

Universal Human Rights and End-of-Life Care

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Abstract Universal human rights like dignity, physical integrity, health, and freedom from torture or inhuman treatment have special relevance to the end-of-life debate and form the basis on which is built the emergence of new biorights. Over the last decades, such rights as the right to informed consent, the right to die with dignity, and the right not to suffer have gained increasing importance in the international legal order. These rights have also contributed to the setting of generally accepted human rights standards that offer authoritative guidance to both domestic legislators and judges. This is particularly important in light of the fact that the regulation of legal questions surrounding the end of life is quite different in domestic jurisdictions, even in a rather homogeneous and integrated region like Europe, where the relevant legal frameworks still differ according to cultural, ideological, and religious diversities and the more or less liberal attitude adopted by individual States, as it is the case with Germany and Italy. Moving from the above considerations, this chapter will discuss some critical aspects of end-of-life decision-making and care within the international human rights framework, with a view to disclosing the relevant legal standards and obligations that may serve as general reference and starting points for a comparison between national jurisdictions. This investigation could also open up the door to a more specific debate on the consistency of domestic legislation on end-of-life issues with international (biomedical and human rights) law.

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Contents

1	The Relevance of International Human Rights Law to the Legal Regulation of Ethical Issues Surrounding the End of Life	2
2	Advance Care Planning, Patient Autonomy, and the Right to Informed Consent	5
2.1	The Doctrine of Informed Consent	6
2.2	Informed Consent and Universal Human Rights	10
2.3	The Emergence of the “Right to Informed Consent” as an International Human Right and its Relevance to Advance Directives Regulation	14
3	The Euthanasia Debate and the Right to Die with Dignity	17
3.1	Advance Refusal of Treatments and Requests for Euthanasia and Physician-Assisted Death	17
3.2	Euthanasia and Universal Human Rights	18
3.3	The Controversial Emergence of a “Right to Die with Dignity” as Part of the Right to Personal Autonomy and Privacy	22
4	Palliative Care and the Right Not to Suffer	24
4.1	Objectives of Palliative Care	24
4.2	A Human Rights Approach to Palliative Care: The Relevance of Universal Rights	25
4.3	The “Right Not to Suffer” as an Emerging International Human Right	31
5	Concluding Remarks	33
	References	34

1 The Relevance of International Human Rights Law to the Legal Regulation of Ethical Issues Surrounding the End of Life

End-of-life care and advance care planning require a range of extremely sensitive decisions that deeply affect the patients’ autonomy and their personal conception of life, death, and dignity.¹ Such decisions touch upon highly debated ethical dilemmas and raise topical medico-legal questions, including the definition of the boundaries of informed consent, the ethics and efficacy of aggressive or futile medical treatments, the withholding or withdrawing of life-sustaining measures, access to palliative care, and the permissibility of euthanasia or assisted suicide.

Legal questions related to these and other key issues concerning end-of-life decision-making and care are regulated quite differently in domestic law, if not regulated at all. This is mainly due to cultural, ideological, and religious diversities and the ensuing pluralistic approach adopted by States to moral, social, and legal values. At the international level—despite a quest for universal bioethical standards

¹ Advance care planning is a voluntary process of discussion about future care between an individual and their care providers, which might include the individual’s concerns and wishes, their important values or personal goals for care; their understanding about their illness and prognosis; their preferences and wishes for types of care or treatment that may be beneficial in the future and the availability of these.

that may overcome the diversities inherent in human societies²—bioethically-sensitive issues related to the end of life are not specifically regulated. This is one of the evident limits of the emerging international law of bioethics, which has not so far succeeded in expressing those commonly shared values and globally accepted standards necessary for a possible harmonisation of domestic legislations in this field. In fact, although a certain degree of rapprochement between States was achieved in certain areas of biomedical practice and research, considerable differences still exist in their approach to ethico-legal questions concerning, for example, the patients' will to terminate their life, the problematic qualification and efficacy of certain life-sustaining measures (such as artificial nutrition and hydration), physician conscientious objection, and so on. Such a lack of generalised consensus resulted in a noticeable lacuna in both the Universal Declaration on Bioethics and Human Rights³ and the Oviedo Convention on Human Rights and Biomedicine,⁴ both lacking any relevant disposition in this respect.

