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Richard Hamran

Overview of the Bioethics Convention and its protocols (No. II. 6)

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About the author

Richard Hamran, graduated from the Charles University in Prague (Master of Law, 2010; Juris Doctor, 2012), passed the bar exam in the Czech Republic (2014), currently a lawyer at Kocián Šolc Balaštík, advokátní kancelář, a law firm based in Prague, the Czech Republic, a Ph.D. candidate at the Charles University in Prague, and an LL.M candidate at the Europa-Institut of Saarland University in Saarbrücken.

Preface

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Editor

Lehrstuhl Prof. Dr. Thomas Giegerich
Universität des Saarlandes
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66041 Saarbrücken
Germany

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A. Few Introductory Words

As the heading indicates, the seminar paper will revolve around 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, also known as the Bioethics Convention, Biomedicine Convention, or Oviedo Convention (hereinafter the "Bioethics Convention"), which was adopted by the Council of Europe in 4 April 1997.[1]

One of the most interesting and, at the same time, surprising things about the Bioethics Convention might consist in its paradoxical nature. While the official name thereof might indicate that it deals only with highly specialized and distant-from-practical-life social relations, the content of the Bioethics Convention discloses its broad applicability in daily life.

The formulation of the topic, nevertheless, makes to the object and purpose of the seminar paper a bit complicated in two ways. On one hand, the task of "overview" requires that the scope of aspects to be dealt with be quite broad so that everything of importance is covered. On the other hand, however, such quantity might endanger the quality required for an academic writing of this kind in terms of its depth, whereas the restriction put on the number of pages does not make the task easier.

Therefore, apart from addressing distinctive elements forming together a whole picture of the Bioethics Convention while using mostly historic, descriptive, synthesis and limited-analysis methodological approaches, deeper analysis will be dedicated to one selected topic, it being informed consent. The reason for this choice is twofold. Firstly, it, in author's opinion, best represent the fundamental principles of the Bioethics Convention, secondly, it is itself a broadly applicable legal rule required not only for any biomedical interventions, but also for specific bioethics practices including biomedical research, genetic testing and transplantation.

The paper consists of eight parts including this introductory (A.) one. In the second chapter (B.) the issue of bioethics, facts leading to adoption of the Bioethics Convention and its factual background will be introduced; in addition, other international legal documents concerning bioethics will be briefly mentioned. The third (C.) chapter will look at the characteristic elements of the Bioethics Convention shaping its legal nature. The next part (D.) sheds light on its fundamental principles, whereas a brief list of most important provisions will be drawn up. The fifth chapter (E.) informed consent, its origins, nature and elements will be analyzed. The following part (F.) we will look at the system of procedural protection of the rights guaranteed in

[1] The Bioethics Convention, Council of Europe Treaties Series (CETS) No. 164, entered into force in 1 December 1999. The convention is complemented by the Explanatory Report as published in 1997 (hereinafter the "Explanatory Report to the Bioethics Convention").

the Bioethics Convention; in particular, the jurisdiction and case-law of the European Court of Human Rights in this regard will also be dealt with. Before the end (G.) the author will also try to shed a little light on the circumstances behind the Germany's non ratification of the Bioethics Convention. The last chapter (H.) is to summarize main elements of the Convention and protocols, its significance and implication on the area of bioethics and, last but not least, its deficiencies.

B. From Nuremberg to Oviedo

I. Decrypting Bioethics

Before going any further, one may wonder what should be understood behind the expression *bioethics*. Bioethics (Greek *bios*, life; *ethos*, behavior or *ethikos,* theory of life) is being defined in literature as "the systematic study of human behavior in the area of bio-sciences and health care, when such conduct is examined in the light of values and moral principles"[2]. To put it in simpler words, it might be described as the examination of ethical issues in biology and medicine[3], such issues being, inter alia, medical research, organ transplantation, euthanasia and assisted fertilization.

Bioethics emerged in order to set ethical boundaries within the fast evolving medical and biological sciences for the purposes of balancing their application with fundamental human rights[4]. Scientists and practitioners have often worthy aims, however, some of the known or alleged developments of their work are taking or could potentially take a dangerous turn. "Science, with is new complexity and ramifications, thus presents a dark side or a bright side according to how is used".[5]

[2] *Di Pietro*, From bioethics to informed consent: analysis of international legislation and euthanasia ruling, Medicine and Law. Vol. 1, N. 1-4, 2013, p. 15.

[3] See e.g. http://en.wikipedia.org/wiki/Bioethics [01/01/2015] or http://bioethics.msu.edu/what-is-bioethics [01/01/2015]. For further reading on bioethics see *Irving*, What is "Bioethics"? Tenth Annual Conference: Life and Learning X, University Faculty For Life. Georgetown University, Washington, D.C. June 3, 2000, 54 p.

[4] *Di Pietro*, cited above, p. 15.

[5] See Explanatory Report of the Convention on Human Rights and Biomedicine, para. 2-3.

II. Historical Excursion

Reminiscences of abuse of medical science during the Second World War[6] resulted in a need of international protection of human rights in this regard for future. As a direct consequence thereof and / or in response of concerns of rapid development in the medical sciences and their application,[7] growing patients' movement[8] led to several international instruments have been adopted; the need for creation of international dimension of patients' rights, however, also resulted from consequence of migration, tourism, cross border mobility of patients or cross frontier co-operation in provision of health services[9]. Among such international documents might be mentioned, inter alia, the Nuremberg Code (of 1947)[10]; the Universal Declaration of Human Rights (of 1948)[11]; the European Convention of Human Rights (of 1950)[12]; the International Covenants on Civil and Political Rights and on Economic, Social and Cultural Rights (of 1966)[13]; or the Declaration of Helsinki (of 1964)[14]. None of them, however, had proved to be satisfactory for the protection of the human rights within the scope of the medical sciences, either due its non-binding character or unsufficient reflection of specific elements concerning bioethics.

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[6] See *Samková,* Informed consent of the patient in the Czech Republic in connection with the Convention on Human Rights and Biomedicine, Journal of Health Sciences Management and Public Health, Vol. 6, No. 2, 2005, p. 124.

[7] *Abbing.* Health and Human Rights in the European Context, in: Rynning / Hartlev. Nordic health law in a European context: welfare state perspectives on patients' rights and biomedicice. Leiden: Martinus Nijhoff, c2011, p. 20-21.

[8] *Felt / Bister / Strassnig et al.*, Refusing the information paradigm: Informed consent, medical research, and patient participation, health: An Interdisciplinary Journal for the Social Study of Health, Illness and Medicine Vol. 13, Iss. 1, 2009, p. 2.

[9] *Abbing*, Rights of Patients in the European Context, Ten Years and After, European Journal of Health Law, No. 11, 2004, p. 11.

