

**General Assembly**

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**Ad Hoc Committee on an International Convention
against the Reproductive Cloning of Human Beings**

25 February-1 March 2002

Information document prepared by the Secretariat**A. Introduction**

1. The General Assembly, in its resolution 56/93 of 12 December 2001, decided to establish the Ad Hoc Committee on an International Convention against the Reproductive Cloning of Human Beings, and also decided that the Ad Hoc Committee would meet from 25 February to 1 March 2002 to consider the elaboration of a mandate for the negotiation of such an international convention, including a list of the existing international instruments to be taken into consideration and a list of issues to be addressed in the convention.
2. Pursuant to that resolution, the present document, in section B, contains a list of international instruments, adopted at both global and regional levels, prepared by the Secretariat for the convenience of delegations. While no attempt has been made to provide an exhaustive listing of all instruments, the list includes legal and other instruments containing norms and guidelines pertaining to the reproductive cloning of human beings.
3. In addition, a list of selected international instruments dealing with other relevant or related issues, such as the rights of the individual, biotechnology and medical and scientific research, is presented in section C also for the information of delegations. The list includes documents developed by international professional associations.
4. Section D contains a list of instruments from which general examples of penal, moratorium and review provisions have been drawn for inclusion in annex I, on the request of delegations.
5. Annex I to the present document contains selected excerpts from the listed instruments, arranged by topic, and is intended to be without prejudice to the eventual inclusion of any particular topic or issue in the list of issues to be addressed in the convention. The order of the sections in annex I has been revised to reflect more closely the order of the list of issues proposed in document A/AC.263/2002/DP.1.

6. Annex II contains, also for the benefit of delegations, a further list of selected key reports on the question of human reproductive cloning and bioethics, prepared either under the auspices of various United Nations bodies and specialized agencies, or by regional intergovernmental organizations.

B. Selected international instruments concerning the reproductive cloning of human beings

Global instruments

United Nations Educational, Scientific and Cultural Organization

- Universal Declaration on the Human Genome and Human Rights, 11 November 1997

United Nations General Assembly

- Resolution 53/152 on the human genome and human rights, 9 December 1998

United Nations Commission on Human Rights

- Resolution 2001/71 on human rights and bioethics, 25 April 2001
- Resolution 1999/63 on human rights and bioethics, 28 April 1999
- Resolution 1997/71 on human rights and bioethics, 16 April 1997
- Resolution 1995/82 on human rights and bioethics, 8 March 1995
- Resolution 1993/91 on human rights and bioethics, 10 March 1993

World Health Organization

- Resolution WHA 51.10 on ethical, scientific and social implications of cloning in human health, 16 May 1998
- Resolution WHA 50.37 on cloning in human reproduction, 14 May 1997

Regional instruments and documents

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, 4 April 1997
- Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings, 12 January 1998
- Council of Europe, Parliamentary Assembly, Order No. 534 (1997) on research and the cloning of human beings, 23 September 1997
- Council of Europe, Parliamentary Assembly, Recommendation 1046 (1986) on the use of human embryos and fetuses for diagnostic, therapeutic, scientific, industrial and commercial purposes, 24 September 1986

- Council of Europe, Parliamentary Assembly, Recommendation 1100 (1989) on the use of human embryos and fetuses in scientific research, 2 February 1989
- Council of Europe, Parliamentary Assembly, Opinion No. 202 (1997) on the draft additional protocol to the Convention on Human Rights and Biomedicine on the prohibition of cloning human beings, 23 September 1997

European Union

- Charter of Fundamental Rights of the European Union, 7 December 2000
- European Council, Declaration on Banning the Cloning of Human Beings, 16 June 1997
- European Parliament, Resolution on human cloning, 7 September 2000
- European Parliament, Resolution on human cloning, 15 January 1998
- European Parliament, Resolution on cloning, 12 March 1997
- European Parliament, Resolution on the cloning of the human embryo, 22 November 1993
- European Parliament, Resolution on the ethical and legal problems of genetic engineering, 17 March 1989

Organization of African Unity

- Resolution on bioethics, 32nd Assembly of OAU Heads of State and Government, 10 July 1996

Group of Eight

- Communiqué, Denver Summit of the Eight, 22 June 1997

C. Other instruments dealing with related issues

United Nations Environment Programme

- Convention on Biological Diversity, 1992

United Nations General Assembly

- Universal Declaration of Human Rights, 1948
- International Covenant on Civil and Political Rights, 1966

World Trade Organization (WTO)

- Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS), 15 April 1994
- Ministerial Declaration adopted on 14 November 2001 at the Fourth Session of the Ministerial Conference, held at Doha from 9 to 14 November 2001
- Declaration on the TRIPS Agreement and Public Health adopted on 14 November 2001 at the Fourth Session of the Ministerial Conference, held at Doha from 9 to 14 November 2001

Council of Europe

- Council of Europe, Parliamentary Assembly, Recommendation 1468 (2000) on biotechnologies, 29 June 2000
- Council of Europe, Parliamentary Assembly, Recommendation 1425 (1999) on biotechnology and intellectual property, 23 September 1999

European Union

- Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions, 6 July 1998
- Decision 182/1999/EC of the European Parliament and of the Council concerning the fifth framework programme of the European Community for research, technological development and demonstration activities, 1 February 1999
- Council Decision 1999/167/EC adopting a specific programme for research, technological development and demonstration on quality of life and management of living resources, 12 March 1999

European Patent Office (EPO)

- European Patent Convention, 1973

Group of Eight (G-8)

- G-8 Communiqué, Kyushu-Okinawa Summit 2000, 23 July 2000

Relevant documents prepared by international professional associations

World Medical Association (WMA)

- Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects, June 1964
- Resolution on cloning, adopted by the 147th Council Session of the World Medical Association, Paris, May 1997, and endorsed by the 49th WMA General Assembly, Hamburg, Germany, November 1997

D. Instruments from which examples of penal, moratorium and review provisions have been drawn

- Convention for the Suppression of Unlawful Acts against the Safety of Civil Aviation, 1971
- Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, 1972
- Convention on the Prevention and Punishment of Crimes Against Internationally Protected Persons, including Diplomatic Agents, 1973
- Convention on International Trade in Endangered Species of Wild Fauna and Flora, 1973

- Convention on Long-Range Transboundary Air Pollution, 1979
- Convention for the Prohibition of Fishing with Long Driftnets in the South Pacific, 1989
- International Convention for the Suppression of Terrorist Bombings, 1997
- International Convention for the Suppression of the Financing of Terrorism, 1999
- United Nations Convention against Transnational Organized Crime, 2000
- General Assembly resolution 2574 D (XXIV) of 15 December 1969
- General Assembly resolution 44/225 of 22 December 1989
- General Assembly resolution 46/215 of 20 December 1991
- General Assembly resolution 48/75 K of 16 December 1993
- Convention on the Safety of United Nations and Associated Personnel, 1994
- General Assembly resolution 50/70 O of 12 December 1995

Annex I

Selected excerpts arranged by topic

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*Instrument**Excerpts***1. General provisions****(a) Global instruments****(i) United Nations Educational,
Scientific and Cultural
Organization (UNESCO)**

Universal Declaration on the
Human Genome and Human
Rights, 11 November 1997

Article 1

The human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity. In a symbolic sense, it is the heritage of humanity.

Article 2

(a) Everyone has a right to respect for their dignity and for their rights regardless of their genetic characteristics.

(b) That dignity makes it imperative not to reduce individuals to their genetic characteristics and to respect their uniqueness and diversity.

**(ii) United Nations General
Assembly**

Resolution 53/152 on the human
genome and human rights,
9 December 1998

*Third preambular
para.*

Recalling also that, in accordance with the Universal Declaration of Human Rights, recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family is the foundation of freedom, justice and peace in the world,

*Fourth preambular
para.*

Aware of the rapid development of the life sciences and of ethical concerns raised by certain of their applications with regard to the dignity of the human race and the rights and freedoms of the individual,

*Fifth preambular
para.*

Seeking to promote scientific and technical progress in the fields of biology and genetics in a manner respectful of fundamental rights and for the benefit of all,

*Single operative
para.*

Endorses the Universal Declaration on the Human Genome and Human Rights adopted by the General Conference of the United Nations Educational, Scientific and Cultural Organization on 11 November 1997;

(iii) World Health Organization (WHO)

a. Resolution WHA 51.10 on ethical, scientific and social implications of cloning in human health, 16 May 1998

First preambular para.

Recalling resolution WHA 50.37 and its condemnation of human cloning for reproductive purposes as contrary to human dignity;

Second preambular para.

Noting the general consensus reached at the national and international levels since the Fifth World Health Assembly regarding human cloning for reproductive purposes;

Third preambular para.

Noting in particular UNESCO's Universal Declaration on the Human Genome and Human Rights and the Council of Europe's Additional Protocol to the Convention on Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, which deal with the prohibition of cloning of human beings;

Fourth preambular para.

Considering that the currently available information from animal studies involving cloning by somatic cell nuclear transfer indicates that this would be an unsafe procedure for reproductive purposes in the human;

Fifth preambular para.

Recognizing that developments in cloning have unprecedented ethical implications and raise serious matters for concern in terms of safety of the individual and subsequent generations of human beings,

Para. 1

Reaffirms that cloning for the replication of human individuals is ethically unacceptable and contrary to human dignity and integrity;

b. Resolution WHA 50.37 on cloning in human reproduction, 14 May 1997

Para. 1

Affirms that the use of cloning for the replication of human individuals is ethically unacceptable and contrary to human dignity and morality;

(b) Regional instruments and documents

(i) Council of Europe

a. Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, of 4 April 1997. (Convention on Human Rights

Article 2

The interests and welfare of the human being shall prevail over the sole interest of society or science.

<i>Instrument</i>	<i>Excerpts</i>
and Biomedicine) (Council of Europe document DIR/JUR(96)14, European Treaty Series No. 164)	
b. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings, 12 January 1998 (European Treaty Series No. 168)	<p><i>First preambular para.</i> Noting scientific developments in the field of mammal cloning, particularly through embryo splitting and nuclear transfer;</p> <p><i>Fifth preambular para.</i> Considering however that the instrumentalization of human beings through the deliberate creation of genetically identical human beings is contrary to human dignity and thus constitutes a misuse of biology and medicine;</p> <p><i>Sixth preambular para.</i> Considering also the serious difficulties of a medical, psychological and social nature that such a deliberate biomedical practice might imply for all the individuals involved;</p>
(ii) European Union (EU)	
a. Charter of Fundamental Rights of the European Union, adopted at Nice, France, 7 December 2000 (2000 O.J. (C 364) 01)	<p><i>Article 1</i> Human dignity is inviolable. It must be respected and protected.</p> <p><i>Article 3 (1)</i> Everyone has the right to respect for his or her physical and mental integrity.</p>
b. European Council, Declaration on Banning the Cloning of Human Beings, 16 June 1997 (<i>Bulletin of the European Union</i> 6-1997, Annexes to the Proceedings of the Presidency, 7/7)	<i>Para. 1</i> [The] European Council notes that the growth of new technologies in the area of genetic engineering poses acute ethical problems.
c. European Parliament, Resolution on human cloning, 7 September 2000 (<i>Bulletin of the European Union</i> 9-2000, Human Rights, 5/12)	<i>Preambular para. F</i> ... there is a consensus within the Community that interventions in the human germ line and the cloning of human beings offends against <i>ordre public</i> and morality,

