to such questions as research on those incapable of consenting, and that states can claim their opposing national regulations with regard to these questions to be in accordance with the concept of human dignity as inscribed into standards in the area of bioethics suggests that there is no clearly defined role or requirement for the state re the protection of human dignity in the area of bioethics. As long as the standards lack a clear cut definition of the term human being they, however, ultimately remain open to an infinite variety of possible interpretations of the term and hence more likely than not, not to regulate anything at all.

2.3. The Utility of Human Dignity

Given the confusions and ambiguities that surround contemporary uses of the term human dignity some scholars have come to question the utility or overall value of the concept of human dignity in

¹⁰⁷⁷ O. Schachter, "Human Dignity as a Normative Concept", 77 *American Journal of International Law*, 1983, 848, 850.

¹⁰⁷⁸ Ibid., 850. N. Jecker, "Exploiting Subjects in Placebo-Controlled Trials", 22 *The American Journal of Bioethics*, 2002, 19 et seq. The question of who may and who may not be subjected to research without his or her explicit consent is far from being clear or answered in the same manner in every state.

¹⁰⁷⁹ See for example Germany's Explanation of Vote concerning the UDBHR, note 274.

¹⁰⁸⁰ Schachter, "Human Dignity as a Normative Concept", note 1077, 850.

¹⁰⁸¹ Ibid.

bioethical debates or suggested to altogether replace the concept with other 'slogans'.¹⁰⁸² Richard Ashcroft summarises several different positions on the concept of human dignity as relevant to the bioethical debate in the following quote:

Currently, scholars divide into four distinct groups as regards dignity. One group regards all “dignity-talk” as incoherent and at best unhelpful, at worst misleading. I venture to suggest that this group is the mainstream of current English speaking bioethics. Another group finds dignity talk illuminating in some respects, but strictly reducible to autonomy as extended to cover some marginal cases...[...] The third group considers dignity to be a concept in a family of concepts about capabilities, functionings, and social interactions. This group is ...[...] inspired by the writings of Amartya Sen and Martha Nussbaum on development and freedom. The final group considers dignity as a metaphysical property possessed by all and only human beings, and which serves as a foundation for moral philosophy and human rights. This group is perhaps the mainstream in European bioethics and much theological writing on bioethical topics...¹⁰⁸³

With regard to these disparaging positions two questions will be of particular relevance in this section. For one, to what extent can the concept of human dignity conceptually be distinguished from such concepts as autonomy and/or respect and secondly, whether it makes sense or is appropriate to use this concept at all.

Regarding the distinction between human dignity and other concepts, most importantly that of respect and autonomy, Ruth Macklin, representing several bioethicists of the first two groups mentioned in the quote, for example asserts that “dignity is a useless concept in medical ethics and can be eliminated without any loss of content.”¹⁰⁸⁴ In her critique of human dignity as a concept used in bioethical debate, she claims that the concept functions as “a mere slogan”¹⁰⁸⁵, “a poor, blurred substitute” for what she describes as the principle of medical ethics, respect for persons' autonomy.¹⁰⁸⁶ She concludes that “a close inspection of leading examples shows that appeals to dignity are either vague restatements of other, more precise, notions or mere slogans that add nothing to an understanding of the topic.”¹⁰⁸⁷ This approach finds some support in Sen's and Nussbaum's capabilities approach. Although, according to Sen and Nussbaum, dignity might not be coextensive with autonomy or capabilities, they suggest that without achieving autonomy or capabilities an individual cannot have basic freedoms without which the individual cannot have dignity.¹⁰⁸⁸ Dignity and autonomy are thus interrelated to an extent that they can often be used interchangeably. Other scholars, particularly of the fourth group mentioned above, counter by that

¹⁰⁸² R. Macklin, "Dignity Is A Useless Concept," 327 *British Medical Journal*, 2003, 1419, 1419.

¹⁰⁸³ R. Ashcroft, "Making Sense of Dignity", 31 *Journal of Medical Ethics*, 2005, 679, 680. See also J. Nida-Rümelin, "Menschenwürde und Selbstachtung", note 1055, 236 describing three problems related to the concept of human dignity: "Drei krankheiten haben ihn [den Begriff] befallen: Diese sind die Jurifizierung, die Theologisierung und die Idealisierung."

¹⁰⁸⁴ Macklin, note 1082, 1419.

¹⁰⁸⁵ Ibid., 1420.

¹⁰⁸⁶ Ibid.

¹⁰⁸⁷ Ibid., 1419. Autonomy and respect, like dignity, according to Macklin's and other scholars' view, are thereby usually understood as being absolute, not relative to a particular culture.

¹⁰⁸⁸ Marmot, note 1053, 1020. See also A. Sen, *Inequality Reexamined*, 1992. M. Nussbaum, *Women and Human Development*, 2000.

there seems to be something more to the abstract notion of “dignity” that sets it apart from the practical notions of autonomy and respect. That is, according to these scholars, the latter notions are understood as the consequence of human dignity, not dignity itself.¹⁰⁸⁹ Moreover, if dignity indeed was the same as, for example, respect this “would inevitably beg the question and lead to circular reasoning: we are obliged to respect persons because... they deserve respect.”¹⁰⁹⁰

While it indeed seems that respect and dignity can be distinguished by that respect flows from a person's dignity or what makes him or her human it seems more difficult to meaningfully distinguish between autonomy and dignity in that way. The literature in the area of bioethics sometimes seems to use both concepts more or less interchangeably. Often the concept of human dignity is thereby portrayed as “a capacity for rational thought and action, the central features conveyed in the principle of respect for autonomy”.¹⁰⁹¹ If for example an analysis of the implications of dignity in a bioethical context comes to the conclusion that individuals are to be taken seriously, that a state may not engage in abuse of its citizens, that personal liberty, especially the liberty to choose and lead one's own life are entailed by the principle of equal respect of each individual's dignity, that emphasis on respect for individuals and their choices also implies proper regard for their distinct identity, their capacity to make choices, this ultimately, simply seems to restate the idea of autonomy of the human being.¹⁰⁹² Moreover, it is in fact not so clear whether autonomy or dignity precedes the other and which is the consequence of which and whether there is at all a causal relationship between the two. Both concepts are usually derived or are related somehow to human beings' special status among all beings, usually allocated to their capacity to reason.¹⁰⁹³ That is, the capacity to reason and to thereby form moral or good or correct decisions is the source of human beings' humanness, and thereby the source of their dignity and their autonomy. Autonomy, understood as the exercise of that human capacity in that sense is a more definite statement than the idea of dignity which then seems to be the ability to exercise reason. Since the source of these concepts is the same and since both concepts aim at preserving or protecting this source, the concepts' subsequent relationship and respective roles are also often the same or at least blurred. The only difference between both concepts in many accounts then seems to be that dignity is understood as an absolute, inviolable principle that cannot be taken away by others (i.e. the ability to exercise reason), whereas autonomy (i.e. the exercising and following

¹⁰⁸⁹ R. Andorno, Human Dignity and Human Rights as a Common Ground for a Global Bioethics, note 885, 225.

¹⁰⁹⁰ Ibid.

¹⁰⁹¹ Macklin, note 1082, 1420.

¹⁰⁹² See for example Schachter, "Human Dignity as a Normative Concept", note 1077, 850 arguing that human dignity entails "recognition of a distinct personal and individual identity, individual autonomy and individual responsibility." And that the individual's choices, autonomy and responsibility therefore must be respected.

¹⁰⁹³ In Kant's understanding for example, all persons have dignity and are therefore owed respect because they are persons, that is, free rational beings who are capable and morally obliged to form their own moral decisions. To be a person is to have a status and worth that is unlike that of any other kind of being: it is to be an end in itself with dignity. And the only response that is appropriate to such a being is respect. Respect and dignity is entailed by one formulation of the Categorical Imperative, which is to "act in such a way that you treat humanity, whether in your own person or the person of any other, never simply as a means but always at the same time as an end," Kant, *Grundlegung zur Metaphysik der Sitten*, note 724, 4:429 which again, as explained above, is also the source of or requirement for human beings' autonomy. See under chapter VI, 1.2.

through with the autonomously formed decisions), can be taken away or threatened by others. The debate between those arguing for the utility of the concept of human dignity and those against then seems, in many ways, to hinge on exactly this question of whether both or only the concept of human dignity is taken to be an absolute principle as both concepts can in fact be used mostly interchangeably as long as they are both taken to be absolute and not relative to particular cultures or societal understandings.¹⁰⁹⁴ If, however, only one of these concepts, usually that of dignity is understood to be inviolable then in fact, there is a difference between both concepts as only a person's dignity is independent of how others relate to and treat a person, whereas, in that understanding, a person's autonomy could potentially be taken away by others.

The just stated distinction, however, does not sit easily with the wording of many of the human rights provision of the UDHR and the standards in the area of bioethics in which human dignity itself is portrayed as something that needs protection through individual human rights. In these examples human dignity is not taken to be absolutely inviolable but, like autonomy, it can be threatened or restricted through actions of others. Moreover, if human dignity in the context of human rights and in contradistinction to autonomy, was really taken to be absolute it makes little sense to even consider actions that can promote respect for or protect human dignity, as doing so means to take dignity to the same level as autonomy, i.e. a level on which it can be threatened or discharged. And, in reverse, if there are acts that are more or less conducive to or protective of human dignity, does the concept of dignity allow for degree? Does someone who lives a life in abject poverty live a less dignified life than someone who does not?¹⁰⁹⁵ Ashcroft contemplating the possibility of a concept of dignity that admits of degree, for example opines that

“For example, racist abuse insults the abused person through an implied claim that he or she lacks human dignity, but it does not thereby destroy that person's dignity. On the other hand, tortures are designed to destroy torture victims' sense of their own dignity, and the perception that they are a bearer of dignity in the eyes of the torturer. It is, however, a point worth debating whether some torture breaks through actually to destroy the dignity of the torture victim. ...[.]... Shaming punishments can be considered to aim to lessen the dignity of those who are punished. Dignity in this sense is not an intrinsic property of the person but a synonym for self-respect or social standing.”¹⁰⁹⁶

Yet, it is clear that human dignity cannot be both, inviolable and non-dischargeable and at the same time depend on how a person is treated by others or under which external conditions he or

¹⁰⁹⁴ Ashcroft, "Making Sense of Dignity", note 1083. M. Nussbaum, *Hiding from Humanity: Disgust, Shame and the Law*, 2004.

¹⁰⁹⁵ Ashcroft, "Making Sense of Dignity", note 1083, 680.

¹⁰⁹⁶ Ibid. The Explanatory Memorandum, note 8, para 37 for example seems to suggest that human dignity admits of degree in that it states that "the declaration makes a distinction between (1) the principles directly related to human dignity such as respect for human rights and fundamental freedoms, benefit and harm, autonomy, consent and confidentiality; (2) the principles concerning the relationships between human beings, such as solidarity, cooperation, social responsibility, equity, justice, cultural diversity; and (3) the principles governing the relationship between human beings and other forms of life and the biosphere, such as responsibility towards the biosphere. The order of the principles in the declaration therefore follows a particular rationale and endures a systemic approach." "The rationale followed in the draft declaration is to present principles in the following way: they determine gradually widening obligations and responsibilities in relation to the individual human being itself; to another human being; to human communities; to humankind as a whole; and towards all living beings and their environment.

she lives. Nevertheless, the way human dignity is treated, portrayed and advanced in the standards in the area of bioethics does exactly that, it suggests that dignity is a relative concept that needs to be protected and that can be enhanced through certain actions. In that sense human dignity is treated like the concept of autonomy and autonomy and dignity of the person can be found on the same level and can or rather are in fact used interchangeably. Moreover, both concepts seem in fact to admit of degree if there can be more dignified ways of living one's life or more autonomous decision than others. Of course all that does not mean that human dignity or autonomy are not nevertheless valid and distinct concepts. Yet it is to say that the way human dignity is used in the standards in the area of bioethics and in a human rights discourse generally often makes it indistinguishable from the concept of autonomy.¹⁰⁹⁷

One answer that might cut through and explain some of this confusion around these two terms can be found in McIntyre's idea, briefly mentioned above, that certain concepts were meant for another context. That is, according to MacIntyre some kinds of talk about, for example, virtue simply make no sense today, but that this is not to show that this talk never made sense or can never make sense or that they are "false" or "meaningless".¹⁰⁹⁸ Rather, these concepts had meaning and were right in their original context. Taken out of this context they, however, must fail as they are inapt to describing or handling the newly assigned context.¹⁰⁹⁹ Applied to the concept of human dignity and how it is used in a human rights context it could be argued that human rights and now many bioethical debates have taken the concept of human dignity out of its original context and use it in a different context, for which it simply is not fit. That is, human dignity and its functionally equivalent concepts, such as dharma or li etc. are concepts that seek to state the often deeply but not necessarily spiritual or religious notion that all beings are worthy and 'blessed', that they exist for a worthwhile reason, that they have a valid purpose in the world, and that human beings' are innately good, in the sense that they, by their nature and through the means they were endowed with can live a morally good life.¹¹⁰⁰ If that was the original idea behind the concept of human dignity, it, arguably, was never meant to solve technical questions of stem cell research, biotechnology or reverse engineering. In fact it was never meant to be further discussed at all as it just is.

¹⁰⁹⁷ USA Presidential Commission Report on Human Dignity and Bioethics, 2009, at:

<http://www.bioethics.gov/transcripts/> (last visited 27.04.2012). For example, H. Baranzke/G. Duttge, *Würde und Autonomie als Leitprinzipien der Bioethik: Grundzüge einer moralphilosophischen Verständigung*, 2012. A. de Silva, *Human Rights, Dignity and Autonomy in Health Care and Social Services: Nordic Perspectives*, 2009

¹⁰⁹⁸ Ashcroft, "Making Sense of Dignity", note 1083, 680.; MacIntyre, *After Virtue*, note 1023, 1.

¹⁰⁹⁹ Ibid.

¹¹⁰⁰ Cf. R. Spaemann, "Ueber den Begriff der Menschenwürde" in: E. Böckenförde/R. Spaemann (eds.), *Menschenrecht und Menschenwürde*, 1987, 297 et seq. In that sense human dignity is inviolable and would not require protection through human rights standards.

For all these reasons it seems that ethical controversies cannot easily be settled simply by stating that this or that solution respects or violates human dignity¹¹⁰¹ and there indeed is a risk that talking about bioethical relevant issues by reference to the concept of human dignity simply “collapses into claim and counterclaim about moral intuitions concerning what dignity is, or what has it, or what would affect it.”¹¹⁰² In these instances bioethical debates might indeed be better off using the more clearly defined concept of autonomy, although that too comes with certain difficulties, to be discussed below. Nevertheless, it should not be forgotten that in spite of the apparent vagueness of the notion of human dignity and the difficulties that flow from that, the central role assigned to it in international standards in the area of bioethics is not the result of a merely rhetoric strategy, but usually reflects a real concern about the need to protect the integrity and identity and to guarantee respect for humans and humanity and as such has a valid place in these discussions.¹¹⁰³

2.5. Conclusion

The ethical concept of human dignity is the corner stone of human rights doctrine and philosophy. It is a fluid concept that so far lacks a terminal definition yet its central role in any debate in the area of bioethics has frequently been confirmed and has helped the standards in the area to succeed.

While it is defined in relation to specific conduct, such as for example in relation to torture, discrimination, and more specifically in the area of bioethics as a barrier to human cloning and to germ line intervention in large parts the concept has remained rather ill-defined. When then used outside of these narrowly confined cases human dignity remains a rather vague concept, which then comes with several difficulties. The concept, for example, does not authoritatively settle who exactly the bearer of human dignity is, what actions are conducive to respect for human dignity in such areas as human genetic enhancement and what the state has to do in relation to human dignity to honour its obligations under international law. It is furthermore not quite clear how the concept of dignity can be distinguished from other concepts such as autonomy and, consequently, what the concept of human dignity really adds to the debate.

¹¹⁰¹ M. Haery, "Another Look at Dignity", 13 *Cambridge Quarterly of Healthcare Ethics*, 2004, 7 et seq. This does of course not mean that the concept of human dignity can be successfully used to resolve legal problems in other context. Cf. for example B. Zypries, "From Procreation to Generation? Constitutional and Legal-Political Issues in Bioethics", in: R. Wolfrum/S. Vöneky (eds.), *Human Dignity and Human Cloning*, 2004, 107, 111.

¹¹⁰² Ashcroft, "Making Sense of Dignity", note 1083, 680

¹¹⁰³ Knoppers, note 400, 385.

3. Sovereignty

It was shown above how human rights almost only exist in relation to the state. The implications of tying human rights so closely to the sovereign nation state will be discussed over the following sections.

3.1. *The Resilience of the State*

While there may be many critical points of note with regard to the role of the state in a human rights framework, to be further explained over the next sub-sections, it first has to be noted that several critical factors not only explain but also speak for the resilience of the sovereign nation state and its central role in human rights frameworks. For one, so far the sovereign nation state alone has been able to provide the structures of authority needed to cope with incessant claims of competing societal groups and to provide public justice essential to social order and responsibility.¹¹⁰⁴ In the area of bioethics that means that in the current set up only the state so far can – if at all - provide the structure and authority needed to commit differing societal or other groups with strong and diverging interests or different views to the same legal standards. The state thereby offers a widely accepted platform for negotiations between various groups and, in case no consensus can be achieved on relevant matters, 'enforce' one standard for all or broker a compromise.¹¹⁰⁵ In the area of bioethics where issues of relevance usually spark much controversy and corresponding fault lines run through all segments of society the state might be the only entity that can establish standards, necessary to create protection by and certainty of the law.

It has also been submitted that “the weak and vulnerable are, on the whole, more likely to obtain protection and benefits through their territorial state”¹¹⁰⁶ than through alternative arrangements such as free markets or nongovernmental associations that lack effective authority.¹¹⁰⁷ That is so because only the state so far seems able to counterbalance the processes of, for example, free markets and unequal distributions of wealth within societies as well as to ensure that natural resources are exploited and processed in fair and egalitarian ways. The territorial nexus attached to sovereignty thus has a profound significance as it ensures “an arena in which all in the defined territory have access to common institutions and the equal protection of law”¹¹⁰⁸.