10 An international (non-binding) set of research ethics principles developed in connection with the trial against 23 German doctors at the end of the Second World War. For the text thereof see *U.S. National Institutes of Health*, Nuremberg Code. http://history.nih.gov/research/downloads/nuremberg.pdf [01/01/2015]; for more information thereon see http://en.wikipedia.org/wiki/Nuremberg_Code [05/01/2015].

[11] Adopted by the United Nations General Assembly on 10 December 1948. For the wording thereof and more information thereon see http://www.ohchr.org/EN/UDHR/Pages/Introduction.aspx or http://www.un.org/en/documents/udhr/ [both 05/01/2015].

[12] As adopted by the Council of Europe in Rome on 1 November 1950 (entered into force in 1976). For the wording thereof and more information thereon see http://www.echr.coe.int/Pages/home.aspx?p=basictexts [05/01/2015].

[13] As adopted by the United Nations General Assembly on 16 December 1966 (entered into force in 1976). Available from: http://www.refworld.org/docid/3ae6b36c0.html and http://www.ohchr.org/en/professionalinterest/pages/ccpr.aspx [both 05/01/2015].

[14] A non-binding set of ethical principles regarding human experimentation developed by the World Medical Association; for its wording, as amended. Available from: http://www.wma.net/en/30publications/10policies/b3/ [05/01/2015].

III. Birth of the Bioethics Convention

After long years of preparations and negotiations[15] and the effort of the Council of Europe – an intergovernmental organization assembling 47 states, whose main purpose is the promotion of rule of law, human rights and democratic values in the European context, and which also elaborated the European Convention on Human Rights of 1950[16] – the Bioethics Convention was adopted in 1997 (and took into force in 1999[17]) as the first binding international treaty in the area of bioethics not only in Europe but also in the world. The Bioethics Convention is ratified / acceded to date by 29 member states[18] of the Council of Europe[19].

The Bioethics Convention comprises of preamble and 38 articles covering the following areas of biology and medicine: biomedical treatment in general (Art. 1-10); human genome (Art. 11-14); scientific research (Art. 15-18); organ and tissue removal (Art. 19-20), and financial gain and disposal of a part of the human body (Art. 21-22). As an effort to respond to the evolution in bioethics, additional protocols are being adopted from time to time, so far four, which regulate issues of prohibition of cloning human beings (of 1998[20]); transplantation of organs and tissues of human beings (of 2002[21]); biomedical research (of 2005[22]); and genetic testing for health

[15] In 1991 the Parliamentary Assembly recommended the elaboration of a framework convention, the preparation of which was entrusted to the Ad Hoc Committee of Experts on Bioethics ("CAHBI"), as established in 1985, and later substituted by the Steering Committee on Bioethics ("CDBI"). Even though a first draft of the convention was presented already in July 1992, the final version thereof, as being later adopted, emerged in June 1996. For more detail of the history of the Bioethics Convention see *Andorno,* The Oviedo Convention: A European Legal Framework at the Intersection of Human Rights and Health Law. Journal of International Biotechnology Law, Vol. 02, Iss. 01, 2005, p. 133-134.

[16] *Andorno,* The Oviedo Convention: A European Legal Framework at the Intersection of Human Rights and Health Law, cited above, p. 133.

[17] After the fifth ratification. See Article 33 of the Bioethics Convention.

[18] Further, 6 countries signed the treaty but have not ratified it yet. For reasons thereof see *Goffin / Borry / Dierickx et al*, Why eight EU Member States signed, but not yet ratified the Convention for Human Rights and Biomedicine. Health Policy, No. 86, 2008, 222–233. Among the states not having signing the Bioethics Convention are, e.g., the United Kingdom and Germany. While the United Kingdom considered the Convention to be too restrictive, Germany viewed it to be too permissive. See *Andorno,* The Oviedo Convention: A European Legal Framework at the Intersection of Human Rights and Health Law, cited above, p. 134. As regards the Germany's stance see also *Schirrmacher*, Human Rights Threatened in Europe: Euthanasia – Abortion – Bioethics Convention, contra-mundum.org, 2001, p. 10-16. For the detailed list of signatures and ratifications consult http://conventions.coe.int/Treaty/Commun/ChercheSig.asp?NT=164&CM=&DF=&CL=ENG [17/01/2015].

[19] The Bioethics Convention is also open for accession to non-member states of the Council of Europe.

[20] Protocol on the prohibition of cloning human beings, CETS No. 168, as signed on 12 January 1998 and entered into force on 1 March 2001.

[21] Protocol concerning transplantation of organs and tissues of human beings, as signed on 24 January 2002 and entered into force on 1 May 2006.

[22] Protocol on biomedical research, CETS No. 195, as signed on 25 January 2005 and entered into force on 1 September 2007.

purposes (of 2008[23]). De *lege ferenda*, we might expect to see adopted further additional protocols to the Bioethics Conventions, e.g., concerning the protection of human rights and dignity of persons with mental disorders, which is currently under preparation, or the uses of xenotransplantation, end of life, nanotechnology, cognitive science and other emerging technologies, which are so far subject to studies and "soft law" instruments[24].

[23] Protocol concerning genetic testing for health purposes, as signed on 27 November 2008 and not yet entered into force on.
[24] For further information see http://www.coe.int/t/dg3/healthbioethic/default_en.asp [19/01/2015].

IV. Other International Instruments

The adoption of the Bioethics Convention was, of course, not the last international document aiming to respond to development in biomedical field. Among other international instruments being adopted after the Bioethics Convention are those either having binding or non-binding character, concerning with the bioethical questions directly or indirectly, generally or specifically. For the purpose of this paper it might be worth mentioning a list of few of them, such as Universal Declaration on the Human Genome and Human Rights (of 1997)[25]; Directive 2001/20/EC of the European Parliament and of the Council concerning medicinal products for human use (of 2001)[26]; International ethical guidelines for biomedical research involving human subjects (of 2002)[27]; International Declaration on Human Genetic Data (of 2003)[28]; Universal Declaration on the Bioethics and Human Rights (of 2005)[29]; European Commission Directive 2005/28/EC concerning investigational medicinal products for human use (of 2005)[30]; Report of the International Bioethics Committee (IBC) on consent (of 2008)[31]; and Charter of Fundamental Rights of the European Union (of 2010)[32].

[25] Adopted by United Nations Educational, Scientific and Cultural organization (hereinafter the "UNESCO"). Available from: http://portal.unesco.org/en/ev.php-URL_ID=13177&URL_DO=DO_TOPIC&URL_SECTION=201.html [19/01/2015].

[26] Available from http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:121:0034:0044:en:PDF [19/01/2015].

[27] Adopted by Council for International Organizations of Medical Sciences. Available from: http://www.cioms.ch/publications/layout_guide2002.pdf [19/01/2015].

[28] Adopted by UNESCO. Available from: http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/human-genetic-data/ [19/01/2015].