<i>Instrument</i>		<i>Excerpts</i>
	<i>Para. 2</i>	Considers that “therapeutic cloning”, which involves the creation of human embryos solely for research purposes, poses a profound ethical dilemma, irreversibly crosses a boundary in research norms and is contrary to public policy as adopted by the European Union.
d. European Parliament, Resolution on human cloning, 15 January 1998 (1998 O.J. (C 34) 164 (15 January 1998))	<i>Preambular para. C</i>	... the cloning of human beings, whether carried out on an experimental basis, in the context of fertility treatments, pre-implantation diagnosis, for tissue transplantation or for any other purpose whatsoever, is unethical, morally repugnant, contrary to respect for the person and a grave violation of fundamental human rights which cannot under any circumstance be justified or accepted,
	<i>Para. 1</i>	Reiterates that every individual has the right to his own genetic identity and that human cloning must be prohibited;
e. European Parliament, Resolution on cloning, 12 March 1997 (1997 O.J. (C 115) 14.4/92 (12 March 1997))	<i>Preambular para. A</i>	... cloning breaks new ethical ground and has led to great public concern,
	<i>Preambular para. B</i>	... the cloning of human beings, whether experimentally, in the context of fertility treatment, pre-implantation diagnosis, tissue transplantation or for any other purpose whatsoever, cannot under any circumstances be justified or tolerated by any society, because it is a serious violation of fundamental human rights and is contrary to the principle of equality of human beings as it permits a eugenic and racist selection of the human race, it offends against human dignity and it requires experimentation on humans,
	<i>Preambular para. 1</i>	Stresses that each individual has a right to his or her own genetic identity and that human cloning is, and must continue to be, prohibited;
f. European Parliament, Resolution on the ethical and legal problems of genetic engineering, 17 March 1989 (<i>Official Journal</i> C 96, 17 April 1989, pp. 165-171)	<i>Preambular para. D</i>	... genome analysis may, on the one hand, bring about possible improvements in diagnostics, preventive medicine and therapy, but on the other, entails the risk of creating compulsory eugenic and preventive objectives, of applying genetic analysis for the purpose of social control

Instrument	Excerpts
g. European Parliament, Resolution on the cloning of the human embryo (<i>Official Journal</i> C 315, 22 November 1993)	<p>and the segregation of whole social strata, of selecting embryos and fetuses on the basis of their genetic characteristics alone and of producing fundamental changes in our society,</p> <p><i>Para. 29</i> Considers that the legal status of the human embryo must be defined to provide unequivocal protection of genetic identity;</p> <p><i>Para. 30</i> Considers that even [if] a recombination of genes only partly alters the genotype, the identity of the individual is falsified, which is both irresponsible and unjustifiable because a very individual legal asset is involved;</p> <p><i>Para. 32</i> procedures involving live human embryos or fetuses or experiments on them are justified only if they are of direct and otherwise unattainable benefit in terms of the welfare of the child concerned and its mother and respect the physical and mental integrity of the woman in question;</p> <p><i>Preambular para. C</i> In the firm conviction that the cloning of human beings, whether on an experimental basis, in the context of fertility treatments, pre-implantation diagnosis, for tissue transplantation or for any other purpose whatsoever, is unethical, morally repugnant, contrary to respect for the person, and a grave violation of fundamental human rights which cannot under any circumstances be justified or accepted,</p> <p><i>Para. 1</i> Condemns the cloning of humans for any purpose whatsoever, including research, as a grave violation of fundamental human rights, contrary to respect for the individual, morally repugnant, and ethically unacceptable;</p>
(iii) Organization of African Unity (OAU)	
Resolution on bioethics, 32nd Assembly of OAU Heads of State and Government, 10 July 1996 (AHG/Res.254 (XXXII))	<p><i>Fifth preambular para.</i> <i>Recognizing</i> the rapid progress achieved in the area of life sciences, and the dangers which could be posed to the dignity and integrity of the individual by certain practices;</p> <p><i>Para. 3</i> <i>Pledges</i> to promote within the continent the following universal rights and principles under conditions of respect for cultural, social and religious values: ...</p>

- (b) Inviolability of the human body and of the genetic heritage of the human species,
- (f) Supervision of research facilities on embryos, especially those produced as a result of medical procedures offering assistance towards procreation, and the attendant application of such procedures, so as to obviate selective eugenic by-products, particularly those relating to sex considerations,

(c) Other instruments dealing with related issues

(i) United Nations Environment Programme (UNEP)

Convention on Biological Diversity, 1992 (United Nations, *Treaty Series*, vol. 1760, No. 30619, p. 79) *Article 15 (1)*

Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national Governments and is subject to national legislation.

(ii) United Nations General Assembly

Universal Declaration of Human Rights, 1948 (resolution 217 A (III) of 10 December 1948) *Article 1*

All human beings are born free and equal in dignity and rights ...

2. Definitions

(a) Regional instruments and documents

(i) Council of Europe

a. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings, of 12 January 1998 (European Treaty Series No. 168) *Article 1*

1. Any intervention seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited;
2. For the purpose of this article, the term human being “genetically identical” to another human being means a human being sharing with another the same nuclear gene set.

b. Council of Europe, Parliamentary Assembly, Recommendation 1100 (1989) on the use of human embryos and *Appendix, para. 25*

“[V]iable” embryos shall be understood to mean embryos which are free of biological characteristics likely to prevent their development; however, the non-viability of

Instrument	Excerpts
foetuses in scientific research, of 2 February 1989, adopted by the Assembly, 40th Ordinary Session, 3rd Part, 30 January-3 February 1989	human embryos and foetuses shall be determined solely by objective biological criteria based on the embryo's intrinsic defects.
(ii) European Union (EU)	
a. European Parliament, Resolution on human cloning, of 7 September 2000 (<i>Bulletin of the European Union</i> 9-2000, Human Rights, 5/12)	[P]arliament defines human cloning as the creation of embryos having the same genetic make-up as another human being, dead or alive, at any stage of their development, without any possible distinction as regards the method used,
b. European Parliament, Resolution on human cloning, of 15 January 1998 (1998 O.J. (C 34) 164 (15 January 1998))	[H]uman cloning is defined as the creation of human embryos having the same genetic make-up as another human being, dead or alive, at any stage of its development from the moment of fertilization, without any possible distinction as regards the method used,
(b) Other instruments dealing with related issues	
United Nations Environment Programme (UNEP)	
Convention on Biological Diversity, of 1992 (United Nations, <i>Treaty Series</i> , vol. 1760, No. 30619, p. 79)	“Genetic material” means any material of plant, animal, microbial or other origin containing functional units of heredity. “Genetic resources” means genetic material of actual or potential value.
3. Prohibition	
(a) Global instruments	
World Health Organization (WHO)	
Resolution WHA 51.10 on ethical, scientific and social implications of cloning in human health, 16 May 1998	<i>Urges</i> member States to foster continued and informed debate on these issues and to take appropriate steps, including legal and judicial measures, to prohibit cloning for the purpose of replicating human individuals;
(b) Regional instruments and documents	
(i) Council of Europe	
a. Convention for the Protection	Tests which are predictive of genetic diseases or

<i>Instrument</i>		<i>Excerpts</i>
of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, of 4 April 1997 (Convention on Human Rights and Biomedicine) (Council of Europe document DIR/JUR(96)14, European Treaty Series No. 164)		which serve either to identify the subject as a carrier of a gene responsible for a disease or to detect a genetic predisposition or susceptibility to disease may be performed only for health purposes or for scientific research linked to health purposes, and subject to appropriate genetic counselling.
	<i>Article 13</i>	An intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants.
	<i>Article 18</i>	... 2. The creation of human embryos for research purposes is prohibited.
	<i>Article 26</i>	No restrictions shall be placed on the exercise of the rights and protective provisions contained in this Convention other than such as are prescribed by law and are necessary in a democratic society in the interest of public safety, for the prevention of crime, for the protection of public health or for the protection of the rights and freedoms of others.
	<i>Article 27</i>	None of the provisions of this Convention shall be interpreted as limiting or otherwise affecting the possibility for a Party to grant a wider measure of protection with regard to the application of biology and medicine than is stipulated in this Convention.
b. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings, of 12 January 1998 (European Treaty Series No. 168)	<i>Article 1</i>	1. Any intervention seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited; 2. For the purpose of this article, the term human being “genetically identical” to another human being means a human being sharing with another the same nuclear gene set.
c. Council of Europe, Parliamentary Assembly, Order No. 534 (1997) on research and the cloning of human beings, of	<i>Para. 2</i>	The Assembly, in its Opinion No. 202 (1997), has supported the principle that any intervention seeking to create a human being genetically identical to another human being, whether living

<i>Instrument</i>	<i>Excerpts</i>
23 September 1997, adopted by the Assembly, 1997 Ordinary Session, Fourth Part, 22-26 September 1997	or dead (“genetically identical human beings” meaning “human beings sharing the same nuclear gene set”), should be prohibited.
<i>Para. 3</i>	The Assembly and the European Parliament have also called for an explicit worldwide ban on the cloning of human beings.
d. Council of Europe, Parliamentary Assembly, Recommendation 1046 (1986) on the use of human embryos and foetuses for diagnostic, therapeutic, scientific, industrial and commercial purposes, 24 September 1986, adopted by the Assembly, 38th Ordinary Session, 2nd Part, 17-25 September 1986	<p data-bbox="885 562 1419 583"><i>Para. 14.A</i></p> <p data-bbox="885 562 1419 583">Recommends that the Committee of Ministers:</p> <p data-bbox="885 615 1419 636">Call on the Governments of the member States:</p> <p data-bbox="885 678 906 699">...</p> <p data-bbox="885 720 1455 1062">ii. To limit the use of human embryos and foetuses and materials and tissues therefrom in an industrial context to purposes which are strictly therapeutic and for which no other means exist, according to the principles set out in the appendix, and to bring their legislation in line with these principles or to enact rules in accordance therewith which should, inter alia, specify the conditions in which removal and use may be undertaken for a diagnostic or therapeutic purpose;</p> <p data-bbox="885 1104 906 1125">...</p> <p data-bbox="885 1146 1455 1234">iv. To forbid anything that could be considered as undesirable use or deviations of these techniques, including:</p> <ul data-bbox="927 1262 1455 1686" style="list-style-type: none"> <li data-bbox="927 1262 1455 1350">– The creation of identical human beings by cloning or any other method, whether for race selection purposes or not; <li data-bbox="927 1377 1455 1434">– The implantation of a human embryo in the uterus of another animal or the reverse; <li data-bbox="927 1461 1455 1518">– The fusion of human gametes with those of another animal ... <li data-bbox="927 1545 1455 1602">– The creation of embryos from the sperm of different individuals; <li data-bbox="927 1629 1455 1686">– The fusion of embryos or any other operation which might produce chimeras;

<i>Instrument</i>	<i>Excerpts</i>
<p>e. Council of Europe, Parliamentary Assembly, Recommendation 1100 (1989) on the use of human embryos and fetuses in scientific research, 2 February 1989, adopted by the Assembly, 40th Ordinary Session, 3rd Part, 30 January-3 February 1989</p>	<ul style="list-style-type: none"> – Ectogenesis, or the production of an individual and autonomous human being outside the uterus of a female, that is, in a laboratory; – The creation of children from people of the same sex; – Choice of sex by genetic manipulation for non-therapeutic purposes; – The creation of identical twins; – Research on viable human embryos; – Experimentation on living human embryos, whether viable or not; – The maintenance of embryos in vitro beyond the fourteenth day after fertilization (having deducted any time necessary for freezing); <p>Embryos at the pre-implantation stage which have been expelled spontaneously from the uterus shall in no circumstances be re-transferred back.</p>
	<p><i>Appendix, para. 7</i></p> <p><i>Appendix, para. 9</i></p> <p>The removal of cells, tissues or embryonic or foetal organs, or the placenta or membranes, if live, for investigations other than of a diagnostic character and for preventive or therapeutic purposes shall be prohibited.</p>
	<p><i>Appendix, para. 11</i></p> <p>Persons removing embryos or fetuses or parts therefrom from the uterus without clinical or legal justification or without the prior consent of the pregnant woman and, where appropriate, of her husband or partner in a stable relationship, and persons using such embryological materials in breach of the relevant legislation or regulations shall be duly penalized.</p>
	<p><i>Appendix, para. 16</i></p> <p>The use of biological matter from dead embryos or fetuses for scientific, preventive, diagnostic, therapeutic, pharmaceutical, clinical or surgical purposes shall be permitted within the framework</p>