Furthermore, it is remarkable that some legal questions concerning the end of life are regulated quite differently even in a rather homogeneous and integrated region like Europe, where the relevant legal frameworks still differ substantially according to the more or less liberal attitude adopted by States and their inclination to adopt restrictive or permissive legislations. In Germany and Italy, for example, it is evident that the relevant domestic norms testify to a very diverse approach to the legal regulation of end-of-life issues from both the civil and the criminal law perspectives, as this book will show.

Moving from these considerations, this chapter will discuss some critical issues concerning end-of-life care and decision-making within the international human rights framework, with a view to disclosing those legal standards and State obligations stemming from human rights law that may serve as general reference and starting points for a comparison between domestic legal orders. In short, it aims to assess whether in the three core domains where the comparative analysis between German and Italian law is developed in the chapters that follow (patient autonomy and advance care planning, euthanasia, and palliative care) it is possible to affirm that some relevant international human rights standards exist, whether new rights have emerged at the general level and to what extent they pose international

² On the issue whether “universal bioethical standards” can be translated into legal norms, see Ida (2004), pp. 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” (pp. 377–378).

³ Unesco, Universal Declaration on Bioethics and Human Rights, 19 October 2005.

⁴ Council of Europe, Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, Oviedo, 4 April 1997, ETS No. 164, entered into force on 1 December 1999 (hereinafter ‘Oviedo Convention’). The problems left unsolved by the Convention include the definition of the boundaries of patient autonomy, the refusal of treatments, and euthanasia: see Taupitz (2002b), p. 5.

obligations on States, and whether the relevant international remedies offer a better protection than the one that is available under domestic law. This investigation could also open up the door to a more specific debate on the compatibility of domestic legislation on end-of-life issues with international (biomedical and human rights) law.

The reflections that follow will build on two basic assumptions.

The first is the idea that international human rights law at the universal level can be considered quite “neutral”, in the sense that it does not suffer—at least not to a considerable extent—from the influence that ideological, political, and religious factors exert on domestic legislations. Based on the recognition of universal values, generally agreed standards, and internationally acknowledged rights, it can offer a reliable and objective term of reference for domestic legislation, thus guiding legislators in the passing of statutes that do not privilege any dominant ethics (be it laic, Catholic, or others). Moreover, general principles and minimum standards set at the international level can also lend help to national judges when they interpret domestic provisions extensively and evolutively, with a view to making the law “live” and have margins of manoeuvre in its application to the new bioethical dilemmas.⁵ Therefore, even if unable to achieve real harmonisation, the human rights standards affirmed and accepted at the universal level can nonetheless realise a certain degree of rapprochement between State legislations around commonly shared values and principles.

The second basic assumption refers to the asserted derivation of biomedical law from human rights law: the most influential literature on the subject insists on the concept that international instruments of biolaw are the “natural extension” of human rights instruments to life sciences and biomedicine.⁶ Moreover, according to a commonly shared scholarly view, it is most opportune that biolaw be conveyed within the framework of human rights law, so that human rights and fundamental freedoms may find appropriate tools of legal protection from the challenges of medical technological progress.⁷ In this respect, it is often pointed out that all major human rights treaties contain some guarantees related to the protection of fundamental rights in patient care⁸ and that, despite the fact that only some of these conventions have been almost universally ratified, they all set minimum standards

⁵ In this sense, see Maljean-Dubois (2000), p. 92; Tancredi (2004) pp. 408–409; Campiglio (2012), p. 112.

⁶ See Byk (1999); Maljean-Dubois (2000), p. 93; Boschiero (2006), p. 13, 15; Mathieu (2006), p. 85; Andorno (2011), p. 75.

⁷ Loreti Beghè and Marini (2001), p. 44; Andorno (2002), p. 960; Boschiero (2006), p. 14.

⁸ See Andorno (2005b), p. 133. The Author states that the essence of some principles enunciated by the Oviedo Convention were already framed in more general terms in previous human rights treaties.

that can be considered at least morally binding also on non-Party States.⁹ Moreover, the link between international human rights law and biomedical law is ever more apparent in the wording of the majority of biolaw instruments, which regularly refer to the key human rights instruments and endorse them as foundational framework 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.¹⁰

Following this line of thought, this chapter will especially focus on universal human rights—such as life, health, human dignity, physical integrity, freedom from torture—in order to attest to the relevance of international human rights law, and the prominence of universally accepted human rights standards, to the legal regulation of ethical dilemmas surrounding the end of life.