[29] Adopted by UNESCO. Available from: www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/bioethics-and-human-rights [19/01/2015]. For further reading see *Andorno*, Global bioethics at UNESCO: in defence of the Universal Declaration on Bioethics and Human Rights. Journal of Medical Ethics. Vol. 33, No. 3, Mar 2007, p. 150–154.

[30] Available from http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:091:0013:0019:en:PDF [19/01/2015].

[31] Adopted by UNESCO. Available from: http://unesdoc.unesco.org/images/0017/001781/178124E.pdf [19/01/2015].

[32] See Art. 3 thereof. Available from: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2010:083:0389:0403:en:PDF [19/01/2015]. For further reading on this topic in relation to bioethics see *Krajewska,* Fundamental Rights Concerning Biomedicine in the Constitutional Treaty and their Effect on the Diverse Legal Systems of Member States, German Law Journal, Vol. 6, No. 11, 2005, 1693- 1710.

C. Nature of the Bioethics Convention

I. Binding Character

The Bioethics Convention is by its nature an international binding treaty[33]. Upon its ratification the states parties thus shall incorporate it into national legislation. As the Bioethics Convention expressly states, each state party shall take in its internal law the necessary measures to give effect to the provisions of this[34]. Unlike prevailing "soft law" agreements[35] developed in the area of bioethics, the Bioethics Convention is considered as the first "hard law" instrument in this regard.[36] Without any prejudice to the implementation obligation of the states, some provisions of the Bioethics Convention may have quality of self-executing norms[37]. In such a case, the right at issue may become directly applicable, i.e. without the prior requirement of its transformation into national law, and thus an individual may invoke it directly before a national court[38].

As results from the principle of supremacy of international agreements over national law, as typically maintained by counties with civil law tradition, in the case of conflict between an international treaty and national law, the former shall, subject to further conditions as the case may be, override the latter[39].

However, the Bioethics Convention provides for some exceptions to exercise of the rights and protective provisions guaranteed thereunder; these may be restricted provided that such restrictions are laid down 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[40]. Nevertheless, those restrictions shall be proportionate to the legitimate aim pursued, as highlighted in the case-law of the European Court of Human Rights (hereinafter the "ECtHR")[41] in respect of restrictions to the rights protected by the

[33] And therefore, the default of a state to comply with obligation thereunder will give rise to international liability. See *Scalabrino*, Rules and principles of international law in the field of health, in: Council of Europe, The human rights, ethical and moral dimensions of health care, Strasbourg, Council of Europe Publ, 1998, p. 46-47.
[34] See Art. 1 of the Bioethics Convention.
[35] Such as declarations and recommendations.
[36] *Andorno,* The Oviedo Convention: A European Legal Framework at the Intersection of Human Rights and Health Law, cited above, p. 134.
[37] E.g. right to privacy, right to information and requirement of informed consent are deemed to have the self-executing character. See *Andorno*, The Oviedo Convention: A European Legal Framework at the Intersection of Human Rights and Health Law, cited above, p. 136.
[38] See *Shaw*, International Law, 6th ed., Cambridge, University Press, 2008, p. 162,177.
[39] E.g. in Germany, Netherland, Italy, Portugal, Belgium, Poland, Russia. See *Shaw*, cited above, p. 171-176.
[40] See Art. 26 para. 1 of the Bioethics Convention.
[41] See e.g. *Case of W v. the United Kingdom*, 08/07/1987, No. 9749/82, s. 60; or *Case of Olsson v. Sweden*, 24/03/1988, No. 10465/83, s. 67.

European Convention of Human Rights, such case-law being also applicable to the Bioethics Convention[42]. The restrictions, may not, however, regard some provisions[43].

II. Comprehensive and Framework Approach

These two features make the Bioethics Convention unique amidst international instruments touching the area of bioethics. First, the Bioethics Convention seeks to deal with the domain of bioethics as a whole, i.e. in spite of focusing only on certain biomedical areas or its new developments, it also covers some general rights of patients in relation to any biomedical intervention[44].

Second, it was drafted rather as a framework instrument, establishing only broad, general rules, which, on one hand, aimed to prevent the most serious breaches of human rights, and, on the other hand, were intended to be further developed in the upcoming years by additional protocols. This (framework) approach accordingly outlines the relationship between the Bioethics Convention and its protocols, which might be described as a baseplate being subject to gradual upgrading at convenience of its constructors. One may, of course, consider this rather general approach as its disadvantage, nevertheless, it should not be forgotten that too much ambition from the very beginning would have been politically inacceptable and thus it could have caused the failure of the project as such[45]. In fact, the following years after the adoption of the Bioethics Convention have proved feasibility of such "upgrading" thought, as the additional protocols as being so far adopted have further enhanced regulation in four areas of bioethics[46].

[42] *Andorno*, The Oviedo Convention: A European Legal Framework at the Intersection of Human Rights and Health Law, cited above, p. 136.
[43] Pursuant to Art. 26 para. 6 of Bioethics Conventons the full list of these „unconditional" provisions involves art. 11, 13, 14, 16, 17, 19, 20 a 21 thereof.
[44] *Abbing,* Rights of Patients in the European Context, Ten Years and After, European Journal of Health Law, No. 11, 2004, p. 8.
[45] *Andorno*, The Oviedo Convention: A European Legal Framework at the Intersection of Human Rights and Health Law, cited above, p. 136.
[46] For more details on the protocols see section B. paragraph III. of the paper above.

III. Minimum Common Standards

The political purpose of the Bioethics Convention was to harmonize the national legislation of all the state parties to the treaty, and to offer – as a compromise – a common *minimum standard* of legal protection of the patients in the context of biomedical sciences, especially regarding their physical and psychical integrity.[47] The nature of the minimum standards lies in that each state party to the Bioethics Convention shall not provide a lower level of protection of human rights with regard to bioethics, which ensures that an individual has "a common, minimum level" of protection throughout Europe[48].

This compromise had double effect. While there were states for which adoption of the Bioethics Convention would not allegedly bring anything new to well develop medical law[49], for other it meant a huge step forward to modern understanding of a patient as an autonomous person enjoying right to dignity and self-determination[50].

Nevertheless, the obligation to introduce into national law at least the common rules adopted shall not be construed, as it is done by critics of the Bioethics Convention, as a "deliberate preference for a 'liberal' bioethics or as an encouragement of those practices that are not explicitly prohibited"[51]. This is expressly avoided by the Bioethics Convention itself through a so called "wider protection" clause setting forth that none of the provision thereof shall be interpreting as limited or otherwise affecting the possibility for a party to grant to patients a wider measure of protection than stipulated therein[52].

[47] *Peterkova.* Convention on Human Rights and Biomedicine – outcome for national regulation of patients´ rights? Mezinárodněprávní aspekty ochrany lidských práv. Prague, Charles University in Prague, Faculty of Law, 2013, p. 61.