Instrument	Excerpts
<p>f. Council of Europe, <i>Para. 8</i> Parliamentary Assembly, Opinion No. 202 (1997) on the draft additional protocol to the Convention on Human Rights and Biomedicine on the prohibition of cloning human beings, 23 September 1997, adopted by the Assembly, 1997 Ordinary Session, 4th Part, 22-26 September 1997</p>	<p>of the rules governing investigation, experimentation, diagnosis and therapy, in accordance with the terms of this recommendation.</p> <p>... the Assembly recommends that the Committee of Ministers:</p> <p>...</p> <p>v. Ask the United Nations General Assembly to adopt provisions for an explicit worldwide ban on the cloning of human beings, seeking inspiration from the Council of Europe's additional protocol on the prohibition of cloning human beings;</p>
<p>(ii) European Union (EU)</p> <p>a. Charter of Fundamental <i>Article 3 (2)</i> Rights of the European Union, adopted at Nice, France, 7 December 2000 (2000 O.J. (C 364) 01)</p>	<p>In the fields of medicine and biology, the following must be respected in particular:</p> <p>...</p> <ul style="list-style-type: none"> – The prohibition of eugenic practices, in particular those aiming at the selection of persons; – The prohibition on making the human body and its parts as such a source of financial gain; – The prohibition of the reproductive cloning of human beings.
<p>b. European Council, <i>Para. 4</i> Declaration on Banning the Cloning of Human Beings, June 1997 (<i>Bulletin of the European Union</i> 6-1997, Annexes to the Proceedings of the Presidency, 7/7)</p>	<p>The European Council also stresses the determination of the member States, for their part, to take all measures necessary to prohibit human cloning.</p>
<p>c. European Parliament, <i>Para. 9</i> Resolution on human cloning, 7 September 2000 (<i>Bulletin of the European Union</i> 9-2000, Human Rights, 5/12)</p>	<p>... the best way to implement this decision is to ensure that no research institution that is in any way involved in the cloning of human embryos gets money from the EU budget for any of their work;</p>

<i>Instrument</i>		<i>Excerpts</i>
	<i>Para. 10</i>	Repeats its insistence that there should be a universal and specific ban at the level of the United Nations on the cloning of human beings at all stages of formation and development;
d. European Parliament, Resolution on human cloning, 15 January 1998 (1998 O.J. (C 34) 164 (15 January 1998))	<i>Para. 1</i>	Reiterates that every individual has the right to his own genetic identity and that human cloning must be prohibited;
	<i>Para. 4</i>	Calls on member States, the European Union and the United Nations to take all the steps necessary to bring about a universal and specific ban, which is legally binding, on the cloning of human beings, including the convening of a world conference on this subject;
	<i>Para. 6</i>	Reminds the Council of Parliament's insistence that no Community funds should be used, directly or indirectly, for research programmes which make use of human cloning, and calls for confirmation that this prohibition is being fully applied;
e. European Parliament, Resolution on cloning, of 12 March 1997 (1997 O.J. (C 115) 14.4/92 (12 March 1997))	<i>Para. 1</i>	Stresses that each individual has a right to his or her own genetic identity and that human cloning is, and must continue to be, prohibited;
	<i>Para. 2</i>	Calls for an explicit worldwide ban on the cloning of human beings;
f. European Parliament, Resolution on the cloning of the human embryo (<i>Official Journal</i> C 315, 22 November 1993)	<i>Para. 7</i>	Urges the Community to take initiatives in the appropriate international forums aimed at achieving an international accord for a worldwide ban on the cloning of humans, and declares its wish to participate in such negotiations;
g. European Parliament, Resolution on the ethical and legal problems of genetic engineering, 17 March 1989 (<i>Official Journal</i> C 96, 17/04/1989 pp. 165-171)	<i>Para. 27</i>	Calls for an absolute ban on all experiments designed to reorganize on an arbitrary basis the genetic make-up of humans;
	<i>Para. 38</i>	Insists that any commercial or industrial use of embryos or foetuses, whether it involves the production of in vitro fertilized embryos for such purposes or imports of embryos or foetuses from third countries, must be a criminal offence;

Instrument	Excerpts
Para. 40	Calls for trade in frozen embryos for scientific, industrial or commercial purposes to be prohibited and made a criminal offence;
Para. 41	Considers that the only possible response to the possibility of producing humans by cloning and to experiments with a view to the cloning of humans must be to make them a criminal offence;
Para. 42	<p>Calls for the following to be prohibited as criminal offences:</p> <ul style="list-style-type: none"> – The generation of viable hybrid embryos with various genomes and using human DNA; – Fertilization of a human egg cell with animal sperm or the fertilization of an animal egg cell with human sperm to produce a viable embryo; – The transfer of the cell combinations or embryos referred to above to a woman; – All experiments designed to generate chimera and hybrids using human and animal genetic material;
(iii) Organization of African Unity (OAU)	
Resolution on Bioethics, 32nd Assembly of OAU Heads of State and Government, 10 July 1996 (AHG/Res.254 (XXXII))	<p>Para. 3</p> <p><i>Pledges</i> to promote within the continent the following universal rights and principles under conditions of respect for cultural, social and religious values:</p> <p>...</p> <p>(c) Inalienability of the person, which prohibits the subjection of the human body, its components, particularly the human genes and the sequences thereof, to commercial and property rights purposes,</p>
(iv) Group of Eight (G-8)	
Communiqué, Denver Summit of the Eight, 22 June 1997	<p>Para. 47</p> <p>... need for appropriate domestic measures and close international cooperation to prohibit the use of somatic cell nuclear transfer to create a child.</p>

4. National implementation, sanctions and moratoria

(a) Regional instruments and documents

(i) Council of Europe

a. Council of Europe, *Para. 9.A*
Parliamentary Assembly,
Recommendation 1100 (1989) on
the use of human embryos and
foetuses in scientific research,
2 February 1989, adopted by the
Assembly, 40th Ordinary Session,
3rd Part, 30 January-3 February
1989

Recommends that the Committee of
Ministers:

Provide a framework of principles from
which national laws or regulations can be
developed in as universal and uniform a
manner as possible, as proposed by its
Recommendations 934 (1982) and 1046
(1986) as well as by this recommendation
and its appendix;

b. Council of Europe, *Para. 14.A*
Parliamentary Assembly,
Recommendation 1046 (1986) on
the use of human embryos and
foetuses for diagnostic,
therapeutic, scientific, industrial
and commercial purposes, 24
September 1986, adopted by the
Assembly, 38th Ordinary Session,
2nd Part, 17-25 September 1986

Recommends that the Committee of Ministers:

Call on the Governments of the member States:

...

ii. To limit the use of human embryos and
foetuses and materials and tissues therefrom in an
industrial context to purposes which are strictly
therapeutic and for which no other means exist,
according to the principles set out in the
appendix, and to bring their legislation in line
with these principles or to enact rules in
accordance therewith which should, inter alia,
specify the conditions in which removal and use
may be undertaken for a diagnostic or therapeutic
purpose;

...

v. To provide appropriate sanctions to ensure the
application of the rules enacted pursuant to this
recommendation;

c. Council of Europe, *Para. 8*
Parliamentary Assembly, Opinion
No. 202 (1997) on the draft
additional protocol to the
Convention on Human Rights and
Biomedicine on the prohibition of
cloning human beings,
23 September 1997, adopted by
the Assembly, 1997 Ordinary

... the Assembly recommends that the Committee
of Ministers:

...

iv. Call on Governments of Council of Europe
member and observer States, in line with the
provisions of the draft additional protocol on the
prohibition of cloning human beings, to create
and implement legislation that bans any

Instrument	Excerpts
Session, 4th Part, 22-26 September 1997	intervention seeking to create a human being genetically identical to another human being, whether living or dead (“genetically identical human beings” meaning “human beings sharing the same nuclear gene set”), and to provide for severe penal sanctions to deal with any violation. The parties should, however, guarantee the protection of human beings resulting from genetic interventions, albeit prohibited under the additional protocol to the Convention on Human Rights and Biomedicine;
(ii) European Union (EU)	
a. European Parliament, Resolution on human cloning, 7 September 2000 (<i>Bulletin of the European Union</i> 9-2000, Human Rights, 5/12)	Para. 4 Repeats its call to each member State to enact binding legislation prohibiting all research into any kind of human cloning within its territory and providing for criminal penalties for any breach;
Para. 8	Calls on the appropriate national and Community authorities to ensure that the ban on patenting or cloning human beings is reaffirmed and to adopt rules to this end;
b. European Parliament, Resolution on human cloning, 15 January 1998 (1998 O.J. (C 34) 164 (15 January 1998))	Para. 3 Calls on each member State to enact binding legislation prohibiting all research on human cloning within its territory and providing for criminal sanctions for any breach;
c. European Parliament, Resolution on cloning, of 12 March 1997 (1997 O.J. (C 115) 14.4/92 (12 March 1997))	Para. 3 Urges the member States to ban the cloning of human beings at all stages of formation and development, regardless of the method used, and to provide for penal sanctions to deal with any violation;
d. European Parliament, Resolution on the ethical and legal problems of genetic engineering, 17 March 1989 (<i>Official Journal</i> C 96, 17/04/1989 pp. 165-171)	Para. 28 Calls for legislation prohibiting any gene transfer to human germ line cells;
Para. 38	Insists that any commercial or industrial use of embryos or fetuses, whether it involves the production of in vitro fertilized embryos for such purposes or imports of embryos or fetuses from third countries, must be a criminal offence;

Instrument	Excerpts
Para. 40	Calls for trade in frozen embryos for scientific, industrial or commercial purposes to be prohibited and made a criminal offence;
Para. 41	Considers that the only possible response to the possibility of producing humans by cloning and to experiments with a view to the cloning of humans must be to make them a criminal offence;
Para. 42	<p>Calls for the following to be prohibited as criminal offences:</p> <ul style="list-style-type: none"> – The generation of viable hybrid embryos with various genomes and using human DNA; – Fertilization of a human egg cell with animal sperm or the fertilization of an animal egg cell with human sperm to produce a viable embryo; – The transfer of the cell combinations or embryos referred to above to a woman; – All experiments designed to generate chimera and hybrids using human and animal genetic material;
(iii) Group of Eight (G-8)	
Communiqué, Denver Summit of the Eight, 22 June 1997	Para. 47 ... need for appropriate domestic measures ... to prohibit the use of somatic cell nuclear transfer to create a child.
(b) Other instruments dealing with related issues	
United Nations Environment Programme (UNEP)	
Convention on Biological Diversity, 1992 (United Nations, <i>Treaty Series</i> , vol. 1760, No. 30619, p. 79)	Article 15 (1) Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national Governments and is subject to national legislation.

