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COUNCIL OF EUROPE CONSEIL DE L'EUROPE

Strasbourg, 29 February 2000
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ADDENDUM I CDBI/INF (2000) 1
Provisional

STEERING COMMITTEE ON BIOETHICS (CDBI)

CONVENTION ON THE PROTECTION OF HUMAN RIGHTS AND DIGNITY OF THE HUMAN BEING WITH REGARD TO THE APPLICATION OF BIOLOGY AND MEDICINE:

CONVENTION ON HUMAN RIGHTS AND BIOMEDICINE
(ETS N°164)

PREPARATORY WORK ON THE CONVENTION

ADDENDUM I

(Document prepared by the Directorate General of Legal Affairs)

Draft Convention on Human Rights and Biomedicine
resulting from the meetings of CDBI-CO-RED and CDBI

8-12 March 1993

PRELIMINARY DRAFT CONVENTION FOR THE PROTECTION OF HUMAN RIGHTS AND DIGNITY OF THE HUMAN BEING WITH REGARD TO THE APPLICATION OF BIOLOGY AND MEDICINE: BIOETHICS CONVENTION

PREAMBLE

The Member States of the Council of Europe and the other signatories hereto,

Bearing in mind the Universal Declaration of Human Rights proclaimed by the General Assembly of the United Nations on 10 December 1948;

Bearing in mind the International Covenant on Civil and Political Rights of 19 December 1966;

Bearing in mind the Convention for the Protection of Human Rights and Fundamental Freedoms of 4 November 1950;

Bearing also in mind the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data of 28 January 1981;

Conscious of the accelerating developments in biology and medicine;

Convinced of the need to respect the human being both as an individual and as a member of the human species and recognising the importance of ensuring the dignity of the human being;

Conscious that the misuse of biology and medicine may lead to acts endangering human dignity;

Affirming that progress in biology and medicine should only be used for the benefit of present and future generations;

Considering that the aim of the Council of Europe is the achievement of a greater unity between its members and that one of the methods by which that aim is to be pursued is the maintenance and further realisation of human rights and fundamental freedoms;

Recognising the need for international co-operation so that all humanity may enjoy the benefits of biology and medicine;

Recognising the importance of promoting a public debate on the questions posed by the application of biology and medicine and the responses to be given thereto;

Wishing to remind all members of society of their rights and responsibilities;

Resolving to take such measures as are necessary to safeguard human dignity and the fundamental rights of the individual with regard to the application of biology and medicine;

Taking account of the work of the Parliamentary Assembly in this field, including Recommendation 1160 (1991) on the preparation of a Convention on bioethics;

Have agreed as follows:

CHAPTER I

Article 1

Parties to this Convention shall protect the dignity, identity and integrity of all human beings and guarantee all individuals, without discrimination, respect for their rights and fundamental freedoms with regard to the application of biology and medicine.

Article 2

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

There shall be no interference with the exercise of the rights contained in this Convention except such as is in accordance with the law and is necessary in a democratic society for the protection of public health or the rights and freedoms of others.

Article 3

Any intervention in the health field may only be carried out if it meets relevant professional standards.

Article 4

Parties recognise equity of access to applications of biology and medicine for health care.

Article 5

No intervention may be carried out in the health field without the free and informed consent of the person undergoing it.

The person concerned may freely withdraw consent at any time.

Article 6

Interventions may be carried out on legally incapacitated persons and those, legally capable, who are incapable of understanding, only for their direct benefit and under protective conditions approved by national law.

Exceptionally, subject to appropriate consent, national law may provide for non beneficial interventions in instances where there is an overriding interest, provided that they are of minimal risk and that there is no possible alternative subject or an equally effective alternative method.

In any event, the individual undergoing the intervention should, as far as possible, be involved in the consenting procedure.

If adults, though legally incapacitated, are capable of understanding, their consent is required.

The consent of minors shall be regarded as an increasingly determining factor in proportion to their age and capacity for discernment.

Article 7

When because of an emergency situation the appropriate consent cannot be obtained,any medically necessary intervention may be carried out for the immediate benefit of the health of the individual concerned.

Article 8

Wherever relevant, the previously expressed wishes of the patient on a medical intervention should be respected.

Article 9

Patients whose ability to decide what is in their best interests is impaired by mental illness, may be submitted to an intervention without their consent, under protective conditions defined by national law, where, without treatment for this mental illness, serious harm is likely to result to their health; such national conditions shall include appropriate supervisory, control and appeal procedures.

Article 10

Any agreement concerning the human body or its parts shall respect the principle of dignity of the human being.

The human body and its parts shall not, as such, give rise to financial gain.

Article 11

Everyone has the right to privacy in the health field.

Individuals are entitled to know any information collected about their health status.

However, if individuals request not to be so informed they should have their wishes respected.

Article 12

When in the course of an intervention any part of a human body is removed, it can only be stored and used for a purpose other than that for which it was removed, provided this is done in conformity with appropriate information and consent procedures.

Article 13

Scientific research in the field of biology and medicine shall be carried out freely with respect for the dignity, identity and integrity of the human being and in accordance with the legal provisions ensuring this protection.

Article 14

Where research on embryos in vitro is allowed by national law, such research may only be authorised in the case of embryos which are not more than 14 days old [and shall be restricted to research aimed at treating infertility.]

Article 15

An intervention on the human genome shall only be undertaken for therapeutic purposes and as long as there is no interference with the germ cell line.

Article 16

Tests which are predictive of genetic diseases shall only be performed for health care purposes or scientific research.

Article 17

The communication of results of genetic testing outside the health field shall only be possible if authorised by national law when there is an overriding interest.

Article 18

The Parties shall provide appropriate judicial protection to prevent at short notice an unlawful infringement of the principles set forth in this Convention.

Article 19

Parties shall provide for appropriate sanctions to be applied in the event of infringement of the provisions contained in this [Chapter].

Article 20

The person who has suffered undue damage resulting from an intervention is entitled to fair compensation according to the conditions and procedures defined by national law.

Article 21

None of the provisions of this chapter shall be interpreted as limiting or otherwise affecting the possibility for a Party to grant a wider measure of protection than is stipulated in this convention.

CHAPTER ...

Article 22

The Parties shall see that the fundamental questions raised by the developments of biology and medicine are appropriately discussed in the light, in particular, of relevant medical, social, economic, ethical and legal implications, and that their possible application is made the subject of appropriate public consultation.

Article 23

Protocols may be concluded in pursuance of Articles ..., with a view to developing, in specific fields, the principles contained in this Convention.

24-27 November 1992

PRELIMINARY DRAFT CONVENTION FOR THE PROTECTION OF HUMAN RIGHTS AND DIGNITY OF THE HUMAN BEING WITH REGARD TO THE APPLICATION OF BIOLOGY AND MEDICINE[1]: BIOETHICS CONVENTION

PREAMBLE

The Member States of the Council of Europe and the other signatories hereto,

Bearing in mind the Universal Declaration of Human Rights proclaimed by the General Assembly of the United Nations on 10 December 1948;

Bearing in mind the International Covenant on Civil and Political Rights of 19 December 1966;

Bearing in mind the Convention for the Protection of Human Rights and Fundamental Freedoms of 4 November 1950;

Bearing also in mind the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data of 28 January 1981;

Conscious of the accelerating development of biology and medicine;

Convinced of the need to respect human beings both as individuals and as members of the human species;

Affirming that the progress of biology and medicine shall be used for the benefit of present and future generations;

Mindful of acts contrary to human dignity when biology and medicine are misused;

Considering that the aim of the Council of Europe is to achieve a greater unity between its Members for the purpose of safeguarding and realising the ideals and principles which are their common heritage;

Considering that one of the methods of achieving that aim is the further realisation of human rights and fundamental freedoms, which constitute the very basis of the common understanding which they advocate;

Resolved to take appropriate measures with regard to the application of biology and medicine in order to safeguard human dignity and the fundamental rights of the individual;

Recognising the need for international co-operation so that all mankind may enjoy the benefits of biology and medicine and so as to prevent these sciences from being used otherwise than for human welfare;

Recognising the importance of promoting a **public debate** on the questions posed by the applications of biology and medicine and the responses to be given thereto;

Wishing to remind all members of society of their rights and responsibilities,

Have agreed as follows:

[1] The texts in square brackets have not so far been adopted by the Working Party.

Article 1

The purpose of this Convention is to protect the dignity, identity and integrity of human beings and guarantee all individuals, without discrimination, the respect for their rights and fundamental freedoms with regard to the application of biology and medicine.

Article 2

Whenever the need arises, protocols relating to specific fields of application shall be concluded in pursuance of Articles ...

Article 3

The law shall safeguard the dignity, identity and integrity of the human being in the application of biology and medicine in compliance with the principles contained in this Convention.

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

There shall be no interference with the exercise of the rights contained in this Convention except such as is in accordance with the law and is necessary in a democratic society for the protection of health or the rights and freedoms of others.

Article 4

No intervention may be carried out in the medical or biological field without the free, informed consent of the persons undergoing it.

The persons concerned may freely withdraw consent at any time.

Article 5

Notwithstanding the provisions of Article 4, in recognised emergency situations, any medically necessary intervention may be carried out for the benefit of the health of patients who are not able to give their consent.

Whenever possible, the persons close to the patients shall be consulted in order to ascertain the wishes of the patients.

Article 6 [Provisional wording]

National law shall provide for [additional] conditions under which minors and adults who are not capable of understanding shall be subject to an intervention.