Finally, despite good reason to question concentrated and absolute sovereign powers in the state, the issue of sovereignty and non-intervention often remain the main line of defence against foreign

¹¹⁰⁴ Schachter, *International Law in Theory and Practice*, note 607, 14.

¹¹⁰⁵ Ibid.

¹¹⁰⁶ Schachter, "The Decline of the Nation-State and its Implications for International Law", note 933, 9.

¹¹⁰⁷ Ibid. see also Alston/ Steiner, note 214, 538 et seq.

¹¹⁰⁸ Schachter, *International Law in Theory and Practice*, note 607, 9. see also M. Koskenniemi, "The Wonderful Artificiality of States", 88 *American Society of International Law*, 1995, 28, 28-29. For example, subsidies or funding for research that is generally of public interest but unlikely to be carried out by private companies can be granted on the national level. Natural resources can be exploited for the common good of all citizens.

efforts to limit domestic and international choices that third world states - and their citizens - can make. In that sense the resilience of the nation state is more than a tribute to governing elites as it can help protect nations and societies from undue interference and moral 'chauvinism'.¹¹⁰⁹

3.2. Minimum Consent

Yet, developing standards in the area of bioethics within the context of international states' society of sovereign states also comes with several potential drawbacks. One is that international standards that have been formulated in such an environment usually result in a minimum consent. That is, formally all states are equal and no sovereign can force other states to accept and adhere to certain standards. As a result human rights standards in the area of bioethics can only come into existence if all states involved form a consensus. Such consensus, however, will most likely be reached on the lowest common denominator, i.e. delimit the "lower limits on tolerable human conduct" rather than stating "great aspirations and exalted ideals."¹¹¹⁰ As such the standards in the area of bioethics will often be minimal standards.¹¹¹¹

The UNESCO process, for example, in shaping the UDBHR gave equal weight to all member states' representations - or, as Ashcroft remarks, if not equal at least some weight to all representatives. By actively promoting consensus on the Declaration UNESCO thus avoided division between the developed and developing countries and was able to forge widespread consensus on the UNESCO Declaration.¹¹¹² Yet this consensus came at the price of that the Declaration in many ways only embodies the minimum consent between states. To the extent that those drafting and adopting the declaration represented a range of different views, consensus could only be obtained if the declaration made minimalist claims that all could support.¹¹¹³

One of the many examples of how the minimum consent is embodied in the standards is Article 18 para 1 of the Oviedo Convention, which ensures the protection of the embryo in vitro in the framework of research and Article 18 para 2, which prohibits the creation of embryos for research purposes. Since states could not agree on the level of protections that should be given to all

¹¹⁰⁹ Schachter, *International Law in Theory and Practice*, note 607, 9.

¹¹¹⁰ Shue, note 639, 23.

¹¹¹¹ Schneider, note 21, 16. See also G. Jellinek, *Die Sozialethische Bedeutung von Recht, Unrecht und Strafe*, 1908, 45, characterizing law as "the minimum ethics" (das ethische Minimum) which only embodies those moral requirements that have to do with "the indispensable conditions of social life."

¹¹¹² Ashcroft, "The Troubled Relationship Between Bioethics and Human Rights", note 993, 35, citing R. Levine/S. Gorovitz/J. Gallagher (eds.), *Biomedical Research Ethics: Updating International Guidelines - A Consultation*, 2000.

¹¹¹³ D. Benatar, "The Trouble with Universal Declarations", 5 *Developing World Bioethics*, 2005, 220 et seq. Similarly, earlier drafts of the UDBHR, note 4, for example meant Article 3 b to read "any decision or practice shall respect the principle that the interests and welfare of the human person prevail over the sole interest of science or society." while the final version reads somewhat weaker "the interest and welfare of the individual should have priority over the sole interest of science or society". For a discussion of this and further examples of how UNESCO's IGBC, as the representative of states, watered down the draft of the UDBHR presented to it by the IBC, see Vöneky, *Recht, Moral und Ethik. Grundlagen und Grenzen Demokratischer Legitimation für Ethikgremien*, note 15, Chapter 6 II 2 d.

embryos in vitro in the framework of research they were only able to agree on a minimalist consent of what must be avoided with regard to the embryo. The formulation of para 1, stating that “where the law allows research on embryos in vitro, it shall ensure adequate protection of the embryo” leaves it open whether research on embryos in vitro is compatible with human rights at all and what kind of protection is to be afforded. The Convention also does not include the more contentious topic of research on embryos in vivo as states had vastly different ideas of the good with regard to these questions.

Another example might be Article 8 of the Oviedo Convention which deals with emergency situations. It states that “when the appropriate consent cannot be obtained, any medically necessary intervention may be carried out immediately for the benefit of the health of individuals”. This statement was generally criticised as being so basic and minimalist that it is de facto superfluous.¹¹¹⁴ While in principle no harm comes from minimalist statements they also certainly do not more than that, i.e. than providing minimalist answers to sometimes very complex problems. Moreover, these standards will likely feature in future debates in the area and thereby set the tone of the debate to some extent. As such setting a minimum standard as basis for future discussions in the area might negatively influence the debate if the aim is to set standards that provide a considerably higher level of protection than the one agreed to so far.

3.3. Consent by few States

Alternatively do states simply not sign up to a standard at all that they deem either irrelevant or not compatible with their interests, including their moral or ethical point of view. This is arguably the case with the Oviedo Convention and its Protocols. While it might be fair to say that the majority of European states have signed the Convention (23 have ratified and 11 signed it so far), several important and influential states have not signed or ratified the Convention and show no intention of doing so. For example Germany, the United Kingdom, Russia, Austria, Belgium and several others have not signed or ratified the Convention. Of the non-member states that were invited to sign the Convention, including Australia, the USA, Japan, Canada and the international organisation invited to do so, the European Union, none have so far signed the Convention or made any sign of doing so any time soon. As only those states that have ratified the Convention can sign or ratify the Additional Protocols even fewer states have ratified or signed the Additional Protocols. 18 States have ratified the Additional Protocol on the Prohibition of Human Cloning and 13 signed it. The Additional Protocol on Organ Transplantation has been signed by 11 and ratified by 9 Member States, the Additional Protocol on Biomedical Research has been signed by 16 and ratified by 5 states and the Additional Protocol on Genetic testing has so far only been ratified by Slovenia

¹¹¹⁴ U. Schuecklenk/R. Ashcroft, "International Research Ethics", in: R. Chadwick/H. Kuhse/W. Landman/U. Schuecklenk, *The Bioethics Reader*, 2007, 243 et seq.

and signed by 4 more countries.¹¹¹⁵ While it might be that states like Germany and the United Kingdom will sign up to or ratify the Oviedo Convention in the future, nothing in the international community of states or under international law could force them to do so. The lack of support of such large and economically highly prosperous countries as Germany and the United Kingdom, however, can considerably weaken a Convention's impact and it certainly makes it more difficult to find common European standards with regard to such questions as organ transplantation, human cloning, biomedical research and genetic testing. Yet, here again, international law can do nothing to make a state sign or ratify a standard.

3.4. Vagueness

One alternative to such minimalist claims in the standards that also stems from the structural prerequisite of negotiating standards between sovereign states is to make provisions vague enough so that they can be interpreted to every state's satisfaction. That is, in order to gloss over disagreement among different stakeholders formulations are chosen that are sufficiently vague so that each sovereign state can then interpret them consistently with its' view.¹¹¹⁶

One example in that respect is Article 16 of the UDBHR on the protection of future generations, which stipulates that the “impact of life sciences on future generations...should be given due regard”. Since it is left unclear what constitutes “due regard” and just how much weight one must give to the interests of future generations, what future generations are, and which impacts must be considered relevant the formulation is so conveniently vague that most states can safely agree to it without actually committing to anything.¹¹¹⁷

Another example is the Cloning Declaration which calls upon all UN member states to “prohibit all forms of human cloning inasmuch as they are incompatible with human dignity and the protection of human life”¹¹¹⁸ and to adopt “all measures necessary to protect adequately human life in the application of life sciences”¹¹¹⁹ and “the measures necessary to prohibit the application of genetic engineering techniques that may be contrary to human dignity.”¹¹²⁰ As mentioned above, the wording of the Declaration is so ambiguous that it seems to hardly reflect any agreement at all. For example, the Declaration does not explicitly and unqualifiedly prohibit human cloning, either for reproductive or therapeutic purposes.¹¹²¹ Consequently, nations which support a comprehensive ban on all forms of human cloning have since interpreted the provisions of the Declaration on Human Cloning so as to call for an absolute prohibition on all forms of human cloning, including

¹¹¹⁵ Steering Committee on Bioethics, Chart of Signatures and reservations or explanations of vote, CDBI/INF, 2009, 3.

¹¹¹⁶ Benatar, note 1113, 220 et seq.

¹¹¹⁷ Ibid., 221

¹¹¹⁸ UN Declaration on Human Cloning, note 35, para b.

¹¹¹⁹ Ibid., para a.

¹¹²⁰ Ibid., para c.

¹¹²¹ Arsanjani, "Negotiating the UN Declaration on Human Cloning", note 552, 167.

on cloning for therapeutic reasons. In contrast, States in favour of a ban on reproductive cloning alone have generally interpreted the Declaration on Human Cloning as prohibiting only those cloning processes which they consider contrary to human dignity, i.e. those used for reproductive cloning.¹¹²²

To the extent that a declaration is characterized by vagueness it then hardly ever says “anything we do not already know”¹¹²³ and as such hardly provides guidance where needed.

3.5. *Non or only Partial Regulation*

Where standards fail to reach a minimalist consensus and/or do not result in vaguely or ambiguously framed provisions, standards then often remain silent altogether on issues in question. That is, the standards present their addressees with the uncontested and remain silent about the contested.

Henk Ten Have, referring to the UDBHR, seems to confirm that point when claiming that

“the Declaration on Bioethics aims to determine those principles in the field of bioethics that are universally acceptable, in conformity with human rights as ensured by international law. It does not pretend to resolve all the bioethical issues presently raised and that evolve every day. Rather its aim is to constitute a basis of frame of reference for states wishing to endow themselves with legislation or policies in the field of bioethics.”¹¹²⁴

The consistent absence of such contested issues of bioethical interest as abortion, euthanasia or embryonic stem cell research from any of the standards in the area of bioethics suggests that no consensus, not even a minimalist one, can be reached on them and that therefore they have been excluded from the scope of these standards. If in fact there already was an answer somehow inferable from the standards, then, as Michel Selgelid remarks “this would already be the obvious decision of choice for any decision maker with enough ethical conscience or motivation to be looking to UNESCO for guidance.”¹¹²⁵ As such the absence of clear regulations is a sign of that standards in the area of bioethics through the structure in which they are conceived only include items that all states can agree upon, and ignore others.

Gaps in the UDBHR therefore generally are the result of the necessary or the unavoidable. As a result standards often only provide guidance where none is actually needed and where it is actually needed or could be helpful they provide none.

¹¹²² Ibid., 176 and generally Arsanjani, "The Negotiations on a Treaty on Cloning: Some Reflections", note 553, 145 et seq.

¹¹²³ Benatar, note 1113, 222

¹¹²⁴ ten Have, note 504, 341.

¹¹²⁵ Selgelid, note 1008, 267-268.

3.6. The Need for National Regulations to Supplement International Regulation

Whenever standards result in either minimalist or vague regulation, national legislation and/or courts' or other institutions' dealings with these issues determine how an issue is effectively dealt with at the national level. These processes in turn then might result in that the underlying international standards' contents are further diluted.¹¹²⁶

Such dilution can occur when a broad variety of national regulations stretch the meaning of international standards in an area beyond any meaningful limit. For example if both, a regulation outlawing and one that allows for embryonic stem cell research can be justified by reference to the same international legal standard that international standard seems to say little if anything at all about how such an issue as embryonic stem cell research should be regulated at the national level and the resulting variety of national regulations then render the international provisions in the area meaningless.¹¹²⁷ While it might be necessary and even desirable to leave it to national courts and legislatures to clarify the exact meaning of international standards and to tune them in to local needs and sensitivities such a process, can rip standards off their meaning and thereby further call into question their utility.

3.7. Two Forms of Hegemony

To the extent that an international standard avoids the problem of minimalism, vagueness or lack of provisions, and takes a stance, it does so usually by privileging a hegemonic view.¹¹²⁸ Two kinds of hegemony must be noted in that respect.

The first kind occurs where some of those responsible for drafting and adopting the standard in question exert greater power or have more influence in drafting or adopting the standard and can thus endorse a substantial position with which others disagree.¹¹²⁹ Here, a variety of issues can have a bearing on the outcome of negotiations leading up to the conclusion of a treaty. For example, some countries dispose over more advanced expert knowledge in a certain field, for example in areas of modern biotechnology which require high standards in money intensive technical or scientific resources, or can send more or better informed delegates into negotiations

¹¹²⁶ Ibid., 268.

¹¹²⁷ B. Knoppers, "Regulatory Approaches to Reproductive Genetic Testing", 19 *Human Reproduction*, 2004, 12 et seq., analysing the legal and moral aspects of genetic testing in 11 different countries. See also Euro Stem Cell, What Does the Law Say About Human Embryonic Stem Cell Research in Europe? Chart on Regulations in EU Member States regarding hES1 cell research, at:

http://archive.eurostemcell.org/Documents/Outreach/stemcell_hesc_regulations_2007FEB.pdf (last visited 27.04.2012).

¹¹²⁸ Benatar, note 1113, 223.

¹¹²⁹ Ibid., noting that "It is possible, of course, for the dominant view also to be the right one... However, given that there is no guarantee of such a happy coincidence, and because it is influence rather than rectitude that carries the day in formulating a declaration, we should exercise a healthy scepticism, especially about those contested views that are canonized in a declaration. Their inclusion in the declaration may be the result only of their hegemony within the process."

which can then participate in several as opposed to one of the usually formed subcommittees and thereby considerably shape the work of sub-committees concerned with the drafting of specific provisions.¹¹³⁰ Better knowledge of the language in which the negotiation are held, particularly when it comes to dealing with highly technical or scientific wordings, are also famously known to have considerable influence on the outcome of negotiations.¹¹³¹ Other factors that can influence negotiations might be whether one country 'trades' its agreement in such areas as bioethics for privileges in other areas such as trading rights.¹¹³²

The second kind of hegemony occurs when important decisions are shifted from those forums which endorse the one country one vote principle to those forums where certain states have greater voting powers than others, such as for example the World Bank or IMF, or where matters are dealt with in certain ways which grant for example certain, usually more developed countries more standing in negotiations, such as WTO.¹¹³³ It is at least worth asking why UNESCO should not address the delicate and potentially financially intense questions of patents relevant to the area of bioethics and why it is not concerned with such issues as trade related to products needed for bioethical research. Instead, such issues are dealt with within the TRIPS agreement and thus within WTO, where theoretically, all member states' consensus is needed for negotiations to advance, yet where the consensus often is first arranged in the 'quad' i.e. among the developed countries.¹¹³⁴ That is, many cases potentially of very real bioethical interest are simply not addressed by those standards that are most directly concerned with bioethics, i.e. in the UNESCO standards or the Oviedo Convention. Instead, important matters related to trade, technology transfer etc. are in fact dealt with in those forums where some states can more easily assert their standing and hence where a certain, often more subtle and somewhat hidden form of hegemony can be practiced.

3.8. The Crimes Committed by Non-State Agencies

One further corollary of the central role assigned to the state is that some violations, in particular those not perpetrated by the state or its officials, cannot be adequately dealt with under a human rights framework. Human rights, including those in the area of bioethics, are primarily meant to protect individuals against the abuse by powerful states.

¹¹³⁰ A. Kapoor, *Planning for International Business Negotiations*, 1975; see also A. Anghie, Imperialism, Sovereignty, and the Making of International Law, note 930, 12. With regard to the development of the UDHR, note 270, see M. Glendon, *A World Made New*, 2001, 221 et seq.

¹¹³¹ Kapoor, note 1130, 13.

¹¹³² Hestermeyer, note 345, 56.

¹¹³³ S. Pahuja, "The Postcoloniality of International Law", 46 *Harvard Journal of International Law*, 2005, 459 et seq. S. Pahuja, "Global Formations: IMF Conditionality and the South as Legal Subject", in: P. Fitzpatrick/P. Tuitt (eds.), *Critical Beings: Race, Nation and the Global Legal Subject*, 2003, 161 et seq.

¹¹³⁴ In the WTO, agreements, for example, bind states as long as they do not object to being bound. Yet, that seems to mean little in those instances where decisions are reached between smaller circles of states that exclude certain other states from negotiation rounds Hestermeyer, note 223, 134.

Yet as Makau Mutua and many others have pointed out “there is nothing intrinsic about human beings that requires only their protection from the state and not the asymmetries of power between them.”¹¹³⁵ To the contrary private or non-governmental actors, such as biotech firms, academic research institutions as well as individuals are active in all major fields subject to bioethical debate.¹¹³⁶ Biotech firms for example are involved in many fields relevant to bioethics in that they research and develop new therapies and vaccines, they conduct clinical trials to get approval for drugs and research and promote genetically modified food, biopesticides and other agricultural products.¹¹³⁷ The industry of biotechnology is also a huge economic power, providing employment for many million people and administrating billions in research and results.¹¹³⁸ Given all this, biotech firms have the capacity to yield both, great benefits as well as great harm to individuals. Benefits, when they invent new therapies and drugs that alleviate millions of people from physical or mental ailment or when they research special types of crops that might help combat world hunger and starvation.¹¹³⁹ Harm can results e.g. in cases of unethical research, such as when research is conducted on subjects unable to provide informed consent¹¹⁴⁰, when hazardous material is dumped in developing countries¹¹⁴¹ or would they engage in a range of activities that might incur criminal liability under several national laws, such as the development of e.g. human cloning processes.¹¹⁴² The potential for abuse thereby is not likely to stop any time soon. Rather biotech firms seem to gain importance both quantitatively and qualitatively as the biotechnology industry will likely remain a strong economic factor and as biotechnological research will remain an important field of interest for a variety of stakeholders, such as all industry related to health care or food producers.¹¹⁴³ Similarly, with revolutionary developments in medicine, genetics, and

¹¹³⁵ Mutua, "Human Rights and Powerlessness: Pathologies of Choice and Substance", note 961, 1027. See also R. McCorquodale/R. La Forgia, "Taking Off the Blindfolds: Torture by Non-State Actors", 1 *Human Rights Law Review*, 2001, 189 et seq., in particular 199, discussing in particular the case of *Velasquez Rodriguez v. Honduras*, 28 ILM 294, 1989.