Instrument

Excerpts

(c) Selected examples from penal instruments

(i) Convention for the Suppression of Unlawful Acts against the Safety of Civil Aviation, 1971 (United Nations, <i>Treaty Series</i> , vol. 974, p. 178)	<i>Article 5</i>	1. Each Contracting State shall take such measures as may be necessary to establish its jurisdiction over the offences in the following cases: ... 3. This Convention does not exclude any criminal jurisdiction exercised in accordance with national law.
(ii) Convention on the Safety of United Nations and Associated Personnel, 1994 (United Nations, <i>Treaty Series</i> , vol. 2051, p. 363)	<i>Article 9</i>	2. Each State Party shall make the crimes set out in paragraph 1 punishable by appropriate penalties which shall take into account their grave nature.
	<i>Article 13</i>	1. Where the circumstances so warrant, the State Party in whose territory the alleged offender is present shall take the appropriate measures under its national law to ensure that person's presence for the purpose of prosecution or extradition.
	<i>Article 17</i>	1. Any person regarding whom investigations or proceedings are being carried out in connection with any of the crimes set out in article 9 shall be guaranteed fair treatment, a fair trial and full protection of his or her rights at all stages of the investigations or proceedings.
(iii) International Convention for the Suppression of Terrorist Bombings, 1997 (General Assembly resolution 52/164, annex)	<i>Eleventh preambular para.</i>	... the exclusion of certain actions from the coverage of this Convention does not condone or make lawful otherwise unlawful acts, or preclude prosecution under other laws,
	<i>Article 4</i>	Each State Party shall adopt such measures as may be necessary: (a) To establish as criminal offences under its domestic law the offences set forth in article 2 of this Convention;
	<i>Article 5</i>	(b) To make those offences punishable by appropriate penalties which take into account the grave nature of those offences. Each State Party shall adopt such measures as may be necessary, including, where appropriate, domestic legislation, to ensure that criminal acts within the scope of this Convention ... are

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Excerpts

(iv) International Convention for the Suppression of the Financing of Terrorism, 1999 (General Assembly resolution 54/109, annex)

Article 8

punished by penalties consistent with their grave nature.

1. Each State Party, in accordance with its domestic legal principles, shall take the necessary measures to enable a legal entity located in its territory or organized under its laws to be held liable when a person responsible for the management or control of that legal entity has, in that capacity, committed an offence as set forth in article 2. Such liability may be criminal, civil or administrative.

2. Such liability is incurred without prejudice to the criminal liability of individuals who have committed the offences.

3. Each State Party shall ensure, in particular, that legal entities liable in accordance with paragraph 1 above are subject to effective, proportionate and dissuasive criminal, civil or administrative sanctions. Such sanctions may include monetary sanctions.

1. Each State Party shall take appropriate measures, in accordance with its domestic legal principles, for the identification, detection and freezing or seizure of any funds used or allocated for the purpose of committing the offences set forth in article 2 as well as the proceeds derived from such offences, for purposes of possible forfeiture.

2. Each State Party shall take appropriate measures, in accordance with its domestic legal principles, for the forfeiture of funds used or allocated for the purpose of committing the offences set forth in article 2 and the proceeds derived from such offences.

3. Each State Party concerned may give consideration to concluding agreements on the sharing with other States Parties, on a regular or case-by-case basis, of the funds derived from the forfeitures referred to in this article.

4. Each State Party shall consider establishing mechanisms whereby the funds derived from the forfeitures referred to in this article are utilized to compensate the victims of offences referred to in

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(v) United Nations Convention *Article 11*
 against Transnational Organized
 Crime, 2000 (General Assembly
 resolution 55/25, annex I)

article 2, paragraph 1, subparagraph (a) or (b), or their families.

5. The provisions of this article shall be implemented without prejudice to the rights of third parties acting in good faith.

1. Each State Party shall make the commission of an offence established in accordance with articles 5, 6, 8 and 23 of this Convention liable to sanctions that take into account the gravity of that offence.

2. Each State Party shall endeavour to ensure that any discretionary legal powers under its domestic law relating to the prosecution of persons for offences covered by this Convention are exercised to maximize the effectiveness of law enforcement measures in respect of those offences and with due regard to the need to deter the commission of such offences.

3. In the case of offences established in accordance with articles 5, 6, 8 and 23 of this Convention, each State Party shall take appropriate measures, in accordance with its domestic law and with due regard to the rights of the defence, to seek to ensure that conditions imposed in connection with decisions on release pending trial or appeal take into consideration the need to ensure the presence of the defendant at subsequent criminal proceedings.

4. Each State Party shall ensure that its courts or other competent authorities bear in mind the grave nature of the offences covered by this Convention when considering the eventuality of early release or parole of persons convicted of such offences.

5. Each State Party shall, where appropriate, establish under its domestic law a long statute of limitations period in which to commence proceedings for any offence covered by this Convention and a longer period where the alleged offender has evaded the administration of justice.

6. Nothing contained in this Convention shall affect the principle that the description of the offences established in accordance with this Convention and of the applicable legal defences

<i>Instrument</i>	<i>Excerpts</i>
	<p>or other legal principles controlling the lawfulness of conduct is reserved to the domestic law of a State Party and that such offences shall be prosecuted and punished in accordance with that law.</p> <p><i>Article 12</i></p> <p>1. States Parties shall adopt, to the greatest extent possible within their domestic legal systems, such measures as may be necessary to enable confiscation of:</p> <p>(a) Proceeds of crime derived from offences covered by this Convention or property the value of which corresponds to that of such proceeds;</p> <p>(b) Property, equipment or other instrumentalities used in or destined for use in offences covered by this Convention.</p> <p>2. States Parties shall adopt such measures as may be necessary to enable the identification, tracing, freezing or seizure of any item referred to in paragraph 1 of this article for the purpose of eventual confiscation.</p> <p>...</p> <p>9. Nothing contained in this article shall affect the principle that the measures to which it refers shall be defined and implemented in accordance with and subject to the provisions of the domestic law of a State Party.</p>
<p>(d) Selected examples of moratorium provisions</p> <p>(i) Anti-personnel land mines</p> <p>a. General Assembly resolution 50/70 O of 12 December 1995</p> <p><i>Para. 1</i></p> <p><i>Para. 2</i></p> <p><i>Para. 3</i></p>	<p>Welcomes the moratoria already declared by certain States on the export of anti-personnel landmines;</p> <p>Urges States that have not yet done so to declare such moratoria at the earliest possible date;</p> <p>Requests the Secretary-General to prepare a report on steps taken by Member States to implement such moratoria, and to submit it to the General Assembly at its fifty-first session under the item entitled "General and complete disarmament";</p>

Instrument	Excerpts
b. General Assembly resolution 48/75 K of 16 December 1993	<p><i>Fourth preambular para.</i> Convinced that a moratorium by States exporting anti-personnel landmines that pose grave dangers to civilian populations would reduce substantially the human and economic costs resulting from the use of such devices ...,</p> <p><i>Fifth preambular para.</i> Noting with satisfaction that several States have already declared moratoria on the export, transfer or purchase of anti-personnel landmines and related devices,</p> <p><i>Para. 1</i> Calls upon States to agree to a moratorium on the export of anti-personnel landmines that pose grave dangers to civilian populations;</p> <p><i>Para. 2</i> Urges States to implement such a moratorium;</p> <p><i>Para. 3</i> Requests the Secretary-General to prepare a report concerning progress on this initiative, including possible recommendations regarding further appropriate measures to limit the export of anti-personnel landmines, and to submit it to the General Assembly at its forty-ninth session under the item entitled "General and complete disarmament".</p>
(ii) Driftnet fishing	
a. General Assembly resolution 46/215 of 20 December 1991	<p><i>Para. 3</i> Calls upon all members of the international community to implement resolutions 44/225 and 45/197 by, inter alia, taking the following actions:</p> <p>...</p> <p>(c) Ensure that a global moratorium on all large-scale pelagic driftnet fishing is fully implemented on the high seas of the world's oceans and seas, including enclosed seas and semi-enclosed seas, by 31 December 1992;</p>
b. General Assembly resolution 44/225 of 22 December 1989	<p><i>Para. 4</i> Also recommends that all members of the international community ... agree to the following measures:</p> <p>(a) Moratorium should be imposed on all large-scale pelagic driftnet fishing by 30 June 1992, with the understanding that such a measure will not be imposed in a region or, if implemented, can be lifted, should effective conservation and management measures be taken based upon statistically sound analysis to be jointly made by concerned parties of the international community</p>

Instrument		Excerpts
		with an interest in the fishery resources of the region, to prevent the unacceptable impact of such fishing practices on that region and to ensure the conservation of the living marine resources of that region;
(iii) Seabed		
General Assembly resolution 2574 D (XXIV) of 15 December 1969	<i>Sole para.</i>	Declares that, pending the establishment of the aforementioned international regime:
		(a) States and persons, physical or juridical, are bound to refrain from all activities of exploitation of the resources of the area of the seabed and ocean floor, and the subsoil thereof, beyond the limits of national jurisdiction;
		(b) No claim to any part of that area or its resources shall be recognized.
5. Intellectual property and commercialization aspects		
(a) Global instruments		
United Nations Educational, Scientific and Cultural Organization (UNESCO)		
Universal Declaration on the Human Genome and Human Rights, 11 November 1997	<i>Article 4</i>	The human genome in its natural state shall not give rise to financial gains.
(b) Regional instruments and documents		
(i) 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, of 4 April 1997. (Convention on Human Rights and Biomedicine) (Council of Europe document DIR/JUR(96)14, European Treaty Series No. 164)	<i>Article 21</i>	The human body and its parts shall not, as such, give rise to financial gain.
(ii) European Union (EU)		
European Parliament, Resolution on the ethical and legal problems	<i>Para. 38</i>	Insists that any commercial or industrial use of embryos or fetuses, whether it involves the

Instrument	Excerpts
of genetic engineering, 17 March 1989 (<i>Official Journal C</i> 96, 17/04/1989 pp. 165-171)	production of in vitro fertilized embryos for such purposes or imports of embryos or foetuses from third countries, must be a criminal offence;
Para. 40	Calls for trade in frozen embryos for scientific, industrial or commercial purposes to be prohibited and made a criminal offence;
(iii) Organization of African Unity (OAU)	
a. Resolution on Bioethics, 32nd Assembly of OAU Heads of State and Government, 10 July 1996 (AHG/Res.254 (XXXII))	Pledges to promote within the continent the following universal rights and principles under conditions of respect for cultural, social and religious values: ...
	(c) Inalienability of the person, which prohibits the subjection of the human body, its components, particularly the human genes and the sequences thereof, to commercial and property rights purposes,
(c) Other instruments dealing with related issues	
(i) United Nations Environment Programme (UNEP)	
Convention on Biological Diversity, of 1992 (United Nations, <i>Treaty Series</i> , vol. 1760, No. 30619, p. 79)	... In the case of technology subject to patents and other intellectual property rights, such access and transfer shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights ...
(ii) World Trade Organization (WTO)	
a. Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS), 15 April 1994 (Marrakesh Agreement establishing the World Trade Organization, annex 1C, United Nations, <i>Treaty Series</i> , vol. 1869, No. I-31874, p. 299)	Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect <i>ordre public</i> or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