In any case if the minors are capable of understanding, their consent shall be required.

Article 7

[Practitioners shall not be required to carry out a direct intervention which is contrary to their conscience.] **This provision has been deleted.**

Article 8

The pursuit of scientific knowledge in the field of biology and medicine shall be carried out freely with respect for the dignity, identity and integrity of the human being and in accordance with the legal provisions ensuring this protection.

Article 9 (Provisional wording)

9 a. Where research on embryos in vitro is allowed by national law, such research shall only be authorised in the case of embryos which are not more than 14 days old.

9 b. The creation of embryos solely for research shall be forbidden.

[9 c. Ectogenesis is prohibited, as is asexual reproduction and the creation of hybrids.]

Article 10[2]

An intervention on the human genome shall only be undertaken for therapeutic purposes and as long as there is no interference with the germ cell line.

Article 11

The Parties shall see that the fundamental questions raised by the application of biology and medicine are made the subject of independent multidisciplinary and appropriate consultation whose results are made available to the public.

Article 12

The Parties shall guarantee judicial protection to everyone in order to prevent or suspend at short notice an unlawful impairment of his body or an infringement of his private or family life.

[Even in the absence of a personal interest, this right should also be accessible if and when the infringement which it is desired to prevent or stop affects several persons.]

Article 13

The person who has suffered damage resulting from an intervention is entitled to fair compensation according to the conditions and procedures defined by national law.

Article 14

The human body and its parts shall not, as such, give rise to financial gain.

No person is entitled to sell his body or its parts.

Any agreement concerning the human body or its components shall respect the principle of dignity of the human being.

Article 15

Everyone has the right to respect for his private and family life in the field of biology and medicine.

[Right not to know]

Article 16 [Provisional wording]

No genetic test can be carried out on a human being except for purposes of medical treatment or scientific research or as part of a judicial procedure.

[2] The CDBI has not examined the Articles in italics.

Article 17

[This Article has been suppressed: see paragraphs 55/58 of the CDBI-CO-RED (92) 6.]

Article 18

[This Article has been suppressed by the Bureau: see paragraph 29 of the present report]

Article 19

When States authorise artificial procreation, they shall take measures so as to ensure that the child may realise his/her right to family life.

Article 20 *[The place of this Article shall be reexamined]*

Article 21

None of the provisions of [this chapter] shall be interpreted as limiting or otherwise affecting the possibility for a Party to grant a wider measure of protection than is stipulated in this convention.

Article 24

States shall provide for appropriate sanctions to be applied in the event of infringement of the provisions contained in this Convention.

[Infringement of the Convention in States which are not Party to the Convention.]

1-3 June 1993

PRELIMINARY DRAFT CONVENTION FOR THE PROTECTION OF HUMAN RIGHTS AND DIGNITY OF THE HUMAN BEING WITH REGARD TO THE APPLICATION OF BIOLOGY AND MEDICINE: BIOETHICS CONVENTION

PREAMBLE

The Member States of the Council of Europe and the other signatories hereto,

Bearing in mind the Universal Declaration of Human Rights proclaimed by the General Assembly of the United Nations on 10 December 1948;

Bearing in mind the Convention for the Protection of Human Rights and Fundamental Freedoms of 4 November 1950;

Bearing in mind the International Covenant on Civil and Political Rights of 19 December 1966;

Bearing also in mind the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data of 28 January 1981;

Conscious of the accelerating developments in biology and medicine;

Convinced of the need to respect the human being both as an individual and as a member of the human species and recognising the importance of ensuring the dignity of the human being;

Conscious that the misuse of biology and medicine may lead to acts endangering human dignity;

Affirming that progress in biology and medicine should only be used for the benefit of present and future generations;

Considering that the aim of the Council of Europe is the achievement of a greater unity between its members and that one of the methods by which that aim is to be pursued is the maintenance and further realisation of human rights and fundamental freedoms;

Recognising the need for international co-operation so that all humanity may enjoy the benefits of biology and medicine;

[Recognising the importance of promoting a public debate on the questions posed by the application of biology and medicine and the responses to be given thereto;]

Wishing to remind all members of society of their rights and responsibilities;

Taking account of the work of the Parliamentary Assembly in this field, including Recommendation 1160 (1991) on the preparation of a Convention on bioethics;

Resolving to take such measures as are necessary to safeguard human dignity and the fundamental rights of the individual with regard to the application of biology and medicine;

Have agreed as follows:

CHAPTER I

Article 1 (Purpose and object)

Alternative I

Parties to this Convention shall protect the dignity, identity and integrity of all human beings and guarantee everyone, without discrimination, respect for their rights and fundamental freedoms with regard to the application of biology and medicine.

Alternative II

Parties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their rights and fundamental freedoms, in particular their integrity, with regard to the application of biology and medicine.

Article 2 (Primacy of the human being)

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

No restrictions shall be placed on the exercise of the rights contained in this Convention other than such as are prescribed by law and are necessary in a democratic society [in the interest of national security], for the protection of public health or public order or the rights and freedoms of others.

Article 3 (Professional standards)

Any intervention in the health field may only be carried out if it meets relevant professional standards.

Article 4 (Equitable access)

Parties recognise equitable access to applications of biology and medicine for health care with [due] regard to medical needs and available resources.

Article 5 (Consent)

No intervention may be carried out in the health field without the free and informed consent of the person undergoing it.

The person concerned may freely withdraw consent at any time.

Article 6 (Incapacity)

Interventions may be carried out on legally incapacitated persons and those who, though legally capable, have a reduced capacity of understanding, only for their direct benefit and under protective conditions approved by national law.

Exceptionally, for research purposes in the health field representing a minimal risk or burden for the individual or for purposes of transplantation of regenerative tissues between close relations and friends, national law may authorise non-beneficial interventions on incapacitated persons, in cases where there is an overriding interest, provided that sufficient protection is guaranteed and that there is no possible alternative subject nor any equally effective alternative method.

The individual undergoing the intervention shall, as far as possible, be involved in the consenting procedure.

Article 7 (Consent of incapacitated persons)

If adults, though legally incapacitated, are capable of understanding, their consent is required.

The consent of minors shall be regarded as an increasingly determining factor in proportion to their age and capacity for discernment.

Article 8 (Emergency situation)

When because of an emergency situation the appropriate consent cannot be obtained, any medically necessary intervention may be carried out for the immediate benefit of the health of the individual concerned.

Article 9 (Previously expressed wishes)

The previously expressed wishes of the patient on a medical intervention shall be taken into account.

Article 10 (Mental illness)

Patients whose ability to decide what is in their best interests is impaired by mental illness, may be submitted to an intervention without their consent, under protective conditions defined by national law, where, without treatment for this mental illness, serious harm is likely to result to their health; such national conditions shall include appropriate supervisory, control and appeal procedures.

Article 11 (Prohibition of financial gain)

The dignity of the human body and its parts shall be respected and [therefore] shall not, as such, give rise to financial gain.

Article 12 (Privacy and access to information)

Everyone has the right to privacy in the health field.

Individuals are entitled to know any information collected about their health status.

However, if individuals request not to be so informed they should have their wishes respected.

Article 13 (Disposal of a removed part of the human body)

When in the course of an intervention any part of a human body is removed, it can only be stored and used for a purpose other than that for which it was removed, provided this is done in conformity with appropriate information and consent procedures.

Article 14 (Scientific research)

Scientific research in the field of biology and medicine shall be carried out freely with respect for the dignity, identity and integrity of the human being and in accordance with the legal provisions ensuring this protection.

Article 15 (Research on embryos in vitro)

Where research on embryos in vitro is allowed by national law, such research may only be authorised in the case of embryos which are not more than 14 days old [and shall be restricted to research aimed at treating infertility.].

Article 16 (Human genome)

An intervention on the human genome shall only be undertaken for therapeutic purposes and as long as there is no interference with the germ cell line.

Article 17 (Genetic tests)

Tests which are predictive of genetic diseases shall only be performed for health care purposes or scientific research.

Article 18 (Communications of results)

The communication of results of genetic testing outside the health field shall only be possible if authorised by national law when there is an overriding interest.

Article 19 (Infringements of the principles)

The Parties shall provide appropriate judicial protection to prevent at short notice an unlawful infringement of the principles set forth in this Convention.

Article 20 (Sanctions)

Parties shall provide for appropriate sanctions to be applied in the event of infringement of the provisions contained in this [Chapter].

Article 21 (Compensation for undue damage)

The person who has suffered undue damage resulting from an intervention is entitled to fair compensation according to the conditions and procedures defined by national law.

Article 22 (Wider protection)

None of the provisions of this chapter shall be interpreted as limiting or otherwise affecting the possibility for a Party to grant a wider measure of protection than is stipulated in this convention.

[In their mutual relations, Parties which are members of the European Economic Community shall apply Community rules and shall therefore not apply the rules arising from this Convention except in so far as there is no Community rule governing the particular subject concerned.]

CHAPTER II

Article 23

The Parties shall see that the fundamental questions raised by the developments of biology and medicine are appropriately discussed in the light, in particular, of relevant medical, social, economic, ethical and legal implications, and that their possible application is made the subject of appropriate public consultation.

CHAPTER III

Article 24

Protocols may be concluded in pursuance of Article 29, with a view to developing, in specific fields, the principles contained in this Convention.