¹¹³⁶ See Report of the Organisation of the Biotechnology Industry, at: <http://bio.org/speeches/pubs/bioethicsbrochure.pdf>. (last visited 27.04.2012).

¹¹³⁷ Ibid.

¹¹³⁸ Ibid. According to the webpage the U.S. biotech industry spent \$19.8 billion on research and development in 2005 and has increased spending since.

¹¹³⁹ Ibid.

¹¹⁴⁰ K. Moodley, "HIV Vaccine Trial Participation in South Africa: An Ethical Assessment", 27 *Journal of Medicine & Philosophy*, 2000, 197 et seq. S. Stegemann-Boehl, *Fehlverhalten von Forschern*, 1994. F. Mauro/P. Hardison, "Traditional Knowledge of Indigenous and Local Communities: International Debate and Policy Initiatives", 10 *Ecological Applications*, 2000, 1263 et seq.

¹¹⁴¹ See Press Release of the Office of the High Commissioner of Human Rights, "UNEP Responds to Abidjan Hazardous Wastes Crisis", 2006, at:

<http://www.unep.org/Documents.Multilingual/Default.asp?DocumentID=487&ArticleID=5347&l=en> (last visited 27.04.2012). See also G. Maio, *Ethik der Forschung am Menschen*, 2002.

¹¹⁴² With regard to the relevant German legal provisions on human cloning see Zypries, note 1101, and J. Ipsen, "Does the German Basic Law Protect against Human Cloning?", in: R. Wolfrum/S. Vöneky, *Human Dignity and Human Cloning*, 2004, 69 et seq.

¹¹⁴³ Ernst & Young, *Fünfter deutscher Biotechnologie-Report*, 2007, at:

http://www.ey.com/Global/content.nsf/Germany/Branche_-_Health_Sciences_-_Biotech_Reports_Deutschland (last visited 27.04.2012).

ecology, biotech firms are also likely to expand both, their research within current fields as well as the totality of their research fields.¹¹⁴⁴

Yet, international law so far neither attaches criminal or civil liability for violations of international legal standards that specifically concern bioethics nor does it cover biotech firms other than through committing states to ensure standards within their territories.¹¹⁴⁵ Liability can thus only result from violations of general international law, and only if it can be linked to a state, or from individual criminal liability as stipulated e.g. in the Rome statute of the International Criminal Court. Corporate responsibility, i.e. the idea to make corporations themselves liable for breaches of international law so far only exists in theory.¹¹⁴⁶ While both, civil liability and criminal responsibility can theoretically attach at several levels ultimately it seems a better way to hold the firms as legal persons accountable separately from their respective state of residence, operation or client.¹¹⁴⁷ Yet international law, apart from voluntary guidelines can do little to address such questions.¹¹⁴⁸

3.9. Conclusion

The mostly state centric model used in the standards in the area of bioethics comes at a significant price. In particular, it renders standards likely to be formulated at a minimum level, vaguely worded or can lead to that no regulation is found at all. Furthermore, it is by no means only states that engage in conduct that could resemble that of human rights abuse, a trend which is unlikely to stop. The growing importance of non-state actors as regards their capacity to both, violate and protect human rights has led many to advocate for a system in which the state is confined to being one among many actors, of which all are equally charged with human rights enforcement.¹¹⁴⁹

¹¹⁴⁴ Ibid.

¹¹⁴⁵ See the International Law Commission, Report on State Responsibility, at: http://untreaty.un.org/ilc/summaries/9_6.htm (last visited 27.04.2012), also in: The Work of the International Law Commission, 2004, at: http://untreaty.un.org/ilc/publications/ilc_work/ilc_work_6th_edition.htm (last visited 27.04.2012). A. Crane/A. McWilliams/D. Matten/J. Moon/D. Siegel (eds.), *The Oxford Handbook of Corporate Social Responsibility*, 2009, 3 et seq. and L. Backer, "Multinational Corporations, Transnational Law: United Nations Norms on the Responsibilities of Transnational Corporations as a Harbinger of Corporate Social Responsibility in International Law", 37 *Columbia Human Rights Law Review*, 2005, 613 et seq.

¹¹⁴⁶ Stegemann-Boehl, note 1140, 47. See also R. Miller, "Establishing a 'Duty of Care' for Pharmaceutical Companies", 40 *Hastings Center Report*, 2010, 18 et seq.

¹¹⁴⁷ Liability can attach at four different levels: the individual working for a biotech firm, the country within which the firm is registered or the country in which the firm operates, the firm's client (a state, NGO, international or supranational organisation, or a corporate entity) and the firm itself as a corporate entity. For an analogous argument see C. Schaller, *Private Sicherheits- und Militärfirmen in Bewaffneten Konflikten: Völkerrechtliche Einsatzbedingungen und Kontrollmöglichkeiten*, 2005 and H. Koh, "Separating Myth from Reality about Corporate Responsibility Litigation", 7 *Journal of International Economic Law*, 2000, 263 et seq.

¹¹⁴⁸ Of course the UDBHR seeks to provide guidance to non-state actors. See UDBHR, note 4, Article 2 b. However, as a non-binding document it also commands no legal power over non-state actors.

¹¹⁴⁹ See for example J. Alves, "The Declaration of Human Rights in Postmodernity", 22 *Human Rights Quarterly*, 2000, 478 or J. Oloka-Onayango/D. Udagama, 'Globalization and its Impact on Human Rights', UN Doc. ECN.4/Sub.2/2000/13, 2000.

4. Universality

Universality was identified as one further grid point relevant to the presently examined discourse as legal standards, while not creating a legal commitment to promote universal respect for human rights, frequently invoke ideas and ideals related to the concept of a universal applicability of human rights. If these references are taken seriously, i.e. if it is assumed that states have incorporated them deliberately into the standards and thereby intended for them to have some meaning then that begs the question what these references imply and how they relate to other values and tenets such as that of cultural diversity.

4.1. The Benefit of Linking Human Rights with Notions of Universality

It should first of all be noted that, however vaguely done, linking any human rights project, be that on the legal, political or philosophical plane with a concept of universality can greatly benefit a human rights project. That is so because the claim to universality can, if taken seriously, provide a robust justification for human rights to receive unconditional support from everyone involved in their formulation, implementation, in their advocacy and from those who are meant to benefit from them – in short from everyone. If all human beings are endowed with dignity and human rights simply because they are human, and if these rights therefore must be universal, these rights will also have to be recognised and promoted as such by all human beings, states, international organisations and other actors. In theory at least, a universal human right to something must trump all other rights and concerns, a consideration which again adds a powerful edge to human rights rhetoric.¹¹⁵⁰

In fact, without stressing a connection between human rights and universal validity it is difficult to see how human rights can, at the philosophical and political level, withstand charges of cultural diversity or defences based on a claim to exercise national sovereign rights. That is, only if rights are to some extent transcendentally, trans-historically and trans-culturally valid can they also claim to be valid at all times under all circumstances and hence be independent of whether or not a particular state deems them relevant. Universality in that sense makes the recognition of human rights 'right', 'just' and 'inevitable' and not a choice for states.

Claims to universality can thus undergird and justify human rights' scope and content. In reverse, a viewpoint of ethical relativism¹¹⁵¹ can dilute and diminish the force of human rights as it questions

¹¹⁵⁰ Donnelly, *Universal Human Rights in Theory and Practice*, note 776, 13. See also generally T. Risse/S. Ropp/K. Sikkink, *The Power of Human Rights: International Norms and Domestic Change*, 1999.

¹¹⁵¹ See J. Nida-Rümelin, "Über die Vereinbarkeit von Universalismus und Pluralismus in der Ethik", in: W. Lütterfelds/T. Mohr (eds.), *Eine Welt - Eine Moral?*, 1997, 104-117, in particular 107 et seq. on two meanings of the term relativism.

their applicability to every human being at all times and under all circumstances.¹¹⁵² Linking standards in the area of bioethics with notions of universality can thus help to further rally support for the spreading and implementation of the standards.

4.2. Universality and Cultural Diversity

One difficulty with assuming that the standards' references to ideals and ideas of universal validity is not devoid of meaning is, however, that it is not quite clear what is actually entailed by these references. That is, it is not quite clear what universality means if it is attached to a standard or referred to in a provision, whether at all or how such references should be honoured, and, particularly, in how far they limit or curtail expressions of cultural diversity in relation to questions of bioethical relevance.

Generally speaking, in the philosophical, jurisprudential and political literature on human rights two opposing positions with regard to the meaning of the term universality can be made out and most scholarly writing on the subject will be found somewhere in between these two positions. One is that international human rights are and must be the same everywhere, and that they have validity at all times in all cultures and at all places, nations and states. This position, sometimes referred to as 'moral universalism', usually is correlated with the belief that there exist rationally identifiable trans-cultural and trans-historical moral truths and a truly universal moral community comprising all human beings.¹¹⁵³ According to the universalist stance culturally based defences of violations of human rights norms must then be dismissed since "the International Community has an obligation to protest human rights violations wherever they are perpetrated."¹¹⁵⁴ Practices, such as discrimination based on gender or age - even if condoned by culture or tradition - fall outside of what can be justified on the ground of culture.

The idea of moral universalism has been and continues to be challenged by advocates of cultural relativism who claim that rights and rules, as codification of morality, are culturally contingent and depend on context and that thus any imposition of any of these codifications of morality constitutes a form of moral imperialism.¹¹⁵⁵ To the relativist notions of right and wrong and the moral or legal rules that encode them necessarily differ throughout the world because the cultures in which they root and inhere differ. 'Weak' relativists thereby simply seem to maintain and describe the fact that

¹¹⁵² See for example H. Lewis, "Between Irua and 'Female Genital Mutilation': Feminist Human Rights Discourse and the Cultural Divide", 8 *Harvard Human Rights Journal*, 1995, 1 et seq. Donnelly, *The Relative Universality of Human Rights*, note 766, 284 et seq.

¹¹⁵³ Alston/Steiner, note 214, 366.

¹¹⁵⁴ K. Boyle, "The International Obligation to Prosecute Human Rights Violators: Spain's Jurisdiction over Argentine Dirty War Participants", 22 *Hastings International & Comparative Law Review*, 1998, 187 et seq.

¹¹⁵⁵ The term culture thereby is usually used in a broad and rather diffuse sense that often reaches beyond indigenous traditions and customary practices to include political and religious ideologies and institutional structure. E. Hatch, *Culture and Morality: The Relativity of Values in Anthropology*, 1983, 8.

the world hosts a broad variety of cultures and that views of right and wrong are linked to these underlying cultures.¹¹⁵⁶ 'Strong' relativists, on the other hand, argue a point that goes beyond the empirical observation of the variety of cultures around the world.¹¹⁵⁷ They attach great importance to the consequence of diversity, which they claim to be the reason for why no transcendent or trans-cultural idea of right can be found or agreed upon. Knowledge

“and truth are culturally contingent, creating a barrier to cross-cultural understanding; and that all cultures are equally valid. Combined with the empirical observation of cultural diversity worldwide, these two premises lead to the conclusion that human rights norms do not transcend cultural location and cannot be readily translated across cultures.”¹¹⁵⁸

Consequently no culture and no state would be justified in attempting to force on other cultures or states, unless of course those states or cultures freely accept these standards, what must be understood to be ideas associated particularly with this culture or state, no matter whether these ideas might be universally true at some level. For to claim that they are so always implies an argument of false consciousness of others.¹¹⁵⁹ Moreover, cultural relativists also usually argue that, no matter the ulterior motivation of seeking to spread human rights, this has in fact often been done in a spirit of abusive imperialism.¹¹⁶⁰ In this strong form cultural relativism then usually leads to a non-interventionist stance as there is a perceived need to preserve the observed cultural diversity. Any value judgement, condemnation, or effort to eradicate practices that can be justified on the basis of cultural preference will be perceived as a form of a 'cultural imperialism' where moral dictates are imposed by other value systems which legitimise their doing so with a reference to their own moral superiority.¹¹⁶¹

To date neither universal moralists nor relativists have convinced the respectively opposing side of their point of view. In the area of bioethics the debate between universalists and ethical relativists usually translates e.g. into the claims made by some authors that values enshrined in the major documents in this area are of lesser relevance to many Asian and African countries.¹¹⁶² It is urged that Asian and African bioethics generally emphasise more the society's well-orderdness than individual's interest and the fulfilment of corresponding responsibilities and that they lack the notion of one unique and absolute God, free will, autonomy, and categorical imperative from which to deduce the categories of goodness or justice and such concrete notions as autonomy and informed consent prevalent in international human rights standards on bioethics.¹¹⁶³ Others argue similarly that human rights' emphasis on individualism as opposed to a focus on “holistic,

¹¹⁵⁶ Alston/Steiner, note 214, 367.

¹¹⁵⁷ Ibid., 367.

¹¹⁵⁸ T. Higgins, "Anti-Essentialism, Relativism and Human Rights", 19 *Harvard Women's Law Journal*, 1996, 89, 92.

¹¹⁵⁹ Ibid.

¹¹⁶⁰ A. Anghie, "Finding the Peripheries: Sovereignty and Colonialism in Nineteenth-Century International Law", 40 *Harvard International Law Journal*, 1999, 1 et seq.

¹¹⁶¹ M. Mutua, *Human Rights: A Political and Cultural Critique*, 2002, 5 and 98 et seq.

¹¹⁶² Po-Wah, note 100, introduction.

¹¹⁶³ Ibid. Report of the World Congress of Bioethics Bioethics in a globalised world, 28 – 31 July 2010, at: <http://www.bioethics-singapore.org/wcb2010/> (last visited 27.04.2012).

contextualised thinking, family relationships, sense of duties and the idea of living with nature as opposed to ruling it”¹¹⁶⁴ as well as human rights' focus on the state as the main perpetrator of human rights violations reflects an 'ethnocentric bias'. In a similar vein have feminist scholars also pointed out that the UDHR and other human rights documents rely on concepts of universality, rights, persons, and equality that derive from the logic of fraternity and Enlightenment philosophies, including that of 'man's' common sense.¹¹⁶⁵

“these concepts ... inevitably reflect a certain history of power. In this philosophical tradition, moral agency has been marked explicitly as male, white, and European in descent. Within this conceptual history women have been defined not as agents but as property, the medium of exchange through which bonds of brotherhood are elaborated. From Aristotle's account of her as a 'nutritive medium' to Hegel's sequestering of her apart from public life in the family where she tends the body, this tradition renders 'woman' a supplement to 'man's' agency, lacking the self-consciousness and rational capacities necessary for autonomous, self-directed activity. Moreover, as Irigaray has argued, this subjection of 'woman' through the denial of women's agency is reflected in other forms of subjection and hierarchies of power based on race, class, and ethnicity.”¹¹⁶⁶

Based on these criticism these authors hold that articulating current 'universal principles' requires a “critical recognition of the implication of enlightenment and liberal concepts of persons, rights, and equality in the hegemony of particular racial, cultural, and sexual identities.”¹¹⁶⁷ Failing to acknowledge this conceptual history, however, and by relying on abstract concepts of equality the UDBHR it is argued

“obscures the real inequities that characterize contemporary ethical urgencies, and it fails to articulate a sense of universality ample enough to address the actual inequalities of power and resources that prevail across the globe. Figures of universality ought to call for and sustain solidarity without reducing the specificities of experience to any single generic form.”¹¹⁶⁸

The fear is that the UDBHR by failing to take into account underlying structural inequalities such as vast differences and inequities of wealth and power loses its relevance to large segments of society and populations in the world. The attempt to set universal norms is laudable yet, according to Rawlinson, it can run the danger of missing the realities, needs and 'ethical urgencies' of most of the world's human beings. Setting universal standards then at least does nothing to address these inequities.¹¹⁶⁹

It should, however, be noted that the standards in the area of bioethics recognize the value of and the need to pay regard to cultural diversity. The UDHR for example makes concessions to cultural

¹¹⁶⁴ H. Sakamoto, "Globalisation of Bioethics as an Intercultural Social Tuning Technique", 16 *Journal International de Bioéthique*, 2005, 17, 22.

¹¹⁶⁵ Rawlinson/ Donchin, note 1019, 262.

¹¹⁶⁶ Ibid.

¹¹⁶⁷ Ibid.

¹¹⁶⁸ Ibid., 263.

¹¹⁶⁹ Ibid.

pluralism and cultural variations for example in Article 12.¹¹⁷⁰ Yet it also qualifies this respect by the injunction that such diversity may not be 'invoked to infringe upon human dignity, human rights and fundamental freedoms nor upon the principles set out in this Declaration'¹¹⁷¹ hence rendering it somewhat unclear to what extent and how notions of cultural diversity and respect for human rights might best be balanced. Nevertheless, standards in the area of bioethics are certainly eclectic enough, particularly in their wording, to allow for culturally varied approaches to bioethical questions and/or for a timely interpretation of its provisions that remedies some of the biased premises referred to above. Moreover, all standards, as discussed above, leave large areas of bioethical interest to be regulated by national legislations which can then accommodate particular cultural needs.

4.3. The Basis of Universalism

Given the criticism towards the standards' references to universality it may also be asked why these human rights should at all aspire to set universal standards, i.e. on what basis these references and aspirations to universal applicability are made. Failing to provide a justification will otherwise give further ammunition to those critical voices who challenge the 'universal' outreach of the standards.

