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THE RIGHT TO INFORMED CONSENT AT THE CONVERGENCE OF INTERNATIONAL BIOLAW AND INTERNATIONAL HUMAN RIGHTS LAW

Stefania Negri*

I. EXPLORING INFORMED CONSENT IN INTERNATIONAL LEGAL PERSPECTIVE

Informed consent is a fundamental tenet of medical ethics conjugating ethical imperatives and respect for human rights in biomedical research as well as in the exercise of the medical profession. It is considered the foundation of the “new ethos of patient autonomy”,¹ since recognition of autonomy in health care decision-making has enabled and empowered competent patients to retain control of their lives and has come to govern the doctor-patient relationship consistently with respect for the right to self-determination.

From the legal viewpoint, informed consent represents a well-established rule of both biolaw and of human rights law. In fact, the bioethical and human rights-based approaches to the life sciences share common foundations and values, converging over the common objective of protecting human dignity and the integrity of every human being from the risks posed by the progress of technology and its applications to the natural processes governing the beginning and the end of life.² Hence, in the relative paucity of universally agreed principles providing a framework for ethical conduct in the biomedical field, informed consent—just like the basic principle of respect for human dignity—stands as the cornerstone of biomedical law and human rights law alike.³

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³ On the fundamental role of dignity in the fields of bioethics and biolaw, see especially the introductory chapter to this book: Angela Di Stasi, Human Dignity: From Cornerstone in International Human Rights Law to Cornerstone in International Biolaw?.
Exploring the nature and scope of informed consent is definitely not sailing into uncharted waters, especially in consideration of the fact that an impressive wealth of important contributions has been devoted to the subject in both philosophical and legal literature. However, since informed consent has mainly been studied within the framework of domestic law and jurisprudence, it is worth making the point on its present status from the viewpoint of international law and case law. This perspective reveals some interesting insights inasmuch as informed consent has gained remarkable importance in the international legal framework too, and it is by now widely recognised that also “from the standpoint of international law, the only accepted position is that no medical act may be performed without the patients’ freely given and informed consent.” Moreover, it is particularly telling that some relevant steps were recently taken within the United Nations human rights system—namely, the issuance of a specific report in November 2009 by the Special Rapporteur on the right to health and the adoption in September 2010 of the Human Rights Council’s resolution on the right to health—inviting all States to “safeguard informed consent within the health counselling, testing and treatment continuum, including in clinical practice, public health and medical research, as a critical element of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.”

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6 Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover, U.N. Doc. A/64/272, 10
Therefore, attempting to systematise the origin, nature and scope of informed consent in an international law perspective, this chapter will first expand on its evolution in international biolaw from the Nuremberg Code to the Unesco Universal Declaration on Bioethics and Human Rights, illustrating the normative process through which informed consent has come to acquire the status of a generally accepted legal principle. Then, the ‘filiation’ of informed consent from some fundamental human rights such as the prohibition of inhuman and degrading treatment, the right to physical integrity and the right to health will be examined as a starting point to support the argument that an autonomous ‘right to informed consent’ has emerged from the convergence of international biolaw and international human rights law. Further this chapter will deal with the reverse side of the coin of informed consent, that is the right to refuse treatment and its relevance for treatment options at the end of life and for the debate on the controversial existence of a ‘right to die in dignity’, to suggest that the non-derogable nature of the right to informed consent for competent patients should be given paramount consideration in determining the legal value of advance treatments directives.

II. Informed Consent in International Biolaw

A. Historical Origins and Legal Sources of Informed Consent in International Biolaw

Over the last century, following the famous and mostly cited opinion delivered by Justice Benjamin Cardozo in the landmark Schloendorff case—“every human being of adult years and sound mind has a right to determine what shall be done with his own body”—informed consent has been developed as a legal doctrine mainly by Western domestic courts. Today, this doctrine is globally recognized as dictating the conditio sine qua non for clinical practice and biomedical research. Its significance in international biolaw is reflected by the fact that virtually all international agreements and declarations on ethical and legal standards in medicine and biomedical research endorse the basic rule of informed consent.
Although it is argued that truly universal acceptance of informed consent as a key bioethical principle is probably linked to the adoption of the Unesco Universal Declaration on Bioethics and Human Rights of 2005, the acknowledgement of its importance at the international level is not such recent phenomenon. From a historical point of view, in fact, the start of a rising tide in favour of the recognition of the right to bodily integrity in the medical field, accompanied by the shaping of corresponding duties and responsibilities of healthcare providers and researchers, can be traced back to the aftermath of World War II and the Nuremberg Trials. In that regard, the international community’s revulsion at the disclosure of the medical atrocities committed by Nazi physicians, especially the ‘scientific experiments’ performed by the infamous Josef Mengele, led to the harsh condemnation of non-voluntary human experimentation and prompted the drafting of the Nuremberg Code. Being the first internationally recognized set of ethical standards in non-therapeutic research, the Code was meant to avert that similar crimes be committed in the future in the name of science. To this end it articulated a universal standard of physician responsibility and set forth those fundamental principles that still today lie at the heart of research ethics (including voluntary and informed consent, absence of coercion, opt-out possibility, protection against grievous bodily harm, and proportionality of risk). This is the reason why the Code is considered a ‘pioneer’ text in international bioethics or even “le véritable acte de naissance du droit de la bioéthique.”

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The first and best known provision of the Nuremberg Code stated:

The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. …

Since then, informed consent has enjoyed growing widespread consensus and gained over time broader scope. Well before professional associations worldwide endorsed it within their deontological guidelines and codes of ethics, their most representative international institution, the World Medical Association, had proclaimed the right of competent patients to accept or refuse treatment in its 1949 International Code of Medical Ethics. The WMA later upheld the rule of informed consent both in the Helsinki Declaration on Ethical Principles for Medical Research and in the Lisbon Declaration on the Rights of the Patient. Although not binding, these acts predated domestic laws regulating biomedical issues and served as reference codes of conduct for biomedical practice and research worldwide.

The same objective was also achieved by the several legal instruments—of both ‘hard’ and ‘soft’ law—adopted by the major international organisations engaged at different levels in the field of health care and ethics.


which have later substantially contributed to the legal recognition of informed consent as a basic principle of the emerging international biomedical law.\textsuperscript{15} In this respect, it is necessary to recall, first and foremost, the WHO Declaration on the Promotion of Patients’ Rights in Europe of 1994,\textsuperscript{16} the Council of Europe’s Convention on Human Rights and Biomedicine of 1997 and its Additional Protocols,\textsuperscript{17} as well as the Unesco Universal Declarations on the Human Genome and Human Rights of 1997 and on Bioethics and Human Rights of 2005.\textsuperscript{18} To these it is worth also adding the WHO Guidelines for Good Clinical Practice,\textsuperscript{19} the International Ethical Guidelines for Biomedical Research Involving Human Subjects prepared by the WHO in collaboration with the Council for International Organizations of Medical Sciences,\textsuperscript{20} and at regional level, the European Union Clinical Trials Directive of 2001.\textsuperscript{21}

Through these and other relevant documents, international organisations have codified the basic legal and regulatory standards of biomedical

\textsuperscript{16} WHO/EURO, European Consultation on the Rights of Patients, Amsterdam 28–30 March 1994, \textit{A Declaration on the Promotion of Patients’ Rights in Europe}, ICP/HLE 121, 28 June 1994 (hereinafter ‘Amsterdam Declaration’).
\textsuperscript{18} See Article 5 of the \textit{Universal Declaration on the Human Genome and Human Rights}, 11 November 1997, and Articles 6 and 7 of the \textit{Universal Declaration on Bioethics and Human Rights}, 19 October 2005. As far as the collection, use and storage of biological samples are concerned, see the Unesco \textit{International Declaration on Human Genetic Data}, 16 October 2003, in particular Articles 8, 9 and 16.
\textsuperscript{21} Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical
ethics—which have by now gained the status of internationally accepted principles—thus contributing to international biomedical law-making.22

B. The Scope of Informed Consent: Voluntas aegroei suprema lex

It is indisputable that the doctrine of informed consent is today widely acknowledged as the expression of one of the basic principles in international biolaw, serving as the cornerstone for the protection of the fundamental rights to physical integrity and self-determination in every field of medical intervention.

According to a commonly used formula, informed consent provides in its essence that any preventive, diagnostic and therapeutic medical intervention as well as any scientific research involving human subjects may only be performed after the person concerned has given prior, free, and informed consent, based on adequate information. This approach has definitely superseded all paternalistic—and even ‘imperialistic’23—medical attitudes and enhanced the ‘rooting’ of the key concepts of patients’ self-determination and autonomy in health care decision-making.24 Therefore, from a legal viewpoint, informed consent is not merely a ‘prerequisite’ to treatment, as it is often labelled:25 it is the very foundation of legitimacy for any medical treatment, so much so that, even if administered in the patient’s interest, interventions and cares provided without prior consent could be qualified as illegal ‘bodily assaults’, potentially triggering the liability, both civil and criminal, of health care providers.26
In the same vein, biomedical research performed without the informed consent of the research subjects is considered unethical and illegal.

However, simply consenting to treatment is not enough. In his report on informed consent, the UN Special Rapporteur on the right to health stressed that consent is “not mere acceptance of a medical intervention, but a voluntary and sufficiently informed decision, protecting the right of the patient to be involved in medical decision-making, and assigning associated duties and obligations to health-care providers.” Indeed, there are several preconditions that have to be fulfilled to make consent to treatment valid. In essence, to deploy its legal effects prior consent must be ‘free and informed’, which means that the patient’s autonomous decision to accept or refuse to undergo a medical treatment or to take part in scientific research has to meet some specific requirements. It should be noted in this respect that the formulas consistently adopted by the aforementioned international legal instruments evidence that such requirements are definitely acknowledged as well-established rules at the international level.

First of all, such documents provide that in order to validly consent to treatment the person involved must be conscious and fully competent; he/she must have legal capacity to give consent. Consent must be voluntary, i.e. the outcome of a decision-making process devoid of any element of force, fraud, deceit, duress, threat or any other form of constraint or coercion. It must be based on the appropriate disclosure to the patient, by the responsible healthcare professional, of adequate and understandable information concerning the diagnostic assessment, the purpose, method, likely duration, expected benefit and chances of success of the proposed treatment; of the alternative modes of treatment, including those less intrusive; of possible pain or discomfort, risks and side-effects of the proposed treatment; of the chances and risks associated with lack of treatment. Moreover, consent must be clearly given and recorded (in some cases in written form) and can be withdrawn at any time, even if withdrawal appears to be contrary to the person’s best interest.