Chapter IV -

Article 25 - Reports on the application of the Convention

1 On receipt of a request from the Secretary General of the Council of Europe any Party shall furnish an explanation of the manner in which its internal law ensures the effective implementation of any of the provisions of the Convention. [source: Article 57 of the Human rights Convention]

2 The reports presented by the Parties shall be examined by the Standing Committee. [source: European Charter for Regional or Minority Languages, Article 16.5]

3 The Secretary General of the Council of Europe shall make a two-yearly report to the Committee of Ministers and the Parliamentary Assembly on the application of the Convention. [source: ibidem, Article 16.6]

Article 26 - The Standing Committee

1 For the purposes of this Convention, a Standing Committee is hereby set up.

2 The Standing Committee shall be composed of one member per Party, appointed by the Committee of Ministers of the Council of Europe from a list of three individuals of the highest integrity and recognised competence in the matters dealt with in the Convention, who shall be nominated by the Party concerned. [source: ibidem, Article 17.1]

3 Members of the Committee shall be appointed for a period of six years and shall be eligible for reappointment. A member who is unable to complete a term of office shall be replaced in accordance with the procedure laid down in paragraph 2, and the rplacing member shall complete his predecessor's term of office. [source: ibidem, Article 17.2]

4 Any State referred to in Article 30 or invited to accede to the Convention in accordance with the provisions of Article 31 which is not a Party to this Convention may be represented on the Standing Committee by an observer. [If the European Economic Community is not a Party it may be represented on the Standing Committee by an observer.]

5 Unless, at least one month before the meeting, a Party has informed the Secretary General of its objection, the Standing Committee may invite the following to attend as observers at all its meetings or one or part of a meeting:

- *any State not referred to in paragraph 4 above;*

- *any international or national, governmental or non-governmental body technically qualified in the fields covered by this Convention.*

6 The Standing Committee may seek the advice of experts in order to discharge its functions.

7 The Standing Committee shall be convened by the Secretary General of the Council of Europe. It shall meet whenever one-third of the Parties or the Committee of Ministers or the Secretary General of the Council of Europe so request.

8 A majority of members shall constitute a quorum for holding a meeting of the Standing Committee.

9 Subject to Articles 27 and 29 the decisions of the Standing Committee shall be taken by a majority of the members present.

10 Subject to the provisions of this Convention the Standing Committee shall draw up its own rules of procedure.

11 The Secretariat of the Standing Committee shall be provided by the Secretary General of the Council of Europe.

Article 27 - Functions of the Standing Committee

The Standing Committee shall keep under review problems relating to this Convention. It may, in particular:

a consider any question of a general nature referred to it concerning interpretation or implementation of the Convention. The Standing Committee's conclusions concerning implementation of the Convention may take the form of a recommendation; recommendations shall be adopted by a three quarters majority of the votes cast;

b propose any necessary amendments to the Convention including its Protocols and examine those proposed in accordance with Article 29.

Article 28 - Reports of the Standing Committee

After each meeting, the Standing Committee shall forward to the Parties and the Committee of Ministers of the Council of Europe a report on its discussions and any decisions taken.

Chapter VII - Amendments to the Convention

Article 29

1 Any proposal for an amendment to this Convention, including any proposal for a new Protocol, presented by a Party or the Standing Committee shall be communicated to the Secretary General of the Council of Europe and forwarded by him at least two months before the meeting of the Standing Committee to the member States of the Council of Europe, [to the European Economic Community,] to any Signatory, to any Party, to any State invited to sign this Convention in accordance with the provisions of Article 30 and to any State invited to accede to it in accordance with the provisions of Article 31.

2 Any proposal presented in accordance with the provisions of the preceding paragraph shall be examined by the Standing Committee which:

a for amendments to Articles 1 to 22 shall submit the text adopted by a three-quarters majority of the votes cast to the Parties for acceptance;

b for amendments to Articles 23 to 35 shall submit the text adopted by a three-quarters majority of the votes cast to the Committee of Ministers for approval. After its approval, this text shall be forwarded to the Parties for acceptance.

3 Any amendment to Articles 1 to 22 shall enter into force, in respect of those Parties which have accepted it, on the first day of the month following the expiration of a period of one month after the date on which three Parties, including at least two member States of the Council of Europe, have informed the Secretary General that they have accepted it.

In respect of any Party which subsequently accepts it, the amendment shall enter into force on the first day of the month following the expiration of a period of one month after the date on which that Party has informed the Secretary General of its acceptance.

4 Any amendment to Articles 23 to 35 shall enter into force on the first day of the month following the expiration of a period of one month after the date on which all Parties have informed the Secretary General that they have accepted it.

Chapter VI - Final clauses

Article 30 - Signature, ratification and entry into force

1 This Convention shall be open for signature by the member States of the Council of Europe, the non-member States which have participated in its elaboration [and by the European Economic Community].

2 This Convention is subject to ratification, acceptance or approval. Instruments of ratification, acceptance or approval shall be deposited with the Secretary General of the Council of Europe.

3 This Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date on which three States, including at least two member States of the Council of Europe, have expressed their consent to be bound by the Convention in accordance with the provisions of paragraph 2 of the present Article.

4 In respect of any Signatory which subsequently expresses its consent to be bound by it, the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of the deposit of its instrument of ratification, acceptance or approval.

Article 31 - Non-member States

1 After the entry into force of this Convention, the Committee of Ministers of the Council of Europe may, on its own initiative or following a proposal from the Standing Committee and after consultation of the Parties, invite any non-member State of the Council of Europe to accede to this Convention by a decision taken by the majority provided for in Article 20, sub-paragraph d of the Statute of the Council of Europe, and by the unanimous vote of the representatives of the Contracting States entitled to sit on the Committee of Ministers.

2 In respect of any acceding State, the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of deposit of the instrument of accession with the Secretary General of the Council of Europe.

Article 32 - Territories

1 Any Signatory may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, specify the territory or territories to which this Convention shall apply. Any other State may formulate the same declaration when depositing its instrument of accession.

2 Any Party may, at any later date, by a declaration addressed to the Secretary General of the Council of Europe, extend the application of this Convention to any other territory specified in the declaration and for whose international relations it is responsible or on whose behalf it is authorised to give undertakings. In respect of such territory the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of receipt of such declaration by the Secretary General.

3 Any declaration made under the two preceding paragraphs may, in respect of any territory specified in such declaration, be withdrawn by a notification addressed to the Secretary General. The withdrawal shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of such notification by the Secretary General.

Article 33 - Reservations

1 Any Signatory may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, make one or more reservations to Articles [ ] of this Convention. No other reservation may be made.

Any other State may formulate the same reservations when depositing its instrument of accession.

2 Any Signatory or any other State which makes use of a reservation shall notify the Secretary General of the Council of Europe of the relevant contents of its internal law.

3 Any Party which extends the application of this Convention to a territory mentioned in the declaration referred to in Article 32, paragraph 2, may, in respect of the territory concerned, make a reservation in accordance with the provisions of the preceding paragraphs.

4 Any Party which has made one of the reservations mentioned in this Article may withdraw it by means of a declaration addressed to the Secretary General of the Council of Europe. The withdrawal shall become effective on the first day of the month following the expiration of a period of one month after the date of its receipt by the Secretary General.

Article 34 - Denunciation

1 Any Party may at any time denounce this Convention by means of a notification addressed to the Secretary General of the Council of Europe.

2 Such denunciation shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of notification by the Secretary General.

Article 35 - Notifications

The Secretary General of the Council of Europe shall notify the member States of the Council, any Signatory, any Party and any other State which has been invited to accede to this Convention of:

a any signature;
b the deposit of any instrument of ratification, acceptance, approval or accession;
c any date of entry into force of this Convention in accordance with Articles 30 or 31;
d any amendment adopted in accordance with Article 29, and the date on which such an amendment enters into force;
e any declaration made under the provisions of Article 32;
f any reservation and withdrawal of reservation made in pursuance of the provisions of Article 33;
g any other act, notification or communication relating to this Convention.

In witness whereof the undersigned, being duly authorised thereto, have signed this Convention.

Done at ....., the ....., in English and French, both texts being equally authentic, in a single copy which shall be deposited in the archives of the Council of Europe. The Secretary General of the Council of Europe shall transmit certified copies to each member State of the Council of Europe, to the non-member States which have participated in the elaboration of this Convention, [to the European Economic Community] and to any State invited to accede to this Convention.

27-29 September 1993

PRELIMINARY DRAFT CONVENTION FOR THE PROTECTION OF HUMAN RIGHTS AND DIGNITY OF THE HUMAN BEING WITH REGARD TO THE APPLICATION OF BIOLOGY AND MEDICINE: BIOETHICS CONVENTION

PREAMBLE

The Member States of the Council of Europe and the other signatories hereto,

Bearing in mind the Universal Declaration of Human Rights proclaimed by the General Assembly of the United Nations on 10 December 1948;

Bearing in mind the Convention for the Protection of Human Rights and Fundamental Freedoms of 4 November 1950;

Bearing in mind the International Covenant on Civil and Political Rights of **16** December 1966;

Bearing also in mind the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data of 28 January 1981;

Conscious of the accelerating developments in biology and medicine;

Convinced of the need to respect the human being both as an individual and as a member of the human species and recognising the importance of ensuring the dignity of the human being;

Conscious that the misuse of biology and medicine may lead to acts endangering human dignity;

Affirming that progress in biology and medicine should only be used for the benefit of present and future generations;

Considering that the aim of the Council of Europe is the achievement of a greater unity between its members and that one of the methods by which that aim is to be pursued is the maintenance and further realisation of human rights and fundamental freedoms;

Recognising the need for international co-operation so that all humanity may enjoy the benefits of biology and medicine;

Recognising the importance of promoting a public debate on the questions posed by the application of biology and medicine and the responses to be given thereto;

Wishing to remind all members of society of their rights and responsibilities;

Taking account of the work of the Parliamentary Assembly in this field, including Recommendation 1160 (1991) on the preparation of a Convention on bioethics;

Resolving to take such measures as are necessary to safeguard human dignity and the fundamental rights of the individual with regard to the application of biology and medicine;

Have agreed as follows:

CHAPTER I

Article 1 (Purpose and object)

Parties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their rights and fundamental freedoms, in particular their integrity, with regard to the application of biology and medicine.