4.3.1. Human Needs, Capabilities or Will

One way to explain and justify human rights' link with notions of universal validity is to ground human rights in human needs. According to this view all humans have a common essential nature and common essential human needs that determine that certain kinds of goods and behaviours are essential to satisfy these needs.¹¹⁷² A universal right to food and a right not to be tortured for example are often cited as essential to meet such universal human needs.

Yet human needs or human nature generally are difficult to pin down, particularly once one ventures beyond basic life sustaining biological needs, such as nutritional needs and it is not always evident which human rights correlate and/or are necessitated by human nature or human needs. Until very recently, for example, no human rights standard included a right to water.¹¹⁷³ Similarly, many 'good' things that seem to correlate with very basic human needs, such as 'loving' and 'nurturing' or 'supportive parents' or 'friendships', are not the object of human rights.¹¹⁷⁴ In reverse it is difficult to correlate some human rights with human needs. For example, most of the

¹¹⁷⁰ UDBHR, note 4, Art 12.

¹¹⁷¹ Rawlinson/ Donchin, note 1019, 262. UDBHR, note 4, Recital 15.

¹¹⁷² Donnelly, Universal Human Rights in Theory and Practice, note 776, 11.

¹¹⁷³ See WHO, The Right to Water, note 227.

¹¹⁷⁴ Donnelly, Universal Human Rights in Theory and Practice, note 776, 11.

rights or principles specified in the area of bioethics, except maybe for the right to access to medicine, do not seem to be based on immediate human needs.

A further variation of the needs driven justification of human rights' universal aspirations is to root human rights in human capabilities. Martha Nussbaum and Amartya Sen, for example understand the promotion of human capabilities to be at the core of human rights as they enable humans to 'live life in a truly human way.'¹¹⁷⁵ According to Nussbaum, several capabilities have to be made possible for all human beings in all societies:

“The idea of capabilities is that you ask the question: What are people actually able to do and to be? ... I specify ten central things that I think are central indicators that any decent society would make quite pivotal and would guarantee to all citizens up to an adequate threshold level. I look at: life, health, bodily integrity; development of senses, imagination, and thought through education; practical reason; affiliation; access to recreation and play...control over material and social environment and ...access to a good relationship with nature and the environment... and then emotional health.”¹¹⁷⁶

Human rights, according to this view, are among the primary means by which the realization of human capabilities can be ensured and they should therefore be universally recognised.¹¹⁷⁷ Yet again, just what kind of universal human rights the promotion of human capabilities gives rise to is sometimes difficult to determine. For one, it is difficult to determine a final list of human capabilities necessary to lead a life worthy of a human being. Nussbaum herself has frequently changed or amended her list of 'essential human capabilities.'¹¹⁷⁸ Hence the list of correlated human rights which supposedly are universal has had to change too which seems to somewhat contradict the idea of their universality. Besides, hardly any of the more specific human rights in the area of bioethics have been mentioned in Nussbaum's list of human rights that enable a 'life worthy of human beings' so that the standards' references to universality cannot be based on a need to satisfy basic capabilities needed to life a worthy live.

One further variation of this overall theme is to justify the philosophical validity of the universality claim by reference to a single human attribute, that of the capacity to express free will.¹¹⁷⁹ Many “will theorists” thereby argue that what is distinctive about human agency is the capacity for expressing free will and that this ought to constitute the core of any account of rights.¹¹⁸⁰ Will

¹¹⁷⁵ M. Nussbaum, "Capabilities as Fundamental Entitlements: Sen and Social Justice", 9 *Feminist Economics*, 2003, 33 et seq.

¹¹⁷⁶ Interview with Martha Nussbaum, "The Rights and Capabilities of Women", *Conversations with History*: Institute of International Studies, UC Berkeley, at: <http://globetrotter.berkeley.edu/people6/Nussbaum/nussbaum-con3.html> (last visited 27.04.2012).

¹¹⁷⁷ Ibid.

¹¹⁷⁸ "Justified anger," for example is relatively new addition to her list. Yet Nussbaum herself admits that her list of capabilities is open-ended and will change. M. Nussbaum, "Capabilities as Fundamental Entitlements: Sen and Social Justice", note 1175, 40.

¹¹⁷⁹ T. Connor, "Free Will", in: E. Zalta (ed.), *Stanford Encyclopedia of Philosophy*, Summer 2011 Edition, at: <http://plato.stanford.edu/archives/sum2011/entries/freewill/> (last visited 27.04.2012). For an opposing view see B. Waller, *Against Moral Responsibility*, 2011.

¹¹⁸⁰ S. Buss, "Personal Autonomy", in: E. Zalta (ed.), *Stanford Encyclopedia of Philosophy*, Fall 2008 Edition, at: <http://plato.stanford.edu/archives/fall2008/entries/personal-autonomy/> (last visited 27.04.2012). See

theorists thus ultimately view human rights "as originating in, or reducible to, a single, constitutive right which is that of free will".¹¹⁸¹ Because human rights constitute the means through which the exercise of free will can be (best) secured they should be universally valid. While this approach certainly has its merits it raises some difficult questions. It, for example, leaves it open to what extent human rights apply to human beings who are temporarily or permanently incapable of acting in a rationally autonomous fashion i.e. individuals who cannot express their free will or to embryos and other marginal beings, as discussed above.¹¹⁸² Human rights for example, might not apply to those individuals who are diagnosed to be suffering from dementia, schizophrenia, or individuals who remain in a comatose condition.¹¹⁸³ Also babies and toddlers might then be excluded from the scope of human rights. Finally, it is again not quite clear which human rights in the area of bioethics are correlated to free will other than those relating to autonomy or informed consent. It is for example not clear how the protection of future generation or solidarity can be based on a will based theory of human rights.

4.3.2. Religious Tenets

One further way in which human rights' universal aspirations has sometimes been justified is to found it on religious tenets, i.e. on the idea of a specific 'natural' or 'human-specific' order foreseen by God(s) which humans have to strive to keep up or live up to by means of universally applicable human rights. Bishop Schindehütte of the Evangelical Church in Germany on the Anniversary of the Universal Declaration of Human Rights, for example, claims that the commitment to human rights is a matter of Christian obligation

“...God's love of humankind triumphs by virtue of the resurrection of his Son. The human dignity conferred by God...can be violated, perhaps, but it cannot be destroyed. The Church, by speaking out against violations of human dignity and advocating for the preservation of the rights which are rooted in that dignity, is following the path indicated to it by our Lord Jesus Christ himself.”¹¹⁸⁴

Similarly, Buddhism, for example, understands the taking of human life as one of the four cardinal offences, thus allocating human life and human dignity a special status which deserves universal

also J. Heilinger, "Einleitung: Naturgeschichte der Freiheit", in: J. Heilinger (ed.), *Naturgeschichte der Freiheit*, 2007, 1 et seq., focusing on questions of free will.

¹¹⁸¹ See A. Fagan, "Human Rights", in: *Internet Encyclopedia of Philosophy of International Encyclopedia of Philosophy*, at: <http://www.iep.utm.edu/hum-rts/> (last visited 27.04.2012).

¹¹⁸² Ibid.

¹¹⁸³ Ibid. But see M. Nussbaum, *Frontiers of Justice*, 2006, 96 et seq. On the question of what constitutes consciousness (Bewusstsein) see J. Nida-Rümelin, "Bewusstsein und Freiheit", in: D. Ganten/V. Gerhardt/J. Nida-Rümelin (eds.), *Funktionen des Bewusstseins*, 2008, 177 et seq.

¹¹⁸⁴ See press release of the EKD, Bishop Schindehütte on "Human Rights Are a Matter of Christian Obligation-on the Anniversary of the Declaration of Human Rights", December 8, 2008, at: http://www.ekd.de/english/ekd_press_releases-4361.html (last visited 27.04.2012).

recognition and universal respect.¹¹⁸⁵ Human rights, to the extent that they uphold this status and the idea of human worth are then also endorsed by Buddhist thought.

Yet, even though it may be fair to say that all known religions in one way or another endorse some concept of human dignity, sanctity of human life and human rights and that this indeed is the source of human dignity, it is problematic to root human rights in a common concept of human dignity. That is so because different religions differ in their concrete understandings of human dignity and human rights in about the same way as they differ in their specific understanding of who or what God(s) is/are and in what constitutes righteous or pious behaviour and/or a good order of society. Reaching some middle ground so far has been rather difficult as centuries of religiously motivated warfare and/or civil war prove even today. To elevate one such understanding of a good order over others, however, would likely meet with fierce opposition as well as it would defeat the very object of the exercise, i.e. to root human rights in all existing religions.¹¹⁸⁶

Moreover, doing so would violate one central tenet of human rights philosophy which is respect for all religions and belief systems, including that of atheism or agnostics. While human rights' aspirations to universal validity in fact are often justified by reference to human dignity, doing so, as was seen above often comes at the price of precision and clarity of what it actually is that is protected or universally promoted. That is, in order to be able to speak to people over a long period of time and across various cultural backgrounds, human rights that are based on an idea of human dignity have to remain rather abstract and general, such as valuing life, liberty and love. The more specific human rights are formulated, such as is the case with the rather specific cases addressed in the standards in the area of bioethics, the more problematic it is again to link them to the idea of human dignity in any meaningful way.

4.3.3. Common Moral Standards or Good Reasons

Another related way of explaining human rights' universal aspirations is to combine the idea of basic human needs with the idea of common or universal moral standards that are said to govern all human relations.¹¹⁸⁷ According to this scenario there exists in some form or another an identifiable moral order the legitimacy of which precedes contingent social and historical conditions and which applies to all human beings everywhere and at all times.¹¹⁸⁸

Indeed, it appears that all human groups or societies have morally inspired laws, that is, imperative norms of behaviour backed by reasons and values, as well as they have concepts of human

¹¹⁸⁵ S. Hongladarom, "Buddhism and Human Rights in the Thoughts of Sulak Sivaraksa and Phra Dhammpidok (Prayudh Prayutto)," in: D. Keown/C. Prebish/W. Husted (eds.), *Buddhism and Human Rights*, 1998, 97 et seq.

¹¹⁸⁶ D. Forsythe, "Human Rights Fifty Years after the Universal Declaration", 31 *Political Science and Politics*, 1998, 505 et seq.

¹¹⁸⁷ A. Gewirth, "Common Morality and the Community of Rights", in: G. Outka/J. Reeder, *Prospects for a Common Morality*, 1993, 29.

¹¹⁸⁸ See Fagan, note 1181..

dignity.¹¹⁸⁹ If human rights can be shown to exist as norms accepted in all or almost all actual human moralities they may then in fact be universal.¹¹⁹⁰ If, for example, almost all human groups have moralities containing norms prohibiting murder, or mandating a model of informed consent these norms could constitute the universal human right to life and to informed consent.¹¹⁹¹ Yet again, it is extremely difficult to pin down the moralities of all human cultures, societies and other groups and it seems almost impossible to make them agree to common standards.¹¹⁹² Even with regard to such universally condemned crimes as that of torture, unfair criminal trials, discrimination based on sex, a right to form autonomous decisions and to be treated in a beneficiary way by doctors or physicians concrete agreement is sometimes difficult to reach.¹¹⁹³ A group or nation may think that deliberately inflicting death on a person is generally condemnable and yet consider the murdering of certain human beings, e.g. of a certain sex, or religious affiliation or with a certain criminal record to be more justifiable than others.¹¹⁹⁴ Some states and groups accept that people that are unable to consent may be subjected to medical research, others would consider doing so to constitute some form of torture.¹¹⁹⁵ Others see no human rights violation in providing more and better health care to certain segments of society or to restrict the exercise of autonomous decision making of these segments.¹¹⁹⁶ Hence it seems difficult to reach a common standard of morality that all states could agree on. One further problem with this approach is that human rights declarations and treaties are "often intended to change existing norms, not just describe the existing moral consensus".¹¹⁹⁷ As such grounding human rights in existing moralities might be too short-sighted.

One further variation of this justification of human rights' claim to universality is to assert that with regard to certain human rights, such as the right against torture or the one to be treated according to the first do no harm principle, "there are strong reasons for believing that it is almost always wrong to engage in torture"¹¹⁹⁸ or in preventing persons from making autonomous decisions. This approach would view the Universal Declaration as attempting to formulate a justified political morality, which was not necessarily trying to identify a pre-existing moral

¹¹⁸⁹ Nickel, note 985.

¹¹⁹⁰ Ibid.

¹¹⁹¹ Ibid.

¹¹⁹² See discussion above under 3.

¹¹⁹³ Alston/Steiner, note 214, 439 et seq.

¹¹⁹⁴ A. Sen, "100 Million Women Missing", in: The New York Book Review, at:

<http://www.nybooks.com/articles/archives/1990/dec/20/more-than-100-million-women-are-missing/> (last visited 27.04.2012).

¹¹⁹⁵ The Oviedo Convention, note 5, for example has not been signed by some states exactly because this point. E. Schewior, Speech on the Impact of the Biomedicine Convention on the national level, delivered at the Conference to celebrate ten years of the Convention on Human Rights and Biomedicine of the Council of Europe, at:

http://www.coe.int/t/dg3/healthbioethic/Activities/10th_Anniversary/Eva%20Schewior.pdf (last visited 27.04.2012).

¹¹⁹⁶ Sex bias in the family allocation of food and health care in rural Bangladesh. L. Hayden, "Gender Discrimination Within the Reproductive Health Care System: Viagra V. Birth", 13 *Journal of Law and Health*, 1998, 171.

¹¹⁹⁷ Human rights are often used as a motor for social change T. Risse/S. Ropp/K. Sikkink, *The Power of Human Rights*, 1999, 1.

¹¹⁹⁸ Nickel, note 985. But see C. Lepora/J. Millum, "The Tortured Patient: A Medical Dilemma", 41 *Hastings Center Report*, 2011, 38 et seq, discussing when medical complicity in torture is 'appropriate'.

consensus but to create a consensus on how governments should behave that was supported by the most plausible moral and practical reasons.¹¹⁹⁹ While this approach is compelling the problem is, however, that existence of good reasons can be a rather thin line for the existence of universal human rights that inhere in a universal human nature and hence should exist independently of or beyond good reason.¹²⁰⁰

4.3.4. Acceptance

It is also arguable that no matter their (lack of) commonly shared deeper roots, human rights are universal and universally justified as they, in the form of today's human rights standards, have been signed or ratified on a nearly universal basis. No matter whether human rights as a concept can be found or rooted in all cultures and societies around the world the fact that they have subsequently been accepted by almost all states makes human rights universal.¹²⁰¹ In particular norms enshrined in the UDHR that have become part of customary international law and hence bind states irrespective of whether they have accepted them or not could be mentioned in that regard.

However, as was explained above, that would only apply in so far as states have in fact signed up to a standard and only to the limited number of human rights that are actually part of customary international law. It does not explain why a whole standard and particularly not the ones in the area of bioethics should be universally applicable.

4.3.5. Necessity

One further reason for why human rights' claim to universality is important and valid is the argument that human rights have arisen as a response to conditions created by modernity and as such constitute "the only effective remedy against the downsides of this development as it spreads around the world."¹²⁰² That is, while the processes connected with modernity, such as the process of socio-political individuation and the building of the modern nation state, discussed above, may have first been played out in Europe or North America, they are increasingly the rule throughout the world. As a result, it is argued that

¹¹⁹⁹ Ibid.

¹²⁰⁰ Ibid. An objectively good justification is brought about, if the reason given for it would convince an ideally rational person. On the relationship between reasons [Gründe] and what humans do and believe see J. Nida-Rümelin, "Naturalismus und Humanismus", in: V. Gerhardt/J. Nida-Rümelin (eds.), *Evolution in Natur und Kultur*, 2010, 3 et seq. On qualities of (pragmatic) good reasons see J. Nida-Rümelin, *Philosophie und Lebensform*, 2009, 27 et seq. and 99 et seq. And J. Nida-Rümelin, "Warum Moralisch Sein", in: J. Wils (ed.), *Orientierung durch Ethik? Eine Zwischenbilanz*, 1993, 57 et seq.

¹²⁰¹ Nickel, note 985.

¹²⁰² M. Perry, "Are Human Rights Universal? The Relativist Challenge and Related Matters", 19 *Human Rights Quarterly*, 1997, 461.

“the structural basis for a society of equal and autonomous individuals and the idea of the modern nation state is being universalized too and by this the idea of a society which nurtures and conditions the existence of human rights.”¹²⁰³

According to proponents of this view individual human rights increasingly appear not merely as moral ideals, but as both objectively and subjectively necessary to protect and realize human dignity in modern societies. Hence, even if human rights are not of a *prima facie* universal nature that should not keep them from becoming so if necessary.¹²⁰⁴

Yet while this may well mean that human rights should receive universal validity, there is also something troublesome to this idea. This is so because the culture “which has given birth to the concept of human rights will also be called upon to become universal”¹²⁰⁵, a line of thinking that is understandably troubling to many since they rightly fear the loss of their own culture. Also, past experiences have made it clear that it is highly counterproductive -let alone the question of desirability¹²⁰⁶- to try to export standards of normative and social ordering in an unqualified way. Not only does such an approach tend to produce a backlash against “cultural imperialism” but it would also foreclose the possibility of mutual learning from each other's “moral universe”¹²⁰⁷ which might be necessary to detect truly universal answers that can speak to all cultures and cater for all humans' needs equally.

4.3.6. Conclusion

In effect then, each single justification of human rights' aspirations to set standards of universal validity is to some extent problematic. Particularly the less abstract and less general the rights, including those in the area of bioethics the more difficult it is to justify an aspiration of these rights to general applicability by connecting this statement with a reference to basic human needs or capabilities, common moral standards or notions of human dignity.

4.4. Conclusion

While human rights' aspirations to set universally applicable norms may overall be a desirable and laudable effort it can result in some unwanted side-effects. Those that do not accept or feel threatened by the aspirations to universal validity will not accept the provisions enshrined in these standards and continue to criticise them. What is more important is that the standards may in fact

¹²⁰³ Donnelly, *Universal Human Rights in Theory and Practice*, note 776, 12.

¹²⁰⁴ K. Pannikar, "Is the Notion of Human rights a Western Concept", 120 *Diogenes*, 1982, 75 et seq.

¹²⁰⁵ Ibid.