[48] *Simonsen*, European Integration – a Case Example from European Biomedical Research Law. in: Rynning, Elisabeth / Hartlev, Mette (eds.). Nordic health law in a European context: welfare state perspectives on patients' rights and biomedicice. Leiden: Martinus Nijhoff, c2011 , p. 262.

[49] E.g. Great Britain and Germany. See also *Manuel / Hairion / Aauquier et al*, Is the legislation of European states in keeping with the recent convention on human rights and biomedicine? European Journal of Health Law, No. 6, 1999, p. 55-69.

[50] *Peterkova*, cited above, p. 62. For implication of the Bioethics Convention on 13 Central and Eestern European Countries see Oviedo Convention in Central and Eastern European Countries. Medicínska etika & Bioetika – Medical Ethics & Bioethics. Vol. 16, 2009, Supplementum 1, 32 p.

[51] *Andorno*, The Oviedo Convention: A European Legal Framework at the Intersection of Human Rights and Health Law, cited above, p. 135.

[52] See Art. 27 of the Bioethics Convention.

D. Principles and Key Provisions

I. Roots

The scope of rights of patients protected by the Bioethics Convention arises out of the fundamental rights of a human being, recognized and guaranteed by the European Convention of Human Rights.[53]

Certain principles and rights implied in the Bioethics Convention were also laid down in preceding international human rights treaties, such as the International Covenant on Civil and Political Rights of 1966 and the European Convention on Human Rights of 1950[54]. However, this is the first time that these rights have been developed and assembled in one single multilateral binding instrument entirely devoted to biomedical issues.[55]

II. Dignity, Identity, Equality and Integrity

The goal[56] of the Bioethics Convention is to guarantee to all human beings fundamental freedoms, especially integrity of an individual, and secure dignity and identity[57] within the application of biology and medicine.

The predominant focus of the Bioethics Convention lies in the human dignity[58]. It may be described as "a multifaceted, multilayered concept that has been developed within the discipline of philosophy, theology and law".[59] The concept of human dignity, being attributable to every human being, derives from Immanuel Kant's idea that "no man shall be treated solely as a

[53] *Peterkova*, cited above, p. 61.

[54] E.g. the right to life, to physical integrity and to privacy, and to be free of any form of discrimination.

[55] *Andorno,* The Oviedo Convention: A European Legal Framework at the Intersection of Human Rights and Health Law, cited above, p. 133.

[56] Expressed in Art. 1 thereof as „object and purpose".

[57] The meaning of these notions is dealt with in *Sass,* Introduction: European Bioethics on a Rocky Road. Journal of Medicine and Philosophy, Vol. 26, No. 3, 2001, p. 219-220.

[58] For further reading on dignity in bioethics see *Cuica,* The concept of "dignity" of the human being in bioethics and biolaw (II), Romanian Journal of Bioethics, Vol. 8, No. 3, July – September 2010, p. 125-128; or *Andorno*, Four paradoxes of human dignity, in: Joerden, E.; Hilgendorf, N., Petrillo, F. et al. (eds.), Menschenwürde und moderne Medizintechnik, Series: Interdisciplinäre Studien zu Recht und Staat, n. 50, Baden Baden, Nomos Verlag, 2011, p. 131-140.

[59] *Walin*, Human Dignity as a Legal Argument in the Era of Modern Biomedicine, in: Rynning / Hartlev, Nordic health law in a European context: welfare state perspectives on patients' rights and biomedicice. Leiden: Martinus Nijhoff, c2011, p. 250.

means, bus as the end",[60] and was mentioned for the first time in the Universal Declaration of Human Rights in 1948.[61]

Hence, human dignity assigns to every person the right to be respected and recognized as a human being. As the direct consequence thereof, such person may not be treated in a way that would jeopardize its quality as a legal person. A patient, therefore, shall be treated as a right-holder, not an object of medical treatment. In this regard we speak of respect of patient's autonomy, it being an inherent part of human dignity[62].

Stemming from the Bioethics Convention, human dignity can be interfered with by many ways, e.g. discrimination against access to health care, medical intervention *non-lege artis*[63] or without informed consent, breach of right to self-determination, insufficient protection of children and mentally incapable persons, non-compliance with confidentiality of information on health, discrimination on grounds of genetic heritage or cloning.[64]

III. Protective Provisions

When providing a brief list of the key provisions of the Bioethics Convention, the regard is to be taken to the systematic character of the regulative measures. These are thus to be mentioned with regard to their application to (1) any biomedical intervention, on one hand, and (2) specific bioethical issues, such as human genome, biomedical research and transplantation of organ and tissue, on the other hand. While in the former case the most fundamental rules will be stated, the latter will be listed by way of synthesis of *prohibited* and *conditionally authorized* activities. In addition, a protection of (3) minors and mentally incapable persons in this regard will be shortly described.

1. Any Biomedical Intervention

The Bioethics Conventions provides for the protection of patients in relation to any biomedical intervention by stating that:

[60] See *Walin*, cited above, p. 248; *Harris*, Consent and end of life decisions, Journal of Medical Ethics. Vol. 29, Iss. 1, 2003, p. 10; or *Delkeskamp-Hayes,* Respecting, Protecting, Persons, Humans, and Conceptual Muddles in the Bioethics Convention. Journal of Medicine and Philosophy, Vol. 25, No. 2, 2000, p. 152.
[61] *Walin*, cited above, p. 243.
[62] *Harris*, cited above, p. 10.
[63] I.e. in violation of relevant professional obligations and standards.
[64] *Peterkova*, cited above, p. 64.

- in the case of conflict, the interests of a person shall have priority over the sole interest of society or science;[65]
- relevant professional obligations and standards shall be complied with[66];
- a medical treatment on a patient shall not, save for exceptional cases[67], be carried out without his / her prior informed and free consent[68];
- right of a patient to privacy of health information, right to be informed (save for exceptional cases[69]) as well as right not to be informed about the health shall be respected[70];

2. Specific Bioethics Issues

Under the Bioethics Convention, the following activities may be carried out subject to meeting conditions as further prescribed therein:

- predictive genetic tests for health purposes or scientific research[71];
- interventions on the human genome for preventive, diagnostic or therapeutic purposes[72];
- biomedical research with prior informed consent of participants, absence of alternatives, proportionality of risks, and approval by the competent body[73];
- organ and tissue donation by deceased as well as living donors for the purpose of transplantation[74];

Under the Bioethics Convention, the following activities are prohibited:

- any form of discrimination against a person on grounds of his or her genetic heritage[75];
- interventions on the human genome with the aim of modification in the human genome of any descendants[76];

[65] See Art. 2 of the Bioethics Convention. Also see *Abbing,* Health and Human Rights in the European Context, cited above, p. 21.
[66] See Art. 4 of the Bioethics Convention.
[67] The prior informed consent is not needed in the event of intervention in an emergency situation, or where it is required to avert serious harm to a mentally disordered person, both subject to meeting further conditions (see Art. 7 and 8 of the Bioethics Convention respectively).
[68] See Art. 5-9 of the Bioethics Convention.
[69] When "not knowing the truth" is in the interest of the patient.
[70] See Art. 10 of the Bioethics Convention.
[71] See Art. 12 of the Bioethics Convention and the Protocol relating to genetic testing for health purposes.
[72] See Art. 13 of the Bioethics Convention.
[73] See Art. 15-17 of the Bioethics Convention, and the Protocol on Biomedical Research.
[74] See Art. 18 of the Bioethics Convention and the Protocol on Transplantation.
[75] See Art. 11 of the Bioethics Convention and the Protocol relating to genetic testing for health purposes.