Article 2 (Primacy of the human being)

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

No restrictions shall be placed on the exercise of the rights contained in this Convention other than such as are prescribed by law and are necessary in a democratic society in the interest **of national security and public safety, for the prevention of disorder or crime, for the protection of public health or for the protection of the rights and freedoms of others.**

Article 3 (Professional standards)

Any intervention in the health field must be carried out in accordance with relevant professional obligations and standards.

Article 4 (Equitable access)

[Parties recognise equitable access to] [Parties undertake to enable everyone to benefit equitably from] applications of biology and medicine for health care with due regard to medical needs and available resources.

Article 5 (Consent)

No intervention may be carried out in the health field without the free and informed consent of the person undergoing it.

The person concerned may freely withdraw consent at any time.

Article 6 (Incapacity)

Interventions may be carried out on legally incapacitated persons and those who, though legally capable, have a reduced capacity of understanding, only for their direct benefit and under protective conditions approved by national law.

Exceptionally, for research purposes in the health field representing a minimal risk and burden for the individual or for purposes of transplantation of regenerative tissues between persons having close personal or family relations, national law may authorise non-beneficial interventions on incapacitated persons, in cases where there is an overriding interest, provided that sufficient protection is guaranteed and that there is no possible alternative subject [or group of subjects] [possessing full capacity] nor any equally effective alternative method.

Article 7 (Consent of incapacitated persons)

The individual undergoing the intervention shall, as far as possible, be involved in the consenting procedure [under protective conditions approved by national law].

[National law shall determine the conditions of consent applicable to incapacitated persons.]

If adults, though legally incapacitated, are capable of understanding, their consent is required.

The consent of minors shall be regarded as an increasingly determining factor in proportion to their age and capacity for discernment.

Article 8 (Emergency situation)

When because of an emergency situation the appropriate consent cannot be obtained, any medically necessary intervention may be carried out for the immediate benefit of the health of the individual concerned.

Article 9 (Previously expressed wishes)

The previously expressed wishes of the patient on a medical intervention shall be taken into account.

[The wishes relating to a medical intervention expressed previously by a patient not is not in a state to express his wishes shall be taken into account.]

Article 10 (Mental disorders)

Patients whose ability to decide what is in their best interests is impaired by mental disorders, may be submitted to an intervention without their consent, under protective conditions defined by national law, where, without treatment for these mental disorders, serious harm is likely to result to their health; such national conditions shall include appropriate supervisory, control and appeal procedures.

Article 11 (Prohibition of financial gain)

The dignity of the human body shall be respected. The human body and its parts shall not, as such, give rise to financial gain.

Article 12 (Privacy and access to information)

Everyone has the right to privacy in the health field.

Individuals are entitled to know any information collected about their health status.

However, the wishes of individuals not to be so informed shall be respected.

Article 13 (Disposal of a removed part of the human body)

When in the course of an intervention any part of a human body is removed, it can only be stored and used for a purpose other than that for which it was removed, provided this is done in conformity with appropriate information and consent procedures.

Article 14 (Scientific research)

Scientific research in the field of biology and medicine shall be carried out freely in accordance with the legal provisions ensuring the protection of the human being.

Article 15 (Research on embryos in vitro)

Where research on embryos in vitro is by **[]** law, such research may only be authorised in the case of embryos which are not more than 14 days old.

[The creation of human embryos solely for research purposes is prohibited.]

Article 16 (Human genome)

An intervention on the human genome shall only be undertaken for therapeutic **or diagnostic** purposes and as long as [there is no interference with] [the aim is not to interfere with] the germ cell line.

Article 17 (Genetic tests)

Tests which are predictive of genetic diseases shall only be performed for health care purposes or scientific research.

Article 18 (Communications of results)

The communication of results of genetic testing outside the health field shall only be **[**possible] if authorised by **[]**law when there is an overriding interest.

Article 19 (Infringements of the principles)

The Parties shall provide appropriate judicial protection to prevent [or to put a stop to] an unlawful infringement of the principles set forth in this Convention at short notice.

Article 20 (Sanctions)

Parties shall provide for appropriate sanctions to be applied in the event of infringement of the provisions contained in this [Chapter].

Article 21 (Compensation for undue damage)

The person who has suffered undue damage resulting from an intervention is entitled to fair compensation according to the conditions and procedures defined by national law.

Article 22 (Wider protection)

None of the provisions of this chapter shall be interpreted as limiting or otherwise affecting the possibility for a Party to grant a wider measure of protection than is stipulated in this convention.

[In their mutual relations, Parties which are members of the European Economic Community shall apply Community rules and shall therefore not apply the rules arising from this Convention except in so far as there is no Community rule governing the particular subject concerned.]

CHAPTER II

Article 23

The Parties shall see that the fundamental questions raised by the developments of biology and medicine are appropriately discussed in the light, in particular, of relevant medical, social, economic, ethical and legal implications, and that their possible application is made the subject of appropriate public consultation.

CHAPTER III

Article 24

Protocols may be concluded in pursuance of Article 29, with a view to developing, in specific fields, the principles contained in this Convention.

Chapter IV -

Article 25 - Reports on the application of the Convention

1 *On receipt of a request from the Secretary General of the Council of Europe any Party shall furnish an explanation of the manner in which its internal law ensures the effective implementation of any of the provisions of the Convention. [source: Article 57 of the Human rights Convention]*

2 *The reports presented by the Parties shall be examined by the [Standing Committee]. [source: European Charter for Regional or Minority Languages, Article 16.5]*

3 *The Secretary General of the Council of Europe shall make a two-yearly report to the Committee of Ministers and the Parliamentary Assembly on the application of the Convention. [source: ibidem, Article 16.6]*

Article 26 - [The Standing Committee]

1 *For the purposes of this Convention, a [Standing Committee] is hereby set up.*

2 *The [Standing Committee] shall be composed of one member per Party, appointed by the Committee of Ministers of the Council of Europe from a list of three individuals of the highest integrity and recognised competence in the matters dealt with in the Convention, who shall be nominated by the Party concerned. [source: ibidem, Article 17.1]*

3 *Members of the Committee shall be appointed for a period of six years and shall be eligible for reappointment. A member who is unable to complete a term of office shall be replaced in accordance with the procedure laid down in paragraph 2, and the rplacing member shall complete his predecessor's term of office. [source: ibidem, Article 17.2]*

4 *Any State referred to in Article 30 or invited to accede to the Convention in accordance with the provisions of Article 31 which is not a Party to this Convention may be represented on the [Standing Committee] by an observer. [If the European Economic Community is not a Party it may be represented on the [Standing Committee] by an observer.]*

5 *Unless, at least one month before the meeting, a Party has informed the Secretary General of its objection, the [Standing Committee] may invite the following to attend as observers at all its meetings or one or part of a meeting:*

- *any State not referred to in paragraph 4 above;*
- *any international or national, governmental or non-governmental body technically qualified in the fields covered by this Convention.*

6 *The [Standing Committee] may seek the advice of experts in order to discharge its functions.*

7 *The [Standing Committee] shall be convened by the Secretary General of the Council of Europe. It shall meet whenever one-third of the Parties or the Committee of Ministers or the Secretary General of the Council of Europe so request.*

8 *A majority of members shall constitute a quorum for holding a meeting of the [Standing Committee].*

9 *Subject to Articles 27 and 29 the decisions of the [Standing Committee] shall be taken by a majority of the members present.*

10 *Subject to the provisions of this Convention the [Standing Committee] shall draw up its own rules of procedure.*

11 *The Secretariat of the [Standing Committee] shall be provided by the Secretary General of the Council of Europe.*

Article 27 - Functions of the [Standing Committee]

The [Standing Committee] shall keep under review problems relating to this Convention. It may, in particular:

a *consider any question of a general nature referred to it concerning interpretation or implementation of the Convention. The [Standing Committee]'s conclusions concerning implementation of the Convention may take the form of a recommendation; recommendations shall be adopted by a three quarters majority of the votes cast;*

b *propose any necessary amendments to the Convention including its Protocols and examine those proposed in accordance with Article 29.*

Article 28 - Reports of the [Standing Committee]

After each meeting, the [Standing Committee] shall forward to the Parties and the Committee of Ministers of the Council of Europe a report on its discussions and any decisions taken.

Chapter V - Amendments to the Convention

Article 29

1 Any proposal for an amendment to this Convention, including any proposal for a new Protocol, presented by a Party or the [Standing Committee] shall be communicated to the Secretary General of the Council of Europe and forwarded by him at least two months before the meeting of the [Standing Committee] to the member States of the Council of Europe, [to the European Economic Community,] to any Signatory, to any Party, to any State invited to sign this Convention in accordance with the provisions of Article 30 and to any State invited to accede to it in accordance with the provisions of Article 31.