In light of the foregoing factual and legal requirements, it is ‘genuine consent’ that represents the core element of the doctor-patient relationship, which has to be understood as a fiduciary relationship in which enhanced dialogue and mutual trust and confidence are essential. In this

\[ ^{27} \text{Report 2009, supra note 6, para. 9.} \]

perspective, the quality of the communication between health care providers and patients becomes of dramatic importance for the exercise of the latters’ right to self-determination and autonomy. This means that relevant information should be provided in plain language and readily understandable terms, and in sufficient amount so as to ensure that the patient’s ultimate decision is based on an appreciable knowledge of their condition. According to the aforementioned UN Report, “[t]his requires States to ensure that information is fully available, acceptable, accessible and of good quality, and imparted and comprehended by means of supportive and protective measures such as counselling and involvement of community networks.”29 Nonetheless, while it is self-evident that the role of health professionals is central in the process of informed consent, other important concurring elements demand special attention. In this connection it is interesting to note that, with regard to scientific research involving human participants, the manual prepared for the World Health Organization by Professor Carl Coleman and other international experts—which outlines ethical guidelines aimed to support the work of national research ethics committees—highlights the following factors that might undermine the process of informed consent: “the social and economic context: illiteracy, inadequate access to care; the cultural environment: the role of the community and family and of different sets of values; the asymmetrical nature of the knowledge of the investigators and that of the participants, which puts the latter in a subordinate relationship; the tendency of individuals to confuse being a participant in research with receiving individualized medical care (the ‘therapeutic misconception’).”30 Here again, it is confirmed that only ‘genuine consent’ lies at the basis of the researcher-subject relationship.

Once the contours of consent have been shaped, it is necessary to consider any legitimate exception and limitation that will help to better define its scope. On this point, it is agreed that the general rule of informed consent is not absolute. Special regimes and derogations have progressively been accepted in particular situations, or in respect of groups of vulnerable patients that call for increased protection and appropriate legal regulation.31 There has resulted a set of derogatory rules applicable in specific conditions.

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29 Report 2009, supra note 6, para. 93.
31 See Christian P. Selinger, “The right to consent: Is it absolute?”, 2 British Journal of Medical Practitioners (2009), pp. 50–54. The Author argues that on the basis of
First of all, in case of medical emergency and whenever the patient is unconscious or otherwise unable to express their will and their life is at risk, urgent interventions and life-saving treatments are in any case legitimate and lawful; in these circumstances the patient’s consent may be presumed, unless it is obvious from a previous declared expression of will that consent would have been refused in a similar situation. In different conditions, interventions on persons who find themselves in a de facto incapacity (e.g. the consequences of an accident or a state of coma) can be performed only if of direct benefit to them and under conditions approved by law; normally, the previously expressed wishes of a patient who is not able to give their consent at the time of the intervention should be taken into account.

For patients with a reduced capacity of understanding or whose legal capacity is limited by law for reasons of age or because of mental illness (e.g. minors, incapacitated adults and adults with mental disorders) the consent is provided by a legal representative (guardian or proxy) or

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philosophical, ethical, legal and practical considerations there is no absolute right to consent. The situations of incompetent minors, adults lacking capacity, some mentally ill patients and patients suffering from some infectious diseases would be cases in point. It should also be noted that, consistently with the exceptions stated in Articles 6 to 8, the Oviedo Convention does not include Article 5 among those non-derogable dispositions mentioned in Article 26, para. 2, while it only provides that no restrictions be placed on its protective provisions contained in Article 17, concerning persons not able to consent to research.

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32 See Article 8 of the Oviedo Convention: “When because of an emergency situation the appropriate consent cannot be obtained, any medically necessary intervention may be carried out immediately for the benefit of the health of the individual concerned”, and paras. 56–58 of the Explanatory report: “In emergencies, doctors may be faced with a conflict of duties between their obligations to provide care and seek the patient’s consent. This article allows the practitioner to act immediately in such situations without waiting until the consent of the patient or the authorisation of the legal representative where appropriate can be given. … First, this possibility is restricted to emergencies which prevent the practitioner from obtaining the appropriate consent. The article applies both to persons who are capable and to persons who are unable either de jure or de facto to give consent. An example that might be put forward is that of a patient in a coma who is thus unable to give his consent …, or that of a doctor who is unable to contact an incapacitated person’s legal representative who would normally have to authorise an urgent intervention. … Next, the possibility is limited solely to medically necessary interventions which cannot be delayed. …”

33 See Article 9 of the Oviedo Convention and the observations on advance directives, infra para. V and most of all in the chapter authored by Professor Roberto Andorno, “Regulating Advance Directives at the Council of Europe”, in this book.


35 See also: Article 7 of the Oviedo Convention; Principle 11 of the United Nations Principles for the Protection of Persons with Mental Illness and the Improvement of Mental
independent body provided for by law; however, the participation of adults unable to consent must not be totally ruled out: in principle, the appointment of a representative does not relieve from the obligation to involve the subject in the decision-making process to the fullest extent which his capacity allows. When a legal representative is appointed as substitute decision-maker, an intervention in case of urgent need can be performed whenever there is no possibility to obtain the representative’s consent and if the legal representative refuses consent to an intervention that the physician deems appropriate and useful in the best interest of the patient, it is necessary to resort to a court or some form of arbitration of an independent body for super partes decision. Moreover, legal representatives have no right to withdraw consent unless withdrawal is clearly justified in light of the patient’s best interest.

According to well-established standards, in all other situations where the patient is unable to give consent and where there is no legal representative or proxy, appropriate measures should be taken to provide for a substitute decision-making process, taking into account what is known and, to the greatest extent possible, what may be presumed about the wishes of the patient. Even in emergency situations, where no previous expression of will exists, health care professionals must make every reasonable effort to determine what the patient would want.

Last but not least, medical research should not in principle involve subjects who are physically or mentally unable to express their will, unless...

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6 See Article 6 of the Oviedo Convention and the *Amsterdam Declaration*, supra note 16, at para. 3.5. This rule is in line with Article 12 of the United Nations Convention on the Rights of the Child, which stipulates that “States Parties shall assure the child, who is capable of forming his or her own views the right to express those views freely in all matters affecting the child, the views of the child being given due weight in accordance with the age and maturity of the child”.

36 *Amsterdam Declaration*, supra note 16, para. 3.4.

37 *Amsterdam Declaration*, supra note 16, para. 3.6.

38 Ibid., para. 3.7. This brings to the question of the difficult task of reconstructing, sometimes within judicial proceedings, the patient’s wishes in crucial situations such as those concerning end-of-life care and substitute decision-making. On the reconstruction of the patient’s wishes according to his ideas, beliefs and life style, see, e.g., the much debated Englaro case occurred in Italy and examined in Part III of this book.

39 See the Explanatory report to the Oviedo Convention, at para. 57.

40 According to the *Helsinki Declaration*, supra note 13, research “may be done only if the physical or mental condition that prevents giving informed consent is a necessary
the consent of a legally authorized representative has been sought and obtained, and the research would likely be in the direct interest of the person.44 Incompetent persons may be involved in observational research of significant value which is not of direct benefit to their health, provided that there is a negligible risk and minimal burden for them;45 lacking any potential direct benefit to incompetent research subjects, the research “should only be undertaken by way of exception, with the utmost restraint”.44

All this said, it is remarkable that according to international (hard and soft) biolaw exceptions to the basic rule of informed consent are allowed solely when provided by law in accordance with ethical and legal standards adopted by States, strictly for “compelling reasons within the bounds of public international law” and subject to compliance with international human rights law.45 This important caveat, included in the Oviedo...
Convention,\(^{46}\) in the Unesco Declarations as well as in the resolutions of the United Nations Commission on Human Rights and of the Committee of Ministers of the Council of Europe,\(^{47}\) recalls very closely the pattern of lawful limitations adopted within conventional human rights regimes\(^{48}\) and lends support to the argument that informed consent is by now a rule grounded in international law, including human rights law, just as much as it is in bioethics.

C. Informed Consent as a General Principle of International Biolaw

Strictly connected to other key ethical and legal principles such as respect for human dignity and autonomy, informed consent has come to enjoy the status of a general principle of international biomedical law due to its widespread recognition and application.\(^{49}\) It represents one of those principles which, “ethical in nature, ... have been incorporated into the rule of law by means of legal instruments, either laws within national legal systems or conventions and/or declarations or recommendations at the international level”.\(^{50}\) In effect, it is upheld and proclaimed by the most authoritative international instruments issued from those normative processes aimed at providing an international regulation of biomedical issues.

In this last perspective, informed consent can be considered one of those founding principles upon which a body of international biolaw is

\(^{46}\) See Article 26 of the Oviedo Convention, which however does not allow restrictions on the rules governing protection of persons not able to consent to research or to organ removal. These are considered ‘unconditional norms’ (see Roberto Andorno, “The Oviedo Convention: A European Legal Framework at the Intersection of Human Rights and Health Law”, 2 Journal of International Biotechnology Law (2005), pp. 133–143, at 136).


\(^{48}\) Compare the proviso formulated in Articles 8 to 11 of the European Convention on Human Rights; Articles 12, 18–19, 21–22 of the International Covenant on Civil and Political Rights; Articles 12–13, 15–16 and 22 of the American Convention on Human Rights; Articles 11–12 of the African Charter on Human and Peoples’ Rights. The conditions of legitimacy of the restrictions placed on human rights are by now considered the object of a customary rule: see David P. Fidler, International Law and Public Health (New York, 2000), pp. 293–294.

\(^{49}\) According to Professors Lenoir and Mathieu the bioethical principles enunciated in the Nuremberg Code are now part of customary law: see Noëlle Lenoir and Bertrand Mathieu, Les normes internationales de la bioéthique (Paris, 1998), p. 19.

being progressively built, notwithstanding the objective difficulties in the setting of common standards and in their transformation into positive law. It is in fact generally acknowledged that cultural and religious diversity, and the ensuing pluralistic approach to moral and legal values, play a crucial role in preventing easy consensus on bioethical issues (and their possible legal regulation). Nevertheless, despite the diversities inherent in human societies and also characterising the international community, a quest for universal standards is the distinctive feature of international bioethics. This aspiration has posed the greatest challenge to the emerging international biolaw: to succeed in translating shared values into a globally accepted codification of ethical and normative rules applicable to biomedical research and practice.51

Such generalised strive to overcome the contrast between pluralism and universalism has led to the entrustment of the task to frame general principles of biomedical law to widely representative international fora, where all the relevant actors and stakeholders can make their voice heard. The negotiation of the emerging norms of international biolaw has thus moved from traditional interstate agreement to multi-level institutionalised norm-making processes, carried out within international organisations and mainly based on the work of international bioethics committees.52 With this shift in paradigm, States and non-State actors have made sensitive efforts to surmount the differences in traditions and ideologies with the aim to achieve a progressive development of international biomedical law. In this perspective, achieving a global consensus on rules and principles of universal significance has come to be considered the proper instrument to legitimise international legal regulation of life sciences and biomedicine.53