- generally any use of assisted procreation techniques with the purpose of choosing a future child's sex, save for exceptional cases[77];
- human reproductive cloning[78];
- the creation of human embryos for research purposes[79];
- any financial gains relating to the human body and its parts, as well as organ and tissue trafficking [80];

3. Minors and Mentally Incapable Persons

Without going into much details in this regard it is worth mentioning that the Bioethics Convention introduces extra protective measure that have to be observed everywhere the rights and interest of such persons might be jeopardized by performance of biomedical interventions[81].

E. Informed Consent

I. Origins and Nature

The Bioethics Convention provides that, in general (save for exceptional case), any intervention in medical field, it being all medical acts including those carried out for purposes of preventive care, diagnosis, treatment, rehabilitation or research,[82] may only be carried out after a patient has been informed of the purpose, nature, risks and consequences of the intervention, and has freely consented to it.[83] To put it in other words, where the informed and free consent has not been given (and the conditions for intervention without informed consent have not been met), the patient may not be forced to undergo the intervention.[84] Subsequently, any such intervention carried out without the informed consent shall be deemed unlawful. The consent thus

[76] See Art. 13 of the Bioethics Convention.
[77] When serious hereditary sex-related disease is to be avoided. Art. 14 of the Bioethics Convention.
[78] See the Protocols on prohibition of cloning human beings.
[79] See Art. 18 of the Bioethics Convention. This raises question of whether or not it is justified in the event such research were to be the sole method of finding ways of preventing and curing very serious illnesses. See *Abbing*, Health and Human Rights in the European Context, cited above, p. 21.
[80] See Art. 21 of the Bioethics Convention and the Protocol on Transplantation.
[81] In this regard see, e.g., provisions of Bioethical Convention concerning any biomedical intervention (Art. 6), biomedical research (Art. 17), transplantation (Art. 20), as well as those regarding genetic testing (Art. 10-12 of the Protocol Concerning Genetic Testing for Health Purposes).
[82] See para. 34 of the Explanatory Report to the Bioethics Convention.
[83] This principle has its origins in the Nuremberg Code of 1947 and was also included in the Declaration of Helsinki of the World Medical Association (1964/2000). See *Andorno*, The Oviedo Convention: A European Legal Framework at the Intersection of Human Rights and Health Law, cited above, p. 138.
[84] See para. 34 of the Explanatory Report to the Bioethics Convention.

constitutes the basic principle of the ethics of medicine, legitimizing any intervention to the patient[85].

The importance of the consequence of the said rule rises with the number of cases where the informed consent is required. This is especially crucial from the view of the Bioethics Convention, which subjects the legality of a particular practice to the informed consent not only in cases of "routine" medical interventions, but also that of biomedical research[86], organ and tissue removal for transplantation purposes[87] and genetic testing[88].

What is the scope and range of the consequences of the "informed consent" for the biomedical practice? Indeed, this issue prompted bioethicists to analyze a number of related issues, which range from the redefinition of the relationship between patient-doctor from paternalist[89] to rather equal[90]; a patient's refusal of so-called "aggressive" medical treatment; and their choice of which treatment to undergo, "right to hear the truth" about their conditions, prognosis and the treatment options available.[91] Last but not least, it also concerns "supportive care", consisting of the loss of self-consciousness, notably nutrition and hydration of patients in a vegetative state, in the event that their interruption will inevitably lead to death[92], and accordingly the question of „passive" euthanasia[93].

To respond to these issues, one may look at the "informed consent" issue from a broader perspective. This concept derives from the principles of patient's autonomy[94] and of supremacy

[85] *Papamichail*, The patient's right to information and consent in the execution of medical procedures: The legal and sociological dimension, Hellenic journal of Nursing Science, Vol. 3, Iss. 4, 10-12/2010, p. 103.

[86] See Art. 16 of the Bioethics Convention and Art. 14 of the Protocol concerning Biomedical Research.

[87] See Art. 19 of the Bioethics Convention and Art. 13 of the Protocol concerning Transplantation of Organs and Tissues.

[88] See Art. 9 of the Protocol concerning Genetic Testing for Health Purposes.

[89] The paternalist approach, simply speaking, prefers the option that „is for the good" of the patient without taking into consideration his or her wishes. See also para. 34 of the Explanatory Report to the Bioethics Convention.

[90] Such redefinition, however, has been proved to be implemented in practice with difficulties. See *Krizova / Simek*, Theory and practice of informed consent in the Czech Republic, Journal of Medical Ethics, No. 33, 2007, p. 273–277; *Dostal*, Patient rights protection in Czech Republic: Challenges of a transition from communism to a modern legal system, p. 102.

[91] *Di Pietro*, cited above, p. 16.

[92] *Di Pietro*, cited above, p. 16.

[93] The Bioethics Convention does not regulate the permissibility of an "active" euthanasia.

[94] See *O'Neill*, Some limits of informed consent, Journal of Medical Ethics, No. 29 2003, 5. The foundations of the concept of patient's autonomy and informed consent go back to the beginning of the 20th century in the national law of the USA and France. See *Dantas*, When consent is not enough: the construction and development of the modern concept of autonomy. Medicine and Law, 2011, No. 30, 464-466. Indeed, the formulation of the informed consent was influenced by American construction and Canadian and Australian elaboration. See *Murray*, The Future of Informed Consent in British Common Law, European Journal, Health Law, No. 6, 1999, 244.

of his / her interests and well-being over the sole interest of society of science[95]. The latter principle in practice means that, in general, where there is a conflict between the interest of a patient and that of society or science, the former shall prevail. This principles shall further be taken into account when interpreting the provisions of the Bioethics Convention, including those relating to biomedical research, genetic tests or transplantation.[96]

Having in mind the above-said, we can consciously, though carefully, deduce that the medical intervention may be freely refused by the patient[97], even where such refusal of the consent could lead to a fatal outcome. It should be noted, that ECtHR holds the same position. Its jurisprudence maintains that the imposition of medical treatment without the consent of a mentally-competent adult patient would interfere with her/his right to physical integrity and impinge on the rights[98] guaranteed by the European Convention of Human Rights. ECtHR expressly states that "the freedom to accept of refuse medical treatment, or to select an alternative form of treatment, is vital to the principle of self-determination and personal autonomy. Accordingly, absent any indication of the need to protect third parties, for example, mandatory vaccination during an epidemic, the state must abstain from interfering with the individual freedom of choice in the sphere of healthcare for such interference can only be lessen and not enhance the value of life. A person, therefore, may claim to exercise a choice to die by declining to consent to treatment which might have the effect of prolonging his life".[99]