¹²⁰⁶ A. An-Na'im/F. Deng/Y. Ghai/U. Baxi (eds.), *Human Rights - Southern Voices*, 2009, 11.

¹²⁰⁷ Y. Onuma, "Toward an Intercivilizational Approach to Human Rights" in: D. Bell/J. Bauer, *The East Asia Challenge For Human Rights*, 1999, 103 et seq.

miss to answer to the needs and realities of large segments of societies and populations around the world which could diminish their relevance and ultimately weaken their impact. It might then be more desirable to either better explain what is entailed or implied by using the term universal in the standards or to avoid this term altogether. If a more specific consensus on human rights norms in the area of bioethics is to be achieved the international community needs to be responsive to the needs and experiences of all people. Only by this way can it simultaneously “honour the diversity of cultures and build towards common principles that all can support”¹²⁰⁸ and hence build a form of legitimacy of the provisions that makes them acceptable and most importantly relevant to all.

5. Autonomy

It was shown above that respect for human beings' autonomy is one central tenet of human rights doctrine and that it, in some way or another, means to place the individual and his or her choices or decisions in the centre of human rights thought. In bioethical debates it is often synonymous to ensuring that a patient gives his or her informed consent to a decision.

5.1. Autonomy vs. Paternalism

In the area of bioethics respect for patient autonomy has become the discipline's 'ineradicable birthmark' and one of its most clearly pronounced principles. As Carl Schneider observes: “It is now common to make such strong and categorical assertions as: the fact that the patient bears rights as citizens should preclude any form of medical paternalism”¹²⁰⁹. And in the words of Arthur Caplan, “there are relatively few bioethicists who argue that respect for autonomy is not the preeminent value governing the actions of health care providers.”¹²¹⁰ Paternalism, Caplan goes on to argue, has become the “Freddy Kruger of bioethics”.¹²¹¹

The literature on the topic of autonomy in the area of bioethics thereby provides many convincing reasons for why the principle of autonomy should be the reigning principles in bioethics, as respect for autonomy of patients is meant to safeguard patients' interests in many different ways.¹²¹² For

¹²⁰⁸ R. Schwartz, "Human Rights in an Evolving World Culture", in: A. An-Na'im/F. Deng/Y. Ghai/U. Baxi, *Human Rights - Southern Voices*, 2009, 27 et seq.

¹²⁰⁹ Schneider, *The Practice of Autonomy*, note 963, 4.

¹²¹⁰ A. Caplan, "Can Autonomy be Saved?", in: A. Caplan (ed.), *If I were a Rich Man Could I Buy a Pancreas? And Other Essays on the Ethics of Health Care*, 1992, 257 et seq.

¹²¹¹ *Ibid.*, 259.

¹²¹² J. Garcia, "The Pre-eminence of Autonomy in Bioethics", in: D. Oderberg/J. Laing, *Human Lives: Critical Essays on Consequentialist Bioethics*, 1996, 112, 115. See also J. Katz, *The Silent World of Doctor and Patient*, 1984. J. Ende/L. Kazis/A. Ash/M. Moskowitz (eds.), "Measuring Patients' Desire for Autonomy: Decision Making and Information Seeking Preferences Among Medical Patients", 4 *Journal of General International Medicine*, 1989, 23 et seq.; E. Pellegrino/D. Thomasma, *For the Patients' Good: The Restoration of Beneficence in Health Care*, 1984. B. Fateh-Moghadam/S. Sellmaier/W. Vossenkuhl, *Grenzen des Paternalismus*, 2009.

one, as Janet Garcia remarks "many medical procedures have been introduced which, while offering some chance of cure or prolongation of life, are burdensomely painful or expensive"¹²¹³ or of limited effectiveness or come with unwanted side effects. Patients facing painful procedures or procedures with potentially severe side effects or those of high costs should have the option of declining such treatment.¹²¹⁴ From the point of view of fairness it also seems right that a patient should be adequately informed about effectiveness and risks of proposed medication.¹²¹⁵ Generally, the idea, encapsulated in the concept of autonomy (as opposed to paternalism), is to provide patients with more control over the course of their medical treatment and with a possibility to have their view respected and their wishes taken seriously, a rationale which has also been acknowledged in various case law.¹²¹⁶

Another advantage of patients' autonomy replacing models of paternalism is that apart from cherishing an individual's right to form decisions and to be the master of his or her life it also protects individuals or minorities against abuse. That is, in pluralistic societies doctors and patients sometimes have very different conceptualisations of the good. Fear that the doctor and patient may not share the same moral commitments or that doctors, in a paternalistic fashion assume that they know what is in a patient's best interest is one of the chief factors undergirding an interest in autonomy.¹²¹⁷ Out of this concern Tristram Engelhardt therefore for example argues that autonomy, as a mechanism and principle in pluralist societies constitutes a robust means against the imposition of values by one group on another.¹²¹⁸ Moreover, autonomy also necessitates transparency towards the patient which in turn makes it more difficult for doctors or carers to act in a paternalistic way and to override a patient's wish. That is, through the processes of ensuring that patients have the possibility to take autonomous decisions "medicine is no longer

¹²¹³ Garcia, note 1212, 115. See also H. Murray/J. Johnston, *Trust and Integrity in Biomedical Research. The Case of Financial Conflicts of Interest*, 2010, introduction.

¹²¹⁴ Ibid. See also C. Schneider, "After Autonomy", in: 41 Wake Forest Law Review, 2006, 411, 413. But see P. Schwartz, "Questioning the Quantitative Imperative: Decision Aids, Prevention, and the Ethics of Disclosure", 42 *Hastings Center Report*, 2011, 30 et seq., arguing that patients should not be given quantitative information about the risks and benefits of a test or treatment they are considering, especially when it serves a preventive function.

¹²¹⁵ H. Minkoff/M. Marshall, "Government-Scripted Consent: When Medical Ethics and Law Collide", 39 *Hastings Center Report*, 2009, 21 et seq.

¹²¹⁶ Justice Benjamin Cardozo's following statement in *Schloendorff v. Society of New York Hospital*: "Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault." 105 NE 92, NY, 1914; No right is held more sacred, or is more carefully guarded, by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law. Cf. also *Union Pacific R. Co. v. Botsford*, 141 U.S. 250, 1891. K. Bergmann, "Patientenaufklärung vor Arzneimitteltherapie im Krankenhaus", *Das Krankenhaus* 2006/2, 134 et seq. K. Bergmann/C. Wever, "Anmerkung zu: BVerfG, Beschl. v. 9.1.2006, 2 BvR 443/02" (Anspruch auf Einsichtnahme in Krankenunterlagen im Rahmen des Maßregelvollzugs), 4 *MedizinRecht*, 2006, 210-211. R. Dettmeyer, "Rechtsreport. BGH, Urt. v. 15. 3. 2005" – VI ZR 313 /03" (Aufklärung des Patienten über alternative Behandlungsmöglichkeiten Rechtsmedizin), 3 *MedizinRecht*, 2006, 177. D. Groll, "What Health Care Providers Know: A Taxonomy of Clinical Disagreements", 41 *Hastings Center Report*, 2011, 27 et seq.

¹²¹⁷ Garcia, note 1212, 115.

¹²¹⁸ Engelhardt, note 100, 3 et seq.

considered an art, the physician no longer an artist"¹²¹⁹, which also means that a physician can no longer operate based on authority but has to build his profession on genuine scientific knowledge. Having to educate the patient so that he or she may truly arrive at an autonomous decision consequently makes medicine more transparent and makes it more difficult for doctors to hide behind a perceived authority and to abuse their power.¹²²⁰

Besides fostering respect for patient's wishes and safeguarding him or her against abuse there is also a more philosophical argument in favour of patient's autonomy, advanced by several philosophers who have given support to the idea that only an autonomous life can be a good and joyful life. The philosophical deliberations of Kant and Mill are frequently invoked in that respect.¹²²¹ The ability to form autonomous decisions is to Kant one necessary ingredient to leading a good life and human's ability to act autonomously is a source of human beings' dignity, as explained above.¹²²² Paternalism cannot be reconciled with this understanding of the human being, his capabilities and worth. Mill's ethics again see one major source of man's happiness in his autonomous pursuit of self-defined goals.¹²²³ Individuals should be free to form their moral views and live their life accordingly within the limits of not harming others or harming his own ability to make free choices¹²²⁴. Finally, some proponents of autonomy also specifically react against utilitarianism or other philosophical strands, which might be construed so as to override the wishes and good of the individual in favour of the good of the community.¹²²⁵ For example, some strands of utilitarianism could be interpreted to allow for forced organ transplantation if that could save a greater number of people than those at risk through the transplantation.¹²²⁶

In all these instances the principle of autonomy means to empower patients to form their own decisions, and acts as safeguard against abuse through doctors or dominant groups in any society.

5.2. Practical Problems with the Concept of Patient's Autonomy

Yet, while autonomy certainly has its value in bioethical debates on a practical level, it is not clear how respect for patient's autonomy has to be translated into day to day practice of doctors and physicians. For example, while most scholars and practitioners can agree that the most important

¹²¹⁹ Garcia, note 1212, 116.

¹²²⁰ J. Tao lai Po-Wah, "A Confucian Approach to a "Shared Family-Decision Model" in Health Care: Reflections on Moral Pluralism", in: T. Engelhardt, *Global Bioethics*, 2006, 154 et seq.

¹²²¹ Garcia, note 1212, 116. See also Buss, note 1180.

¹²²² See Chapter VI, 1.2.

¹²²³ Garcia, note 1212, 116. J. Mill, *Essay on Liberty*, 1859, noting that "The only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others. His own good, either physical or moral, is not sufficient warrant."

¹²²⁴ Garcia, note 1212, 117.

¹²²⁵ Ibid.

¹²²⁶ Cf. for example P. Foot, "Utilitarianism and the Virtues", 57 *Proceedings and Addresses of the American Philosophical Association*, 1983, 273 et seq. and J. Thomson, "Goodness and Utilitarianism", 4 *Proceedings and Addresses of the American Philosophical Association*, 1994, 7 et seq.

goal of informed consent, as one major aspect of autonomy, is that patients have an opportunity to be an informed participant in their health care decisions it is not clear how that is to be done. In most discussions about the requirements of informed consent some or most of the following elements are mentioned as relevant units: (a) the nature of the decision/procedure has to be explained to the patients and (b) reasonable alternatives to the proposed intervention have to be shown to him or her. (c) The relevant risks, benefits, and uncertainties related to each alternative have to be discussed and (d) an assessment of patient understanding of the information provided has to be undertaken. Finally, (e) the acceptance of the intervention by the patient has to be clear.¹²²⁷

Yet for a concept of informed consent that pays regards to all these elements to work several things have to be in place. First, doctors need to have and take adequate time to explain to patients the procedures and nature of decisions.¹²²⁸ Evidence however suggest that doctors sometimes cannot or do not have or take the time needed to convey to patients the nature of the decision at hand and that information provided is often hardly understandable.¹²²⁹

Second, the information disclosed must be the right information in the sense of it being relevant, true, clear and complete.¹²³⁰ The information also has to be sufficient to make it possible at all for the patient to form an informed decision. However, it is sometimes not quite clear what relevant, true and clear is and how best to disclose it. For example, so Schneider, "some safety warnings apparently make people less cautious, not more cautious"¹²³¹ and complete information about a subject can be too overwhelming to have any real meaning to the patient.¹²³² It is, moreover, not clear, on a technical level, how and what exactly is sufficient information, and how it has to be prepared or conveyed, i.e. whether booklets and information sheets in addition to a personal conversation are enough to educate patients or whether there is a need for several conversations, whether patients can be educated in a group or must have one on one conversations with their doctors.¹²³³

Third, patients have to hear, understand, remember and assimilate the information correctly as well as to analyse the information critically and insightfully.¹²³⁴ Yet, Schneider and others have collected evidence that suggests that in many cases patients are utterly unable to cope with the abundant information material on certain diseases, that they have been given, particularly if there

¹²²⁷ Schneider, *After Autonomy*, note 1214, 412.

¹²²⁸ *Ibid.* On prerequisites for the working of autonomy see also B. Schöne-Seifert, note 50, 568 et seq.

¹²²⁹ C. Braddock, "Informed Decision Making in Outpatient Practice, Time to Get Back to the Basics", 282 *Journal of the American Medical Association*, 1999, 2313, 2313-2315. See also J. Fisher, "Procedural Misconceptions and Informed Consent: Insights from Empirical Research on the Clinical Trials Industry", 16 *Kennedy Institute of Ethics Journal*, 2006, 251 et seq.

¹²³⁰ Schneider, *After Autonomy*, note 1214, 412.

¹²³¹ *Ibid.*

¹²³² *Ibid.*

¹²³³ D. Hertz, "Informed Consent, is it a Myth?", 30 *Neurosurgery*, 1992, 453 et seq. and generally Schneider, *After Autonomy*, note 1214, 418.

¹²³⁴ Schneider, *After Autonomy*, note 1214, 413.

are aggravating conditions such as that they have just received a severe diagnosis or where they are restricted in terms of finances etc.¹²³⁵ Other studies suggest that certain presupposed ideas about treatment prevail that even a considerable amount of information will not change. Many patients, for example, when faced with tough decisions regarding their medical treatment often seem to rather rely on folk wisdom than on evidence provided in the information.¹²³⁶

Fourth, recipients often have difficulty believing what they are told.¹²³⁷ Many patients have been reported "to shut out information that does not fit their view of the world. Furthermore, recipients often have reasons to fear that disclosers are shaping information to serve their own interests and not the recipients."¹²³⁸ For example, patients can be suspicious about the utility of certain cost intensive medical procedures if they believe that them paying for it benefits the treating physician.¹²³⁹

Finally, people must use the information intelligently.¹²⁴⁰ That is, if they can be convinced that it is useful for them to make an effort to incorporate the information in their decision making structure, people still can be carried away by emotions. Advertisements, the media and statistics all help influencing people's judgements about the amount of money they should have, the type of car they should drive and the type and amount of food they should eat. Even against better judgement people overspend in order to buy a new car, eat junk food or believe that they are less worth with lesser amount of money in their bank account. To put this "crucial point differently, people's decisions often do not change, much less improve, with more information."¹²⁴¹

On a very practical level it is therefore not quite clear whether at all and if so how the requirements of informed consent can be met. Disregard for individual patient preference or "resistance, reluctance, or incompetence by physicians can all too easily result in pro forma and useless autonomy rituals."¹²⁴² Overall, so Schneider concludes "it has become undeniable that in area after area patients remain far from making genuinely autonomous decisions."¹²⁴³ Nevertheless, "the list of things doctors, hospitals, and researchers must do if they are really and truly to honour patients'

¹²³⁵ Ibid. see also in particular Ende/Kaziz/Ash/Moskowitz, note 1212, and S. Thompson/J. Pitts/L. Schwankovsky, "Preferences for the Involvement in Medical Decision Making: Situational and Demographic Influences", 22 *Patient and Education Counselling*, 1993, 133 cited in Schneider, After Autonomy, note 1214, 36. See also D. Redelmeies/P. Rozin/D. Kahneman, "Understanding Patients' Decisions", 72 *Journal of the American Medical Association*, 1993, 270 et seq. and I. Lanis, "The Patient as Decision Maker", in: W. Doyle Gentry (ed.), *Handbook of Behavioural Medicine*, 1984, 326.

¹²³⁶ Schneider, The Practice of Autonomy, note 963, 47 et seq.

¹²³⁷ Schneider, After Autonomy, note 1214, 413.

¹²³⁸ Ibid.

¹²³⁹ Ibid., 412.

¹²⁴⁰ Ibid.

¹²⁴¹ Ibid.

¹²⁴² Ibid., 413.

¹²⁴³ Ibid.

autonomy (or ensure his or her informed consent) grows and grows"¹²⁴⁴, a trend which is, however, not necessarily leading to the desired results.

5.3. *Compatibility with Human Nature?*

Moreover, on a more theoretical or anthropological level it may be questioned to what extent a focus on autonomy is compatible with human nature. That is, even if doctors and hospitals comply with all the requirements and provide the possibility for patients to form informed decisions, as discussed above, it is not clear whether patients would then actually form autonomous or rather informed decisions. In other words, there is a more philosophical or anthropological question about whether or not the image of an individualistic and autonomously acting human being as portrayed or reflected in the provisions on informed consent and generally in human rights philosophy is at all realistic and tenable.¹²⁴⁵

Schneider cites several case studies in order to show that humans and human decision making frequently deviates from the ideal of informed consent. First of all, he shows that "patients make poor (autonomous) decisions in that they do not really know what they want."¹²⁴⁶ In fact, people make "systematic mistakes" in anticipating what they will enjoy. They "regularly miswant."¹²⁴⁷ This might be so because patients' preferences are unstable and the intensity of an emotional reaction to a situation hard to predict.¹²⁴⁸ Another reason might be that patient's values might be too

¹²⁴⁴ Ibid., noting that "One modest proposal, for instance, demands that patients be told not only the benefits and risks of proposed treatments but also imagines that (take a deep breath): (1) "Providers" should undertake an "in-depth exploration" of patients' "affective and cognitive processes." (2) Providers should "explore uncertainties and limitations both in the provider's own knowledge and in the state of the science." (3) "[P]roviders must understand and disclose their own motivations, beliefs, and values to patients." (4) "[P]roviders ought to explore what kind of role expectations [about how decisions should be made] the patient has for herself and her provider." (5) "[I]nformed consent ought to be individualized . . . and take place in the context of an ongoing relationship with a trusted health care provider."

¹²⁴⁵ Schneider, *The Practice of Autonomy*, note 963, 47 et seq. and 92 et seq. and 109 et seq. See for example D. Brook, "The Ideal of the Shared Decision Making Between Physicians and Patients", 1 *Kennedy Institute of Ethics*, 1991, 28 et seq.