51 On the issue whether ‘universal bioethical standards’ can possibly be translated into legal norms, see Ryuichi Ida, “Bioethics and International Law”, in N. Boschiero (ed.), Ordine internazionale e valori etici (Naples, 2004), pp. 366–380, at 376–377. According to this Author, “Although bioethics legislation exists at the national level ... and at the regional level ..., there are no international or universal legal rules. The diversity of values within each community is the main reason for this absence of universal legal instruments” (at 377–378).
52 See also Hélène Boussard, “The ‘Normative Spectrum’ of an Ethically-inspired Legal Instrument: The 2005 Universal Declaration on Bioethics and Human Rights”, in Biotechnologies, supra note 50, pp. 97–127. With special reference to the Unesco Declarations, the Author states that they started a new norm-making process characterized by the convergence of legal and ethical norm-making processes (at 100).
53 This idea has been expressed several times by Professor Bertrand Mathieu in his writings on international bioethics. However this Author also contends that universal consensus is reached on rules that represent an ‘empty shell’, since bioethical rules cannot
The most telling example of this change in paradigm is the normative activity performed at both universal and regional levels by international organisations such as Unesco and the Council of Europe, which—to say it with Professor Sandrine Maljean-Dubois—have “largement soutenu la dynamique du droit international de la bioéthique”.54

This new process of norm-making, where a plurality of stakeholders have made efforts to reach consensus over general principles of international biomedical law, has been the subject of diverging views. On the one hand the critique was put forward by Professor David Benatar that:

When a number of people with a range of different ethical views seek to formulate a declaration that enjoys the support of all (or even most) of them, the resultant declaration will suffer from one or both of two possible shortcomings—minimalism and vagueness. By ‘minimalism’ I mean the phenomenon of agreeing on the lowest common denominator. In other words one includes items that everybody agrees upon, and one ignores items about which there is no consensus. The other way to gloss over disagreement is to choose formulations that are sufficiently vague that each person can interpret them consistently with his or her own view.55

By contrast—while conceding that a certain generality in the formulation of principles is needed to aptly balance universalism and cultural diversity—the same process has been considered by Professor Roberto Andorno as an important step to achieve the goal of agreeing on global minimum standards and promoting responsible biomedical research and clinical practice consistently with human rights and fundamental freedoms:56

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Certainly, the search for common responses to the new bioethical dilemmas is an arduous task. One may even get the impression that it is impossible to reach substantive agreement on such sensitive issues between countries with different socio-cultural and religious backgrounds. Fortunately, however, the situation is not as desperate as it might seem. The enterprise of setting common standards in the biomedical field, although difficult, is possible because international human rights law presupposes that some basic principles transcend cultural diversity. Of course, the major challenge is to identify those universal principles with regard to biomedical issues, but it is possible through promotion of an open and constructive dialogue between cultures. This would explain why international organizations, in which different cultural traditions and values are represented, seem to provide the ideal arena for the discovery of such common criteria.57

In effect, while it is a commonly shared objective consideration that international law-making in this field is not a straightforward endeavour, it is indubitable that the Council of Europe and Unesco have provided so far the most authoritative sources of legal principles and biorights of universal significance. However, to some extent, scholarship disagrees also on this last point.

The real scope of the Oviedo Convention—which is the first international binding instrument devoting a specific chapter to consent—is not yet univocally gauged in legal literature.58 On the one hand, it is contended...
that the Convention seeks to promote the universal dimension of the bio-
rights it enunciates;\(^59\) on the other hand, it is denied any ‘universal aspiration’, although it is conceded that the participation to its negotiation of
Canada, the USA, Japan, Australia, the European Union and the Holy See
undoubtedly confers an added value to the quality and representativeness
of its rules.\(^60\) In any case, the major criticism addressed to the Convention
is its very low rate of ratification, which diminishes its strength and pre-
vents it from invoking any truly universal ‘vocation’.

Quite different is the case of the relevant declarations adopted by
Unesco and of their legal value.\(^61\) They are considered as the expression of
an international \textit{opinio juris} that can foster the later creation of legal
norms, thus contributing to the progressive development and advance-
ment of international law. In this perspective, the Unesco declarations
prepare the difficult transition from ethical values to legal rights through
a gradual crystallisation of general standards into written rules. Providing
“a universal framework of principles and procedures to guide States in
the formulation of their legislations, policies or other instruments in the
field of bioethics”,\(^62\) such \textit{soft law} rules may in their turn influence the


\(^{60}\) Maljean-Dubois, “Bioéthique”, supra note 54, at 91–92.


\(^{62}\) Article 2.a of the Universal Declaration on Bioethics and Human Rights.
production of legal norms at the national level. Therefore, although they do not immediately create justiciable rights, their influence on the conduct of States is not negligible.\textsuperscript{63}

Notwithstanding some harsh criticism on the effectiveness of the results achieved,\textsuperscript{64} the Unesco declarations represent the normative expression of those values that are considered common to humankind and hence worth of universal protection. They

proclaim some basic principles and standards in the field of bioethics that have provided, and continue to provide, inspiration and guidance to States in decisions in this area. … The norms they articulate appear to enjoy a broad consensus at the international level. They also seem to have become a standard of reference and a source of inspiration for legal or ethical rules to be established by States or by professional bodies throughout the world.\textsuperscript{65}

According to Professor Maljean-Dubois it is necessary to assess the legal effects of these documents with a less formalistic approach, which may allow to appraise their normative value as extending beyond the mere role of pre-legal texts.\textsuperscript{66} Her opinion is in line with the one expressed by the late Professor Héctor Gros Espiell, former Chairman of the Unesco Legal Committee, who stated that

les déclarations proclamées par l’organe suprême d’une organisation intergouvernementale, plus particulièrement de la famille des Nations Unies – si elles sont adoptées dans certaines conditions … – produisent


\textsuperscript{66} See Maljean-Dubois, “Bioéthique”, supra note 54, at 89: “en rejetant une approche trop formaliaste, force est de convenir que ces résolutions et déclarations ... n’ont pas seulement un rôle préparatoire à l’adoption de textes contraignants. Bien souvent, elles tiennent lieu de droit et s’auto-suffisent". 
un effet juridique et deviennent sources de droits et d’obligations internationales.\textsuperscript{67}

Thus, just like the Universal Declaration of Human Rights,\textsuperscript{68} the Universal Declarations adopted by Unesco—first and foremost the Declaration on the Human Genome, which was also endorsed by the General Assembly of the United Nations\textsuperscript{69}—set universally recognised standards and translate shared values into positive law.

This means that informed consent is by now a global bioethical standard translated into positive law. It enjoys robust consensus since there is a substantial convergence and complementarity of norms disseminated through formal and informal instruments that proclaim, uphold, repeat and detail the contents of this principle. The stratification of these norms has “gradually shaped social consciousness in the international community”\textsuperscript{70} around this basic rule, which epitomizes the current generally accepted decision-making model in health care and embodies the essence of key concepts such as self-determination and autonomy, as well as integrity and inviolability of the human being.

In consideration of the above, not only can informed consent be considered a universally recognised imperative of bioethics, but also, legally speaking, it can be viewed as one of those principles imposed by the will of the international society\textsuperscript{71} as expressed by its various actors and
stakeholders in those institutionalised fora where international biolaw has been emerging out of an interdisciplinary debate interfacing scientific legitimacy and political legitimacy. Moreover, contrary to what is usually stated with regard to many biolaw rules, this principle is couched in clear and plain terms, and since its content and scope have so far achieved an appreciable degree of specification, it seems not to suffer from the aforementioned ‘vagueness and minimalism’ shortcomings.

III. INFORMED CONSENT IN INTERNATIONAL HUMAN RIGHTS LAW

A. The “Filiation” of Informed Consent from Human Rights

Although we are used to consider informed consent as one of the core principles of medical ethics transposed into national and international biolaw, its filiation from international human rights law is quite evident. Actually, there is a clear relationship of derivation between biomedical law and human rights law: the most influential literature on the subject insists on the concept of international biolaw texts being the ‘natural extension’ of human rights instruments as applied to the life sciences and biomedicine. Moreover, according to a commonly shared scholarly view,
it is most opportune and correct that biolaw be conveyed within the framework of human rights law in order that human rights and fundamental freedoms may find appropriate tools of legal protection from the challenges of progress.\(^{75}\)

It is also interesting to note that, in the context of a more general discussion on the emergence of international biolaw, Professor Michelle Lenoir observed that well before becoming a new field of academic endeavour “la bioéthique apparaissait déjà en filigrane dans les grands instruments internationaux relatifs aux droits de l’homme”.\(^{76}\) In this respect, it is often pointed out that all major human rights treaties contain some guarantees relating to the protection of fundamental rights in patient care. Although only some of these conventions have been almost universally ratified, however they all set minimum standards that can be considered morally binding also on non-Party States. Moreover, the link between international human rights law and biomedical law is ever more apparent in the wording of the major biolaw instruments, which regularly refer to the key human rights acts and endorse them as foundational framework and cornerstones for ‘supplements’ of protection urged by the ‘potential implications of scientific actions’ and the need to shield the individual from any threat resulting from the developments in biology and medicine.\(^{77}\)


\(^{76}\) Lenoir, “Le droit international pénal de la bioéthique”, supra note 11, at 407. In the same sense, see also Andorno, “The Oviedo Convention”, supra note 46, at 133, where the Author acknowledges the fact that the essence of some principles enunciated by the Oviedo Convention were already framed in more general terms in previous human rights treaties.

\(^{77}\) See the Explanatory Report to the Oviedo Convention, paras. 11–13. See also the Preambles to the Oviedo Convention and to the Unesco Universal Declarations, all ‘solemnly recalling the attachment to the universal principles of human rights’.
1. The Link with the Right to Physical Integrity: The Evolutive Interpretation of the Rights to Freedom from Torture, Inhuman or Degrading Treatment and to Respect for Private Life

Informed consent is generally interpreted as part of the right to physical integrity. Although not specifically recognised in most human rights conventions, the right to bodily integrity is a well-established fundamental right protecting the universal values of the dignity and inviolability of the human being. It has been considered as a derivation of the rights to security of the person and to privacy, and above all of the right to be free from torture, and from cruel, inhuman and degrading treatment. In this sense, its first indirect sources in international human rights law are usually traced back to Article 5 of the Universal Declaration of Human Rights and Article 3 of the European Convention on Human Rights, both stating the prohibition of torture and of cruel, inhuman or degrading treatment.78

A specific reference to informed consent is to be found in Article 7 of the International Covenant on Civil and Political Rights, which, according to the Human Rights Committee, is aimed at protecting both the dignity and the physical and mental integrity of the individual.79 This provision adds to the aforementioned proscription of torture the express ban on medical and scientific experimentations carried out without the free consent of the person concerned.80 The importance of this specification lies in

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78 According to Annas and Grodin most physicians would never consider their actions as amounting to torture, however they point out that “it is when a doctor disregards a person’s bodily integrity that torture and involuntary human experimentation become virtually indistinguishable” (“Medicine and Human Rights”, supra note 13, at 9).

79 International Covenant on Civil and Political Rights, adopted and opened for signature, ratification and accession by General Assembly Resolution 2200A (XXI), 16 December 1966, entered into force on 23 March 1976; CCPR, General Comment No. 20: Replaces general comment 7 concerning prohibition of torture and cruel treatment or punishment (Art. 7), 10 March 1992.