2 Advance Care Planning, Patient Autonomy, and the Right to Informed Consent

Patient autonomy encompasses the right to participate in advance care planning and to make decisions for the future. Therefore, respect for self-determination implies respect for the patients’ 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. It falls within the purview of patient autonomy—provided that we refer to adults who understand the consequences of their choices—to refuse certain medical treatments and interventions, including those that may be administered at the end of life, and to choose that death come naturally.

Advance directives are the legal instruments designed to enable patients to retain decisional authority even in cases of incompetence; they provide a viable alternative to contemporaneous decisions and serve the scope of protecting precedent

⁹ For example, the scope of the Oviedo Convention has thoroughly been debated in legal literature also with a view to assessing whether it can offer a pattern for global regulation of bioethical issues: see especially Taupitz (2002b). On the one hand, it is contended that the Convention seeks to promote the universal dimension of the biorights it enunciates and it is also remarked that the participation of Canada, the USA, Japan, Australia, the European Union, and the Holy See to its negotiation undoubtedly confers an added value to the alleged “universality” of its rules (see e.g. Millns (2007), p. 78; Gadd (2005); Boschiero (2006), p. 51). On the other hand, it is denied any “universal aspiration”, both because it is substantially a regional treaty with a very low rate of ratification and because its restrictive provisions make it unlikely that it will ever be ratified by third States (on this latter point, see Riedel (2002), pp. 37–38).

¹⁰ The Preambles to the Oviedo Convention and to the Unesco Universal Declarations both “solemnly recall [...] the attachment to the universal principles of human rights”. See also the Explanatory Report to the Oviedo Convention, paragraphs 11–13.

autonomy.¹¹ Except for a specific and limited reference to the patient's "previously expressed wishes" to be found in Article 9 of the Oviedo Convention,¹² advance directives in general are not regulated in international law and the legal effects they have in domestic law vary from one jurisdiction to another.¹³ In order to assess whether a generally accepted standard has emerged so far, it is necessary to focus on the principle of informed consent, which is considered the very foundation of the "new ethos of patient autonomy".¹⁴

2.1 *The Doctrine of Informed Consent*

Informed consent is both a core principle of medical ethics and a well-established fundamental rule of biomedical law. It has gained such remarkable relevance in the international legal framework that virtually all international agreements and declarations on ethical and legal standards in medicine and biomedical research endorse it as a basic rule.¹⁵

After the famous and most cited opinion delivered by Justice Benjamin Cardozo in the landmark *Schloendorff* case, according to which "every human being of adult years and sound mind has a right to determine what shall be done with his own body",¹⁶ and the first significant enunciation in the Nuremberg Code,¹⁷ informed

¹¹ 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).

¹² Article 9 of the Oviedo Convention reads "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". On this provision, see the legal analysis carried out in this book in the chapter authored by Di Stasi and Palladino (2013).

¹³ See Negri (2011a), especially Part II: Advance directives, end-of-life decision-making, and euthanasia in comparative legal perspective.

¹⁴ The quote is from Wear (1992), Chapter two. The body of literature on informed consent is really vast. See, ex plurimis, Faden et al. (1986); Van Oosten (1991); Switankowsky (1998); Berg et al. (2001); Manson and O'Neill (2007); Casonato (2009); Maclean (2009). For deeper insights on the status of informed consent under international law, see Negri (2011c); Negri (2012).

¹⁵ Kollek (2009), p. 124.

¹⁶ Opinion of Justice Benjamin Cardozo, *Schloendorff v. The Society of New York Hospitals* (105 N.E. 92), Court of Appeals of New York, 14 April 1914.