2 Any proposal presented in accordance with the provisions of the preceding paragraph shall be examined by the [Standing Committee] which:

a for amendments to Articles 1 to 22 shall submit the text adopted by a three-quarters majority of the votes cast to the Parties for acceptance;

b for amendments to Articles 23 to 35 shall submit the text adopted by a three-quarters majority of the votes cast to the Committee of Ministers for approval. After its approval, this text shall be forwarded to the Parties for acceptance.

3 Any amendment to Articles 1 to 22 shall enter into force, in respect of those Parties which have accepted it, on the first day of the month following the expiration of a period of one month after the date on which three Parties, including at least two member States of the Council of Europe, have informed the Secretary General that they have accepted it.

In respect of any Party which subsequently accepts it, the amendment shall enter into force on the first day of the month following the expiration of a period of one month after the date on which that Party has informed the Secretary General of its acceptance.

4 Any amendment to Articles 23 to 35 shall enter into force on the first day of the month following the expiration of a period of one month after the date on which all Parties have informed the Secretary General that they have accepted it.

Chapter VI - Final clauses

Article 30 - Signature, ratification and entry into force

1 This Convention shall be open for signature by the member States of the Council of Europe, the non-member States which have participated in its elaboration [and by the European Community].

2 This Convention is subject to ratification, acceptance or approval. Instruments of ratification, acceptance or approval shall be deposited with the Secretary General of the Council of Europe.

3 This Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date on which three States, including at least two member States of the Council of Europe, have expressed their consent to be bound by the Convention in accordance with the provisions of paragraph 2 of the present Article.

4 In respect of any Signatory which subsequently expresses its consent to be bound by it, the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of the deposit of its instrument of ratification, acceptance or approval.

Article 31 - Non-member States

1 After the entry into force of this Convention, the Committee of Ministers of the Council of Europe may, after consultation of the Parties, invite any non-member State of the Council of Europe to accede to this Convention by a decision taken by the majority provided for in Article 20, sub-paragraph d of the Statute of the Council of Europe, and by the unanimous vote of the representatives of the Contracting States entitled to sit on the Committee of Ministers.

2 In respect of any acceding State, the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of deposit of the instrument of accession with the Secretary General of the Council of Europe.

Article 32 - Territories

1 Any Signatory may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, specify the territory or territories to which this Convention shall apply. Any other State may formulate the same declaration when depositing its instrument of accession.

2 Any Party may, at any later date, by a declaration addressed to the Secretary General of the Council of Europe, extend the application of this Convention to any other territory specified in the declaration and for whose international relations it is responsible or on whose behalf it is authorised to give undertakings. In respect of such territory the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of receipt of such declaration by the Secretary General.

3 Any declaration made under the two preceding paragraphs may, in respect of any territory specified in such declaration, be withdrawn by a notification addressed to the Secretary General. The withdrawal shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of such notification by the Secretary General.

Article 33 - Reservations

1 Any Signatory may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, make one or more reservations to Articles [ ] of this Convention. No other reservation may be made.

Any other State may formulate the same reservations when depositing its instrument of accession.

2 Any Signatory or any other State which makes use of a reservation shall notify the Secretary General of the Council of Europe of the relevant contents of its internal law.

3 Any Party which extends the application of this Convention to a territory mentioned in the declaration referred to in Article 32, paragraph 2, may, in respect of the territory concerned, make a reservation in accordance with the provisions of the preceding paragraphs.

4 Any Party which has made one of the reservations mentioned in this Article may withdraw it by means of a declaration addressed to the Secretary General of the Council of Europe. The withdrawal shall

become effective on the first day of the month following the expiration of a period of one month after the date of its receipt by the Secretary General.

Article 34 - Denunciation

1 Any Party may at any time denounce this Convention by means of a notification addressed to the Secretary General of the Council of Europe.

2 Such denunciation shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of notification by the Secretary General.

Article 35 - Notifications

The Secretary General of the Council of Europe shall notify the member States of the Council, any Signatory, any Party and any other State which has been invited to accede to this Convention of:

a any signature;
b the deposit of any instrument of ratification, acceptance, approval or accession;
c any date of entry into force of this Convention in accordance with Articles 30 or 31;
d any amendment adopted in accordance with Article 29, and the date on which such an amendment enters into force;
e any declaration made under the provisions of Article 32;
f any reservation and withdrawal of reservation made in pursuance of the provisions of Article 33;
g any other act, notification or communication relating to this Convention.

In witness whereof the undersigned, being duly authorised thereto, have signed this Convention.

Done at ....., the ....., in English and French, both texts being equally authentic, in a single copy which shall be deposited in the archives of the Council of Europe. The Secretary General of the Council of Europe shall transmit certified copies to each member State of the Council of Europe, to the non-member States which have participated in the elaboration of this Convention, [to the European Economic Community] and to any State invited to accede to this Convention.

29 November-3 December 1993

PRELIMINARY DRAFT CONVENTION FOR THE PROTECTION OF HUMAN RIGHTS AND DIGNITY OF THE HUMAN BEING WITH REGARD TO THE APPLICATION OF BIOLOGY AND MEDICINE: BIOETHICS CONVENTION

PREAMBLE

The Member States of the Council of Europe and the other signatories hereto,

Bearing in mind the Universal Declaration of Human Rights proclaimed by the General Assembly of the United Nations on 10 December 1948;

Bearing in mind the Convention for the Protection of Human Rights and Fundamental Freedoms of 4 November 1950;

Bearing in mind the International Covenant on Civil and Political Rights of 16 December 1966;

Bearing also in mind the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data of 28 January 1981;

Conscious of the accelerating developments in biology and medicine;

Convinced of the need to respect the human being both as an individual and as a member of the human species and recognising the importance of ensuring the dignity of the human being;

Conscious that the misuse of biology and medicine may lead to acts endangering human dignity;

Affirming that progress in biology and medicine should only be used for the benefit of present and future generations;

Considering that the aim of the Council of Europe is the achievement of a greater unity between its members and that one of the methods by which that aim is to be pursued is the maintenance and further realisation of human rights and fundamental freedoms;

Recognising the need for international co-operation so that all humanity may enjoy the benefits of biology and medicine;

Recognising the importance of promoting a public debate on the questions posed by the application of biology and medicine and the responses to be given thereto;

Wishing to remind all members of society of their rights and responsibilities;

Taking account of the work of the Parliamentary Assembly in this field, including Recommendation 1160 (1991) on the preparation of a Convention on bioethics;

Resolving to take such measures as are necessary to safeguard human dignity and the fundamental rights of the individual with regard to the application of biology and medicine;

Have agreed as follows:

CHAPTER I

Article 1 (Purpose and object)

Parties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their rights and fundamental freedoms, in particular their integrity, with regard to the application of biology and medicine.

Article 2 (Primacy of the human being)

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

No restrictions shall be placed on the exercise of the rights contained in this Convention other than such as are prescribed by law and are necessary in a democratic society in the interest of national security and public safety, for the prevention of disorder or crime, for the protection of public health or for the protection of the rights and freedoms of others.

Article 3 (Professional standards)

Any intervention in the health field must be carried out in accordance with relevant professional obligations and standards.

Article 4 (Equitable access)

[Parties recognise equitable access to] [Parties undertake to enable everyone to benefit equitably from] applications of biology and medicine for health care with due regard to medical needs and available resources.

Article 5 (Consent)

No intervention may be carried out in the health field without the free and informed consent of the person undergoing it.

The person concerned may freely withdraw consent at any time.

Article 6 (Incapacity)

Interventions may be carried out on legally incapacitated persons and those who, though legally capable, have a reduced capacity of understanding, only for their direct benefit and under protective conditions approved by national law.

Exceptionally, for research purposes in the health field representing a minimal risk and burden for the individual or for purposes of transplantation of regenerative tissues between persons having close personal or family relations, national law may authorise non-beneficial interventions on incapacitated persons, in cases where there is an overriding interest, provided that sufficient protection is guaranteed and that there is no possible alternative subject [or group of subjects] [possessing full capacity] nor any equally effective alternative method.

Article 7 (Consent of incapacitated persons)

The individual undergoing the intervention shall, as far as possible, be involved in the consenting procedure [under protective conditions approved by national law].

[National law shall determine the conditions of consent applicable to incapacitated persons.]

If adults, though legally incapacitated, are capable of understanding, their consent is required.

The consent of minors shall be regarded as an increasingly determining factor in proportion to their age and capacity for discernment.

Article 8 (Emergency situation)

When because of an emergency situation the appropriate consent cannot be obtained, any medically necessary intervention may be carried out for the immediate benefit of the health of the individual concerned.

Article 9 (Previously expressed wishes)

The previously expressed wishes of the patient on a medical intervention shall be taken into account.

[The wishes relating to a medical intervention expressed previously by a patient not is not in a state to express his wishes shall be taken into account.]

Article 10 (Mental disorders)

Patients whose ability to decide what is in their best interests is impaired by mental disorders, may be submitted to an intervention without their consent, under protective conditions defined by national law, where, without treatment for these mental disorders, serious harm is likely to result to their health; such national conditions shall include appropriate supervisory, control and appeal procedures.

Article 11 (Prohibition of financial gain)

The dignity of the human body shall be respected. The human body and its parts shall not, as such, give rise to financial gain.

Article 12 (Privacy and access to information)

Everyone has the right to privacy in the health field.

Individuals are entitled to know any information collected about their health status.

However, the wishes of individuals not to be so informed shall be respected.