80 According to the Committee’s interpretation, Article 7 allows no limitations or derogations and implies that the Parties to the Covenant have a legal duty to guarantee protection through legislative and other measures against the acts prohibited by this provision, “whether inflicted by people acting in their official capacity, outside their official capacity or in a private capacity”. Moreover, as for the specific prohibition of non-consensual experimentations, the Committee argues that special protection is necessary with regard to persons not capable of giving valid consent, and in fact it recommends that “When there is doubt as to the ability of a person or a category of persons to give such consent, e.g. prisoners, the only experimental treatment compatible with article 7 would be treatment chosen as the most appropriate to meet the medical needs of the individual”. See General Comment No. 20, paras. 2 and 7; Consideration of Reports Submitted by States Parties under Article 40 of the Covenant: Concluding Observations of the Human Rights Committee: United States of America, U.N. Doc. CCPR/C/USA/CO/3, 15 September 2006, para. 31.
the fact that not only does it explicit the link between physical integrity and informed consent, but it also confirms the fact that, although it is usually discussed in the context of protecting individuals from torture, the right to physical integrity extends well beyond that.  

The same formula used in Article 7 of the Covenant was reiterated in Article 15 of the Convention on the Rights of Persons with Disabilities, which however clearly spelt out the right to integrity of the person in Article 17 and also made express reference to informed consent in Article 25, para. d, in the context of the recognition of the right to non-discriminatory enjoyment of the right to health.

Other relevant provisions, as contained in regional instruments, include Article 5, para. 1, of the American Convention on Human Rights, protecting the right to physical, mental and moral integrity, as well as Article 4 of the African Charter on Human and Peoples’ Rights, affirming the inviolability of human beings and their entitlement to respect for their life and integrity of the person. It is also worth mentioning the Protocol to the African Charter on Human and Peoples’ Rights on the Rights of Women in Africa, which states at Article 4, para. 1, that every woman is entitled to respect for life and integrity of her person, while at para. 2.h it mandates States Parties to take appropriate and effective measures to “prohibit all medical or scientific experiments on women without their informed consent”.

At the European level, the most salient expression of the intertwining between the right to physical integrity and informed consent is provided

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81 Unfortunately, there is actually no significant case law by the Human Rights Committee concerning violations of Article 7 for imposition of compulsory medication or experiments. Consult for example the SIM database provided by The Netherlands Institute of Human Rights (Utrecht School of Law), available at http://sim.law.uu.nl/SIM/Dochome.nsf?Open.
86 It should be added that this protection had been earlier invoked by the Committee on the Elimination of Discrimination against Women in its General Recommendation No. 24 of 1999 concerning action by the States parties to the Convention on the Elimination of All Forms of Discrimination against Women, where the Committee stated that States Parties had to “Require all health services to be consistent with the human rights of women, including the rights to autonomy, privacy, confidentiality, informed consent and choice” (para. 31, al. e).
by Article 3 of the Charter of Fundamental Rights of the European Union, where informed consent is listed on top of the core principles of biomedical law, including the prohibitions of selective eugenic practices, of making the human body a source of financial gain, and of reproductive cloning of the human being (and it should be noted that this time the filiation relationship is inverse, since the EU Charter draws on international biolaw, especially on the Oviedo Convention).\textsuperscript{87} In this respect, it will be interesting to appraise to what extent the new binding value of the Charter will enable the Court of Justice of the European Union to develop a new bioethically-oriented, or bioethics-sensitive jurisprudence. For the moment, it is worth recalling that, so long, where needed respect for informed consent was guaranteed at European Union level by means of reference to the right to physical integrity and with respect to the relevant provisions of the European Convention on Human Rights, especially Article 8. For example, in the judgment delivered by the then Court of First Instance (today General Court) in the case \textit{X. v. Commission of the European Communities}, which concerned pre-recruitment medical examination, the Court stated in principle that “the taking of blood in order to investigate the possible presence of HIV antibodies constitutes interference with the physical integrity of the person concerned and can be carried out on a candidate only with his informed consent”. On appeal the Court of Justice justified the refusal to undergo an AIDS screening test in light of the right to respect for private life as protected by Article 8 of the European Convention and the common constitutional traditions of Member States. Declaring that “a person’s refusal must be respected in its entirety”, the Court concluded that medical officers are precluded from carrying out any test liable to point to the existence of the illness in respect of which the person has refused disclosure.\textsuperscript{88}

The approach endorsed by the EU Courts was perfectly in line with the most relevant Strasbourg case law,\textsuperscript{89} which has been construing the imposition of non-consensual medical treatment or testing as a violation of

\begin{itemize}
  \item \textsuperscript{87} See Luca Marini, \textit{Il diritto internazionale e comunitario della bioetica} (Torino, 2006), pp. 65, 70.
  \item \textsuperscript{89} See the survey carried out by the Research Division of the European Court of Human Rights in its working document on \textit{Bioethics and the case-law of the ECHR}, available at http://www.coe.int/t/dg3/healthbioethic/texts_and_documents/Bioethics_and_the_case-law_of_the_Court.pdf.
\end{itemize}
both Article 3 and Article 8 of the Convention, as both encompassing the right to physical and mental integrity\(^9\) by way of their extensive and dynamic interpretation.\(^9\) Of course, the most significant consequence of these two different constructions lies in the admissibility of limitations, provided that Article 3 is absolutely non-derogable while Article 8 allows limitations and interferences “in accordance with the law and ... necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others”.\(^9\)

Turning to Strasbourg jurisprudence, the first ruling linking informed consent to the prohibition of inhuman and degrading treatment was made by the European Commission in the case of \(X v.\) Denmark, when it stated that in principle “medical treatment of an experimental character and without the consent of the person involved may under certain circumstances be regarded as prohibited by Article 3 of the Convention”.\(^9\)

The test is however very strict, since compulsory experimentation or treatment must amount to an ill-treatment attaining a minimum level of severity, consisting in premeditated action causing either actual bodily injury or intense physical and mental suffering or being capable of

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\(^{90}\) See, for example, \(X\) and \(Y v.\) the Netherlands, Judgment of 26 March 1985, Series A no. 91, para. 22.


\(^{92}\) In \(Juhke v.\) Turkey (no. 52515/99, 13 May 2008, para. 72), the Court noted that “Even where it is not motivated by reasons of medical necessity, Articles 3 and 8 of the Convention do not as such prohibit recourse to a medical procedure in defiance of the will of a suspect in order to obtain from him or her evidence of his or her involvement in the commission of a criminal offence. However, any recourse to a forcible medical intervention in order to obtain evidence of a crime must be convincingly justified on the facts of a particular case and the manner in which a person is subjected to a forcible medical procedure must not exceed the minimum level of severity prescribed by the Court’s case-law under Article 3 of the Convention (see \(Jalloh v.\) Germany [GC], no. 54810/00, §§ 70–71, ECHR 2006–...).”

\(^{93}\) ECHR, \(X v.\) Denmark, no. 9974/82, Commission decision of 2 March 1983, DR 32, p. 282. Also the European Committee for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment has repeatedly stressed that “patients should, in principle, be placed in a position to give their free and informed written consent to treatment. Every competent patient, whether voluntary or involuntary, should be given the opportunity to refuse treatment or any other medical intervention. Any derogation from this fundamental principle should be based upon law and only relate to clearly and strictly defined exceptional circumstances” (see at http://www.cpt.coe.int/en/hudoc-cpt.htm).
humiliating and debasing the person concerned and possibly breaking their physical or moral resistance.

In a different perspective, both the Commission and the Court have also developed a consistent case law on Article 8 as embracing the right to be free from non-consensual medical treatment or examination, holding that “a compulsory medical intervention, even if it is of minor importance”\(^{94}\) as well as the imposition of a medical examination, constitute an interference with the right to private life.\(^{95}\)

The Court has also had occasion to distinguish between situations concerning competent adults and minors (be they mentally disabled or not), always highlighting the importance of respect for informed consent consistently with internationally agreed standards (the reference texts being the Oviedo Convention and the Universal Declaration on Bioethics and Human Rights). For example, in *Pretty v. UK*, a case concerning assisted suicide, the Court said that “the imposition of medical treatment, without the consent of a mentally competent adult patient, would interfere with a person’s physical integrity in a manner capable of engaging the rights protected under article 8 § 1 of the Convention”.\(^{96}\) In *Glass v. UK*, a case dealing with the issue of withdrawal of consent and possible derogations in situations of emergency, the Court considered that the decision to impose treatment on a severely handicapped child in defiance of his mother's (acting as legal proxy) objections gave rise to an interference with the child's right to respect for his private life, and in particular his right to physical integrity.\(^{97}\) Recently, in the case of *M.A.K. and R.K. v. UK*, the Court found the same kind of violation of a minor’s rights due to the taking of blood samples and photographs without parental consent.\(^{98}\)

One last consideration is that the Court has also further expanded on the ‘informed consent limb’ of the right to privacy, including in it the duty of States "to adopt the necessary regulatory measures to ensure that doctors consider the foreseeable consequences of the planned medical

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\(^{94}\) See, for example, ECHR, *X v. Austria*, no. 8278/78, Commission decision of 13 December 1979, DR 18, p. 155; *Acmanne and Others v. Belgium*, no. 10435/83, Commission decision of 10 December 1984, DR 40, p. 254.


\(^{98}\) ECtHR, *M.A.K. e RK v. The United Kingdom*, nos. 45901/05 and 40146/06, Judgment of 23 March 2010, para. 75.
procedure on their patients' physical integrity and to inform patients of these beforehand in such a way that they are able to give informed consent.” The Court inferred this duty from a consideration of the importance of having access to information concerning health-related risks, hence concluding that “if a foreseeable risk ... materialises without the patient having been duly informed in advance by doctors, and if ... those doctors work in a public hospital, the State Party concerned may be directly liable under Article 8 for this lack of information”.

2. The Link with the Right to Health: Respect for Informed Consent as Being Instrumental to the Fulfilment of Right to Health Obligations

Informed consent is also considered an integral part of the right to health as protected by several human rights treaties.

According to the Committee’s General Comment on Article 12 of the Covenant on Economic Social and Cultural Rights, the right to health “contains both freedoms and entitlements. The freedoms include the right to control one’s health and body ... and the right to be free from interference, such as the right to be free from torture, non-consensual medical treatment and experimentation”.

Building on the Committee's interpretation of Article 12, the former UN Special Rapporteur on the right to health, Paul Hunt, observed in his Report of 2005 that although the issue of informed consent

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99 ECtHR, Trocellier v. France, no. 75725/01, Decision on admissibility of 5 October 2006, ECHR 2006-XIV, para. 4.
is often considered in relation to the right to liberty and security of the person, as well as the prohibition against inhuman and degrading treatment, it is less frequently considered in the context of the right to health. However, consent to treatment is intimately connected with a vital element of the right to health: the freedom to control one’s health and body.\footnote{Report 2005, supra note 35, para. 87.}

Professor Hunt’s call for an “urgent reconsideration [of that issue] with a view to better protecting, at the international and national levels, the right to informed consent” and for strict respect for “procedural safeguards protecting the right to informed consent”\footnote{Ibid., para. 90.} prompted his successor, Anand Grover, to carry out an in-depth analysis of the evolution and the main components of informed consent, which he discussed in a report specifically dedicated to it.