¹⁷ The Nuremberg Code (1947) was printed in *Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10*, Washington, 1949, vol. 2, pp. 181–182. 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

consent has enjoyed growing widespread consensus in both ‘hard’ and ‘soft’ law and has gained over time broader scope.¹⁸

In 1949, the World Medical Association recognised the ‘right’ of competent patients to accept or refuse treatment in its International Code of Medical Ethics¹⁹ and later upheld the rule of informed consent both in the Helsinki Declaration on Ethical Principles for Medical Research (mentioning both the right to refuse to participate in research and the right to withdraw a previously expressed consent)²⁰ and in the Lisbon Declaration on the Rights of the Patient (where informed consent is subsumed under the right to self-determination).²¹

Turning to the legal instruments adopted by the most relevant international organisations, it is necessary to recall, first and foremost, the WHO Declaration on the Promotion of Patients’ Rights in Europe of 1994,²² the Council of Europe’s Convention on Human Rights and Biomedicine of 1997 and its Additional Protocols,²³ as well as the Unesco Universal Declarations on the Human Genome and Human Rights of 1997 and on Bioethics and Human Rights of 2005.²⁴ To these documents it is also worth adding the WHO Guidelines for Good Clinical

of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. . . .” Among the several relevant contributions, see Weindling (2004).

¹⁸ A collection of the relevant texts is reported in den Exter (2011).

¹⁹ WMA, International Code of Medical Ethics, adopted by the 3rd General Assembly of the World Medical Association, London, October 1949, as amended in 1968, 1983 and 2006.

²⁰ WMA, Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects, adopted by the 18th World Medical Assembly, Helsinki, June 1964, as subsequently amended and revised up to October 2008.

²¹ WMA, Declaration on the Rights of the Patient, adopted by the 34th World Medical Assembly, Lisbon, September/October 1981, and amended by the 47th WMA General Assembly Bali, Indonesia, September 1995.

²² WHO/EURO, European Consultation on the Rights of Patients, Amsterdam 28–30 March 1994, A Declaration on the Promotion of Patients’ Rights in Europe, ICP/HLE 121, 28 June 1994 (hereinafter Amsterdam Declaration).

²³ See Chapter II of the Oviedo Convention; see also Articles 13, 14 and 17 of the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin, Strasbourg, 24 January 2002, ETS No. 186, entered into force on 1 May 2006; Chapters IV and V of the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research, Strasbourg, 25 January 2005, ETS No. 195, entered into force on 1 September 2007; Articles 9 to 15 of the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes, Strasbourg, 27 November 2008, ETS No. 203, not yet in force.

²⁴ See Article 5 of the Universal Declaration on the Human Genome and Human Rights, 11 November 1997, and Articles 6 and 7 of the 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 International Declaration on Human Genetic Data, 16 October 2003, in particular Articles 8, 9 and 16.

Practice,²⁵ 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,²⁶ and at regional level, the European Union Clinical Trials Directive of 2001.²⁷

In light of the above-mentioned instruments, it is indisputable that the doctrine of informed consent is today widely acknowledged as the expression of one of the basic principles of 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. In fact, according to its generally recognised scope, informed consent provides 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 implies 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: the person must have legal capacity to give consent and must also be conscious and fully competent; consent must result from a decision-making process devoid of any element of force, fraud, deceit, duress, threat, or any other form of constraint or coercion. Moreover, consent must be based on the appropriate disclosure to the patient, by the responsible healthcare professional, of adequate and understandable information concerning the diagnostic assessment, purpose, method, likely duration, expected benefit, and chances of success of the proposed treatment; alternative modes of treatment, including those less intrusive; possible pain or discomfort, risks and side effects of the proposed treatment; chances and risks associated with lack of treatment. In this sense, what is called "genuine consent"²⁸ represents the very foundation of legitimacy for any medical treatment, so much so that interventions and care provided without prior consent, even if administered in the patient's best interest, may be qualified as illegal 'bodily assaults' and may trigger both civil and criminal liability of health care providers.²⁹

²⁵ WHO, Guidelines for Good Clinical Practice for Trials on Pharmaceutical Products (Geneva, 1995). See also the UN Special Rapporteur's recommendations as formulated in his Report containing the Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines (U.N. Doc. A/63/263, 11 August 2008, paragraphs 21–22).

²⁶ CIOMS-WHO, International Ethical Guidelines for Biomedical Research Involving Human Subjects (Geneva, 2002), Guideline 4, p. 32.

²⁷ 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 trials on medicinal products for human use, Official Journal of the European Communities, L 121/34, 1 May 2001.