<i>Instrument</i>		<i>Excerpts</i>
	<i>Article 27 (3)</i>	Members may also exclude from patentability:
		(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
		...
b. Ministerial Declaration	<i>Para. 19</i>	
adopted on 14 November 2001 at		
the Fourth Session of the		
Ministerial Conference, held at		
Doha from 9 to 14 November		
2001 (WT/MIN(01)/DEC/1)		We instruct the Council for TRIPS, in pursuing its work programme including under the review of article 27.3(b) ..., to examine, inter alia, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore, and other relevant new developments raised by members pursuant to article 71.1. In undertaking this work, the TRIPS Council shall be guided by the objectives and principles set out in articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension.
c. Declaration on the TRIPS	<i>Para. 4</i>	
Agreement and Public Health,		
adopted on 14 November 2001 at		
the Fourth Session of the		
Ministerial Conference, held at		
Doha from 9 to 14 November		
2001 (WT/MIN(01)/DEC/2)		... the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.
(iii) Council of Europe		
Council of Europe, Parliamentary	<i>Para. 12</i>	
Assembly, Recommendation		
1425 (1999) on biotechnology		
and intellectual property,		
23 September 1999 (<i>Official</i>		
<i>Gazette</i> — Parliamentary		
Assembly — September 1999,		
No. VI/99 (1999))		... neither plant-, animal- nor human-derived genes, cells, tissues or organs can be considered as inventions, nor be subject to monopolies granted by patents.
	<i>Para. 13</i>	
		... the Assembly recommends that the Committee of Ministers, in cooperation with the European Union, the World Intellectual Property Organization, the Food and Agriculture Organization of the United Nations, the World Trade Organization, the United Nations Educational, Scientific and Cultural Organization, and in accordance with the Convention on Biological Diversity:
		(iv) Discuss a suitable alternative system of

Instrument		Excerpts
		<p>protecting intellectual property in the field of biotechnology ...</p> <p>(vi) Consider the ethical aspects of the patentability of inventions involving biological and, in particular, human material.</p>
(iv) European Union (EU)		
<p>Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions, 6 July 1998 (<i>Official Journal</i> L 213, pp. 13-21)</p>	<p><i>Article 5</i></p>	<ol style="list-style-type: none"> 1. The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions. 2. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element. <p>...</p>
	<p><i>Article 6</i></p>	<ol style="list-style-type: none"> 1. Inventions shall be considered unpatentable where their commercial exploitation would be contrary to <i>ordre public</i> or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation. 2. On the basis of paragraph 1, the following, in particular, shall be considered unpatentable: <ol style="list-style-type: none"> (a) Processes for cloning human beings; (b) Processes for modifying the germ line genetic identity of human beings; (c) Uses of human embryos for industrial or commercial purposes; <p>...</p>
(v) European Patent Office (EPO)		
<p>European Patent Convention, 1973 (United Nations, <i>Treaty Series</i>, vol. 1065, No. I-16208, p. 199)</p>	<p><i>Article 53</i></p>	<p>European patents shall not be granted in respect of:</p> <p>(a) Inventions the publication or exploitation of which would be contrary to <i>ordre public</i> or</p>

Instrument		Excerpts
		<p>morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;</p>
<p>(vi) Group of Eight (G-8)</p>		
<p>G-8 Communiqué, Kyushu-Okinawa Summit, 2000, 23 July 2000</p>	<p><i>Para. 63</i></p>	<p>We recognize the need for a balanced and equitable intellectual property protection for gene-based inventions, based wherever possible on common practices and policies. We encourage further efforts in relevant international forums to achieve broad harmonization of patenting policies of biotechnological inventions.</p>
<p>6. Preventive measures/research</p>		
<p>(a) Global instruments</p>		
<p>(i) United Nations Educational, Scientific and Cultural Organization (UNESCO)</p>		
<p>Universal Declaration on the Human Genome and Human Rights, 11 November 1997</p>	<p><i>Article 10</i></p>	<p>No research or research application concerning the human genome, in particular in the fields of biology, genetics and medicine, should prevail over respect for the human rights, fundamental freedoms and human dignity of individuals or, where applicable, of groups of people.</p>
	<p><i>Article 12</i></p>	<p>(a) Benefits from advances in biology, genetics and medicine, concerning the human genome, shall be made available to all, with due regard for the dignity and human rights of each individual.</p> <p>(b) Freedom of research, which is necessary for the progress of knowledge, is part of the freedom of thought. The applications of research, including applications in biology, genetics and medicine, concerning the human genome, shall seek to offer relief from suffering and improve the health of individuals and humankind as a whole.</p>
	<p><i>Article 13</i></p>	<p>The responsibilities inherent in the activities of researchers, including meticulousness, caution, intellectual honesty and integrity in carrying out their research as well as in the presentation and utilization of their findings, should be the subject of particular attention in the framework of research on the human genome, because of its</p>

Instrument	Excerpts
<i>Article 19 (a)</i>	<p>ethical and social implications. Public and private science policy makers also have particular responsibilities in this respect.</p> <p>... States should seek to encourage measures enabling:</p> <p>(i) Assessment of the risks and benefits pertaining to research on the human genome to be carried out and abuse to be prevented;</p> <p>...</p> <p>(iii) Developing countries to benefit from the achievements of scientific and technological research so that their use in favour of economic and social progress can be to the benefit of all;</p> <p>(iv) The free exchange of scientific knowledge and information in the areas of biology, genetics and medicine to be promoted.</p>
(ii) United Nations Commission on Human Rights	
a. Resolution 2001/71 on human rights and bioethics, 25 April 2001	<i>Para. 6</i>
b. Resolution 1999/63 on human rights and bioethics, 28 April 1999	<i>Para. 5</i>
(b) Regional instruments and documents	
(i) Council of Europe	
a. Convention for the Protection	<i>Article 15</i>
	Scientific research in the field of biology and

Instrument	Excerpts
<p>of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, of 4 April 1997. (Convention on Human Rights and Biomedicine) (Council of Europe document DIR/JUR(96)14, European Treaty Series No. 164)</p>	<p>medicine shall be carried out freely, subject to the provisions of this Convention and the other legal provisions ensuring the protection of the human being.</p>
<i>Article 18</i>	<p>1. Where the law allows research on embryos in vitro, it shall ensure adequate protection of the embryo.</p> <p>2. The creation of human embryos for research purposes is prohibited.</p>
<p>b. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings, of 12 January 1998 (European Treaty Series No. 168)</p>	<i>Second preambular para.</i>
<p>Mindful of the progress that some cloning techniques themselves may bring to scientific knowledge and its medical application;</p>	
<p>c. Council of Europe, Parliamentary Assembly, Order No. 534 (1997) on research and the cloning of human beings, of 23 September 1997, adopted by the Assembly, 1997 Ordinary Session, Fourth Part, 22-26 September 1997</p>	<i>Para. 4</i>
<p>The Assembly is of the opinion that work likely to lead to the cloning of humans should not be carried out.</p>	
<p>d. Council of Europe, Parliamentary Assembly, Recommendation 1100 (1989) on the use of human embryos and fetuses in scientific research, 2 February 1989, adopted by the Assembly, 40th Ordinary Session, 3rd Part, 30 January-3 February 1989</p>	<i>Appendix, para. 3</i>
<p>The human gametes employed for investigation or experimentation shall not be used to create zygotes or embryos in vitro for the purpose of procreation.</p>	
<i>Appendix, para. 4</i>	<p>... investigations of viable embryos in vitro shall only be permitted:</p>

*Instrument**Excerpts*

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| <i>Appendix, para. 5</i> | <ul style="list-style-type: none"> – For applied purposes of a diagnostic nature or for preventive or therapeutic purposes; – If their non-pathological genetic heritage is not interfered with. <p>... research on living embryos must be prohibited, particularly:</p> <ul style="list-style-type: none"> – If the embryo is viable; – If it is possible to use an animal model; – If not foreseen within the framework of projects duly presented to and authorized by the appropriate public health or scientific authority or, by delegation, to and by the relevant national multidisciplinary committee; – If not within the time limits laid down by the authorities mentioned above. |
| <i>Appendix, para. 6</i> | <p>... any proposed investigation which meets the above conditions [in paragraph 5] for authorization must be excluded:</p> <ul style="list-style-type: none"> – Unless it is accompanied by all the required details on the embryonic material to be used, its source, foreseen time limits of implementation and the aims pursued; – Unless, on completion of the investigation, those responsible agree to inform the authorizing body of its outcome. |
| <i>Appendix, para. 14</i> | <p>Experiments on living embryos or fetuses, whether viable or not, shall be prohibited. Nonetheless, where a State authorizes certain experiments on non-viable fetuses or embryos only, these experiments must be undertaken in accordance with the terms of this recommendation and subject to prior authorization from the health or scientific authorities or, where applicable, the national multidisciplinary body.</p> |
| <i>Appendix, para. 17</i> | <p>Genetic technology shall only be used for investigations on or with human or recombinant genetic material if appropriate authorization has been obtained. Such authorization shall be granted on the basis of the soundness of projects,</p> |

Instrument	Excerpts
	full details being provided as regards their location, aims, duration and the biological material to be used; it shall be granted by the competent authorities or, by delegation, by the national multidisciplinary body.
<i>Appendix, para. 18</i>	<p>Scientific research projects on genetic engineering using genetic or recombinant genetic material shall be permitted, subject to approval:</p> <ul style="list-style-type: none"> – For diagnostic purposes ... – For industrial purposes of a preventive, diagnostic or therapeutic nature ... – For therapeutic purposes ... – For purposes of scientific investigation ... – For any other purpose considered useful and beneficial to the individual and to humanity, and incorporated in projects already approved.
<i>Appendix, para. 19</i>	Investigations or acts involving genetic technology shall only be authorized at centres and establishments which have been registered, approved and authorized for such purposes, and which have the requisite specialized personnel and technical resources.
<i>Appendix, para. 20</i>	The donation of human embryological material shall be authorized solely for scientific research on diagnostic, prevention or therapeutic purposes. Its sale shall be prohibited.
<p>e. Council of Europe, Parliamentary Assembly, Recommendation 1046 (1986) on the use of human embryos and foetuses for diagnostic, therapeutic, scientific, industrial and commercial purposes, 24 September 1986, adopted by the Assembly, 38th Ordinary Session, 2nd Part, 17-25 September 1986</p>	<p><i>Para. 14.A</i></p> <p>Recommends that the Committee of Ministers:</p> <p>Call on the Governments of the member States:</p> <p>...</p> <p>iii. To forbid any creation of human embryos by fertilization in vitro for the purposes of research during their life or after death;</p>
(ii) European Union (EU)	
<p>a. Charter of Fundamental Rights of the European Union (2000) (2000 O.J. (C 364) 01)</p>	<p><i>Article 13</i></p> <p>The arts and scientific research shall be free of constraint. Academic freedom shall be respected.</p>