The 2009 Report is particularly interesting because it represents an important attempt to systematise informed consent from an international viewpoint. In this perspective, the Special Rapporteur first provided his definition of informed consent, balancing an individual’s right to participate in decision-making with the relevant obligations stemming from it, and stating that it “is not mere acceptance of a medical intervention, but a voluntary and sufficiently informed decision, protecting the right of the patient to be involved in medical decision-making, and assigning associated duties and obligations to health-care providers.”\footnote{Report 2009, supra note 6, para. 9.} He then totally embraced the view that informed consent to treatment is a cornerstone of the right to health, stating that

Guaranteeing informed consent \textit{is fundamental to achieving the enjoyment of the right to health} through practices, policies and research that are respectful of autonomy, self-determination and human dignity. An enabling environment that prioritizes informed consent links counselling, testing and treatment, creating an effective voluntary health-care continuum. \textit{Safeguarding informed consent along the health-care continuum is an obligation placed on States and third parties engaged in respecting, promoting and fulfilling the right to health.}\footnote{Ibid., summary, p. 2 (emphasis added).}

As in the passage above and throughout the whole Report, the Special Rapporteur mainly focused on the obligatory aspects linked to informed consent, addressing the relevant duties incumbent on States in the

\footnote{health-related information for health decision-making (paras. 21–23) since information accessibility is a specific aspect of one of the four cornerstone elements of the right to health, namely availability, accessibility, acceptability, quality (para. 12).}
perspective of fulfilling the obligation to protect the right to health.\textsuperscript{106} This approach is consistent with the existence of indirect references to the rule of informed consent in the definition of State obligations stemming from Article 12 of the Covenant, according to the traditional tripartite typology (to respect, protect, fulfil) employed in the language of the Committee as well as in the relevant scholarship.\textsuperscript{107} In this respect, it is interesting to note that in General Comment No. 14 the Committee explained that the obligations to respect include a State’s obligation to refrain ... from applying coercive medical treatments, unless on an exceptional basis for the treatment of mental illness or the prevention and control of communicable diseases. Such exceptional cases should be subject to specific and restrictive conditions, respecting best practices and applicable international standards ... In addition, States should refrain from ... censoring, withholding or intentionally misrepresenting health-related information ... as well as from preventing people’s participation in health-related matters. ...

Obligations to protect include, inter alia, the duties of States ... to prevent third parties from coercing women to undergo traditional practices, e.g. female genital mutilation ... States should also ensure that third parties do not limit people’s access to health-related information and services.

...

The obligation to fulfil (promote) the right to health requires States to undertake actions that create, maintain and restore the health of the population. Such obligations include: ... (iv) supporting people in making informed choices about their health.\textsuperscript{108}

This approach was recently upheld in a resolution adopted by the Human Rights Council, where all States were for the first time invited to

\textsuperscript{106} Ibid., paras. 5, 18.

\textsuperscript{107} The tripartite typology of State obligations was originally introduced by Henry Shue (see Basic Rights: Subsistence, Affluence and U.S. Foreign Policy, 2nd ed., Princeton, 1996) and later proposed in its present formulation by Asbjorn Eide acting as Special Rapporteur to the UN Sub-Commission on Human Rights: The Right to Food as a Human Right, 7 July 1987, E/CN.4/Sub.2/1987/23. A detailed report of this evolution is made by María Magdalena Sepulveda, The Nature of the Obligations under the International Covenant on Economic, Social and Cultural Rights (Antwerp, 2003), Chapter V. Despite its being questioned as the most appropriate tool for advancing the conceptual clarification of economic, social and cultural rights (see Ida Elisabeth Koch, “Dichotomies, Trichotomies or Waves of Duties?”, 5 Human Rights Law Review n. 1 (2005), 81–103), the ‘respect, protect and fulfil’ paradigm is considered by the former Special Rapporteur on the right to health, Paul Hunt, especially useful as a way of sharpening legal analysis of this right (The right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Report of the Special Rapporteur, Paul Hunt, U.N. Doc. E/CN.4/2004/49, 16 February 2004, para. 43; Report 2005, supra note 35, para. 47).

\textsuperscript{108} General Comment No. 14, supra note 101, paras. 34, 35 and 37.
safeguard informed consent within the health counselling, testing and treatment continuum, including in clinical practice, public health and medical research, as a critical element of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.\textsuperscript{109}

Since no further guidance can be drawn on this subject from international jurisprudence—given the paucity of case law concerning the interpretation and application of conventional norms protecting the right to health at both the universal and the regional level\textsuperscript{110}—it is remarkable that the stance taken within the United Nations, as emerged from the documents examined so far, tends to emphasise the nature of informed consent as an ancillary element of the fundamental right to health, and clearly suggests that respect for informed consent is not an obligation \textit{per se}, but only part of a more general duty to guarantee the enjoyment of that right.

B. Is There an International Human Right to Informed Consent?

1. The Legal Qualification of Informed Consent

It is interesting to note that there is apparently no unequivocal consensus in international instruments and scholarship on the legal qualification of informed consent.

On the one hand, in legal literature it is quite frequent to read that informed consent is a ‘requirement’ that protects the patients’ fundamental rights to integrity and self-determination—of which it is also defined as a ‘corollary’\textsuperscript{111}—and that such ‘requirement’ is based on the principles of ‘respect for persons’ and ‘respect for human dignity’\textsuperscript{112}. It is also very often defined as a general and basic principle of biomedical law,\textsuperscript{113} while

\textsuperscript{109} See supra note 6.

\textsuperscript{110} This is mainly due, as it is well-known, to the still current lack of jurisdiction of the ESCR Committee and to the lack of competence \textit{ratione materiae} of both the Interamerican Commission of Human Rights and of the Strasbourg Court.

\textsuperscript{111} Kolle, “Article 6”, supra note 8, at 126. Similarly, see Millns, who argues that “fundamental bio-rights and freedoms are to be respected through the provisions governing the requirement to obtain an individual’s free and informed consent to medical interventions” (“Consolidating Bio-rights”, supra note 59, at 79) and again she speaks of “the general consent requirements imposed by articles 5 and 6” (at 79–80), however, when dealing with the Charter of Fundamental Rights of the European Union she recognises free and informed consent as one of the four basic principles provided by Article 3 adding that the “remit of these is striking in its overlap with that of the principles enshrined in the Biomedicine Convention” (at 80–81).

\textsuperscript{112} See for instance Maljean-Dubois, “Bioéthique”, supra note 54, at 94–95; Marini, \textit{Il diritto internazionale}, supra note 87, at 69, 328; Boschiero, “Le biotecnologie”, supra note 11,
sometimes it is referred to as a principle and a right at a time. But it also happens that it is not qualified at all.

On the other hand, the textual analysis of international biolaw instruments does not shed any clearer light on this.

The Oviedo Convention, the first binding instrument to address the issue of consent in a detailed fashion, does not provide any specific legal qualification of informed consent. This vague approach is consistently adopted also in its Explanatory Report, save in one single case, where consent is defined as the “general principle in Article 5”. Throughout the Explanatory Report, consent is instead referred to as a “general rule” that affirms at the international level an “already well-established rule”, a “rule [that] makes clear patients’ autonomy”. By contrast, some specific elements of it are clearly defined as individual rights, such as ‘the patient’s right to information’ and ‘the right to withdraw consent’.

The Universal Declarations issued by Unesco do not seem to be of much more help either, since they regulate consent under the rubric of both ‘rights of the persons concerned’ and ‘principles’. However, some guidance is offered by the Explanatory Memorandum on the Preliminary Draft Declaration on Bioethics and Human Rights, which makes it clear that informed consent is one of those ethical guiding principles that are directly related to human dignity, together with respect for human rights and fundamental freedoms, benefit and harm, autonomy and confidentiality.

at 51. Professor Andorno stresses the fact that in the Oviedo Convention informed consent is “required for the first time as a general principle for any biomedical intervention” (“The Oviedo Convention”, supra note 46, at 136, 138).

Compare Antonello Tancredi, “Genetica umana ed altre biotecnologie nel diritto comunitario ed europeo”, in Ordine internazionale e valori etici, supra note 51, pp. 381–411, who observes that the ‘principle’ is considered the basis of the doctor-patient relationship while, illustrating the relevant European case-law, he refers to it as the ‘right in question’ (at 397).

See e.g. Bompiani, Loreti Beghé and Marini, who define informed consent (as well as dissent), as the “expression” of the principles of autonomy and self-determination, while refusal of futile therapies is instead construed as a “right” (Bioetica e diritti dell’uomo, supra note 75, at 13).

See the Explanatory Report to the Oviedo Convention, especially paras. 34, 40, 48, 101 and 136.

See, respectively, Article 5 of the Declaration on the Human Genome and Human Rights and Article 6 of the Declaration on Bioethics and Human Rights. However, Article 9 of the former defined consent as a principle.

Unesco, Explanatory Memorandum on the Elaboration of the Preliminary Draft Declaration on Universal Norms on Bioethics, SHS/EST/05/CONF.203/4, 24 February 2005, para. 37.
Also moving to other relevant soft law acts, it is worthy of note that the WMA Lisbon Declaration proclaims, within the right to self-determination, “the right to give or withhold consent to any diagnostic procedure or therapy”, while the WMA Declaration of Helsinki, though expanding on consent in medical research, only provides that “the potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate”. On the contrary, the European Charter on Patients’ Rights, inspired by the EU Charter of Fundamental Rights, proclaims a ‘right to consent’.