Self-determination, however, is not unlimited, as being also confirmed by the case-law of ECtHR. In this regard patient's wishes may be limited by, e.g, relevant medical professional standards[100], being "brushed" in each particular case by factual availability and economic affordability[101], his / her mental capacities, the rights and freedom of others[102], or public health[103]. As said before, however, restrictions to individual's freedom are not unlimited; on the contrary, any such restriction must meet the condition of necessity, proportionality and

[95] See Art. 2 of the Bioethics Convention. Fur further reading in this regard see *Helgesson, / Eriksson,* Against the principle that the individual shall have priority over science, Journal of Medical Ethics, No. 34, 2008, p. 54-56.
[96] See *Peterkova*, cited above, p. 62.
[97] See para. 34 of the Explanatory Report to the Bioethics Convention.
[98] In particular, the right for respect of the private life as protected under Art. 8 of the European Convention of Human Rights.
[99] ECtHR: *Case of Jehovah's Witnesses of Moscow and others v. Russia*, 10/06/2010, No. 302/02, s. 135,136; See also *Case of Pretty v. The United Kingdom*, 29/04/2002, No. 2346/02, s. 63;
[100] A patient may not require a treatment *non-lege artis*.
[101] Not every health provider can afford to offer a treatment reflecting the latest achieved developments in medical science.
[102] In the case, e.g., of a mentally-ill person endangering others.
[103] E.g. contagious diseases.

subsidiarity, be prescribed by law and respect the essence of the rights and freedoms concerned.[104]

II. Elements

As stemming from the general rule laid down in Art. 5 of the Bioethics Convention, in order for a medical intervention to be lawful, a concerned patient must give a consent, which is (1) free, (2) informed, and (3) given prior to the treatment. Though not regulated by the Bioethics Convention, one also has to consider question of (4) a form of the consent.

1. Freedom of Consent

The Bioethics Convention requires any consent to be in accordance with the patient's free will, absent of any pressure from anyone[105]. In other words, the patient should feel completely free in making a decision to accept or reject the contemplated medical intervention[106].
In addition, an already given consent may be withdrawn at any time and such a decision of a patient shall be generally respected[107].

2. Informed Consent

It has already been said above that an informed consent is required for an intervention to be lawful. But when the consent is deemed informed? In order for a patient to give a genuinely informed consent, as the Bioethics Convention stipulates, he or she must be provided with information about the *purpose*, *nature*, *risks* and *consequences* of the intervention.
These elements of informed consent are just most important, but additional information may be required according to the circumstances. Such may include, for instance, information on alternatives (at least an alternative not to undergo an intervention) together with the reasons why a specific alternative is recommended, possible side-effects, success rates, or prognosis[108]. Furthermore, the patient has right to be given answer to any additional question.[109]

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[104] *Abbing*, Health and Human Rights in the European Context, cited above, p. 23.
[105] See para. 35 of the Explanatory Report to the Bioethics Convention.
[106] *Papamichail*, The patient's right to information and consent in the execution of medical procedures: The legal and sociological dimension, Hellenic journal of Nursing Science, Vol. 3, Iss. 4, 10-12/2010, p. 103.
[107] E.g. withdrawal of the consent during a surgery might lead to serious risk. See para. 38 of the Explanatory Report to the Bioethics Convention.
[108] *Dantas*, When consent is not enough: the construction and development of the modern concept of autonomy, Medicine and Law, 2011, No. 30, 464-468.
[109] See para. 35 of the Explanatory Report to the Bioethics Convention.

In addition information, when providing to the patient, must be sufficiently clear and suitably worded for the particular person who is to undergo the intervention[110]. In other words, the information shall be provided in a way easily understandable for patients[111]. In contrast, the mere act of reading and signing a paper, a consent form, may be not enough[112].

3. Prior Consent

The Bioethics Convention further requires that a consent be given always prior to an intervention. This also means that before giving such consent, the patient must have sufficient time to make decision whether or not to undergo the contemplated intervention, whereas sufficiency will depend upon the nature of the intervention and further circumstances[113].

4. Form of Consent

As regards medical intervention in general, the Bioethics Convention stays silent about question of the form of consent[114]. Therefore it is up to state parties to regulate this question on national level. However, Explanatory Report to the Bioethics Convention provides a little guide in this regard. It suggests that the particular form of consent – it ranging, the same as legal acts in general, from express (verbal or written) to implied ones – is dependent upon the nature of the intervention[115]. Therefore, while in mostly routine medical acts the implied consent might fully sufficient, the express one is to be required in cases of invasive interventions. However, in order to avoid uncertainty about the consent given, and thus reduce risk of dissatisfaction, complaint or litigation, it might be considered to prefer explicit consent over implied as in many cases as possible[116].

[110] See para 36 of the Explanatory Report to the Bioethics Convention.
[111] See *Andorno*, The Oviedo Convention: A European Legal Framework at the Intersection of Human Rights and Health Law, cited above, p. 139.
[112] *Dantas*, When consent is not enough: the construction and development of the modern concept of autonomy. Medicine and Law, 2011, No. 30, 464-467.
[113] *Cisarova* / Sovova, Criminal Law and Health Care, 2nd ed. Prague, Orac, 2004, p. 76.
[114] An express specific consent is required in relation to biomedical research or removal of body parts for transplantation purposes. See Art. 16 and 19 of the Bioethics Convention respectively.
[115] See para 37 of the Explanatory Report to the Bioethics Convention.
[116] *O'Neil*, Accountability, trust and informed consent in medical practice and research, Clinical Medicine, Vol. 4, No. 3, 2004, 274.

III. Exceptions from Informed Consent

Apart from the situation of persons not capable to give an informed consent, where the authorization to the intervention is to be granted by their representatives or state authority[117], the Bioethics Convention expressly recognizes two cases where the biomedical intervention may be performed even without giving prior informed and free consent, it being in the case of mentally disordered persons and emergency situations.

1. Mentally Disordered Persons

In order to perform a medical intervention upon a mentally disordered person without his or her consent, the Bioethics Convention requires four conditions to be met, it being, firstly, existence of a mental disorder; secondly, necessity of the intervention for treating an individual's mental disorder; thirdly, probability of occurrence of serious harm to the individual's health without such intervention; and, fourthly and lastly, observation of protective conditions set forth by national law, involving, inter alia, supervisory, control and appeal procedures. If one of the above-mentioned conditions cannot be met, the contemplated intervention may be carried out only provided the conditions prescribed for medical interventions either for mentally incapable persons or in emergency situation are alternatively met.