Instrument	Excerpts
b. Decision 182/1999/EC of the European Parliament and of the Council concerning the fifth framework programme of the European Community for research, technological development and demonstration activities, 1998-2002 (O.J., L.26, 1 February 1999, pp. 1-32)	<p><i>Annex II, sect. II, First Activity, Theme 1(b), footnote 2</i></p> <p>No research activity which modifies or is intended to modify the genetic heritage of human beings by alteration of germ cells or by acting at any other stage in embryonic development and which can make such an alteration heritable will be carried out under the present framework programme. In the same way, no research activity, understood in the sense of the term “cloning”, will be conducted with the aim of replacing a germ or embryo cell nucleus with that of the cell of any individual, a cell from an embryo or a cell coming from a late stage of development to the human embryo.</p>
c. Council Decision 1999/167/EC adopting a specific programme for research, technological development and demonstration on quality of life and management of living resources, 1998-2002 (O.J., L.64, 12 March 1999, pp. 1-19)	<p><i>Annex II(b), footnote 1</i></p> <p>In the same way, no research activity understood in the sense of the term “cloning”, with the aim of replacing a germ or embryo cell nucleus with that of the cell of any individual, a cell from an embryo or a cell coming from a later stage of development to the human embryo, will be supported.</p>
d. European Council, Declaration on Banning the Cloning of Human Beings, June 1997 (<i>Bulletin of the European Union</i> 6-1997, Annexes to the Proceedings of the Presidency, 7/7)	<p><i>Para. 3</i></p> <p>Considering in particular that the protection of the human being and respect for the integrity of the human being are essential principles to which no exception can be made, the European Council invites the Council and the Commission, when defining Community policies, in particular on research and intellectual property, and when implementing existing programmes, to consider how human cloning may be prevented ...</p>
e. European Parliament, Resolution on human cloning, 7 September 2000 (<i>Bulletin of the European Union</i> 9-2000, Human Rights, 5/12)	<p><i>Preambular para. B</i> ... the undoubted need for medical research resulting from advances in knowledge of human genetics must be balanced against strict ethical and social constraints,</p> <p><i>Preambular para. C</i> ... there are other ways than embryonic cloning of curing serious illnesses, such as those that involve taking stem cells from adults or from the umbilical cords of newborn babies, and other external causes of disease which require research,</p> <p><i>Preambular para. D</i> Whereas the Fifth Framework programme and Council Decision 1999/167/EC of 25 January 1999 adopting a specific programme for research, technological development and demonstration on quality of life and management of living</p>

Instrument	Excerpts
f. European Parliament, Resolution on human cloning, 15 January 1998 (1998 O.J. (C 34) 164 (15 January 1998))	<p>resources (1998 to 2002) state: “In the same way, no research activity understood in the sense of the term ‘cloning’, with the aim of replacing a germ or embryo cell nucleus with that of the cell of any individual, a cell from an embryo or a cell coming from a later stage of development to the human embryo, will be supported”,</p> <p><i>Preamble para. E</i> ... there is a prohibition on the use of community funds, either directly or indirectly, for any such research,</p> <p><i>Para. 6</i> Reaffirms its support for biotechnological scientific research in medicine, provided that [it] is balanced against strict ethical and social constraints;</p> <p><i>Preamble para. D</i> ... scientific research, which is one of the keys to human progress, must be pursued ... however, it may not undermine the dignity and integrity of the human being,</p> <p><i>Para. 5</i> Calls on the international scientific community, in carrying out research on the human genome, to refrain from the cloning of human beings;</p>
g. European Parliament, Resolution on cloning, 12 March 1997 (1997 O.J. (C 115) 14.4/92 (12 March 1997))	<p><i>Para. 11</i> Calls on researchers and doctors engaged in research on the human genome to abstain spontaneously from participating in the cloning of human beings until the entry into force of a legally binding ban;</p>
h. European Parliament, Resolution on the ethical and legal problems of genetic engineering, 17 March 1989 (<i>Official Journal C</i> 96, 17/04/1989 pp. 165-171)	<p><i>Para. 7</i> Reaffirms the principle of freedom of science and research.</p> <p><i>Para. 8</i> Regards the restraints imposed on the freedom of science and research, arising in particular from the rights of third parties and the society they constitute, as the expression in legal terms of the responsibility assumed by society as a whole for the action of the scientist and for research;</p> <p><i>Para. 31</i> Considers that the zygote also needs protection and therefore must not be subject to arbitrary experimentation ...</p>

Instrument	Excerpts
<p style="text-align: right;"><i>Para. 37</i></p> <p>(iii) Organization of African Unity (OAU)</p>	<p>Demands that the use of dead human embryos for therapeutic or scientific purposes be restricted in the same way as the use of human corpses;</p>
<p>Resolution on bioethics, 32nd Assembly of OAU Heads of State and Government, July 1996 (AHG/Res.254 (XXXII))</p> <p style="text-align: right;"><i>Para. 3</i></p>	<p><i>Pledges</i> to promote within the continent the following universal rights and principles under conditions of respect for cultural, social and religious values:</p> <p>...</p> <p>(f) Supervision of research facilities on embryos, especially those produced as a result of medical procedures offering assistance towards procreation, and the attendant application of such procedures, so as to obviate selective eugenic by-products, particularly those relating to sex considerations,</p>
<p>(c) Other instruments dealing with related issues</p>	
<p>(i) United Nations Environment Programme (UNEP)</p>	
<p>Convention on Biological Diversity, 1992 (United Nations, <i>Treaty Series</i>, vol. 1760, No. 30619, p. 79)</p> <p style="text-align: right;"><i>Article 15 (7)</i></p>	<p>Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, ... with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.</p>
<p>(ii) United Nations General Assembly</p>	
<p>International Covenant on Civil and Political Rights, of 16 December 1966 (United Nations, <i>Treaty Series</i>, vol. 999, No. I-14668, p. 171, and vol. 1057, No. A-14668, p. 407)</p> <p style="text-align: right;"><i>Article 7</i></p>	<p>... no one shall be subjected without his free consent to medical or scientific experimentation.</p>

**(d) Relevant documents prepared
by international professional
associations**

**(i) World Medical Association
(WMA)**

a. Declaration of Helsinki:
Ethical Principles for Medical
Research Involving Human
Subjects, adopted in June 1964¹

Para. 8

Medical research is subject to ethical standards that promote respect for all human beings and protect their health and rights ...

Para. 10

It is the duty of the physician in medical research to protect the life, health, privacy and dignity of the human subject.

Para. 13

The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol. This protocol should be submitted for consideration, comment, guidance, and where appropriate, approval to a specially appointed ethical review committee, which must be independent of the investigator, the sponsor or any other kind of undue influence. This independent committee should be in conformity with the laws and regulations of the country in which the research experiment is performed. The committee has the right to monitor ongoing trials. The researcher has the obligation to provide monitoring information to the committee, especially any serious adverse events. The researcher should also submit to the committee, for review, information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest and incentives for subjects.

Para. 14

The research protocol should always contain a statement of the ethical considerations involved and should indicate that there is compliance with the principles enunciated in this Declaration.

Para. 15

Medical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human subject must always

¹ As amended by the 29th WMA General Assembly, Tokyo, October 1975; the 35th WMA General Assembly, Venice, Italy, October 1983; 41st WMA General Assembly, Hong Kong, September 1989; 48th WMA General Assembly, Somerset West, South Africa, October 1996; and the 52nd WMA General Assembly, Edinburgh, Scotland, October 2000.

<i>Instrument</i>	<i>Excerpts</i>
	rest with a medically qualified person and never rest on the subject of the research, even though the subject has given consent.
<i>Para. 16</i>	Every medical research project involving human subjects should be preceded by careful assessment of predictable risks and burdens in comparison with foreseeable benefits to the subject or to others ...
<i>Para. 17</i>	Physicians should abstain from engaging in research projects involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. Physicians should cease any investigation if the risks are found to outweigh the potential benefits or if there is conclusive proof of positive and beneficial results.
<i>Para. 21</i>	The right of research subjects to safeguard their integrity must always be respected. Every precaution should be taken to respect the privacy of the subject, the confidentiality of the patient's information and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.
b. Resolution on cloning, adopted by the 147th Council Session of the World Medical Association, Paris, May 1997, and endorsed by the 49th WMA General Assembly, Hamburg, Germany, November 1997	<i>Para. 3</i> The World Medical Association hereby calls on doctors engaged in research and other researchers to abstain voluntarily from participating in the cloning of human beings until the scientific, ethical and legal issues have been fully considered by doctors and scientists, and any necessary controls put in place.

7. Reporting/monitoring mechanisms

(a) Global instruments

(i) United Nations Commission on Human Rights

a. Resolution 2001/71 on human rights and bioethics, 25 April 2001

Para. 4

Invites the Secretary-General ... to consider establishing a working group of independent experts from, inter alia, the United Nations Educational, Scientific and Cultural Organization, the World Health Organization and the World Intellectual Property Organization, which would reflect, in particular, on the possible follow-up to the Universal Declaration on the

<i>Instrument</i>	<i>Excerpts</i>
	<p>Human Genome and Human Rights and report to the Secretary-General within a period to be determined by him;</p> <p><i>Para. 7</i></p> <p><i>Invites</i> Governments to consider establishing independent, multidisciplinary and pluralist committees of ethics to assess, notably in conjunction with the International Bioethics Committee of the United Nations Educational, Scientific and Cultural Organization, the ethical, social and human questions raised by the biomedical research undergone by human beings and, in particular, research relating to the human genome and its applications, and also invites them to inform the Secretary-General of the establishment of any such bodies, with a view to promoting exchanges of experience between such institutions;</p>
<p>b. Resolution 1999/63 on human rights and bioethics, 28 April 1999</p> <p><i>Para. 2</i></p>	<p><i>Invites</i> the United Nations Educational, Scientific and Cultural Organization, the World Health Organization, the Office of the [United Nations] High Commissioner for Human Rights, and the other United Nations bodies and specialized agencies concerned to report to the Secretary-General on the activities conducted in their respective areas to ensure that the principles set forth in the Universal Declaration on the Human Genome and Human Rights are taken into account;</p> <p>...</p>
	<p><i>Para. 6</i></p> <p><i>Invites</i> Governments to consider establishing independent, multidisciplinary and pluralist committees of ethics to assess, notably in conjunction with the International Bioethics Committee of the United Nations Educational, Scientific and Cultural Organization, the ethical, social and human questions raised by the biomedical research undergone by human beings and, in particular, research relating to the human genome and its applications, and also invites them to inform the Secretary-General of the establishment of any such bodies, with a view to promoting exchanges of experience between such institutions;</p>

<i>Instrument</i>		<i>Excerpts</i>
c. Resolution 1997/71 on human rights and bioethics, 16 April 1997	<i>Para. 2</i>	<i>Invites</i> Governments, the specialized agencies and other organizations of the United Nations system, in particular the United Nations Educational, Scientific and Cultural Organization and the World Health Organization, and other intergovernmental, particularly regional, organizations and non-governmental organizations to inform the Secretary-General of activities being carried out to ensure that the life sciences develop in a manner respectful of human rights and beneficial to humanity as a whole;
	<i>Para. 5</i>	<i>Invites</i> Governments to consider establishing independent, multidisciplinary and pluralist committees of ethics to assess, notably in conjunction with the International Bioethics Committee of the United Nations Educational, Scientific and Cultural Organization, the ethical, social and human questions raised by the biomedical research undergone by human beings and, in particular, research relating to the human genome and its applications, and also invites them to inform the Secretary-General of the establishment of any such bodies, with a view to promoting exchanges of experience between such institutions;
d. Resolution 1995/82 on human rights and bioethics, 8 March 1995	<i>Para. 2</i>	<i>Invites</i> Governments, the specialized agencies and other organizations of the United Nations system, in particular the United Nations Educational, Scientific and Cultural Organization and the World Health Organization, and other intergovernmental, particularly regional, organizations and non-governmental organizations to inform the Secretary-General of activities being carried out to ensure that the life sciences develop in a manner respectful of human rights and beneficial to humanity as a whole;
	<i>Para. 3</i>	<i>Invites</i> States to inform the Secretary-General of legislative or other measures taken to this effect, including the possible establishment of national consultative bodies, with a view to promoting exchanges of experience between such institutions;
e. Resolution 1993/91 on human rights and bioethics, 10 March 1993	<i>Para. 1</i>	<i>Invites</i> Governments, the specialized agencies and other organizations of the United Nations system, in particular the United Nations Educational, Scientific and Cultural Organization