Even the views of the UN Special Rapporteurs on the right to health are not perfectly coincident. In fact, while Professor Hunt straightly referred to a ‘right to informed consent’ and urged the devising of measures for a better protection of this right,121 the 2009 Report seems to embrace a less clear-cut position, setting as its objective the analysis of “the fundamental role that informed consent plays in respecting, protecting and fulfilling the right to health, discussing specifically the areas of clinical practice, public health and medical research”.122 As a matter of fact, the Rapporteur mentions a right to consent a few times: referring to legal capacity, which confers on adults “the right to consent to, refuse or choose an alternative medical intervention”; in respect to “the need for special protections guaranteeing a woman’s right to informed consent” especially in the field of sexual and reproductive health; concerning the fact that “the right to consent to treatment also includes the right to refuse treatment”; and with reference to those regional instruments that he considers to be the legal sources of such a right (i.e. the Oviedo Convention and its Additional Protocol on Biomedical Research, the EU Charter and the EU Directive on Clinical Trials).123 This notwithstanding, the whole Report, as anticipated above, is much more inspired by the idea that informed consent is only an integral part of the right to health and an element instrumental to the successful protection of a number of other relevant fundamental rights. This conclusion seems corroborated by the several passages of the Report where emphasis is laid on the fact that informed consent “promotes” patients autonomy, bodily integrity and well-being and that safeguarding an individual’s “ability” to exercise informed consent in health is

119 See, respectively, para. 3b and para. 24.
121 See supra note 103 and corresponding text.
122 See Report 2009, supra note 6, para. 5.
123 Ibid., paras. 10, 20, 28, and 57.
fundamental to ensuring full enjoyment of those health-related basic rights such as the rights to self-determination, freedom from discrimination, freedom from non-consensual experimentation, security and dignity of the human person, recognition before the law, freedom of thought and expression and reproductive self-determination. 124 These statements convey the idea that informed consent should be respected as a ‘feature’ of other fundamental rights and inasmuch as it guarantees a better protection of the right to health, without itself enjoying almost any independent status. Even the conclusions drawn by the Rapporteur do not hint to the need to enhance and reinforce protection of an individual ‘right to consent’; rather, emphasis is placed on the considerations that “guaranteeing informed consent is a fundamental dimension of the right to health” and that “safeguarding informed consent along the health-care continuum is an obligation placed on States and third parties engaged in respecting, promoting and fulfilling the right to health”, so that it is recommended that national and international bodies “emphasize the importance of informed consent as a fundamental aspect of the right to health in relevant policy and practice” and “that States consider whether they are meeting their obligations to safeguard informed consent as a critical element of the right to health”. 125

All this considered, a contribution to the ongoing debate on the nature and scope of informed consent would require that a crucial point be discussed: is there an internationally protected autonomous right to informed consent?

While a ‘right to informed consent’ is by now well-established in both domestic law and jurisprudence, a positive and clear-cut answer is rarely to be found in the literature devoted to international biolaw. One such influential assertion is made by Professor Nerina Boschiero, who states that the ‘right to express an informed consent’ is codified in the Universal Declaration on Bioethics and Human Rights. 126 In the same vein, Article 5 of the Oviedo Convention has been interpreted as an enunciation of the ‘right of the patient to give his free and informed consent’ by the researchers of the Leuven Centre for Biomedical Ethics and Law working at the EuroGentest Project under the direction of Professor Herman Nys. 127

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124 Ibid., paras. 9, 19, 43.
125 Ibid., paras. 7, 93–94.
However, such clear positions are not at all common and scholars tend to use more vaguely worded expressions.

This said, the argument is here made that under the present status of international law there is evidence to support the view that a human right to informed consent has definitely emerged from the convergence of international human rights law and international biolaw over the same key objective: the protection of dignity and of the inviolability of the human being. In this perspective it is one of those new biorights—or human rights of fourth generation—that are progressively borne out of the intersection of bioethics and law, in order to protect, to say it with the philosopher Norberto Bobbio, the freedom of the individual from the attacks deriving from technological progress and the enhanced power of men to dominate over the nature and other men.¹²⁸

To make the point on its content and scope as illustrated in the paragraphs above, it is clear that the right to informed consent is pivotal in regulating the patient-doctor relationship. In essence, the substantive limb of the right entitles all competent adults to express their free and informed consent or refusal to any medical or scientific intervention, be it performed for preventive care, diagnosis, treatment, rehabilitation, research, etc., and prohibits that any such intervention be carried out in the absence of assent by the person concerned or, where applicable, by a substitute decision-maker provided by law (e.g. legal representative or proxy). The procedural limb of the right prescribes that all health professionals and workers provide the necessary information and seek consent before acting, and that consent be validly expressed according to the forms required by law and medical practice.

Moreover, despite its robust rooting in other basic human rights, the right to informed consent has come to live of its own life and can be considered sufficiently independent of them, of which it constitutes an associate right. In effect, the scope of informed consent is broader and is neither completely linked to the right to health (not only is there a right to assent to or refuse medical treatment, but also a right to consent to organs and tissue removal and donation or to participation in non-therapeutic experimentations, both being independent of any healing activity of direct benefit to the person concerned) nor to the right to bodily integrity (since not all interventions impinge on mental and physical integrity). As it is suggested below, the close link to other human rights has been

emphasised and elucidated in international case law—especially by the Strasbourg Court who has addressed the issue of informed consent through the lens of physical integrity and privacy—to provide this right with judicial protection in the absence of any specific international protective machinery devised by the relevant instruments of international biomedical law.

2. Enforceability, Accountability and Redress

The effectiveness of the asserted right to informed consent depends first and foremost on its enforceability, on the possibility to punish relevant violations amounting to a crime and on appropriate guarantees of redress.

While it is indubitable that at national level this right is justiciable before both civil and criminal courts—inasmuch as unlawful derogations from it entitle the patient, their personal representative, or any interested person to appeal to a judicial or other independent authority in order that it scrutinise the legitimacy of any involuntary treatment performed—the situation at the international level is rather different.

Scholars have often commented negatively on the lack of appropriate jurisdictional guarantees associated to the rights of fourth generation. Many share the view that it is the national judge who is best entitled to satisfy the need for justiciability of bioethical rights, especially through the application of those general guiding principles and minimum standards set at the international level, which may also lend help in the evolutive or extensive interpretation of domestic rules with a view to adapting them to new and previously unforeseen bioethical problems.

But are biorights effectively devoid of international judicial protection?

Chapter VIII of the Oviedo Convention articulates the obligations incumbent on States Parties to guarantee a right to justice through the provision of an appropriate judicial protection for unlawful infringements and threats of infringement of the rights and principles set therein (Article 23), the adoption of sanctioning measures (Article 25) and the

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129 It has also been contended that Articles 5 to 9 of the Oviedo Convention have direct effect in domestic legal orders, so that they can be the object of proceedings before national courts: compare Andorno, “The Oviedo Convention”, supra note 46, at 136; Nys, “The European Convention”, supra note 58; Boschiero, “Le biotecnologie”, supra note 11, at 15.

130 See on this point especially Marini, Il diritto internazionale, supra note 87, at 29, and 56–57; Tancredi, “Genetica umana”, supra note 114, at 408–409; Maljean-Dubois, “Bioéthique”, supra note 54, at 92.
effective guarantee of redress (Article 24). While the Convention establishes a monitoring system based on State reports, no international protective machinery is devised and no litigation before the Strasbourg Court is allowed, unless the jurisdiction of this Court is triggered because the violation of the Oviedo Convention also amounts to a breach of one of the rights protected under the European Convention on Human Rights. 131

Actually, as illustrated above, the wealth of European case law concerning infringements of the right to informed consent under the rubric of Articles 3 and 8 violations shows that, albeit indirectly, biorights such as the one in question can indeed enjoy judicial protection before international human rights courts. Moreover, it has been observed that the Strasbourg Court is increasingly making reference to the Oviedo Convention even in cases where the respondent State is not a Party to it, 132 so that the Biomedicine Convention has become an important reference text 133 offering authoritative guidance on those internationally-shared standards, principles and rights that can help interpreting the European Convention on Human Rights in harmony with international biolaw and in line with the new challenges posed by the scientific progress. 134

The same paradigm may apply at the universal level, but it is not easy to appraise the real chances of quasi-jurisdictional protection offered by treaty-based bodies given the current lack of competence of the Economic, Social and Cultural Rights Committee to receive and consider individual communications concerning Article 12 of the Covenant (due to the fact

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131 Article 29 of the Oviedo Convention only confers on the European Court of Human Rights the competence to deliver advisory opinions on general legal questions concerning the interpretation of the Convention independently of any judicial proceedings pending before national courts (see also the Explanatory Report, paras. 164–165). This advisory competence has raised criticism and perplexities as to its scope and ‘side effects’: see Tancredi, “Genetica umana”, supra note 114, at 408.


133 See the long-sighted reflections made by Professor Roscam Abbing on the prospective value of the Convention in Strasbourg case law in “The Convention on Human Rights”, supra note 58, at 380.

that its Optional Protocol is not yet in force), and the scarcity of relevant case law developed so far by the Human Rights Committee with regard to Article 7 of the Covenant on Civil and Political Rights. In this regard, it should be noted that the potential role of the Human Rights Committee is yet unexpressed, since it could ascertain violations of the right to informed consent (amounting to a violation of the right to physical integrity and of the prohibition of non-consensual experimentation) as committed by any health-care provider, be it an agent of the State or a private individual or entity, which is particularly important in the perspective of guaranteeing effective respect for this right also in case of private health service delivery and in case of privatisation of the public health sector.135

In conclusion, it is evident that much has still to be done to achieve an appropriate protection of biorights at the international level in order to enhance their effectiveness as human rights. The need for such improvement was also urged by the UN Special Rapporteur on the right to health:

Monitoring mechanisms to identify situations compromising informed consent within the health-care continuum need to be established. Mechanisms for redress should be made available at the local, regional and international levels to ensure that those whose actions threaten human dignity and autonomy in the health-care setting are held accountable for their actions and further violations are prevented.136

Such recommendations add new impetus to the views of those scholars who have already addressed criticism over the shortcomings of the

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135 In General Comment No. 31, the Human Rights Committee stated that “The article 2, paragraph 1, obligations are binding on States [Parties] and do not, as such, have direct horizontal effect as a matter of international law. The Covenant cannot be viewed as a substitute for domestic criminal or civil law. However the positive obligations on States Parties to ensure Covenant rights will only be fully discharged if individuals are protected by the State, not just against violations of Covenant rights by its agents, but also against acts committed by private persons or entities that would impair the enjoyment of Covenant rights in so far as they are amenable to application between private persons or entities. There may be circumstances in which a failure to ensure Covenant rights as required by article 2 would give rise to violations by States Parties of those rights, as a result of States Parties’ permitting or failing to take appropriate measures or to exercise due diligence to prevent, punish, investigate or redress the harm caused by such acts by private persons or entities. ... The Covenant itself envisages in some articles certain areas where there are positive obligations on States Parties to address the activities of private persons or entities. ... It is also implicit in article 7 that States Parties have to take positive measures to ensure that private persons or entities do not inflict torture or cruel, inhuman or degrading treatment or punishment on others within their power.” (CCPR, General Comment No. 31 [80] Nature of the General Legal Obligation Imposed on States Parties to the Covenant, 29 March 2004, para. 8, emphasis added).

accountability measures available at present and called for the development of a specific international criminal law of bioethics,137 or even for the institution of an international medical tribunal for criminal prosecution of bioethical crimes and physicians’ abuses of human rights.138

IV. INFORMED CONSENT IN END-OF-LIFE CARE: INFORMED REFUSAL AND THE BOUNDARIES OF PATIENTS’ AUTONOMY

The relevance of informed consent for treatment options at the end of life is particularly replete with ethical conflicts and dilemmas which still prompt attentive discussion and penetrating understanding. In fact, one of the most intensely debated and problematic issues is to define the boundaries of patients’ autonomy in end-of-life decision-making.