2. Emergency Situations

Legitimacy of medical intervention without prior informed consent in an emergency situation should be not challenged, however, its legality is, at least under the Bioethics Convention, subjected to certain conditions. Medical intervention may be carried out immediately without the prior informed consent / authorization where, first of all, the consent or authorization cannot be obtained, second of all, the intended intervention is necessary in that it cannot be delayed without risk of occurrence of harm and, third of all, it is for the benefit of the health of the individual concerned[118].

[117] For more information in this regard see *Stultiëns / Goffin / Borry et al*. Minors and Informed Consent: A Comparative Approach, European Journal of Health Law, No. 14, 2007, p. 21-46.
[118] See Art. 8 of the Bioethics Convention and para. 56-59 of the Explanatory Report thereto.

3. Other Cases

Though not expressly laid down by the Bioethics Convention, it stems from the provision of Art. 26 thereof, allowing restrictions on the exercise of rights thereunder, that further cases where medical interventions may be carried out without prior informed consent are feasible provided that these are prescribed by law and are necessary in a democratic society for the protection of collective interests (such as public safety, prevention of crime and public health) or the rights and freedoms of others. Typical situations contain, e.g., compulsory isolation due to seriously infectious disease or confinement of a mentally person endangering life of health of others.[119]

IV. Living Will

Previously expressed wishes or so called "living will" may be understood as an informed consent, it being either acceptance or refusal, given in advance, or as an exception derogating the previous described exception to performance of medical intervention without the informed consent in cases of the emergency situation.[120]

The practical implication of the living will is in that it allows mentally capable patients to express their will in respect of foreseeable future situations in case they would not be capable to give the informed consent[121].

When such situation occurs, as the Bioethics Convention requires, the previously expressed wishes shall be taken into consideration[122]. However, the observance of the living will is not absolute as the substantial change of circumstances, such as, e.g., progress in science, may render the living will invalid.[123]

[119] See para. 148-159 of the Explanatory Report to the Bioethics Convention.
[120] *Peterkova*, cited above, p. 65.
[121] For more information about the living will see, e.g., *Elliott / Elliott*, From the patient's point of view: medical ethics and the moral imagination, Journal of Medical Ethics, No. 17, Iss. 4, 1991, p. 174-175.
[122] See Art. 9 of the Bioethics Convention.
[123] See para. 60-62 of the Explanatory Report to the Bioethics Convention.

F. Enforcement of the Bioethics Convention

I. Judicial Protection by National Courts

The Bioethics Convention explicitly requires states to provide appropriate judicial protection to prevent or to put a stop to an unlawful infringement of the rights and principles set forth therein[124]. In addition, the states shall lay down appropriate sanctions in the event of infringement of the Bioethics Convention as well as fair compensation to persons suffering undue damage therefrom.

It should be hereby reiterated that, in the first place, the states are obliged to take necessary measure in their internal law to give effect to the provision of the Bioethics Convention. However, where a provision thereof is a self-executory one, i.e., is clear, precise and gives rise to a subjective rights to an individual, it well may be enforced before a national court directly under the Bioethics Convention, it being without the need of its implementation into national law. As such a self-executory right it might be considered, e.g., right to self-determination, right to privacy and to information on health.

II. Protection by European Court of Human Rights

As regards international enforcement of rights protected by the Bioethics Convention, individuals are not entitled to assert a claim stemming from an exclusive infringement of the Bioethics Convention before ECtHR. ECtHR may only provide advisory opinions on legal questions concerning the interpretation of the Bioethics Convention; however, only at the request of states and CDBI, not individuals.

The case thus by may be brought before ECtHR by an individual only if facts which are an infringement of the rights contained in the Bioethics Convention also constitute a violation of one of the rights contained in the European Convention of Human Rights.[125] Regardless of this obstacle ECtHR in its case-law reflects development in medical science and technology by making a dynamic interpretation, in the light of "present day circumstances". "Human rights instruments are 'living instruments', the norm 'floats' in the sphere of philosophical and moral concept and remains a stimulant for innovative jurisprudence and fresh regulation".[126]

[124] See Art. 23 of the Bioethics Convention.
[125] See para. 165 of the Explanatory Report of the Bioethics Convention.
[126] *Abbing*, Health and Human Rights in the European Context, cited above, p. 20.

ECtHR[127] has so far dealt with the bioethical issues several times, concerning issues both covered and uncovered by the Bioethics Convention, it ranging from consent to medical intervention[128] and medically assisted procreation[129], through reproductive rights[130] and the right to know one's biological identity[131], to assisted suicide[132] and ethical issues concerning HIV[133]. In addition, it is also worth mentioning that ECtHR has, in some cases, also made reference to the Bioethics Convention in[134]. Without prejudice to protection provided by ECtHR to human rights within application of bioethics including those guaranteed by the Bioethics Convention, absence of an express judicial complaint procedure before ECtHR based on violation of the Bioethics Convention might be well deemed one of the main weaknesses of the Bioethics Convention[135].

G. Germany's (non)ratification

Germany belongs to those states that have neither ratified, nor signed the Bioethics Convention. In order to understand the reasons behind the Germany's standpoint, one needs to look at the time-period preceding the adoption of the Bioethics Convention by the Council of Europe on 4 April 1997.

[127] For the summary of some cases see the Council of Europe/European Court of Human Rights, Research Report: Bioethics and the case-law of the Court, 2012; for further reading in this regard see *Birmontiene*, Health Legislation in Eastern European Countries: the Baltic States, European Journal of Health Law, No. 11, 2004, p. 78-80.
[128] See, e.g., *Case of Hoffmann v. Austria*, 23/06/1993, No. 12875/87; *Case of Jalloh v. Germany*, 11/07/2006; No. 54810/00; or *Case of Salmanoğlu and Polattaş v. Turkey*, 17/03/2009, No. 15828/03.
[129] See, e.g., *Case of R.R. v. Poland*, 26/05/2011, No. 27617/04, or *Case of S.H and Others v. Austria*, 3/11/2011, No. 57813/00.
[130] See, e.g., *Case of Draon v. France*, 06/10/2005, No. 1513/03; *Case of Tysiąc v. Poland*, 20/03/2007, No. 5410/03; or *Case of A, B, and C v. Ireland*, no. 25579/05, 16/12/2010.
[131] See, e.g., *Case of Odièvre v. France*, 13/02/2003, No. 42326/98; *Case of Jäggi v. Switzerland*, 03/07/2003, No. 58757/00, or *Case of Ahrenz v. Germany*, 22/03/2012, No. 45071/09.
[132] See, e.g., *Case of Haas v. Switzerland*, 20/01/2011, No. 31322/07.
[133] See, e.g., *Case of Enhorn v. Sweden*, 25/01/2005, No. 56529/00; *Case of I. v. Finland*, 17/07/2008, No. 20511/03; *Case of Shchebetov v. Russia*, 10/042012, No. 21731/02.
[134] See, e.g., *Case of Cyprus v. Turkey*, 10/05/2001, No. 25781/94; *Case of Glass v. the United Kingdom*, 09/03/2004, No. 61827/00, s. 58; *Case of Vo. v. France*, 08/07/2004, No. 53924/00, s. 35; *Case of Evans v. the United Kingdom*, 10/0402007, No. 6339/05, s. 40, *Case of Hülya ÖZALP v. Turkey*, 11/10/2007, No. 74300/01; *Case of Juhnke v. Turkey*, 13/05/2008, No. 52515/99, § 56; *Case of M.A.K. and R.K. v. the United Kingdom*, 23/03/2010, Nos. 45901/05 and 40146/06, s. 31; *Case of R.R. v. Poland*, 26/05/2011, No. 27617/04, s. 83; *Case of Arskaya v. Ukraine*, 04/10/2011, No. 45076/05; or *Case of V.C v. Slovakia*, 08/11/2011, No. 18968/07, s. 76-77.
[135] See also Andorno, The Oviedo Convention: A European Legal Framework at the Intersection of Human Rights and Health Law, cited above, p. 136; *Abbing,* The convention on human rights and biomedicine: An appraisal of the council of Europe convention, European Journal of Health Law, No. 5, 1998, p. 380.