¹²⁴⁶ Schneider, *After Autonomy*, note 1214, 419, citing J. Hibbard, "Informing Consumer Decision in Health Care, Implications from Decision Making Research", 75 *Millbank Quarterly*, 1997, 395, 423 et seq. According to varying studies listed here the list of errors people make in forecasting their feelings include "People mispredict what poster they will like, how intensely they will relish yogurt, which snacks they will prefer over the next three weeks, how environmental changes will affect their well-being, how attached they will become to a free coffee mug, how distressed they will be on receiving the results of tests for HIV and for Huntington's disease, whether they will be happier living in Michigan or California, how greatly they will enjoy a bicycle trip, how joyful Bill Clinton's election would make them, how gratified they will be to ace a test, how painfully criticism will wound them, how distraught they will be if their team loses, how agonizing a visit to the dentist and other tormentors will be, etc.

¹²⁴⁷ Schneider, "After Autonomy", note 1214, 413, citing T. Daniel/G. Wilson, "Miswanting: Some Problems in the Forecasting of Future Affective States", in: J. Forgas (ed.), *Feeling and Thinking: The Role of Affect in Social Cognition*, 2000, 178-79.

¹²⁴⁸ Schneider, "After Autonomy", note 1214, 413, explaining that: "I have been describing failures to anticipate one's responses to events. These are partly failures to anticipate which reactions one will have. More commonly, they are failures to anticipate the intensity and the duration of one's reactions. These failures of anticipation have a common tendency--to over-estimate the intensity and duration of emotions. Your pleasure at the victory of your candidate on Tuesday is neither so profound nor so enduring as you

"fragmentary, fractured and febrile to guide their decisions".¹²⁴⁹ But most importantly it seems that people generally have problems predicting other people's or even their own future preferences on a systematic level because humans predict the facts of future situations inaccurately. For example, when envisioning terminal stages of a disease people tend to see themselves as "tied to a bed wasting away rather than planting flowers in a hospice's garden surrounded by [their] most beloved ones."¹²⁵⁰ Such images of what could happen are then taken as the basis of decisions for example re the question of the admissibility of euthanasia. Yet, people make decisions based on their projected thoughts and not based on what will really happen or based on what is even most likely, statistically speaking, to happen to them.¹²⁵¹

Secondly, Schneider holds that it is often the wrong theory is used to predict personal preferences. For example, people base ideas about their future preferences on certain self-images, such as a 'natural predilection' for variety or stability that have often nothing to do with reality. That is, self-perception often varies considerably from what people really do, are or want or how they act in concrete situations.¹²⁵² Using such theories or ideas about oneself in order to make informed decisions about the future, for example in a patient will, then can lead to that patients make decisions based on what they, on some level, think they should want rather than based on what they do actually want. Third, no one can actually predict how he or she is really going to react to an event in the future simply because we are not yet in that situation. No one can accurately determine how he or she might act if faced with difficult situations and choices such as a choice for or against a potentially painful and burdensome operation.¹²⁵³ What seems worse is that "pondering choices does not always improve predictions."¹²⁵⁴ In a study, "some of the people researchers instructed to pick a poster were asked to think about why they liked or disliked each poster ('deep thinkers') and others were not ('shallow thinkers')."¹²⁵⁵ The study showed that "the deep thinkers were the least satisfied,"¹²⁵⁶ which could suggest that patients on the whole might be better off if they formed decisions rapidly and intuitively rather than if they are given a prolonged time to think about them.

expected on Monday. Indeed, "[t]he most prevalent error found in research on affective forecasting is the impact bias, whereby people overestimate the impact of future events on their emotional reactions."

¹²⁴⁹ Ibid.

¹²⁵⁰ Schneider, *The Practice of Autonomy*, note 963, 128

¹²⁵¹ G. Loewenstein/D. Adler, "A Bias in the Prediction of Tastes", 105 *Economics Journal*, 1995, 129 et seq.

¹²⁵² D. Kahneman/E. Diener/N. Schwarz, *Well-Being: The Foundations of Hedonic Psychology*, 2003, 93, explaining: "People go on dates planning to refrain from having sex, engage in foreplay with the expectation of using a condom at the next stage, and initiate sex with the plan to "interrupt" prior to the critical moment. As Gold found in interviews with gay men about their attempts to practice safe sex, however, such resolutions often break down in the "heat of the moment."" And at 94, "Ausubel noted that large numbers of credit card users expect to maintain a zero credit balance but fail to do so - apparently underestimating their own future desire to spend"

¹²⁵³ D. Kahneman/J. Snell, "Predicting a Changing Taste: Do People Know what They Will Like?", 5 *Behavioral Decision Making*, 1992, 187. But see: W. Bartholome, "A Revolution of Understanding," 18 *Quality Review Bulletin*, 1992, 6, 10 and R. Veatch, "Abandoning Informed Consent", 5 *Hastings Centre Report*, 1995, 9 et seq.

¹²⁵⁴ Schneider, "After Autonomy", note 1214, 423.

¹²⁵⁵ Ibid.

¹²⁵⁶ Ibid., 424, citing Kahneman/Diener/Schwarz, note 1253, 88, referring to people who were asked to predict how they would feel about the experience of eating a specific product over a certain period of time. According to the authors "the

Such and other studies suggest that humans, and more specifically patients, might make decisions badly as they often inaptly predict their own "tastes, behaviour, and emotions even over short periods and under familiar circumstances."¹²⁵⁷ In that sense it seems that the way humans form decisions might not be as compatible with what autonomy in a bioethical context actually requires or presupposes them to do which again casts some doubt on the effectiveness of the principle of autonomy as a leading principle in the area of bioethics.

On the other hand it should be noted that none of the so far stated arguments suggests that human beings do not or are not capable of forming autonomous decisions. To the contrary, as long as a person organises his life according to those principles rules and maxims that he or she has him- or herself chosen, it does not matter whether these principles, rules and maxims change over the course of a life time or are to some degree incoherent.¹²⁵⁸ Yet, what some of the above cited studies suggest is that sometimes "people reason in ways that bedevil the work of making medical decisions"¹²⁵⁹ which, however, does not impact their capacity to reason.

5.4. Mandatory Autonomy

It has also been noted that some patients seem to "reject the gift of autonomy", a fact which again meets with some disapproval by those who have over the last century fought hard against paternalism in medicine.¹²⁶⁰ Yet criticising a patient for exercising his or her autonomy to reject autonomy again constitutes an inherent contradiction, sometimes referred to by the notion of "mandatory autonomy."¹²⁶¹ The autonomy principle, so it is argued, "has been transformed from a doctrine that entitles, but does not require the patient to take an active role in treatment decision making, to a mandatory view that treats patients as morally obligated to act autonomously".¹²⁶²

Schneider and others argue that in that respect

"the doctrine of patient autonomy has gone beyond a principle of medical conduct, that is, from prescribing how doctors should treat patients to prescribing how patients should conduct themselves. This refocusing edges towards imposing on patients the duty of freedom, the moral obligation to make their own medical decisions Not only have patients lost the right to decide not to decide, but a refusal to assume the

most striking finding, however, was the near-zero correlation between individual subjects' anticipated and actual reactions to the experience. Subjects' feelings did change substantially over time, but they had little idea, at the outset, about how they would change."

¹²⁵⁷ Ibid.

¹²⁵⁸ Ibid. Cf also Nida-Rümelin, "Wert des Lebens", note 66, 889 et seq.

¹²⁵⁹ Schneider, "After Autonomy", note 1214, 424.

¹²⁶⁰ Schneider, *The Practice of Autonomy*, note 963, xi.

¹²⁶¹ Ibid., 11 and 137 et seq. See also M. Davies/G. Elwyn, "Advocating Mandatory Patient 'Autonomy' in Healthcare: Adverse Reactions and Side Effects", 16 *Health Care Analysis*, 2008, 315 et seq. L. Goodmark, "Autonomy Feminism: An Anti-Essentialist Critique of Mandatory Interventions in Domestic Violence Cases", 1999, at:

http://works.bepress.com/leigh_goodmark/6 (last visited 27.04.2012) but see also D. Rothman, "Revisionism Misplaced: Why This Is Not the Time to Bury Autonomy", 97 *Michigan Law Review*, 1999, 1512 et seq.

¹²⁶² Schneider, "After Autonomy", note 1214, 424.

obligations and responsibilities of mandatory autonomy is viewed as a moral failing deserving of contempt and blame.¹²⁶³

In the worst case, so Schneider, the need to act autonomously can be "pursued regardless of patient preference, reluctance, or incompetence to assume an autonomous role in the medical relationship".¹²⁶⁴

Yet, so Schneider argues many people and particularly sick people deliberately do not want autonomy. That is so because "patients want something more, or different, than autonomy in their relationship with their physician."¹²⁶⁵ As Debra Roter summarises this point:

"In lamenting the small and perhaps even shrinking likelihood of achieving an optimal level of autonomy for each patient, Schneider suggests that patients prize other more attainable goals Patients ... want and value competence and the kindness of solicitous personal care above all else."¹²⁶⁶

They want "to be informed, to know something of their physicians' values, to be assured the physician is acting in their interests, to retain veto power, and to enjoy the degree of autonomy best suited to each as individuals."¹²⁶⁷ This is, however, "a far cry" from the notion of unrestrained self-governance and much closer to the idea of providing patients with a veto power.¹²⁶⁸

5.5. Limited Paternalism

Much in line with this conclusion do some scholars, patients, nurses, and physicians question the moral validity of unrestrained autonomy as the centrepiece of the patient-nurse-physician relationship. Some thereby argue for the need to balance the autonomy equation "in light of the complex emotional and psychosocial exigencies associated with making decisions in the predicament of human illness."¹²⁶⁹ It is in this context that it could be argued that in some cases paternalism can actually be well-suited to medicine as doctors are indeed best situated to know what is in their patients' interests.¹²⁷⁰

These views can be said to be supported in the literature by such renowned scholars as Martha Nussbaum who, for example, champions an approach of limited paternalism. To her, people have to be able to exercise certain capabilities, such as "being able to live to the end of a human life of normal length", "being able to have good health and to be adequately nourished or "being able to

¹²⁶³ Schneider, *The Practice of Autonomy*, note 963, xiv.

¹²⁶⁴ *Ibid.*, 12.

¹²⁶⁵ *Ibid.*, 32.

¹²⁶⁶ D. Roter, "The Practice of Autonomy: Patients, Doctors, and Medical Decisions", 25 *Journal of Health Politics, Policy and Law*, 2000, 770, 770.

¹²⁶⁷ E. Pellegrino, "The Practice of Autonomy: Patients, Doctors, and Medical Decisions", 21 *Theoretical Medicine and Bioethics*, 2000, 361, 362.

¹²⁶⁸ *Ibid.*

¹²⁶⁹ *Ibid.*, 363.

¹²⁷⁰ *Ibid.*

move freely from place to place; to be secure against violent assault, including sexual assault and domestic violence; having opportunities for sexual satisfaction and for choice in matters of reproduction.”¹²⁷¹ Yet Nussbaum explains that “my own view is that health and bodily integrity are so important in relation to all the other capabilities that they are legitimate areas of interference with choice up to a point.”¹²⁷² This statement must be read so as to open up the possibility for some paternalistic curtailing of individual's autonomy. If, in doubt, it is legitimate to interfere with a person's choice when that choice limits his or her important capabilities.¹²⁷³ Moreover, there may also be good reasons for why someone should obey or defer to a doctor's opinion. William James for example holds that

“experience shows that there are times in everyone's life when one can be better counselled by other than by one's self. Inability to decide is one of the commonest symptoms of fatigued nerves; friends who see our troubles more broadly often see them more wisely than we do; so it is frequently an act of excellent virtue to consult and obey a doctor, a partner or a wife.”¹²⁷⁴

The idea of limited paternalism is also supported to some extent by the fact that there are many instances in day-to-day life in which certain forms of paternalism seem justified and it is difficult to see where the line between justifiable and unjustifiable paternalism is. For example, school or university curricula can oblige students to take certain courses, the civil law may declare certain contracts to be against public morals, there exist mandatory pension systems and health care insurances in countries. The consumption of certain drugs or the performance of certain sexual conduct is prohibited by law in many countries. In fact, there are many rules, policies, and actions justified solely on the grounds that the person affected would be better off, or would be less harmed, that seem justifiable and that are paternalistic and there is no coherent rationale that can explain why in the one case an individual is allowed to choose a painful procedure for himself while in the other he or she is not.

In all these instances at least to the extent that people choose paternalism and paternalistic treatment they should not be prevented from doing so by human rights standards.

¹²⁷¹ M. Nussbaum, *Women and Human Development*, note 1088, 95.

¹²⁷² Ibid. S. Deneulin, "Perfectionism, Paternalism and Liberalism in Sen and Nussbaum's Capability Approach", 14 *Review of Political Economy*, 2002, 497, 498.

¹²⁷³ Ibid., 53. Nussbaum for example writes: "Any bill of rights is paternalistic [...], if paternalism means simply telling people that they cannot behave in some way that they have traditionally behaved and want to behave. The Indian Constitution is in that sense 'paternalistic', when it tells people that it is from now on illegal to treat women as unequal in matters of property, or to discriminate against people on grounds of cast or sex. More generally, any system of law is 'paternalistic', keeping some people from doing some things that they want to do. It is fully consistent to reject some forms of paternalism while supporting those that underwrite these central values'. Paternalism thus seems justified as the imposition of certain universal norms that every human being has to respect, whether she chooses those norms or not. M. Nussbaum, "Woman and Human Development. In Defense of Universal Values", in: S. Fainstein/L. Servon, *Gender and Planning: A Reader*, 2005, 104, 112.

¹²⁷⁴ Schneider, *The Practice of Autonomy*, note 963, xi. See also A. Barnhill, "Clinical Use of Placebos: Still the Physician's Prerogative?", 42 *Hastings Center Report*, 2012, 29 et seq.

5.6. *Autonomy versus Morally Good Choices*

A further point of note that has already been made above in relation to rights and principles is that simply opening up the possibility for making autonomous decisions does not necessarily lead to morally good choices of patients. In discussion of cases, so Garcia "bioethicists will often argue in a way that suggests that once it is ensured that the patient's choice is autonomous, the work of the bioethicist or the treating doctor has been done."¹²⁷⁵ This comes back to the critique of rights mentioned above in that they lack an overall *telos*.¹²⁷⁶ Similarly autonomy, without being read against some overall morality and by merely providing a process, lacks a *telos* and cannot ensure that decisions are formed in a way that is somehow conducive to a greater good of the patient.

Much of the bioethical literature today seeks to set standards for determining and ensuring that patients give their informed consent, that they act autonomously and that their privacy is protected. Yet, a bioethicist concerned with that a patient makes a good moral choice would be attempting to explain the principles which might help forming a choice that is morally valuable and to find just ways to persuade the patient to accept these principles and to apply them to his or her choice.¹²⁷⁷ According to Garcia "less and less of bioethical literature, however, argues the ethics of procedures and practices while more and more is directed towards finding means to ensure that choices are autonomous." ¹²⁷⁸ Good moral choices have thus thereby been exchanged with concerns for the autonomous choice.¹²⁷⁹ Of course it cannot be the aim to present the patient with a moral framework that forces him or her to arrive at a certain decision, yet, like is the case with most ethics committees, it might be a better use of doctors' and bioethicists' time and resources to discuss with the patient moral argument and moral implications and to thereby help patients form sound and good decisions that they will not regret than to simply ensure that consent to a treatment is free and informed.

An objection that points to a similar direction has been made by those that understand the idea of autonomy "to have been subject to the tendency of the human mind to be extrapolated to extremes."¹²⁸⁰ The argument is that in the last decades, patient autonomy has been extended by some to a moral right to demand specific treatments, including the administering of death and other highly contentious demands, even sometimes over the declared interest of others, such as

¹²⁷⁵ Garcia, note 1212, 116.

¹²⁷⁶ See discussion above under 1.6.

¹²⁷⁷ Garcia, note 1212, 116. It for example says nothing about whether or not suicide or euthanasia are or should be morally and ethically prohibited.

¹²⁷⁸ Ibid.

¹²⁷⁹ Ibid.

¹²⁸⁰ Pellegrino, note 1267, 361.

physicians' moral or ethical objections.¹²⁸¹ In those cases, patients' autonomy might have been stretched too far. In the same way has it been argued that while the principle of autonomy is likely to empower patients it also on the other hand allows the physician to detach him or herself from his task. He or she can still achieve technically good results while leaving the substantial decision to the patient. This then reiterates the critique that the individualistic nature of human rights in the area of bioethics induces un-social conduct and lessens the sense of responsibilities and self-imposition of duty.¹²⁸² The consolation for patients according to Schneider, is "a formalization of patient rights and of administrative due process".¹²⁸³ However,

“rights exacerbate the impersonality of the relations between doctor and patient ... and the process is self-reinforcing: Trust wanes as relationships become more bureaucratic and less personal. This creates a call for rights. The rights solution further alienates doctor and patient because it distances them and because the doctor resents the distrust that motivated the solution.”¹²⁸⁴

5.7. Conclusion

The points made in the above sections suggests that the emphasis on 'informed consent' and autonomy in bioethical contexts might be less relevant and less suitable to achieve what it actually seeks to ensure than some bioethicists or human rights lawyers would like to see it. Rather than changing patients' decisions and increasing patients' satisfaction, evidence suggests that the only thing more information such as booklets, pamphlets, and articles change are levels of knowledge. This analysis, of course, is not to say that it would be better to return to paternalism, where doctors unquestionably make decisions for patients without consulting them. Nor does this imply that information is unnecessary or unwanted or always wrongly perceived. It merely suggests that the growing reliance on such principles as autonomy might be in need of some modification and that we should not forget that the only cure for some of the problems associated with autonomy is not necessarily more autonomy.”¹²⁸⁵

6. Conclusion

This chapter has shown that discussing bioethical concerns in the language of international human rights, their legal norms and ethical propositions, has several implications for how these issues are thought of, conceptualised and resolved and why this is so.

¹²⁸¹ Ibid. See D. Plantz, "Cynicism, with Consequences", 40 *Hastings Center Report*, 2011, 12 et seq. discussing the case of a nurse refusing to take part in an abortion. Similarly, C. McLeod, "An Institutional Solution to Conflicts of Conscience in Medicine," 40 *Hastings Center Report*, 2010, 41 et seq.