Article 13 (Disposal of a removed part of the human body)

When in the course of an intervention any part of a human body is removed, it can only be stored and used for a purpose other than that for which it was removed, provided this is done in conformity with appropriate information and consent procedures.

Article 14 (Scientific research)

Scientific research in the field of biology and medicine shall be carried out freely in accordance with **this Convention** and with the other legal provisions ensuring the protection of the human being.

Article 15 (Research on embryos in vitro)

Where research on embryos in vitro is by **[]** law, such research may only be authorised in the case of embryos which are not more than 14 days old.

[The creation of human embryos solely for research purposes is prohibited.]

Article 16 (Human genome)

An intervention on the human genome shall only be undertaken for therapeutic or diagnostic purposes and as long as [there is no interference with] [the aim is not to interfere with] the germ cell line.

Article 17 (Genetic tests)

Tests which are predictive of genetic diseases shall only be performed for health care purposes or scientific research.

Article 18 (Communications of results)

The communication of results of genetic testing outside the health field shall only be **[**possible] if authorised by **[]**law when there is an overriding interest.

Article 19 (Infringements of the principles)

The Parties shall provide appropriate judicial protection to prevent [or to put a stop to] an unlawful infringement of the principles set forth in this Convention at short notice.

Article 20 (Sanctions)

Parties shall provide for appropriate sanctions to be applied in the event of infringement of the provisions contained in this [Chapter].

Article 21 (Compensation for undue damage)

The person who has suffered undue damage resulting from an intervention is entitled to fair compensation according to the conditions and procedures defined by national law.

Article 22 (Wider protection)

None of the provisions of this chapter shall be interpreted as limiting or otherwise affecting the possibility for a Party to grant a wider measure of protection than is stipulated in this convention.

[In their mutual relations, Parties which are members of the European Economic Community shall apply Community rules and shall therefore not apply the rules arising from this Convention except in so far as there is no Community rule governing the particular subject concerned.]

CHAPTER II

Article 23

The Parties shall see that the fundamental questions raised by the developments of biology and medicine are appropriately discussed in the light, in particular, of relevant medical, social, economic, ethical and legal implications, and that their possible application is made the subject of appropriate public consultation.

CHAPTER III

Article 24

Protocols may be concluded in pursuance of Article 29, with a view to developing, in specific fields, the principles contained in this Convention.

Chapter IV -

Article 25 - Reports on the application of the Convention

1 On receipt of a request from the Secretary General of the Council of Europe any Party shall furnish an explanation of the manner in which its internal law ensures the effective implementation of any of the provisions of the Convention. [source: Article 57 of the Human rights Convention]

2 *The reports presented by the Parties shall be examined by the [Standing Committee]. [source: European Charter for Regional or Minority Languages, Article 16.5]*

3 *The Secretary General of the Council of Europe shall make a two-yearly report to the Committee of Ministers and the Parliamentary Assembly on the application of the Convention. [source: ibidem, Article 16.6]*

Article 26 - [The Standing Committee]

1 *For the purposes of this Convention, a [Standing Committee] is hereby set up.*

2 *The [Standing Committee] shall be composed of one member per Party, appointed by the Committee of Ministers of the Council of Europe from a list of three individuals of the highest integrity and recognised competence in the matters dealt with in the Convention, who shall be nominated by the Party concerned. [source: ibidem, Article 17.1]*

3 *Members of the Committee shall be appointed for a period of six years and shall be eligible for reappointment. A member who is unable to complete a term of office shall be replaced in accordance with the procedure laid down in paragraph 2, and the rplacing member shall complete his predecessor's term of office. [source: ibidem, Article 17.2]*

4 *Any State referred to in Article 30 or invited to accede to the Convention in accordance with the provisions of Article 31 which is not a Party to this Convention may be represented on the [Standing Committee] by an observer. [If the European Economic Community is not a Party it may be represented on the [Standing Committee] by an observer.]*

5 *Unless, at least one month before the meeting, a Party has informed the Secretary General of its objection, the [Standing Committee] may invite the following to attend as observers at all its meetings or one or part of a meeting:*

- *any State not referred to in paragraph 4 above;*
- *any international or national, governmental or non-governmental body technically qualified in the fields covered by this Convention.*

6 *The [Standing Committee] may seek the advice of experts in order to discharge its functions.*

7 *The [Standing Committee] shall be convened by the Secretary General of the Council of Europe. It shall meet whenever one-third of the Parties or the Committee of Ministers or the Secretary General of the Council of Europe so request.*

8 *A majority of members shall constitute a quorum for holding a meeting of the [Standing Committee].*

9 *Subject to Articles 27 and 29 the decisions of the [Standing Committee] shall be taken by a majority of the members present.*

10 *Subject to the provisions of this Convention the [Standing Committee] shall draw up its own rules of procedure.*

11 *The Secretariat of the [Standing Committee] shall be provided by the Secretary General of the Council of Europe.*

Article 27 - Functions of the [Standing Committee]

The [Standing Committee] shall keep under review problems relating to this Convention. It may, in particular:

a *consider any question of a general nature referred to it concerning interpretation or implementation of the Convention. The [Standing Committee]'s conclusions concerning*

implementation of the Convention may take the form of a recommendation; recommendations shall be adopted by a three quarters majority of the votes cast;

b *propose any necessary amendments to the Convention including its Protocols and examine those proposed in accordance with Article 29.*

Article 28 - Reports of the [Standing Committee]

After each meeting, the [Standing Committee] shall forward to the Parties and the Committee of Ministers of the Council of Europe a report on its discussions and any decisions taken.

Chapter V - Amendments to the Convention

Article 29

1 Any proposal for an amendment to this Convention, including any proposal for a new Protocol, presented by a Party or the [Standing Committee] shall be communicated to the Secretary General of the Council of Europe and forwarded by him at least two months before the meeting of the [Standing Committee] to the member States of the Council of Europe, [to the European Economic Community,] to any Signatory, to any Party, to any State invited to sign this Convention in accordance with the provisions of Article 30 and to any State invited to accede to it in accordance with the provisions of Article 31.

2 Any proposal presented in accordance with the provisions of the preceding paragraph shall be examined by the [Standing Committee] which:

a for amendments to Articles 1 to 22 shall submit the text adopted by a three-quarters majority of the votes cast to the Parties for acceptance;

b for amendments to Articles 23 to 35 shall submit the text adopted by a three-quarters majority of the votes cast to the Committee of Ministers for approval. After its approval, this text shall be forwarded to the Parties for acceptance.

3 Any amendment to Articles 1 to 22 shall enter into force, in respect of those Parties which have accepted it, on the first day of the month following the expiration of a period of one month after the date on which three Parties, including at least two member States of the Council of Europe, have informed the Secretary General that they have accepted it.

In respect of any Party which subsequently accepts it, the amendment shall enter into force on the first day of the month following the expiration of a period of one month after the date on which that Party has informed the Secretary General of its acceptance.

4 Any amendment to Articles 23 to 35 shall enter into force on the first day of the month following the expiration of a period of one month after the date on which all Parties have informed the Secretary General that they have accepted it.

Chapter VI - Final clauses

Article 30 - Signature, ratification and entry into force

1 This Convention shall be open for signature by the member States of the Council of Europe, the non-member States which have participated in its elaboration [and by the European Community].

2 This Convention is subject to ratification, acceptance or approval. Instruments of ratification, acceptance or approval shall be deposited with the Secretary General of the Council of Europe.

3 This Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date on which three States, including at least two member States of the Council of Europe, have expressed their consent to be bound by the Convention in accordance with the provisions of paragraph 2 of the present Article.

4 In respect of any Signatory which subsequently expresses its consent to be bound by it, the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of the deposit of its instrument of ratification, acceptance or approval.

Article 31 - Non-member States

1 After the entry into force of this Convention, the Committee of Ministers of the Council of Europe may, after consultation of the Parties, invite any non-member State of the Council of Europe to accede to this Convention by a decision taken by the majority provided for in Article 20, sub-paragraph d of the Statute of the Council of Europe, and by the unanimous vote of the representatives of the Contracting States entitled to sit on the Committee of Ministers.

2 In respect of any acceding State, the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of deposit of the instrument of accession with the Secretary General of the Council of Europe.

Article 32 - Territories

1 Any Signatory may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, specify the territory or territories to which this Convention shall apply. Any other State may formulate the same declaration when depositing its instrument of accession.

2 Any Party may, at any later date, by a declaration addressed to the Secretary General of the Council of Europe, extend the application of this Convention to any other territory specified in the declaration and for whose international relations it is responsible or on whose behalf it is authorised to give undertakings. In respect of such territory the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of receipt of such declaration by the Secretary General.

3 Any declaration made under the two preceding paragraphs may, in respect of any territory specified in such declaration, be withdrawn by a notification addressed to the Secretary General. The withdrawal shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of such notification by the Secretary General.

Article 33 - Reservations

1 Any Signatory may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, make one or more reservations to Articles [ ] of this Convention. No other reservation may be made.

Any other State may formulate the same reservations when depositing its instrument of accession.

2 Any Signatory or any other State which makes use of a reservation shall notify the Secretary General of the Council of Europe of the relevant contents of its internal law.

3 Any Party which extends the application of this Convention to a territory mentioned in the declaration referred to in Article 32, paragraph 2, may, in respect of the territory concerned, make a reservation in accordance with the provisions of the preceding paragraphs.