The scope of self-determination in end-of-life care is deeply intertwined with the universal recognition of the value and protection of human life. Around this theme, two approaches based on different moral and philosophical rationale contrast each other in medical ethics: the ‘sanctity of life’ approach, according to which life is valuable per se and is worth protecting independently of any physical disability or psychological

137 From the perspective of international criminal law, there is yet no specific regulation concerning liability for violation of human rights linked to biomedical practices. However, it is worth mentioning that the Rome Statute includes in the crimes over which the International Criminal Court has jurisdiction—as patent violations of the right to self-determination and informed consent—enforced sterilization in both the categories of crimes against humanity and war crimes (art. 5, para. 1g; art. 8, para. 2b.xxii; art. 8, para. 2e.vi), and biological experiments (art. 8, para. 2a.ii) as well as “medical or scientific experiments of any kind which are neither justified by the medical, dental or hospital treatment of the person concerned nor carried out in his or her interest” (art. 8, para. 2b.x; art. 8, para. 2e.xi) among war crimes (see Rome Statute of the International Criminal Court, U.N. Doc. A/CONF.183/9, 17 July 1998, entered into force on 1 July 2002). In consideration of the fact that these crimes trigger international criminal liability of individuals only in case of armed conflict or of widespread and systematic violations, several scholars have highlighted the need for a specific regulation at the international level of at least the most heinous biomedical practices contrary to human rights and ethics (i.e. human cloning, illegal traffic of organs, non-consensual experiments). The best means to guarantee such result would be the drafting of specific conventions also concerning transnational crimes, or in the alternative, those international organizations which are more actively engaged in the field of international bioethics should adopt recommendations or general guidelines prompting member States to pass criminal legislation and allowing universal jurisdiction for the most serious bioethical crimes. See Lenoir, “Le droit international pénal de la bioéthique”, supra note 11, at 410–414.

deficiency; the ‘quality of life’ approach, which posits that life can be renounced when physical existence is not supported by mental and social qualities that make living meaningful.\textsuperscript{139} In connection with ethical and legal dilemmas in end-of-life care, the foundational contrast and almost irreconcilable conflict between Christian bioethics and secular bioethics has been the object of in-depth scholarly reflections.\textsuperscript{140}

In the context of international biolaw the principle of autonomy posits that no authority is entitled to deprive the individual of his right to choose what he deems to be best for him, especially in the field of health, life and death.\textsuperscript{140} Hence, autonomy endows individuals with the exclusive right to make independent life choices on the basis of their conscience and beliefs (right to self-determination), and the most significant expression of this principle in health care is the right to informed consent, with its associate right to refuse or halt medical treatments.\textsuperscript{142}

As far as ‘informed refusal’ is concerned, there is substantially no disagreement on the fact that it is to be considered an integral part of autonomy and the reverse side of informed consent. Its scope is narrower than that of the right to self-determination, since the latter shifts the focus from mere refusal of treatment to freedom of choice in one’s own best interest. However, the most controversial aspect of informed refusal is whether respect for the right to refuse or stop treatment should be disregarded when it leads to the patient’s death. In other words, the critical point is whether the freedom element inherent in the right to self-determination may encompass ‘self-termination’.

In this connection, a lively discussion has developed on the legal limits of patients’ autonomy, especially when referred to the practice of end-of-life care. The debate has focused on two major issues: whether there is a recognised right to die, or to die with dignity, and whether respect for individual autonomy may legitimise euthanasia and assistance to suicide at the request of a terminally ill or a dying patient.


\textsuperscript{140} See, for example, among the most recent contributions, H. Tristram Engelhardt, “Christian Bioethics after Christendom: Living in a Secular Fundamentalist Polity and Culture”, 17 \textit{Christian Bioethics} (2011), pp. 64–95; Christopher Tollefsen, “Mind the Gap: Charting the Distance between Christian and Secular Bioethics”, ibid., pp. 47–53.

\textsuperscript{142} See Boschiero, “Le biotecnologie”, \textit{supra} note 11, at 52.
As a preliminary observation, it is necessary to point out that for these patients a clear distinction is to be made between refusal or withdrawal of life-sustaining, life-prolonging, disproportionate or futile treatments upon request or by will of the interested person (including passive euthanasia or ‘letting die’), and the taking of action lacking medical, therapeutic or palliative justification, but intended solely to terminate life (active euthanasia or to some extent assistance to suicide, which are considered as amounting to an arbitrary taking of life contrary to international human rights law).

In the second place, it is remarkable that international law, as it stands today, cannot yet provide any exhaustive and clear-cut answer to such challenging issues. As far as international biolaw is concerned, a lacuna exists on almost all issues related to the end of life, given the absence of any generally accepted standard in this domain – and this is particularly telling of the asserted impossibility to reach universal consensus on the most critical bioethical dilemmas. As for international human rights law, no relevant instrument protects any right to die or to die with dignity, so the debate has mainly developed in the framework of the protection of the right to life.

In this respect, it is noteworthy that human rights treaties are couched in terms that every human being has the inherent right to life which is protected by law, and “no one shall be arbitrarily deprived of his life”. They envisage only limited circumstances in which a person can be deprived of this right and none of these relate to suicide or euthanasia. \(^\text{143}\)

Once again it is the activity of human rights bodies that offers some guidance on the subject, although, in this case too, there is a substantial difference between the contribution given at the universal level by the Human Rights Committee and the one provided at regional level by the European Court of Human Rights.

The Human Rights Committee interpreted the right to life as “the supreme right from which no derogation is permitted”, \(^\text{144}\) that is to say a right which enjoys the status of jus cogens. \(^\text{145}\) This notwithstanding, when

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144 CCPR, General Comment No. 06: The right to life (art. 6), 30 April 1982, para. 1. See, in this respect, Article 15 of the European Convention on Human Rights, Article 4 of the International Covenant on Civil and Political Rights, and Article 27 of the American Convention on Human Rights.
it had the occasion to scrutinise the compatibility of the Dutch law on euthanasia of 2001 with Article 6 of the Covenant—which in essence prescribes the arbitrary taking of someone else’s life—it did not find that such law was contrary to the treaty, but merely recommended that it be revised in light of that provision with a view to strengthening some of its guarantees. Even recently, in considering the Swiss legislation on assisted suicide, the Committee limited itself to recommending that Switzerland ought to “consider amending its legislation in order to ensure independent or judicial oversight to determine that a person who is seeking assistance for suicide is acting with full free and informed consent.”

Turning to the regional framework, it is not necessary to examine in detail the issue of euthanasia and assisted suicide as approached by the organs of the Council of Europe or the European Court of Human Rights, since this subject is extensively treated in other chapters of this book. However, it is important to recall at least the core of the Parliamentary Assembly’s statements and Strasbourg case law on the subject.

In its resolution of 1976 on the rights of the sick and the dying, the Assembly focused on the best interest of these persons viewed through the lens of the effective benefits of aggressive and futile treatments, which is one of the still more controversial issues in end-of-life care, together with the problematic qualification of artificial nutrition and hydration and the possibility to forego life-sustaining treatments. Starting from the assumption that “no other interests may be considered in establishing the moment of death than those of the dying person”, it observed that “the true interests of the sick are not always best served by a zealous application of the most modern techniques for prolonging life” and thus invited “the responsible bodies in the medical profession in the member states to

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examine critically the criteria upon which decisions are currently based with respect to the initiation of reanimation procedures and the placing of patients into long-term care requiring artificial means of sustaining life".150 These questions were again addressed in recommendation 1418 (1999) on the protection of the human rights and dignity of the terminally ill and the dying, where the right of these vulnerable patients to ‘die in dignity’ was balanced with the need to keep faithful to a strict protection of the right to life. According to the Assembly, in fact, while terminally ill and dying patients should be shielded from the risk of being subject to an “artificial prolongation of the dying process by ... disproportionate medical measures or the ... [continuance of] treatment without ... consent”, having regard to the obligation of States Parties under Article 2 of the Convention “a terminally ill or dying person’s wish to die never constitutes any legal claim to die at the hand of another person” or “a legal justification to carry out actions intended to bring about death”.151 These issues raised by the recommendation should be read through the lens of the critical observations made by Professor Douwe Korff in relation to the questions posed by the formulation of Article 2:

First of all: when does life—and therefore the right to protection of life by law—end? Secondly: is it acceptable to provide palliative care to a terminally ill or dying person, even if the treatment may, as a side-effect, contribute to the shortening of the patient’s life? And should the patient be consulted on this? Third, may, or must, the State “protect” the right to life even of a person who does not want to live any longer, against that person’s own wishes? Or do people have, under the Convention, not just a right to life and to live—but also a right to die as and when they choose: to commit suicide? And if so, can they seek assistance from others to end their lives? And fourth: can the State allow the ending of life in order to end suffering, even if the person concerned cannot express his or her wishes in this respect?152

As pointed out by the Committee of Ministers, “as yet, there is no case law of the Court which could provide precise answers to all the questions raised in the Recommendation [1418]”.153 In fact, the so far limited case law

153 Parliamentary Assembly, Doc. 9404, 8 April 2002, Protection of the human rights and dignity of the terminally ill and the dying, Recommendation 1418 (1999), Reply from the
of the European Court has not dealt in any exhaustive manner with such crucial problems, nor has it ever ruled in straight and clear-cut wording that euthanasia is contrary to Article 2.\textsuperscript{54} In principle, the Court stated that Article 2 allows no further derogations than those enunciated therein and that the "circumstances when the deprivation of life may be justified" must be "strictly construed".\textsuperscript{55} However, in consideration of the fact that the cases of Sanles Sanles and Ada Rossi et al. were declared inadmissible \textit{ratione personae},\textsuperscript{56} the only two relevant proceedings dealing with euthanasia and assisted suicide are the already famous \textit{Pretty} case\textsuperscript{57} and the more recent \textit{Haas} case.\textsuperscript{58}

In \textit{Pretty} the Court addressed the question whether the right to life and the right to privacy include a right to die. In the first place, it considered that Article 2 could not be construed in terms implying recognition of a negative aspect of the right to life, that is a right to choose not to live; in the second place, it observed that such provision is phrased in terms that are "unconcerned with issues to do with the quality of living or what a person chooses to do with his or her life", so that it concluded that Article 2 cannot, without a distortion of language, be interpreted as conferring the diametrically opposite right, namely a right to die; nor can it create

\textsuperscript{54} In the \textit{Widmer} case the European Commission found that failure to criminalise passive euthanasia by the Swiss legislator was not incompatible with either Article 2 or Article 8 of the Convention (ECHR, \textit{Widmer v. Switzerland}, no. 20527/92, Commission decision of 10 February 1993).

\textsuperscript{55} In principle the Court found that no further derogations from the proviso of Article 2 could be admitted: see ECtHR, \textit{McCann and others v. the United Kingdom}, no. 18984/91, Judgment of 27 September 1995. A 324, para. 147.

\textsuperscript{56} ECtHR, \textit{Sanles Sanles v. Spain}, no. 48335/99, Decision of 26 October 2000; \textit{Ada Rossi and Others v. Italy}, nos. 53185/08, 55483/08, 55516/08, 55519/08, 56095/08, 56278/08, 58426/08 and 58424/08, Decision of 16 December 2008.