Instrument	Excerpts
	<p>and the World Health Organization, and other intergovernmental, particularly regional, organizations and non-governmental organizations to inform the Secretary-General of activities being carried out to ensure that the life sciences develop in a manner respectful of human rights;</p>
<p><i>Para. 2</i></p>	<p><i>Invites</i> States to inform the Secretary-General of legislative or other measures taken to this effect, including the possible establishment of national consultative bodies, with a view to promoting exchanges of experience between such institutions;</p>
<p>(ii) World Health Organization (WHO)</p>	
<p>a. Resolution WHA 51.10 on ethical, scientific and social implications of cloning in human health, 16 May 1998</p>	<p><i>Para. 3</i></p> <p><i>Requests</i> the Director:</p> <p>(1) To establish a group, involving also government experts, with the aim of clarifying concepts and developing guidelines relating to the use of cloning procedures for non-reproductive purposes;</p> <p>(2) To continue to monitor, assess and clarify, in consultation with other international organizations, national governments and professional and scientific bodies, the ethical, scientific, social and legal implications of the use of cloning for human health; ...</p>
<p>b. Resolution WHA 50.37 on cloning in human reproduction, 14 May 1997</p>	<p><i>Fifth preambular para.</i></p> <p>Recognizing that developments in cloning and other genetic procedures have unprecedented ethical implications, and considering that related research and development should therefore be carefully monitored and assessed, and the rights and dignity of patients respected,</p>
<p>(b) Regional instruments and documents</p>	
<p>(i) Council of Europe</p>	
<p>a. Council of Europe, Parliamentary Assembly, Recommendation 1100 (1989) on the use of human embryos and fetuses in scientific research, 2 February 1989, adopted by the</p>	<p><i>Para. 9.B</i></p> <p>Recommends that the Committee of Ministers:</p> <p>...</p> <p>Invite the Governments of member States:</p> <p>(i) To set up as a matter of urgency ... national or</p>

<i>Instrument</i>		<i>Excerpts</i>
Assembly, 40th Ordinary Session, 3rd Part, 30 January-3 February 1989		regional multidisciplinary bodies ...
	<i>Para. 9.D</i>	Recommends that the Committee of Ministers: ... Establish as a matter of urgency, as a safeguard, an international multidisciplinary body to ensure convergent approaches by the national bodies already operating or to be set up in accordance with subparagraph 9.B (i) above, and to avoid thereby the creation of “genetic havens”.
b. Council of Europe, Parliamentary Assembly, Recommendation 1046 (1986) on the use of human embryos and foetuses for diagnostic, therapeutic, scientific, industrial and commercial purposes, 24 September 1986, adopted by the Assembly, 38th Ordinary Session, 2nd Part, 17-25 September 1986	<i>Para. 14.A</i>	Recommends that the Committee of Ministers: Call on the Governments of the member States: ... vi. To create national registers of accredited medical centres authorized to carry out such techniques and to make use of them for scientific purposes;
c. Council of Europe, Parliamentary Assembly, Opinion No. 202 (1997) on the draft additional protocol to the Convention on Human Rights and Biomedicine on the prohibition of cloning human beings, 23 September 1997, adopted by the Assembly, 1997 Ordinary Session, 4th Part, 22-26 September 1997	<i>Para. 8</i>	... the Assembly recommends that the Committee of Ministers: ... vi. Encourage member States to improve and increase information and education on biotechnological research related to human beings with a view to enhancing public support for the principles contained in the Convention on Human Rights and Biomedicine and its additional protocols;
(ii) European Union (EU)		
a. European Parliament, Resolution on cloning, 12 March 1997 (1997 O.J. (C 115) 14.4/92 (12 March 1997))	<i>Para. 9</i>	Calls for the establishment of a European Union Ethics Committee to assess ethical aspects of applications of gene technology and to monitor developments in this field ...;

Instrument		Excerpts
b. European Parliament, Resolution on the ethical and legal problems of genetic engineering, 17 March 1989 (<i>Official Journal</i> C 96, 17/04/1989 pp. 165-171)	Para. 11	Sees the role of ethical committees and professional regulatory bodies solely as translating into practice the rules laid down by legislation;
(c) Other instruments dealing with related issues		
Council of Europe		
Council of Europe, Parliamentary Assembly, recommendation 1468 (2000) on Biotechnologies, 29 June 2000 (Gazette — Parliamentary Assembly — June 2000, No. IV/2000 (2000))	Para. 6 (iii)	... to prepare, in cooperation with other relevant organizations, for the introduction of an assessment method for ascertaining whether new technologies in medicine and biology are compatible with fundamental ethical principles, human rights and human dignity. This should take into account the decision-making procedures of individual countries and relevant international organizations as well as the different cultural, religious or social traditions or conventions in the member States ...
(d) Selected examples from penal instruments		
Convention on the Safety of United Nations and Associated Personnel, 1994 (United Nations, <i>Treaty Series</i> , vol. 2051, p. 363)	Article 12	<ol style="list-style-type: none">1. Under the conditions provided for in its national law, the State Party in whose territory a crime set out in article 9 has been committed shall, if it has reason to believe that an alleged offender has fled from its territory, communicate to the Secretary-General of the United Nations and, directly or through the Secretary-General, to the State or States concerned all the pertinent facts regarding the crime committed and all available information regarding the identity of the alleged offender.2. Whenever a crime set out in article 9 has been committed, any State Party which has information concerning the victim and circumstances of the crime shall endeavour to transmit such information, under the conditions provided for in its national law, fully and promptly to the Secretary-General of the United Nations and the State or States concerned.
	Article 18	The State Party where an alleged offender is prosecuted shall communicate the final outcome

Instrument	Excerpts
<i>Article 19</i>	<p>of the proceedings to the Secretary-General of the United Nations, who shall transmit the information to other States Parties.</p> <p>The States Parties undertake to disseminate this Convention as widely as possible...</p>
8. International cooperation (a) Global instruments	
(i) United Nations Educational, Scientific and Cultural Organization (UNESCO)	
Universal Declaration on the Human Genome and Human Rights, 11 November 1997	<i>Article 11</i> <p>Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted. States and competent international organizations are invited to cooperate in identifying such practices and in taking, at the national or international level, the measures necessary to ensure that the principles set out in this Declaration are respected.</p>
<i>Article 18</i>	<p>States should make every effort, with due and appropriate regard for the principles set out in this Declaration, to continue fostering the international dissemination of scientific knowledge concerning the human genome, human diversity and genetic research and, in that regard, to foster scientific and cultural cooperation, particularly between industrialized and developing countries.</p>
(ii) World Health Organization (WHO)	
Resolution WHA 51.10 on ethical, scientific and social implications of cloning in human health, of 16 May 1998	<i>Para. 3</i> <p><i>Requests</i> the Director-General:</p> <p>...</p> <p>(3) To ensure that member States are kept informed of developments in [the] area in order to facilitate decisions on national regulatory frameworks;</p>
(b) Regional instruments and documents	
(i) European Union (EU)	
European Parliament Resolution on human cloning, 7 September	<i>Para. 5</i> <p>Urges maximum political, legislative, scientific and economic efforts to be aimed at therapies that</p>

Instrument	Excerpts
2000 (<i>Bulletin of the European Union</i> 9-2000, Human Rights, 5/12)	use stem cells taken from adult subjects;
(ii) Group of Eight (G-8)	
Communiqué, Denver Summit of the Eight, 22 June 1997	... need for appropriate domestic measures and close international cooperation to prohibit the use of somatic cell nuclear transfer to create a child.
(c) Other instruments dealing with related issues	
(i) United Nations Environment Programme (UNEP)	
Convention on Biological Diversity, of 1992 (United Nations, <i>Treaty Series</i> , No. 30619, vol. 1760, p. 79)	<i>Article 16 (1)</i> Each Contracting Party, recognizing that technology includes biotechnology, ... undertakes, subject to the provisions of this article, to provide and/or facilitate access for and transfer to other Contracting Parties of technologies that ... make use of genetic resources and do not cause significant damage to the environment.
(ii) Council of Europe	
Council of Europe, Parliamentary Assembly, Recommendation 1425 (1999) on biotechnology and intellectual property, 23 September 1999 (<i>Official Gazette</i> — Parliamentary Assembly — September 1999, No. VI/99 (1999))	... the Assembly recommends that the Committee of Ministers, in cooperation with the European Union, the World Intellectual Property Organization, the Food and Agriculture Organization of the United Nations, the World Trade Organization, the United Nations Educational, Scientific and Cultural Organization, and in accordance with the Convention on Biological Diversity: (i) Study in detail all aspects linked to the protection of intellectual property in biotechnological innovations with a view to further improving international legislation in this field; ... (iii) Develop a code of conduct for scientists and scientific units working in the field of biotechnology which guarantees both free scientific access to worldwide genetic resources and benefit-sharing with developing countries; (iv) Discuss a suitable alternative system of

Instrument

Excerpts

protecting intellectual property in the field of biotechnology ...

(d) Selected examples from penal instruments

(i) Convention on the Prevention and Punishment of Crimes against Internationally Protected Persons, including Diplomatic Agents, 1973 (United Nations, *Treaty Series*, vol. 1035, p. 167)

States Parties shall cooperate in the prevention of the crimes set forth in article 2, particularly by:

(a) Taking all practicable measures to prevent preparations in their respective territories for the commission of those crimes within or outside their territories;

(b) Exchanging information and coordinating the taking of administrative and other measures as appropriate to prevent the commission of those crimes.

Article 5

1. The State Party in which any of the crimes set forth in article 2 has been committed shall, if it has reason to believe that an alleged offender has fled from its territory, communicate to all other States concerned, directly or through the Secretary-General of the United Nations, all the pertinent facts regarding the crime committed and all available information regarding the identity of the alleged offender.

(ii) Convention on the Safety of United Nations and Associated Personnel, 1994 (United Nations, *Treaty Series*, vol. 2051, p. 363)

States Parties shall cooperate in the prevention of the crimes set out in article 9, particularly by:

(a) Taking all practicable measures to prevent preparations in their respective territories for the commission of those crimes within or outside their territories; and

(b) Exchanging information in accordance with their national law and coordinating the taking of administrative and other measures as appropriate to prevent the commission of those crimes.

Article 13

2. Measures taken in accordance with paragraph 1 shall be notified, in conformity with national law and without delay, to the Secretary-General of the United Nations and, either directly or through the Secretary-General, to:

(iii) International Convention for the Suppression of Terrorist Bombings, 1997 (General Assembly resolution 52/164, annex).

Article 16

- (a) The State where the crime was committed;
- (b) The State or States of which the alleged offender is a national or, if such person is a stateless person, in whose territory that person has his or her habitual residence;
- (c) The State or States of which the victim is a national; and
- (d) Other interested States.

1. States Parties shall afford one another the greatest measure of assistance in connection with criminal proceedings brought in respect of the crimes set out in article 9, including assistance in obtaining evidence at their disposal necessary for the proceedings. The law of the requested State shall apply in all cases.