4 Any Party which has made one of the reservations mentioned in this Article may withdraw it by means of a declaration addressed to the Secretary General of the Council of Europe. The withdrawal shall become effective on the first day of the month following the expiration of a period of one month after the date of its receipt by the Secretary General.

Article 34 - Denunciation

1 Any Party may at any time denounce this Convention by means of a notification addressed to the Secretary General of the Council of Europe.

2 Such denunciation shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of notification by the Secretary General.

Article 35 - Notifications

The Secretary General of the Council of Europe shall notify the member States of the Council, any Signatory, any Party and any other State which has been invited to accede to this Convention of:

a any signature;
b the deposit of any instrument of ratification, acceptance, approval or accession;
c any date of entry into force of this Convention in accordance with Articles 30 or 31;
d any amendment adopted in accordance with Article 29, and the date on which such an amendment enters into force;
e any declaration made under the provisions of Article 32;
f any reservation and withdrawal of reservation made in pursuance of the provisions of Article 33;
g any other act, notification or communication relating to this Convention.

In witness whereof the undersigned, being duly authorised thereto, have signed this Convention.

Done at ....., the ....., in English and French, both texts being equally authentic, in a single copy which shall be deposited in the archives of the Council of Europe. The Secretary General of the Council of Europe shall transmit certified copies to each member State of the Council of Europe, to the non-member States which have participated in the elaboration of this Convention, [to the European Economic Community] and to any State invited to accede to this Convention.

24-27 January 1994

PRELIMINARY DRAFT CONVENTION FOR THE PROTECTION OF HUMAN RIGHTS AND DIGNITY OF THE HUMAN BEING WITH REGARD TO THE APPLICATION OF BIOLOGY AND MEDICINE: BIOETHICS CONVENTION

PREAMBLE

The Member States of the Council of Europe and the other signatories hereto,

Bearing in mind the Universal Declaration of Human Rights proclaimed by the General Assembly of the United Nations on 10 December 1948;

Bearing in mind the Convention for the Protection of Human Rights and Fundamental Freedoms of 4 November 1950;

Bearing in mind the International Covenant on Civil and Political Rights of 16 December 1966;

Bearing also in mind the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data of 28 January 1981;

Conscious of the accelerating developments in biology and medicine;

Convinced of the need to respect the human being both as an individual and as a member of the human species and recognising the importance of ensuring the dignity of the human being;

Conscious that the misuse of biology and medicine may lead to acts endangering human dignity;

Affirming that progress in biology and medicine should only be used for the benefit of present and future generations;

Considering that the aim of the Council of Europe is the achievement of a greater unity between its members and that one of the methods by which that aim is to be pursued is the maintenance and further realisation of human rights and fundamental freedoms;

Recognising the need for international co-operation so that all humanity may enjoy the benefits of biology and medicine;

Recognising the importance of promoting a public debate on the questions posed by the application of biology and medicine and the responses to be given thereto;

Wishing to remind all members of society of their rights and responsibilities;

Taking account of the work of the Parliamentary Assembly in this field, including Recommendation 1160 (1991) on the preparation of a Convention on bioethics;

Resolving to take such measures as are necessary to safeguard human dignity and the fundamental rights of the individual with regard to the application of biology and medicine;

Have agreed as follows:

CHAPTER I

Article 1 (Purpose and object)

Parties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their **integrity and other rights and fundamental freedoms** with regard to the application of biology and medicine.

Article 2 (Primacy of the human being)

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

No restrictions shall be placed on the exercise of the rights contained in this Convention other than such as are prescribed by law and are necessary in a democratic society in the interest of national security and public safety, for the prevention of disorder or crime, for the protection of public health or for the protection of the rights and freedoms of others.

Article 3 (Professional standards)

Any intervention in the health field must be carried out in accordance with relevant professional obligations and standards.

Article 4 (Equitable access)

Parties shall take appropriate measures with a view to providing equitable access to health care, taking into account available resources and medical needs.

Article 5 (Consent)

No intervention may be carried out in the health field without the free and informed consent of the person undergoing it.

The person concerned may freely withdraw consent at any time.

Article 6 (Incapacity)

Interventions may be carried out on legally incapacitated persons and those who, though legally capable, have a reduced capacity of understanding, only for their direct benefit and under protective conditions approved by national law.

Exceptionally, in cases where there is an overriding interest and provided that sufficient protection of the incapacitated person is guaranteed, national law may authorise non-beneficial interventions on an incapacitated person in the two following situations:

- **in the case of medical research where there is a minimal risk and burden for the individual concerned, provided that there is no alternative subject with full capacity nor any equally effective alternative method;**

- **in the case of removal of regenerative tissues for transplantation purposes between persons having close personal or family relations, provided that there is no donor with full capacity nor any equally effective alternative method.**

Article 7 (Consent of incapacitated persons)

The individual undergoing the intervention shall, as far as possible, be involved in the consenting procedure.

The consent of minors shall be regarded as an increasingly determining factor in proportion to their age and capacity for discernment.

If adults, though legally incapacitated, are capable of understanding, their consent is required.

Article 8 (Emergency situation)

When because of an emergency situation the appropriate consent cannot be obtained, any medically necessary intervention may be carried out for the immediate benefit of the health of the individual concerned.

Article 9 (Previously expressed wishes)

The previously expressed wishes relating to a medical intervention by a patient who is not, at the time of the intervention, in a state to express his wishes shall be taken into account.

Article 10 (Mental disorders)

Patients whose ability to decide what is in their best interests is impaired by mental disorders, may be submitted to an intervention without their consent, under protective conditions defined by national law, where, without treatment for these mental disorders, serious harm is likely to result to their health; such national conditions shall include appropriate supervisory, control and appeal procedures.

Article 11 (Prohibition of financial gain)

The dignity of the human body shall be respected. The human body and its parts shall not, as such, give rise to financial gain.

Article 12 (Privacy and access to information)

Everyone has the right to privacy in the health field.

Individuals are entitled to know any information collected about their health. However, the wishes of individuals not to be so informed shall be respected.

Article 13 (Disposal of a removed part of the human body)

When in the course of an intervention any part of a human body is removed, it can only be stored and used for a purpose other than that for which it was removed, provided this is done in conformity with appropriate information and consent procedures.

Article 14 (Scientific research)

Scientific research in the field of biology and medicine shall be carried out freely in accordance with this Convention and with the other legal provisions ensuring the protection of the human being.

Article 15 (Research on embryos in vitro)

1. Where research on embryos in vitro is allowed by law, such research may only be **permitted** in the case of embryos **which have not been developed for** more than 14 days.

2. The creation of human embryos solely for research purposes is prohibited.

Article 16 (Human genome)

An intervention on the human genome shall only be undertaken for therapeutic or diagnostic purposes and as long **as the aim is not to interfere with the germ cell line**.

Article 17 (Genetic tests)

Tests which are predictive of genetic diseases shall only be performed for health purposes **or for** scientific research **linked to health purposes**.

Article 18 (Communications of results)

The communication of results of genetic testing outside the health field shall only be **allowed** if **prescribed** by law when there is an overriding interest.

Article 19 (Infringements of the principles)

The Parties shall provide appropriate judicial protection to prevent or to put a stop to an unlawful infringement of the principles set forth in this Convention at short notice.

Article 20 (Compensation for undue damage)

The person who has suffered undue damage resulting from an intervention is entitled to fair compensation according to the conditions and procedures **prescribed** by national law.

Article 21 (Sanctions)

Parties shall provide for appropriate sanctions to be applied in the event of infringement of the provisions contained in this [Chapter].

Article 22 (Wider protection)

None of the provisions of this chapter shall be interpreted as limiting or otherwise affecting the possibility for a Party to grant a wider measure of protection than is stipulated in this convention.

CHAPTER II

Article 23

The Parties shall see that the fundamental questions raised by the developments of biology and medicine are appropriately discussed in the light, in particular, of relevant medical, social, economic, ethical and legal implications, and that their possible application is made the subject of appropriate public consultation.

CHAPTER III

Article 24

Protocols may be concluded in pursuance of Article 29, with a view to developing, in specific fields, the principles contained in this Convention.

[Protocols shall be open for signature by Signatories of the Convention. They shall be subject to ratification, acceptance or approval. A signatory may not ratify, accept or approve Protocols without previously or simultaneously ratifying the Convention.]