¹²⁸² Sage, note 1031, 1178.

¹²⁸³ Roter, note 1266, 770.

¹²⁸⁴ Schneider, *The Practice of Autonomy*, note 963, 201. See also G. Kaebnick, "Public and Private", 40 *Hastings Center Report*, 2010, 2 et seq.

¹²⁸⁵ Schneider, *The Practice of Autonomy*, note 963, 332.

It has shown that discussing questions of bioethical interest in a framework of human rights has several implications. Using a language of human rights or principles can be overtly simplistic and rigid or too narrow for it to capture the concerns it seeks to address. Rights also often tend to be too indeterminate to offer any substantive guidance with regard to specific questions and rights can conflict with each other, thereby often opening the back door to structural inequalities underlying the rights discourse. On the other hand, using a human rights framework, means using the “lingua franca”¹²⁸⁶ for resolving ethically loaded problems at an international level and as such a language that is widely accepted and respected. International human rights law is also empowering and a tool for action. Using human dignity as an ethically concept in human rights discussions can be equally challenging. While it certainly provides the principle that each and every state can agree upon and hence can be used as starting point for any debate it is also a rather vaguely stated principle which leaves it unclear who exactly the bearer of this dignity is, which actions are in conformity with it and what role the state has in relation to the concept of dignity. Moreover it is not quite clear whether and how the concept, in respect to the way it is presently used, really adds anything to current debates or whether it should not or de facto already has been replaced by the concept of autonomy.

Having to factor in the sovereign state as the agent that agrees on human rights standards and that is principally bound by them has certain implications for how issues of bioethical interest are usually construed in a human rights framework. That is, standards that are agreed upon in this environment are either minimalist, vague or do not exist at all or leave out those areas of concern where no agreement can be reached. Alternatively they factor in some form of hegemony. Moreover, acts of non-state actors cannot be taken into account in this discourse.

Discussing bioethically relevant issues by reference to a framework that claims to be universally valid also has certain implications. While the claim to universality is necessary for human rights to claim universal support and validity it is, for example, not quite clear what universality really means in that debate, nor how to justify its claim and how the concept should be positioned in relation to that of respect for diversity or how universal human rights fare when in conflict with other rights, such as those enshrined in WTO TRIPS standards. Finally, using the concept of autonomy in the way it is currently claimed and charged has implications for the bioethical discourse. For one, it is not quite clear how that concept is to be translated or realised into day to day medical practice. It is also not quite clear whether it really is compatible with human nature and whether it might result in an unwanted obligation on patients to form autonomous decisions even if they would rather not exercise their right to autonomy. Finally it is not clear whether autonomous decisions are necessarily good decisions.

¹²⁸⁶ Alston/Steiner, note 214, chapter 2 and C. Erk, *Health, Rights and Dignity: Philosophical Reflections*, 2001, 3 et seq.

Chapter VIII Conclusion: The Success of the Standards

The preceding chapters have shown that using a legal discourse in the area of bioethics has several implications for how issues of bioethical relevance are approached and dealt with and that these implications result from the way bioethics is approached through international legal standards in the area. According to discourse theory the way discourse deals with a certain matter is neither good nor bad. That is, discourses always just represent one way of dealing with issues at hand which in itself is neither good nor bad but a mere representation of power.

In this final chapter some evaluation, however, as to whether engaging in that type of discourse is at all a valuable enterprise seems in order. This chapter assesses this question by seeking to understand whether or not standards directly addressed to questions of bioethical relevance actually achieve or are likely to achieve what they set out to do, i.e. whether they are successful relative to their own objectives. As far as is relevant to this question will this thesis offer some thoughts on whether law as a means is at all overall suitable to solve the questions and issues that are aimed at being solved through this discourse.

1. A Caveat on Methodology

The question of whether or not the standards achieve the objectives they stipulate for is to a large extent an empirical question. That is so because success most easily is measured relative to what has manifested in terms of actual results. However, as such this question cannot be sufficiently answered at this point.¹²⁸⁷ That is so mostly for two reasons. For one, except for a few rather unsatisfying indices and standards, discussed below, there are hardly any universally agreed methods or benchmarks by which to measure the success of human rights standards in an empirical way. Secondly, even if there were such benchmarks, there hardly exists sufficient data on the various matters involved, i.e. data necessary to judge whether benchmarks have come to be achieved. Gathering such data singlehandedly would go far beyond the scope as well as time and resources available for this project. Finally, it is not clear whether standards have yet had enough time to develop the force necessary to have any impact at all.

¹²⁸⁷ Compare the amount of time and resources spent on a similar project with regard to the ICCPR, note 341. O. Hathaway, "Do Human Rights Treaties Make a Difference?", 111 *Yale Law Journal*, 2002, 1935 et seq.; T. Landman, "Comparative Politics and Human Rights", 24 *Human Rights Quarterly*, 2002, 890 et seq.

1.1. Quantitative Data and Indices

One way success of legal standards is sometimes measured is simply by referring to the existence of a standard in a certain area.¹²⁸⁸ Showing that there exists a standard at all is thereby often already depicted as the actual solution to the problem or at least as a sign of success. Yet the mere existence of a standard does not necessarily say anything about how or whether that standard is successful nor does it say anything about the degree to which results are satisfying.

One further similar empirical method of measuring success has been to analyse how quickly and by how many governments a certain standard has been signed or ratified.¹²⁸⁹ The fact that over the last 11 years so far 23 states have ratified and 11 have signed the Oviedo Convention as well as that all UNESCO member states have adopted the UNESCO standards directly addressed to bioethics by acclamation is seen as a success of the standards which is then usually and impliedly taken to testify to the success of the standards. Yet again it is not quite clear whether the ratification or signing of standards really has any positive influence on success or outcome at all. Several studies suggest in fact the opposite in that they show that despite the growth and proliferation of legal instruments for the protection of human rights, there is a continuing and sometimes even growing disparity between such proclamation and actual implementation of or performance with regard to human rights protection.¹²⁹⁰ States, so the argument, sign or ratify standards, in as much as they speak about human rights so as to avail themselves of further responsibilities and so as to quiescence lobbying or other interest groups.¹²⁹¹ In any event, whether the signing or ratifying of a standard really attest to that standards' success, has no effect at all or has the opposite effect cannot be simply deduced from the act of signing or ratifying.

Another empirical way of measuring success often used by NGOs or International Governmental Organisations in the field of human rights in order to prove their success is to refer to their internal "churn".¹²⁹² That is, they count the numbers of meetings, numbers of reports, mentionings in the press, responses from governments, and so on in relation to them or a certain topic that they pursue. The assumption thereby obviously is that the higher the number of meetings, conferences,

¹²⁸⁸ Hathaway, "Do Human Rights Treaties Make a Difference?", note 1287, 1939. See also O. Hathaway, "Testing Conventional Wisdom", 14 *European Journal of International Law*, 2003, 185 et seq.

¹²⁸⁹ Hathaway, "Do Human Rights Treaties Make a Difference?", note 1287, 1940.

¹²⁹⁰ See for example the Political Terror Scale, at: <http://www.politicalterroryscale.org/levelexamples.php> (last visited 27.04.2012), Human Rights Watch Country Reports, at: <http://www.hrw.org/en/publications> (last visited 27.04.2012) and Amnesty International, *The State of Human Rights – Annual Report 2010*, at: <http://thereport.amnesty.org/> (last visited 27.04.2012). See also P. Alston, *Promoting Human Rights through Bills of Rights: Comparative Perspectives*, 2000 and L. Keith, "The United Nations International Covenant on Civil and Political Rights: Does it Make a Difference in Human Rights Behavior?", 36 *Journal of Peace Research*, 1999, 95 et seq.

¹²⁹¹ T. Landman, "Measuring Human Rights: Principle, Practice, and Policy", 26 *Human Rights Quarterly*, 2004, 906, 906. It remains of course unclear how many human rights abuses happened before the UDHR, note 214, came into being. Nor can anyone say whether the existence of the UDHR did not prevent many more abuses that would have taken place had the UDHR never come into existence.

¹²⁹² T. Buergenthal, "The Evolving International Human Rights System", 100 *American Journal of International Law*, 2006, 791 et seq.

attendees of conferences, mentionings in the press, etc., the more successful a standard is. Relevant data in this respect is available with regard to the activities of the IBC, IGBC and the Council of Europe. The webpages of both organizations account for numerous meetings, activities, conferences and several press clips that all focus on matters of bioethical interest.¹²⁹³ These activities, however, at the most show that UNESCO and the Council of Europe are concerned with issues of bioethical relevance and that they are active in that area as well as that their activities in this area involve other actors as much as they are reviewed or acknowledged by the media or other bodies. Yet, counts of the frequency of meetings and conferences say little about the actual implementation or success of standards. It is for example absolutely unclear whether more meetings and activities will help to reach a broader audience of people nor does a mentioning in a newspaper of one of the standards guarantee that some or in fact anyone has read the newspaper article, whether, as a result of that mentioning the standard has improved the proliferation of the ideas in the standards, and whether more meetings concerned with the issues of bioethical interest really help promoting issues of bioethical relevance.¹²⁹⁴

1.2. Qualitative Data and Indices

Evaluating standards empirically through qualitative analyses is therefore very much in order. Doing so, however, is also much more challenging.¹²⁹⁵ One problem with such an analysis is certainly that measuring achievements in the area of human rights, raise many logistical and methodological difficulties. In terms of the former it is, for example, notoriously difficult to ensure that data is correctly reported. 'Measurable' figures, such as rate of infanticide, death rate due to certain types of illnesses or government spending in certain areas, such as health care, are in many cases difficult or impossible to obtain. Hospitals sometimes lack the means to adequately aggregate such data, for example when they are severely understaffed or do not exist at all in certain areas, or different countries, states or areas within nations have differing monitoring or reporting systems and/or aggregate data differently which can hamper the collection of relevant data and make the

¹²⁹³ UNESCO has for example established and well documents the Ethics of Science and Technology Programme which forms part of UNESCO's Division of Ethics of Science and Technology in the Social and Human Sciences Sector. It has also in 2004 established as part of its capacity building programme the Ethics Education Programme which aims "to reinforce and increase the capacities of member states in the area of ethics education." Through its initiative called "ethics around the World" UNESCO is also organizing a series of ethics conferences in various countries. See UNESCO, Ethics of Science and Technology, at: http://portal.unesco.org/shs/en/ev.php-URL_ID=1373&URL_DO=DO_TOPIC&URL_SECTION=201.html and UNESCO, About the Ethics of Science and Technology, at: http://portal.unesco.org/shs/en/ev.php-URL_ID=1837&URL_DO=DO_TOPIC&URL_SECTION=201.html (last visited 27.04.2012). The Council of Europe has its own Bioethics division at: <http://www.coe.int/t/dg3/healthbioethic/> (last visited 27.04.2012).

¹²⁹⁴ Buergenthal, note 1292, 783.

¹²⁹⁵ Landman, "Measuring Human Rights: Principle, Practice, and Policy", note 1291, 906. See also Carr Center for Human Rights Policy Project Report, *Measurement and Human Rights: Tracking Progress, Assessing Impact Report*, 2005 and R. Barnett/P. Newberg, "Statistical Analysis for Implementing Human Rights Policy", in: P. Newberg (ed.), *The Politics of Human Rights*, 1980, 268 et seq.; P. Richard/T. Jabine, "Exploring Human Rights Issues with Statistics", in: T. Jabine/R. Claude (eds.), *Human Rights and Statistics: Getting the Record Straight*, 1992, 5 et seq.

data useless for comparison.¹²⁹⁶ Moreover, until today no adequate measurement of human suffering has been elaborated. It is unclear whether it is complacent to speak of real progress in the area of bioethics as long as a single person remains subject to exploitative research arrangements or a single child dies due to lack of access to medicine that would be available in another country or due to lack of transfer of relevant knowledge to developing countries.

In addition human rights issues, including those in the area of bioethics, also raise conceptual problems in that measuring progress in any area of human rights involves great conceptual complexity. For example in various countries, scholars, politicians and physicians have argued over an exact definition of 'informed consent' and on how to ascertain whether informed consent has been obtained. The exact propositions of 'informed consent' are nowhere clearly defined, apart from general guidelines discussed above, and hence data relating to these propositions cannot be clearly aggregated. The same might be said for such 'basic' terms as the very term "bioethics", "health" or what constitutes a "natural" or "original" state of being of for example the human genome. In fact as was seen throughout this thesis, many terms used in the context of bioethics are vague and indeterminate.¹²⁹⁷ And even if all conceptual problems were to be resolved with regard to the terms used in the standards there still does not exist the necessary empirical data to evaluate the success in relation to these terms.

One final problem with any empirical analysis of success is the question of correlation versus direct relation.¹²⁹⁸ That is, in many cases it is difficult to ascertain whether a state changes its national legislation as a result of an international agreement in that area, because of public pressure, prevalent religious or other convictions, because it thinks that doing so will offer other trade-off rewards, such as a most-favourite nation status, or for all or several or none of the above mentioned reasons. For example, even if states de facto might change their national patent laws by reference to the TRIPS agreements that does not necessarily mean that they have done so because of the TRIPS agreement. Similarly, it is not clear whether states engage in less human rights abuses because they have signed the UDHR or other relevant documents or because they fear public repercussions or because of some ethical conviction that prevents them from doing so.

¹²⁹⁶ Barnett/Newberg, note 1295, 268. M. Ignatieff/K. Desormeau, *Measurement and Human Rights: Tracking Progress, Assessing Impact*, 2005, 4, stating that "unsure how to square this conviction with the more utilitarian task of setting benchmarks for success, the human rights community has traditionally avoided the endeavour altogether, preferring instead to measure rights problems and progress anecdotally, focusing on the individual story, the illuminating testimonial."

¹²⁹⁷ Of course, some answers have been given regarding such conceptual questions or can be derived from the explanatory memorandums on the standards in the area of bioethics and other human rights standards. The ICESCR, note 341, has for example, in several comments to the ICRSCR, shown that progress can be measured even on such conceptually complex and logistically difficult to measure topics as "health" or "poverty". See for example CESCR, General Comment 9, note 311. Yet similar work lacks for the area of bioethics, i.e. for the terms used in this respect. It should also be kept in mind that with regard to relatively new or emerging terms and subjects, such as genomic research it might sometimes be difficult to arrive at stable definitions of the subject itself and therefore any measurement of success thereof might be difficult.

¹²⁹⁸ Keith, note 1290, 95.

An assessment of the presently examined standards' success will therefore largely have to be carried out on the basis of general, theoretical considerations and subjective intuitions.

2. Success of the Standards

The objectives of the respective standards were discussed above.¹²⁹⁹ In particular standards aimed first at promoting respect for human dignity and to protect human rights in the area of relevance to the standards. Secondly, they aimed to provide a framework of principles and procedures. Thirdly, all standards in one way or another aimed at fostering multidisciplinary and pluralistic dialogue among all stakeholders. Fourth, standards also generally aimed at the establishing of national or international ethics Committees. Fifth, most standards in the words of the UDBHR aim to promote equitable access to medical, scientific and technological developments as well as the greatest possible flow and the rapid sharing of knowledge concerning those developments and the sharing of benefits, with particular attention to the needs of developing countries. Sixth, all standards in some way or another seek to enhance regional or international cooperation. Finally, most standards aim to safeguard and promote the interests of present and future generations.

2.1. The Meaning of Success in Relation to the Objectives

Despite these stated aims it is rather unclear what success actually means with regard to each of these objectives, and how to measure it. For example, the aim to promote respect for human dignity and protection of human rights could be taken to mean anything from thereby wanting to merely remind states and non-state actors of the value of human dignity and human rights over to wanting to shape states' and non-state actors' ideas and legislation about the promotion of respect for human dignity and human rights to wanting to design a full blown, enforceable blueprint for the protection of human dignity and human rights in the area of bioethics that is then to be the model for all national legislation in the area. The report on the possibility of the elaboration of a universal standard in the area of bioethics remains vague regarding a specification of this aim as does the explanatory memorandum on the previous draft of the UDBHR. The former states that the instrument to be (that is the UDBHR) should have a content that contributes to a code of

“universally recognized general principles of bioethics (such as human dignity, solidarity, freedom of research, autonomy, respect for privacy, confidentiality, non-discrimination, informed consent, integrity of research and intellectual honesty) insofar as these principles pertain to bioethics.”¹³⁰⁰

¹²⁹⁹ See Chapter IV, 2.2. in this thesis.

¹³⁰⁰ Report on the Possibility of Elaborating a Universal Instrument on Bioethics, note 128, para 45.

The latter is equally nebulous, specifying merely that “the declaration promotes respect for human dignity and the protection of human rights and fundamental freedoms.”¹³⁰¹ None of the standards or explanatory memorandums, however, provide benchmarks for how success could be measured in relation to this aim nor any clear indices or timelines for the realisation of this aim.

Similarly, without further clarification it is absolutely not clear whether the aim of providing a universal framework of principles for the area of bioethics seeks to endorse a detailed, specific and comprehensive framework of principles that is then endorsed at each national level or whether it merely seeks to set some pointers for national regulations in the area. The Report on the Possibility of Elaborating a Universal Instrument in the area of Bioethics reflects on the importance of this aim, stating in para 7 that “the need for universal ethical guidelines covering all issues raised in this field is increasingly felt by specialists and decision-makers as well as by civil society and the international community.” The explanatory memorandum on the previous draft of the UDBHR in relation to Article 3, is more cautious, stating that

“the declaration is not intended to conclude ongoing bioethics debates. Instead, its major aim is to inspire and stimulate further ethics debates and their resolution within the Member States in order to expand the scope of this declaration and its usefulness.”¹³⁰²

In the light of these explanatory notes it is not quite clear what the objective “to provide a framework or principles and procedures” really means. That is, it is not clear how detailed these procedures and principles have to be, how tailored they should be to specific concerns arising in the area, and how universal the framework is supposed to be in terms of its scope. And again it is left unclear how success looks like in relation to this aim. It is for example not clear to what extent states have to reference or implement the standards in case they enact legislation in an area of bioethical relevance, i.e. whether they have to take them as a blueprint upon which to formulate their legislation, only take some guidance from when they come across a specific problem or may check once their legislation is done whether it is compatible with the framework or whether states should actually look at their existing acts and status and analyse their compatibility with the framework.