²⁸ On the concepts of 'genuine consent' or 'understood consent', see Bhutta (2004), pp. 773–774.

²⁹ See Justice Cardozo in *Schloendorff v. Society of New York Hospital*, supra note 16: "a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages".

Only a few derogations to the above-mentioned rules are allowed for compelling reasons or in particular situations and in respect of vulnerable patients,³⁰ that is to say in case of medical emergency,³¹ de facto incapacity (e.g. patients who have become incompetent in consequence of an accident or patients in a state of coma), reduced capacity of understanding (e.g. adults with mental disorders³²), or limited legal capacity (minors and incapacitated adults). In such circumstances, informed consent is provided by a legal representative (guardian or proxy) with the association to the decision-making process of the person concerned and his active participation to the fullest extent that his capacity allows.³³ However, 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,³⁴ 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.³⁵ Moreover, according to well-established standards, whenever the patient is unable to give consent and there is no legal representative or proxy, appropriate measures should be taken to provide for a substitute decision-making process (for example, an independent body provided for by law), taking into account what is known and, to the greatest possible extent, what may be presumed about the wishes of the patient.³⁶

In respect to derogations from the basic rule of informed consent, it is remarkable that according to international (hard and soft) biolaw such exceptions are admitted 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

³⁰ See Selinger (2009). It should 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, paragraph 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.

³¹ See Article 8 of the Oviedo Convention and paragraphs 56–58 of the Explanatory report; see also Amsterdam Declaration, paragraphs 3.4, 3.6, 3.7.

³² See 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 Health Care, General Assembly Resolution 46/119 of 17 December 1991; Progress of efforts to ensure the full recognition and enjoyment of the human rights of persons with disabilities, Report of the Secretary-General, U.N. Doc. A/58/181, 24 July 2003; Report of Paul Hunt, Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, U.N. Doc. E/CN.4/2005/51, 11 February 2005 (hereinafter 'Report 2005').

³³ See Article 6 of the Oviedo Convention and the Amsterdam Declaration, paragraph 3.5.

³⁴ Amsterdam Declaration, paragraph 3.4.

³⁵ Amsterdam Declaration, paragraph 3.6.

³⁶ Amsterdam Declaration, paragraph 3.7; see also Explanatory report to the Oviedo Convention, paragraph 57.

law” and subject to compliance with international human rights law.³⁷ These important caveats, included in the Oviedo Convention,³⁸ 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,³⁹ recall very closely the pattern of lawful limitations adopted within conventional human rights regimes⁴⁰ and lend support to the argument that informed consent is a rule grounded in international law, especially human rights law, just as much as it is in bioethics and medical law.

2.2 Informed Consent and Universal Human Rights

2.2.1 Informed Consent and the Right to Physical Integrity

Although it is expressly enunciated only in a few 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 is considered as an element of the rights to the 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 main legal sources at the universal level are Article 5 of the Universal Declaration of Human Rights and Article 7 of the International Covenant on Civil and Political Rights (ICCPR). This latter provision, which is aimed at protecting both the dignity and the psychophysical integrity of the individual,⁴¹ specifies that no medical

³⁷ See Article 9 of the Universal Declaration on the Human Genome and Article 6 of the Universal Declaration on Bioethics and Human Rights. According to Article 27 of the latter, such compelling reasons may include the need to protect public safety and public health, a situation that finds application in Article 23, paragraph 3, and Article 31, paragraph 2, of the International Health Regulations (2005), legitimising States to apply health measures to travellers, including compulsory examination and vaccination, when there is evidence of an imminent public health risk. However, it is interesting to note that the protection afforded by the International Covenant on Civil and Political Rights under Article 7 is even stricter than the one guaranteed by the norms of international biolaw, since that provision allows no derogations or limitation, not even in times of emergency (Article 4, paragraph 2).

³⁸ 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 Andorno (2005b), p. 136).

³⁹ Commission on Human Rights, Resolution 2003/69, Human rights and bioethics, adopted by consensus on 25 April 2003; Committee of Ministers, Recommendation R(99)4 to Member States on Principles Governing the Legal Protection of Incapable Adults, 23 February 1999, principle 28.

⁴⁰ Compare the proviso 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 Fidler (2000), pp. 293–294.

⁴¹ 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.

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