„No European country spent as much time debating the draft bioethics convention than did Germany“136. The debate in Germany begun in 1994 after the draft of the Bioethics Convention became publicly available and, subsequently, it relatively quickly became subject to living and rather negative criticism throughout German society. During this period not only German politicians on national as well as state (Länder) level, but also public activists, churches and medical public actively contributed thereto[137].

Even though the reasons for and extent of the criticism more or less slightly differed from one concerned group to another, one point that all the critics had in common might be inferred therefrom. This related to the provision of the Bioethics Convention dealing with biomedical research on persons unable to consent to the participation, i.e. minors and mentally incapable persons; the problem of essence consists, in particular, in the possibility to carry out research on such incapacitated persons even if the research “has not potential to produce results of direct benefit to the health of the person concerned”[138]. In other words, that draft of the Bioethics Convention authorized research without direct benefit for the subject (or so called nontherapeutic research) regarding persons unable to consent. Arguments against such provision were principally based on insufficient exclusion of the risk of abuse of medical research against minors and mentally incapable persons, while reference was being often made to the Nazi era of German history[139].

The aforesaid issue became a part of official German objections against the wording of draft of the Bioethics Convention. However, the German objections were not reflected sufficiently, including preservation the nontherapeutic research on incapacitated persons, which ultimately led to the Bundestag instructing the German representative to abstain from voting at the meeting of the Committee of Ministers at Strasbourg where the Bioethics convention would be presented for adoption[140].

The consequent reluctance of Germany to sign and ratify the Bioethics Convention after its adoption by the Council of Europe thus probably meant nothing more than a logic result of the atmosphere and events preceding the adoption. Even after more than 15 years following the adoption of the Bioethics Convention it is not clear whether or not Germany will accede thereto;

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[136] *Wachter,* The European Convention on Bioethics. Hastings Center Report. Vol. 27, No. 1 (Jan. – Feb., 1997), p. 13-23.
[137] *Wachter,* cited above, p. 16-19.
[138] See Article 17 para. 2 of the Bioethics Convention.
[139] *Wachter,* cited above, p. 16-19.
[140] *Wachter,* cited above, p. 18.

to the knowledge of the author of this paper, there has been no significant signals lately indicating the change of the German position in this regard.

H. Few words in the End

It is both undisputable that advances in bioscience have twofold character. While they have been improving quality of health and life of mankind, the risk of their misuse is clearly inherent. Hence, the concept of freedom of science had to be limited for the sake of protecting human rights.

Stemming from the above-mentioned, it may well be agreed that the Bioethics Convention is to date the best example of how to protect human rights in in this regard at an international level. The significance of this instrument lies in the fact that it is the pioneering comprehensive binding multilateral treaty addressing biomedical human rights issues[141], thus becoming an umbrella of international patients' rights law in this field[142].

Although the framework nature of the Bioethics Convention might attract doubts as to its efficiency to deal with all bioethics issues, progressive work of the Council of Europe, including adoption of several additional protocols and on specific biomedical issues renders any such criticism ill-founded.

As shown above, the principles and norms on which the Bioethics Convention is based aim at protecting patients both in general medical intervention and also in specific practices, ranging from biomedical research, through genetic testing, to transplantation. Amongst all of them, informed consent is currently considered a cornerstone of bioethics[143]. A summary of the analysis as performed hereinbefore, may well be put formulated as follows: that "[t]he quality of information and consent procedures has to be balanced against the values that are at stake and the time available. (…) The greater the risk for damage, the more carefully elaborated we expect the information and consent process to be"[144]. The relationship between patient and doctor[145] is thus well characterized as shared decision-making[146].

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[141] *Andorno,* The Oviedo Convention: A European Legal Framework at the *Intersection* of Human Rights and Health Law, cited above, p. 133.

[142] *Andorno*. Human rights as a framework for global bioethics, in: Ülman / Artvinli (eds.), Bioethics in a changing world. Turkish Bioethics Association, Istanbul, No: XVIII, 2012, p. 13.

[143] *Petrini*, Informed consent in experimentation involving mentally impaired persons: ethical issues, Ann Ist Super Sanità, Vol. 46, No. 4, 2010, 412.

[144] *Hansson*, Balancing the quality of consent, Journal of Medical Ethics, No. 24, 1998, 185-186.

[145] For further reading regarding a doctor-patient relationship see *Messer*, Professional-patient relationships and informed consent, Postgraduate Medical Journal, No. 80, 2004, p. 277–283.

The Bioethics Convention is far from being perfect[147] and, perhaps, the most significant weakness thereof lies in the absence of procedural remedies before ECtHR. Jurisprudence of ECtHR, nevertheless, shows that the court is able, while using flexible interpretation of its provisions, to cope with wide issues of bioethics. To conclude, it might be worth noting that since the Bioethics Convention is part of a body of international human rights law, it must then also be seen as a law-making treaty,[148] the particular consequences of which, such as penetration of „law of the Bioethics Convention" into the ECtHR's case-law are to be seen together with further international development in "bioethics law".

[146] *Hart*, Patients' Rights and Patients' Participation Individual and Colective Involvement: Partnership and Participation in Health Law, European Journal of Health Law, No. 11, 2004, p. 17.
[147] For comprehensive critical analysis of the Bioethics Convention see *Hottois,* A Philosophical and Critical Analysis of the European Convention of Bioethics, Journal of Medicine and Philosophy, Vol. 25, No. 2, 2000, p. 133–146; or *Mori / Neri,* Perils and Deficiencies of the European Convention on Human Rights and Biomedicine, Journal of Medicine and Philosophy, Vol. 26, No. 3, 2001, p. 323-333.
[148] *Simonsen*, cited above, p. 262.

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