With regard to the aim of fostering dialogue in the area of bioethics the report on the possibility of a declaration in the area of bioethics states in para 47 that

“a universal instrument on bioethics must call strong attention to the importance of awareness-raising, information, education, consultation and public debate ...[]....These activities are essential and fundamental to the pursuit of all research in this field in a spirit of solidarity, humanity, reason and harmony. Harmony can only exist if fears, hopes and

¹³⁰¹ Ibid., para 31.

¹³⁰² Ibid., para 29; para 40 further states “legal rules cannot pretend to encompass all fields and cases of bioethics nor to judge or to interfere in every moment of the lives and individual choices of persons. At any level, laws accompanied by effective control should be adopted in order to facilitate personal choices, and only a few substantial issues should be regulated through international rules. In other words, the aim should be to maximize moral evolution and to minimize the need for legislation.

questions are taken into account in the drafting of public policies, laws and regulations. This means that the processes of elaboration and implementation of scientific applications must be accompanied by an ongoing, more accessible and transparent public debate that is open to the lay public and covers both the potential benefits and the hazards of scientific applications. ...[]... UNESCO can also take the opportunity to encourage Member States to involve their scientific community, universities and other academic centres, the media, non-governmental organizations, politicians and civil servants in this dialogue; to promote the active participation of everyone affected by these issues; to provide the means for all citizens to receive clear and precise information on the impact of the procedures available; to ensure that populations can give truly free and informed consent in every circumstance or, if they so wish, decline such procedures; and to publish reports on the agencies and activities that have been put in place to promote bioethics education in their countries.¹³⁰³

Yet again, these specifications do not clarify entirely who has to be involved in that dialogue and to what extent, whether the 'lay public' that has or should be included in the debate, includes every single citizen, the elderly, children, the mentally handicapped or those with Alzheimer disease or all or only parts of these population segments. It is also not clear what a public debate has to look like. That is, 'public debate' could mean anything from disseminating some information to those segments of society that are interested in the debate through occasional informative press coverage or reports on matters of interest over to holding obligatory informative meetings at schools or community centres to interactive webpages that allow every citizen to 'appropriately discuss' or comment on the matters of interest. It also remains rather vague with regard to the question of how education and training relating to these subjects looks like, and it is equally unclear by whom and in what format it has to be imparted.

There are also various questions regarding the meaning of success in relation to the objective of setting up bioethics committees. That is, it is not clear whether success means that each country should simply set up an ethics committees or whether success must also be measured in relation to how these committees work, how many meetings and what material they produce, etc.¹³⁰⁴

Clarifying what success means in relation to the promotion of equitable access to health care and with regard to the aim of sharing of benefit is again beset with difficulties. Regarding access to health care the explanatory memorandum explains in that respect that

serious inequalities in access to health care worldwide increase the importance of including solidarity as one of the principles of the declaration....Five specific elements were singled out: Access to quality health care, including reproductive health care and the health of children; access to adequate nutrition and water; improvement of living conditions and the

¹³⁰³ Ibid., para 49. Cf. also the report on the Round Table of Ministers of Science on "Bioethics: International Implications" (Paris, 22-23 October 2001) at the 32nd Session of the General Conference point in the same direction, at: <http://unesdoc.unesco.org/images/0013/001309/130976e.pdf> (10.12.10).

¹³⁰⁴ Ibid., para 46. The report states in that respect that "The declaration will no doubt contribute to a strengthening of the role and the degree of participation of ethics committees at national and institutional levels: those that are designated by laws or regulations to authorize medical interventions or scientific research and to evaluate the results achieved. The national committees or similar bodies that exist or are being created in many countries represent a rich variety of cultures and experiences; they can be harnessed as an international forum in the preparation of the declaration and in the implementation of its recommendations."

environment; and the elimination of the marginalization and exclusion of persons on the basis of any ground, and reduction of poverty and illiteracy. ... The list is not closed.¹³⁰⁵

Despite the elaboration of these elements it is still, however, fairly unclear whether the duty to provide such health care resides only within the national state vis à vis its own national citizens or whether anyone staying or living in a certain place must have access to health care provided by that state. It is also not clear in how far states have a duty to help one another setting up such adequate health care, whether or to what extent health care standards may be different across or within countries and whether different forms of services may be provided in case of higher payments.

With regard to the sharing of knowledge and benefits the report reiterates that “benefit-sharing and equal access to the advances of science and technology for all humanity it is a truly urgent and universal issue.”¹³⁰⁶

Sharing will in practice take place within the framework of international law and domestic law governing such matters. ... Six concrete elements and one general element are enlisted as forms of sharing benefit: (1) special and sustainable assistance to the persons and groups that have taken part in the research; (2) access to quality health care; (3) provision of new diagnostics facilities for new treatment or medical products stemming from the research; (4) support for health services; (5) access to scientific and technological knowledge; (6) capacity-building facilities for research purposes; and (7) any other form consistent with the principles set out in the declaration.¹³⁰⁷

Yet again, it is left unclear how and to what extent sharing of knowledge and benefits has to be facilitated. No benchmarks for success are offered so that it is not clear whether occasional research cooperation of for example research institutes will be counted as success in relation to this objective, whether it needs a more substantial and institutionalised form of exchange and how that should look like.

Finally, as was already mentioned above the aim to safeguard future interests is rather vague, intangible and not very well defined. The explanatory memorandum states on that subject that

Human beings are an integral part of the biosphere and that they have responsibilities and duties towards other forms of life. Although the principles set out in this declaration apply to human beings, ... human beings have responsibilities towards other forms of life in the biosphere. The concept of human relations with the biosphere underwent substantial changes by the recognition of interdependence between humans and their environment. ...With regard to responsibility towards the biosphere, a special reference to future generations is made in the text to the safeguarding of interests in biodiversity and the biosphere that extend beyond the present generation.¹³⁰⁸

Yet the document does not specify how and to what extent such responsibilities towards the biosphere have changed, nor what the biosphere exactly means or how present and future generations should be safeguarded.

¹³⁰⁵ Ibid., para 75.

¹³⁰⁶ Explanatory Memorandum, note 8, para 10.

¹³⁰⁷ Report on the Possibility of Elaborating a Universal Instrument on Bioethics, note 130, para, 81-82.

¹³⁰⁸ Explanatory Memorandum, note 8, paras 84-86.

2.2. The Success of Standards

In the absence of concrete benchmarks for success in relation to the above described objectives and in the absence of a baseline from which to start measuring incremental successes this section can merely offer some very general observations. First of all with regard to all obligations imposed on states it seems fair to suggest that states in analogy with other human rights standards and the obligations they impose on states at least have to take immediate steps to progressively implement the provisions of the standards even if they only dispose over limited resources.¹³⁰⁹ It is, however, also fair to say that it is left to states which steps they take first in that respect and what they see fit that should, could or has to be done in order to realise these aims.¹³¹⁰ Yet while these reflections generally specify the process by which aims are to be realized it does not make any clearer what is required with regard to each single objective.

It can then merely safely be said that the standards promote some sort of a human rights agenda. As was discussed at length above, the standards are framed as human rights instruments and endorse human rights principles, including that of the promotion of the protection of human dignity as regards questions of bioethical relevance. Similarly, it certainly must be acknowledged that all standards at a very high level provide principles regarding questions of bioethical relevance as discussed above, even though it is not always clear what they actually mean, how they have to be interpreted, and what scope they have. It has also been submitted that the standards at the very least constitute “a rallying cry, an effective political instrument for noble ideas” and to some extent “authoritative guidance – something that open-ended philosophical discussion, for all its value, cannot do.”¹³¹¹ There also certainly takes place some form of dialogue at the national level in the area of bioethics – at least within some states and among certain segments of society. That is, in many states such as for example Germany issues of bioethical relevance are discussed within ethics committees, relevant experts are invited to discuss bioethically relevant issues on TV talk-shows and governmental agencies, NGOs or research institutions raise issues and publicly debate ethical questions as well as they disseminate information so that citizens in principle have some means to attain information and participate in debates if they so wish.¹³¹² With regard to the establishing of research committees, to the extent that these have not already existed in states the ABC has certainly helped setting up a variety of ethics committees over the years, many of which meet

¹³⁰⁹ See CESCR General comment 9, note 311.

¹³¹⁰ Ibid.

¹³¹¹ Benatar, note 1113, 223.

¹³¹² See for example Interessengemeinschaft Kritische Bioethik, at: <http://www.kritischebioethik.de/> (last visited 27.04.2012); Infoportal zum Thema embryonale/adulte Stammzellen, therapeutisches/reproduktives Klonen, Nabelschnurblut-Stammzellen, at: <http://www.stammzellen-debatte.de/> (last visited 27.04.2012); Evangelische Kirche in Deutschland: Bioethik, at: <http://www.ekd.de/bioethik/bioethik.html> (last visited 27.04.2012).

regularly and produce reports etc.¹³¹³ It can finally also be safely assumed that there are meetings and many attempts to facilitate access to medicine and benefit sharing as well as technology transfer.¹³¹⁴ With regard to all these points and as far as attributable to the standards the standards can be said to have produced successful outcomes.

However several points of note speak against an overtly enthusiastic evaluation of the success of standards. For one, it is not clear in how far the standards directly addressed to matters of bioethics – in the same way as all other human rights standards - really do or will affect states' or non-state actors' behaviour in the field of bioethics. As mentioned above, even if states act according to what has been set out in the standards it is never clear whether or not states or non state actors deal with issues of bioethical relevance in a manner that is congruent with human rights principles and promote respect for human dignity in the area of bioethics because of the standards or for other reasons. Given the standards' vagueness and the ambiguity of the concepts used in this discourse, it is also questionable whether the standards really provide enough guidance, content, and substance to constitute a framework of guiding principles for the area of bioethics. Moreover, standards are a far cry from offering comprehensive guidelines in the area. For one, the subject area covered in the standards is just a fracture of what could be considered “issues of bioethical or biomedical relevance.” As was pointed out above, many issues of concern, including those of patent rights or trade rights related to questions of bioethical interest are not even mentioned in the standards.¹³¹⁵ Moreover, aside from what is left to other international legal frameworks, the standards notoriously eschew to provide guidance on many issues that are of very real relevance to any bioethical debate, such as for example questions related to abortion and assisted suicide. In those cases where issues are covered the standards are moreover often so vague and ambiguously worded that they hardly provide any real and definite answer to states seeking guidance. As long as standards serve as a platform for states to read into provisions their individual versions of what is required by them, the standards can hardly be said to offer any real guidance or a framework for decisions. National legislations with regard to such issues as cloning, stem cell research, transplantation etc. have been and continue to be diverse and often in outright opposition with each other which also seems to call into doubt the framework setting function of the standards.¹³¹⁶

With regard to the fostering of dialogue it is also not quite clear in how far dialogues so far really serve or involve more than just a handful of people, i.e. those people that are concerned or

¹³¹³ UNESCO, ABC Country by Country Project and Report, SHS/EST/ABC/03/REV., 2010, at: <http://unesdoc.unesco.org/images/0015/001528/152825e.pdf#page=14> (last visited 27.04.2012).

¹³¹⁴ M. Malinowski, "Technology Transfer in Biobanking: Credits, Debits, and Population Health Futures", 33 *Journal of Law Medicine & Ethics*, 2005, 54 et seq. R. Huggins/A. Johnston/R. Steffenson, "Universities, Knowledge Networks and Regional Policy", 22 *International Journal of Technology Management*, 2001, 321 et seq.

¹³¹⁵ Chapter IV, 3.2. and Chapter VII, 3.4.

¹³¹⁶ See for example different national legislation with regard to human cloning in: K. Matthews, "Overview of World Human Cloning Policies", at: <http://cnx.org/content/m14834/latest/> (last visited 27.04.2012) and 'Stem Cell Policy: World Stem Cell Map', at: www.mbbnet.umn.edu/scmap.html (last visited 27.04.2012).

interested in these matters anyway, either in a professional or personal capacity. Few lay people seem to understand the details of such issues as stem cell research in the same way as only few people really seem to be interested enough in these debates to even seek to understand these issues to an extent that they could participate in the debate at all. Moreover, it is even less clear in how far people could influence the debate when it comes to resulting legislation. It is also not quite clear in how far for example developing countries or least developed countries foster such debates and whether or how such debates are meant to and take place across states.

With respect to the question of how successful ethics committees are it must first be noted that many of these committees already existed before the standards called for their coming into existence. Moreover, it is far from being clear to what extent these ethics committees work successfully nor what successful means, i.e. whether these committees are heterogeneous or diverse enough in terms of experts and lay people involved, whether they assign enough time to a thorough discussion of matters, whether their opinion is at all taken into account by their respective governments, whether they meet regularly, are staffed with independent members, produce objective reports etc.¹³¹⁷

With regard to the question of access to medicine or health care and benefit sharing it should moreover be noted that despite many honourable attempts to increase access to medicine and health care and to share benefits the health indices of many developing countries have far from improved since the standards came into being.¹³¹⁸ Overall it seems that as long as such financially sensitive issues as access to medicine and patent laws are primarily decided within the WTO and TRIPS agreement human rights standards in the area will have little impact.

Finally, the objective to reach a sustainable future is certainly too indeterminate to have much meaning at all. Here the UDBHR seems to do little more than merely raising this issue on paper. While doing so might stimulate awareness and thereby help in the process of the protection of future generation as things stand at the moment it seems as if the UDBHR has done little to actually achieve this objective.

In all these instances it seems that international human rights law seems somewhat overrated in that it hardly has the impact or success rate that those advocating for its use would have it. It also seems that speaking about human rights and putting claims about human rights protection is easier than enforcing them.¹³¹⁹ That is, UNESCO and the Council of Europe have been active in the

¹³¹⁷ See Vöneky, *Recht, Moral und Ethik. Grundlagen und Grenzen Demokratischer Legitimation für Ethikgremien*, note 15, 2010 for a thorough evaluation of ethics committees and, in particular their democratic legitimacy. See also Nida-Rümelin, *Ethische Essays*, note 77, 341-343 on the role of ethics committees.

¹³¹⁸ See for example Report of the WHO Commission on Public Health, Innovation and Intellectual Property Rights, at: <http://www.who.int/intellectualproperty/en/> (last visited 10.12.10) and Access to medicine index for assessment of pharmaceutical companies' performance with regard to increase in access, at: <http://www.accessmedicineindex.org/content/index-2010-0> (last visited 10.12.10).

¹³¹⁹ Benatar, note 1113, 223.

area of bioethics. Yet whether they have actually helped transform the problems that undergird many bioethical debates or offered real and workable solutions to them is somewhat questionable and, in the absence of benchmarks also impossible to assess.

Having said all that it should however also be noted that international human rights while not necessarily successful, so far constitutes the only established way in which states can and do communicate regarding such issues as those in the area of bioethics. States have to or want to negotiate and communicate with each other, if they want to coexist peacefully, to accommodate mutually conflicting interests and to prosper in an international society where common interests and norms are scarce.¹³²⁰ Even if they are in outright disagreement about e.g. the question of whether or not the cloning of human beings should be permissible, they need or want to communicate with each other because they need or want to understand a variety of things, such as whether another state will engage in human cloning processes, how and whether doing so will affect the other states in the community, and how the state will e.g. treat scientists from countries with less permissible regulations undertaking research within its own territory. Also questions about the conditions under which and terms to which states might be willing to agree to a compromise are important factors to know and understand for states. International law and international human rights discourse can and often does provide the only common language and framework within which such communication processes can take place.

Resorting to international law, moreover, signals that states are ready to settle conflicts via a standard procedure and through a framework which is generally known to all states. This means that no state needs an explanation about the “rules of the game”, in that all states generally know substance and processes of law.¹³²¹ For example, states understand the limits of a legal's admissible discourse, i.e. which arguments may count as legal, the timing and setting within which legal arguments may or must be made and, generally, which legal arguments may be most promising. In the negotiations on regulations of the conduct with regard to Genetic Data, for example, it is inconceivable that states openly refer to religiously inspired objections to genetic manipulation processes. Instead they have to focus on the 'legal' issues involved, such as the question of whether or not the storage of data complies or infringes a right to privacy.

Secondly, legal discourse provides a highly developed, conceptually fertile and precise language for thinking about bioethical issues.¹³²² This language has over time been elaborated to include a rich vocabulary not just of terms but of concepts and other ideas that help name and systematically approach bioethical problems, such as the concept of informed consent.¹³²³ Although such concepts, ideas and structures are likely to be in need of further elaboration and specification when

¹³²⁰ Yasuaki, note 777, 112.

¹³²¹ Schneider, "Bioethics in the Language of the Law" note 21, 20.

¹³²² Ibid.

¹³²³ Ibid.

applied to newly emerging issues, they at least set a certain standard upon which such specification work can then be undertaken. International human rights is also apt and well experienced in dealing with both, converging but also with conflicting and diverging interests of states and with those that involve starkly contrasting ethical and religious points of view.

Finally and most importantly law, as pointed out above, is a widely shared and widely accepted tool for resolving ethical, inter-cultural and social conflict. Its' power derives from a general, widely held belief in law and its powers. It is this common belief that makes individuals and states accept and comply with many of law's regulations and hence increase human rights law's suitability to resolve conflict in a determinate way, thus often making law one of the few successful tools that are at states' disposal.¹³²⁴

As such law is certainly here to stay and for the foreseeable future it seems the only tool available or accepted enough to deal with questions of bioethical interest. As such human rights discourse in the area of bioethics is unavoidable. Being aware of the implications that flow from using this framework might help improve it or can be used to enhance its success.

3. Conclusion

This last chapter showed that success is difficult to measure with regard to the objectives that have been set out in the standards. That is mostly so because so far there exist hardly any indices and benchmarks, nor sufficient data that could help in that assessment. Generally, it will have to be left to time to show whether and to what extent the standards are successful and whether and to what extent they have real impact.

¹³²⁴ Ibid.

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