2. The provisions of paragraph 1 shall not affect obligations concerning mutual assistance embodied in any other treaty.

States Parties shall cooperate in the prevention of the offences set forth in article 2, particularly:

- (a) By taking all practicable measures, including, if necessary, adapting their domestic legislation, to prevent and counter preparations in their respective territories for the commission of those offences within or outside their territories, including measures to prohibit in their territories illegal activities of persons, groups and organizations that encourage, instigate, organize, knowingly finance or engage in the perpetration of offences as set forth in article 2;
- (b) By exchanging accurate and verified information in accordance with their national law, and coordinating administrative and other measures taken as appropriate to prevent the commission of offences as set forth in article 2;

*Instrument**Excerpts*

(iv) United Nations Convention against Transnational Crime, 2000 (General Assembly resolution 55/25, annex I)

Article 18

1. States Parties shall afford one another the widest measure of mutual legal assistance in investigations, prosecutions and judicial proceedings in relation to the offences covered by this Convention as provided for in article 3 and shall reciprocally extend to one another similar assistance where the requesting State Party has reasonable grounds to suspect that the offence referred to in article 3, paragraph 1 (a) or (b), is transnational in nature, including that victims, witnesses, proceeds, instrumentalities or evidence of such offences are located in the requested State Party and that the offence involves an organized criminal group.

2. Mutual legal assistance shall be afforded to the fullest extent possible under relevant laws, treaties, agreements and arrangements of the requested State Party with respect to investigations, prosecutions and judicial proceedings in relation to the offences for which a legal person may be held liable in accordance with article 10 of this Convention in the requesting State Party.

...

8. States Parties shall not decline to render mutual legal assistance pursuant to this article on the ground of bank secrecy.

9. States Parties may decline to render mutual legal assistance pursuant to this article on the ground of absence of dual criminality. However, the requested State Party may, when it deems appropriate, provide assistance, to the extent it decides at its discretion, irrespective of whether the conduct would constitute an offence under the domestic law of the requested State Party.

...

13. Each State Party shall designate a central authority that shall have the responsibility and power to receive requests for mutual legal assistance and either to execute them or

to transmit them to the competent authorities for execution. Where a State Party has a special region or territory with a separate system of mutual legal assistance, it may designate a distinct central authority that shall have the same function for that region or territory. Central authorities shall ensure the speedy and proper execution or transmission of the requests received. Where the central authority transmits the request to a competent authority for execution, it shall encourage the speedy and proper execution of the request by the competent authority. The Secretary-General of the United Nations shall be notified of the central authority designated for this purpose at the time each State Party deposits its instrument of ratification, acceptance or approval of or accession to this Convention. Requests for mutual legal assistance and any communication related thereto shall be transmitted to the central authorities designated by the States Parties. This requirement shall be without prejudice to the right of a State Party to require that such requests and communications be addressed to it through diplomatic channels and, in urgent circumstances, where the States Parties agree, through the International Criminal Police Organization, if possible.

...

21. Mutual legal assistance may be refused:

- (a) If the request is not made in conformity with the provisions of this article;
- (b) If the requested State Party considers that execution of the request is likely to prejudice its sovereignty, security, *ordre public* or other essential interests;
- (c) If the authorities of the requested State Party would be prohibited by its domestic law from carrying out the action requested with regard to any similar offence, had it been subject to investigation, prosecution or judicial proceedings under their own jurisdiction;

*Instrument**Excerpts*

(d) If it would be contrary to the legal system of the requested State Party relating to mutual legal assistance for the request to be granted.

...

23. Reasons shall be given for any refusal of mutual legal assistance.

24. The requested State Party shall execute the request for mutual legal assistance as soon as possible and shall take as full account as possible of any deadlines suggested by the requesting State Party and for which reasons are given, preferably in the request. The requested State Party shall respond to reasonable requests by the requesting State Party on progress of its handling of the request. The requesting State Party shall promptly inform the requested State Party when the assistance sought is no longer required.

25. Mutual legal assistance may be postponed by the requested State Party on the ground that it interferes with an ongoing investigation, prosecution or judicial proceeding.

Article 19

States Parties shall consider concluding bilateral or multilateral agreements or arrangements whereby, in relation to matters that are the subject of investigations, prosecutions or judicial proceedings in one or more States, the competent authorities concerned may establish joint investigative bodies. In the absence of such agreements or arrangements, joint investigations may be undertaken by agreement on a case-by-case basis. The States Parties involved shall ensure that the sovereignty of the State Party in whose territory such investigation is to take place is fully respected.

9. Selected examples of review provisions

(a) Driftnet fishing

Convention for the Prohibition of Fishing with Long Driftnets

Article 7

1. Without prejudice to the conduct of consultations among parties by other means,

Instrument	Excerpts
<p>in the South Pacific, 1989 (United Nations, <i>Treaty Series</i>, vol. 1899, p. 3)</p>	<p>the Forum Fisheries Agency, at the request of three Parties, shall convene meetings of the Parties to review the implementation of this Convention and its Protocols.</p> <p>2. Parties to the Protocols shall be invited to any such meeting and to participate in a manner to be determined by the Parties to the Convention.</p>
(b) Biological weapons	
<p>Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, 1972 (United Nations, <i>Treaty Series</i>, vol. 1015, p. 163)</p>	<p><i>Article V</i></p> <p>The States Parties to this Convention undertake to consult one another and to cooperate in solving any problems which may arise in relation to the objective of, or in the application of the provisions of, the Convention. Consultation and cooperation pursuant to this article may also be undertaken through appropriate international procedures within the framework of the United Nations and in accordance with its Charter.</p>
<i>Article XII</i>	<p>Five years after the entry into force of this Convention, or earlier if it is requested by a majority of Parties to the Convention by submitting a proposal to this effect to the Depositary Governments, a conference of States Parties to the Convention shall be held at Geneva, Switzerland, to review the operation of the Convention, with a view to assuring that the purposes of the preamble and the provisions of the Convention, including the provisions concerning negotiations on chemical weapons, are being realized. Such review shall take into account any new scientific and technological developments relevant to the Convention.</p>
(c) Environment	
<p>(i) Convention on Long-Range Transboundary Air Pollution, 1979 (United Nations, <i>Treaty Series</i>, vol. 1302, p. 217)</p>	<p><i>Article 10</i></p> <p>1. The representatives of the Contracting Parties shall, within the framework of the Senior Advisers to [United Nations Economic Commission for Europe] Governments on Environmental Problems, constitute the Executive Body of the present Convention, and shall meet at least annually in that capacity.</p>

*Instrument**Excerpts*

(ii) Convention on International Trade in Endangered Species of Wild Fauna and Flora, 1973 (United Nations, *Treaty Series*, vol. 993, p. 243)

Article XI

2. The Executive Body shall:

(a) Review the implementation of the present Convention;

(b) Establish, as appropriate, working groups to consider matters related to the implementation and development of the present Convention and to this end to prepare appropriate studies and other documentation and to submit recommendations to be considered by the Executive Body;

(c) Fulfil such other functions as may be appropriate under the provisions of the present Convention.

3. The Executive Body shall utilize the Steering Body for the EMEP [cooperative monitoring and evaluation programme] to play an integral part in the operation of the present Convention, in particular with regard to data collection and scientific cooperation.

4. The Executive Body, in discharging its functions, shall, when it deems appropriate, also make use of information from other relevant international organizations.

1. The Secretariat shall call a meeting of the Conference of the Parties not later than two years after the entry into force of the present Convention.

2. ... Thereafter the Secretariat shall convene regular meetings at least once every two years, unless the Conference decides otherwise, and extraordinary meetings at any time on the written request of at least one third of the Parties.

3. At meetings, whether regular or extraordinary, the Parties shall review the implementation of the present Convention and may:

(a) Make such provision as may be necessary to enable the Secretariat to carry out its duties, and adopt financial provisions;

(b) Consider and adopt amendments to

Instrument

Excerpts

appendices I and II in accordance with article XV;

(c) Review the progress made towards the restoration and conservation of the species included in appendices I, II and III;

(d) Receive and consider any reports presented by the Secretariat or by any Party; and

(e) Where appropriate, make recommendations for improving the effectiveness of the present Convention.

Annex II

Selected reports and other documents

United Nations Educational, Scientific and Cultural Organization

International Bioethics Committee (IBC) report: “The Use of Embryonic Stem Cells in Therapeutic Research”, Paris, 6 April 2001, document BIO-7/00/GT-1/2 (Rev.3).

Report of the Second Session of the Intergovernmental Bioethics Committee (IGBC), UNESCO, Paris, 14-16 May 2001.

Second Session of the Intergovernmental Bioethics Committee (IGBC): Report of the Director-General, document 31/C/REP/14, 17 July 2001.

Communiqué of the Round Table of Ministers of Science on “Bioethics: International Implications”, UNESCO, Paris, 22-23 October 2001.

World Health Organization

“Cloning in Human Reproduction”, report of the Director-General, 8 May 1997, WHO/A50/30.

Committee B, provisional summary record of the seventh meeting, 12 May 1997, WHO/A50/B/SR/7.

“Implementation of resolutions and decisions”, 29 October 1997, WHO/EB/101/10.

“Implementation of resolutions and decisions”, 14 January 1998, WHO/EB101/INF.DOC/3.

Provisional summary record of the sixteenth meeting, 27 January 1998, WHO/EB101/SR/16.

“Implementation of resolutions and decisions”, 8 April 1998, WHO/A51/6/Add.1.

“Cloning in human health”, report of the Secretariat, 1 April 1999, WHO/A52/12.

Committee A, provisional summary record of the ninth meeting, 24 May 1999, WHO/A52A/SR/9.

“Cloning in human health”, report of the Director-General, 10 May 2000, WHO/A53/15.

WHO publications and documents on cloning and health issues:

“WHO Director-General condemns human cloning”, 11 March 1997, press release WHO/20.

UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction, Cloning discussion at HRP Scientific and Ethical Review Group meeting, 25 April 1997 — Technical and Ethical Aspects. The Global Response — executive summary, available upon request.

“World Health Assembly states its position on cloning in human reproduction”, 14 May 1997, press release WHO/WHA/9.

UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction, Cloning discussion at HRP

Scientific and Ethical Review Group meeting, 24 October 1997. The Global Response — executive summary, available upon request.

Follow-up to recommendations of the Advisory Committee on Health Research ACHR35: “Cloning and WHO’s Policies”, 20-23 October 1998, WHO/ACHR36/CRP/98.7.

United Nations Commission on Human Rights

“Human rights and bioethics”, report of the Secretary-General, E/CN.4/1995/74.

“Human rights and bioethics”, report of the Secretary-General, E/CN.4/1997/66.

“Human rights and bioethics”, report of the Secretary-General, E/CN.4/1999/90.

“Human rights and bioethics”, report of the Secretary-General, E/CN.4/2001/93 and Add.1.

Subcommission on Prevention of Discrimination and Protection of Minorities

“Human rights and scientific and technological developments”, Note by the Secretary-General, E/CN.4/Sub.2/1995/23.

“Potentially adverse consequences of scientific progress and its applications for the integrity, dignity and human rights of the individual”, Working paper prepared by Mr. Osman El-Hajjé, E/CN.4/Sub.2/1997/34.

Working Group on Indigenous Populations, “Human genome diversity research and indigenous peoples”, Note by the Secretariat, E/CN.4/Sub.2/AC.4/1998/4 and Add.1.

European Union

The Group of Advisers on the Ethical Implications of Biotechnology (GAEIB) to the European Commission, Opinion No. 8, “Ethical Aspects of Patenting Inventions Involving Elements of Human Origin”, 25 September 1996.

The Group of Advisers on the Ethical Implications of Biotechnology (GAEIB) to the European Commission, Opinion No. 9, “Ethical Aspects of Cloning Techniques”, 28 May 1997.

The European Group on Ethics in Science and New Technologies (EGE) to the European Commission, Opinion No. 12, “Ethical Aspects of Research Involving the Use of Human Embryos in the context of the 5th Framework Programme”, 23 November 1998.

Organization of American States

Draft Legislative Guide on Medically assisted Fertility, OAS/Ser. Q, CJI/Res.18 (LVII-O/00), 19 August 2000.