\textsuperscript{58} ECtHR, \textit{Haas v. Switzerland}, no. 31322/07, Judgment of 20 January 2011.
a right to self-determination in the sense of conferring on an individual the entitlement to choose death rather than life. ... The Court accordingly finds that no right to die, whether at the hands of a third person or with the assistance of a public authority, can be derived from Article 2 of the Convention.\textsuperscript{159}

In this regard, it also recalled Recommendation 1418 (1999) as a relevant document confirming this view. Moreover, concerning Article 8, the Court acknowledged the importance of the principle of personal autonomy in the interpretation of the guarantees provided by the European Convention and hence asserted the right to self-determination as included in the right to private life.\textsuperscript{160} It observed that

the ability to conduct one’s life in a manner of one’s own choosing may also include the opportunity to pursue activities perceived to be of a physically or morally harmful or dangerous nature for the individual concerned. The extent to which a State can use compulsory powers or the criminal law to protect people from the consequences of their chosen lifestyle has long been a topic of moral and jurisprudential discussion, the fact that the interference is often viewed as trespassing on the private and personal sphere adding to the vigour of the debate. However, even where the conduct poses a danger to health or, arguably, where it is of a life-threatening nature, the case-law of the Convention institutions has regarded the State’s imposition of compulsory or criminal measures as impinging on the private life of the applicant within the meaning of Article 8 § 1 and requiring justification in terms of the second paragraph.\textsuperscript{161}

In this connection, the Court made some important statements of principle on the intensely debated and controversial right to die transposing the considerations reported above in the sphere of medical treatment. It therefore stated that

the refusal to accept a particular treatment might, inevitably, lead to a fatal outcome, yet the imposition of medical treatment, without the consent of a mentally competent adult patient, would interfere with a person’s physical integrity in a manner capable of engaging the rights protected under Article 8 § 1 of the Convention.\textsuperscript{162}

Most interestingly, it put into close relationship the right to informed refusal with the right to die, and in referring also to domestic case-law, it recognised that “a person may claim to exercise a choice to die by declining to consent to treatment which might have the effect of prolonging his

\textsuperscript{159} Pretty, supra note 157, para. 39
\textsuperscript{160} Ibid., para. 61.
\textsuperscript{161} Ibid., para. 62.
\textsuperscript{162} Ibid., para. 63.
Furthermore, the Court tried to take an equidistant position between the traditional opposite approaches of Christian and secular bioethics, to admit that personal autonomy may lead to choices which are not necessarily respectful of the concept of the inviolability of life:

Without in any way negating the principle of sanctity of life protected under the Convention, the Court considers that it is under Article 8 that notions of the quality of life take on significance. In an era of growing medical sophistication combined with longer life expectancies, many people are concerned that they should not be forced to linger on in old age or in states of advanced physical or mental decrepitude which conflict with strongly held ideas of self and personal identity.\footnote{Ibid., para. 65.}

This important reflection led the Court to conclude that it was “not prepared to exclude” that the existence of a law preventing individuals from exercising their personal choice to avoid what they consider as an undignified and distressing end to their life would constitute an interference with their right to respect for private life.\footnote{Haas, supra note 158, para. 51: “la Cour estime que le droit d’un individu de décider de quelle manière et à quel moment sa vie doit prendre fin, à condition qu’il soit en mesure de forger librement sa propre volonté à ce propos et d’agir en conséquence, est l’un des aspects du droit au respect de sa vie privée au sens de l’article 8 de la Convention”. See also the similar case of Koch v. Germany, no. 497/09, still pending.}

Mutatis mutandis, such cautious approach was later developed in Haas\footnote{Mutatis mutandis, such cautious approach was later developed in Haas v. Switzerland, where the Court for the first time almost recognised an individual ‘right to suicide’, finding that one limb of the right to privacy is the right to decide the time and modalities of the end of one’s own life, provided that such decision be taken freely and knowingly and that suicide be carried out autonomously and without the help of third persons.} v. Switzerland, where the Court for the first time almost recognised an individual ‘right to suicide’, finding that one limb of the right to privacy is the right to decide the time and modalities of the end of one’s own life, provided that such decision be taken freely and knowingly and that suicide be carried out autonomously and without the help of third persons.\footnote{Ibid., para. 67.}

The bolder stance taken by the Court was however ‘mitigated’ by its placing special emphasis on two elements: the need to interpret Article 8 in light of Article 2—which in the Court’s views compels national authorities to avoid that suicidal acts be performed as a result of a decision that is not completely freely and knowingly taken—and the absence of a general consensus among the Members of the Council of Europe as to the existence of a right to choose how and when to put an end to one’s life—which shifts again the attention to the States’ margin of appreciation and explains why the Court implicitly admits that the Swiss legislation is not incompatible with the Convention. Although these considerations finally led the
Court to conclude that no positive obligations existed for the State to adopt measures aimed at guaranteeing a ‘right to a dignified suicide’, and hence a ‘right to die in dignity’, it is nonetheless noteworthy that some steps taken by the Court in this case—especially when, in balancing the opposing interests at stake, it takes note and “admet la volonté du requérant de se suicider de manière sûre, digne et sans douleur et souffrances superflues”—may be considered promising of a further evolution of its case-law in this particularly delicate field.

V. CONCLUDING REMARKS: INFORMED CONSENT, ADVANCE TREATMENT DIRECTIVES AND THE RIGHT TO DIE IN DIGNITY

As it has been suggested so far, a right to informed consent, along with its associate right to refuse treatment, have emerged and gained prominence in the international legal order.

It is also widely accepted that the right to give or withhold consent includes the patient’s right to express in advance their preferences as to the treatment options to be performed in case they lose temporarily or permanently their capacity to take part in medical decision-making.\(^{167}\) The legal instruments designed to enable patients to retain decisional authority even in cases of incompetence are the so-called advance directives, which provide a viable alternative to contemporaneous decisions and serve the scope of protecting precedent autonomy.

Advance decision-making can take the form of either instructional directives, also known as living wills (providing specific instructions or setting out general principles to be followed for health care to be delivered when decision-making capacity has been lost) or proxy directives, also known as durable powers of attorney for health care (naming surrogate decision-makers such as proxies).\(^{168}\)

\(^{165}\) The Directives can apply not only to end-of-life situations but also to situations of a transitory or short term nature where the patient is unable to express himself.

Advance directives have long been in the spotlight of the bioethical and biolegal discourse at both national and the international level. Depending on the jurisdiction, domestic laws may grant specific legal status to either kind of directive and require a specific format and specific procedural rules. However, while there is a general trend in European countries towards regulation of advance directives, the legal effect to be given to these documents is still controversial and debated\(^\text{169}\) and their binding authority has been the object of both moral and practical attacks.\(^\text{170}\)

From the standpoint of international law, advance directives lack any specific regulation and even in international instruments of ‘soft biolaw’ express reference to them is really scant.\(^\text{171}\) The only relevant normative provision is to be found in Article 9 of the Oviedo Convention, which refers to the patient’s “previously expressed wishes”. As explained by Professor Andorno in this book, this proviso is not devoid of ambiguities and shortcomings that the Council of Europe has tried to put right with the Committee of Ministers recent recommendation (2009)\(^\text{11}\) of 9 December 2009 on principles concerning continuing powers of attorney and advance directives for incapacity.

This notwithstanding, it is quite clear that Article 9 of the Convention is considered an important reference point to enhance the status of advance directives both at the global\(^\text{172}\) and regional level. In fact, although the

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\(^{169}\) Andorno, “An Important Step”, supra note 168, at 119, 123.


\(^{171}\) For example, the Amsterdam Declaration, supra note 16, took into account “a previous declared expression of will” to the effect of preventing, even in situations of urgent need, the performance of a medical intervention based on a presumed informed consent when, according to such previous will, it is clear that the patient would have refused consent (para. 3.3).

\(^{172}\) See for example Violeta Beširević, “End-of-Life Care in the 21st Century: Advance Directives in Universal Rights Discourse”, 24 Bioethics (2010), pp. 105–112, at 107: “the standards concerning the role of precedent autonomy in treating incompetent patients, guaranteed in Article 9 of the Oviedo Convention could, at least potentially, be implemented on a territory much wider than the territory of the Council of Europe Member States".
Convention has not yet been ratified by many of the European Union Member States, it is noteworthy that in a recent resolution on the situation of fundamental rights in the Union, the European Parliament invited all Member States lacking a specific legislation on living wills to adopt such laws as necessary

to ensure that, according to Article 9 of the Oviedo Convention on Human Rights and Biomedicine, ‘The previously expressed wishes relating to a medical intervention by a patient who is not, at the time of the intervention, in a state to express his or her wishes shall be taken into account’ and to ensure the right to dignity at the end of life.173

This recommendation is remarkable for two main reasons. First, because it calls for implementation of a principle whose legal source is a provision that is not binding on all EU Member States, which amounts to recognising that the standard set by Article 9 has general scope and effect extending also to States not Parties to the Oviedo Convention. Second, because it associates respect, or at least due consideration, of advance directives to the right to dignity at the end of life.

The latter aspect is particularly interesting since it lends support to the argument that advance directives favour death with dignity inasmuch as they translate into medical instructions the patient’s personal views, values and beliefs as to their idea of a dignified death. This element deserves special consideration and respect because it represents the expression and exercise of two fundamental and non-derogable rights: the right to dignity and the right to informed consent.174

Actually, advance directives originated as a way to avoid the excesses of life-prolonging measures as provided by advanced medical technology, and a means of protecting patients from unnecessary prolonging of the dying process in conditions that they would not want to endure. This is the reason why instructional directives very often consist in the advance refusal of futile, disproportionate or aggressive treatment and life-sustaining measures (such as mechanical ventilation or artificial nutrition and hydration) or in DNR orders (i.e. ‘do not resuscitate’ orders amounting to a refusal of life-saving measures, such as cardiopulmonary

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174 At least for adult competent patients, and where derogations due to emergency situations and public health interests do not apply, the non-derogable nature of informed consent is no longer controversial: see Wear, Informed Consent, supra note 1, p. 1.
resuscitation). Their rationale obviously resides in the patient’s will to escape the risk of being subject either to prolonged unbearable suffering or to a condition of mere physical survival devoid of any cognitive functions, which may be considered contrary to one’s own concept of dignity. In situations like these, it has been contended that there should be no automatic protection of the sanctity of life at the expense of human dignity, least of all in violation of the patient’s expressed will and specific requests.175

Therefore, since international law as it stands today recognises that compulsory treatments or interventions, even if life-saving, are inconsistent and irreconcilable with the right to self-determination and the right to informed consent, but however it does not recognise and protect any right to die or to die in dignity, the relevance of the right to refuse treatment and the fundamental right to human dignity should be the starting point for determining the legal value of advance directives from an international law perspective, as well as for assessing the consistency of relevant domestic regulation with international law.

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