Chapter IV -

Article 25 - Reports on the application of the Convention

1 *On receipt of a request from the Secretary General of the Council of Europe any Party shall furnish an explanation of the manner in which its internal law ensures the effective implementation of any of the provisions of the Convention. [source: Article 57 of the Human rights Convention]*

2 *The reports presented by the Parties shall be examined by the [Standing Committee]. [source: European Charter for Regional or Minority Languages, Article 16.5]*

3 *The Secretary General of the Council of Europe shall make a two-yearly report to the Committee of Ministers and the Parliamentary Assembly on the application of the Convention. [source: ibidem, Article 16.6]*

Article 26 - [The Standing Committee]

1 *For the purposes of this Convention, a [Standing Committee] is hereby set up.*

2 *The [Standing Committee] shall be composed of one member per Party, appointed by the Committee of Ministers of the Council of Europe from a list of three individuals of the highest integrity and recognised competence in the matters dealt with in the Convention, who shall be nominated by the Party concerned. [source: ibidem, Article 17.1]*

3 *Members of the Committee shall be appointed for a period of six years and shall be eligible for reappointment. A member who is unable to complete a term of office shall be replaced in accordance with the procedure laid down in paragraph 2, and the rplacing member shall complete his predecessor's term of office. [source: ibidem, Article 17.2]*

4 *Any State referred to in Article 30 or invited to accede to the Convention in accordance with the provisions of Article 31 which is not a Party to this Convention may be represented on the [Standing Committee] by an observer. [If the European Economic Community is not a Party it may be represented on the [Standing Committee] by an observer.]*

5 *Unless, at least one month before the meeting, a Party has informed the Secretary General of its objection, the [Standing Committee] may invite the following to attend as observers at all its meetings or one or part of a meeting:*

- *any State not referred to in paragraph 4 above;*

- *any international or national, governmental or non-governmental body technically qualified in the fields covered by this Convention.*

6 *The [Standing Committee] may seek the advice of experts in order to discharge its functions.*

7 *The [Standing Committee] shall be convened by the Secretary General of the Council of Europe. It shall meet whenever one-third of the Parties or the Committee of Ministers or the Secretary General of the Council of Europe so request.*

8 *A majority of members shall constitute a quorum for holding a meeting of the [Standing Committee].*

9 *Subject to Articles 27 and 29 the decisions of the [Standing Committee] shall be taken by a majority of the members present.*

10 *Subject to the provisions of this Convention the [Standing Committee] shall draw up its own rules of procedure.*

11 *The Secretariat of the [Standing Committee] shall be provided by the Secretary General of the Council of Europe.*

Article 27 - Functions of the [Standing Committee]

The [Standing Committee] shall keep under review problems relating to this Convention. It may, in particular:

a *consider any question of a general nature referred to it concerning interpretation or implementation of the Convention. The [Standing Committee]'s conclusions concerning implementation of the Convention may take the form of a recommendation; recommendations shall be adopted by a three quarters majority of the votes cast;*

b *propose any necessary amendments to the Convention including its Protocols and examine those proposed in accordance with Article 29.*

Article 28 - Reports of the [Standing Committee]

After each meeting, the [Standing Committee] shall forward to the Parties and the Committee of Ministers of the Council of Europe a report on its discussions and any decisions taken.

Chapter V - Amendments to the Convention

Article 29

1 Any proposal for an amendment to this Convention, and any proposal for a new Protocol **or for an amendment to a Protocol**, presented by a Party, the Committee **or the Committee of Ministers** shall be communicated to the Secretary General of the Council of Europe and forwarded by him at least two months before the meeting of the Committee to the member States of the Council of Europe, [to the European Community,] to any Signatory, to any Party, to any State invited to sign this Convention in accordance with the provisions of Article 30 and to any State invited to accede to it in accordance with the provisions of Article 31.

[The Committee shall be composed of one member per Party, appointed by the Government of the said Party.]

2 Any proposal presented in accordance with the provisions of the preceding paragraph shall be examined by the Committee which shall submit the text adopted by a three-quarters majority of the votes cast to the Committee of Ministers for approval. After its approval **by a two-thirds majority**, this text shall be forwarded to the Parties for acceptance.

3 Any amendment shall enter into force, in respect of those Parties which have accepted it, on the first day of the month following the expiration of a period of one month after the date on which **five** Parties, including at least **four** member States of the Council of Europe, have informed the Secretary General that they have accepted it.

In respect of any Party which subsequently accepts it, the amendment shall enter into force on the first day of the month following the expiration of a period of one month after the date on which that Party has informed the Secretary General of its acceptance.

Chapter VI - Final clauses

Article 30 - Signature, ratification and entry into force

1 This Convention shall be open for signature by the member States of the Council of Europe, the non-member States which have participated in its elaboration [and by the European Community].

2 This Convention is subject to ratification, acceptance or approval. Instruments of ratification, acceptance or approval shall be deposited with the Secretary General of the Council of Europe.

3 This Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date on which **five** States, including at least **four** member States of the Council of Europe, have expressed their consent to be bound by the Convention in accordance with the provisions of paragraph 2 of the present Article.

4 In respect of any Signatory which subsequently expresses its consent to be bound by it, the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of the deposit of its instrument of ratification, acceptance or approval.

Article 31 - Non-member States

1 After the entry into force of this Convention, the Committee of Ministers of the Council of Europe may of its own initiative or on proposal of the Committee and, after consultation of the Parties, invite any non-member State of the Council of Europe to accede to this Convention by a decision taken by the majority provided for in Article 20, sub-paragraph d of the Statute of the Council of Europe, and by the unanimous vote of the representatives of the Contracting States entitled to sit on the Committee of Ministers.

2 In respect of any acceding State, the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of deposit of the instrument of accession with the Secretary General of the Council of Europe.

Article 32 - Territories

1 Any Signatory may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, specify the territory or territories to which this Convention shall apply. Any other State may formulate the same declaration when depositing its instrument of accession.

2 Any Party may, at any later date, by a declaration addressed to the Secretary General of the Council of Europe, extend the application of this Convention to any other territory specified in the declaration and for whose international relations it is responsible or on whose behalf it is authorised to give undertakings. In respect of such territory the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of receipt of such declaration by the Secretary General.

3 Any declaration made under the two preceding paragraphs may, in respect of any territory specified in such declaration, be withdrawn by a notification addressed to the Secretary General. The withdrawal shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of such notification by the Secretary General.

Article 33 - Reservations

1 Any Signatory may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, make **a reservation to Article 15.2** of this Convention. No other reservation may be made.

Any other State may formulate the same reservation when depositing its instrument of accession.

2 Any Signatory or any other State which makes use of a reservation shall notify the Secretary General of the Council of Europe of the relevant contents of its internal law.

3 Any Party which extends the application of this Convention to a territory mentioned in the declaration referred to in Article 32, paragraph 2, may, in respect of the territory concerned, make a reservation in accordance with the provisions of the preceding paragraphs.

4 Any Party which has made the reservation mentioned in this Article may withdraw it by means of a declaration addressed to the Secretary General of the Council of Europe. The withdrawal shall become effective on the first day of the month following the expiration of a period of one month after the date of its receipt by the Secretary General.

Article 34 - Denunciation

1 Any Party may at any time denounce this Convention by means of a notification addressed to the Secretary General of the Council of Europe.

2 Such denunciation shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of notification by the Secretary General.

Article 35 - Notifications

The Secretary General of the Council of Europe shall notify the member States of the Council, any Signatory, any Party and any other State which has been invited to accede to this Convention of:

a any signature;
b the deposit of any instrument of ratification, acceptance, approval or accession;
c any date of entry into force of this Convention in accordance with Articles 30 or 31;
d any amendment adopted in accordance with Article 29, and the date on which such an amendment enters into force;
e any declaration made under the provisions of Article 32;
f any reservation and withdrawal of reservation made in pursuance of the provisions of Article 33;
g any other act, notification or communication relating to this Convention.

In witness whereof the undersigned, being duly authorised thereto, have signed this Convention.

Done at ....., the ....., in English and French, both texts being equally authentic, in a single copy which shall be deposited in the archives of the Council of Europe. The Secretary General of the Council of Europe shall transmit certified copies to each member State of the Council of Europe, to the non-member States which have participated in the elaboration of this Convention, [to the European Economic Community] and to any State invited to accede to this Convention.

18-22 April 1994

PRELIMINARY DRAFT CONVENTION FOR THE PROTECTION OF HUMAN RIGHTS AND DIGNITY OF THE HUMAN BEING WITH REGARD TO THE APPLICATION OF BIOLOGY AND MEDICINE: BIOETHICS CONVENTION

PREAMBLE

The Member States of the Council of Europe and the other signatories hereto,

Bearing in mind the Universal Declaration of Human Rights proclaimed by the General Assembly of the United Nations on 10 December 1948;

Bearing in mind the Convention for the Protection of Human Rights and Fundamental Freedoms of 4 November 1950;

Bearing in mind the International Covenant on Civil and Political Rights of 16 December 1966;

Bearing also in mind the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data of 28 January 1981;

Conscious of the accelerating developments in biology and medicine;

Convinced of the need to respect the human being both as an individual and as a member of the human species and recognising the importance of ensuring the dignity of the human being;

Conscious that the misuse of biology and medicine may lead to acts endangering human dignity;

Affirming that progress in biology and medicine should only be used for the benefit of present and future generations;

Considering that the aim of the Council of Europe is the achievement of a greater unity between its members and that one of the methods by which that aim is to be pursued is the maintenance and further realisation of human rights and fundamental freedoms;

Recognising the need for international co-operation so that all humanity may enjoy the benefits of biology and medicine;

Recognising the importance of promoting a public debate on the questions posed by the application of biology and medicine and the responses to be given thereto;

Wishing to remind all members of society of their rights and responsibilities;

Taking account of the work of the Parliamentary Assembly in this field, including Recommendation 1160 (1991) on the preparation of a Convention on bioethics;

Resolving to take such measures as are necessary to safeguard human dignity and the fundamental rights of the individual with regard to the application of biology and medicine;

Have agreed as follows:

CHAPTER I

Article 1 (Purpose and object)

Parties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine.

Article 2 (Primacy of the human being)

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

No restrictions shall be placed on the exercise of the rights contained in this Convention other than such as are prescribed by law and are necessary in a democratic society in the interest of national security, public safety, for the prevention of disorder or crime, for the protection of public health or for the protection of the rights and freedoms of others.

Article 3 (Professional standards)

*Any intervention in the health field****, including research,*** *must be carried out in accordance with relevant professional obligations and standards.*

Article 4 (Equitable access)

Parties shall take appropriate measures with a view to providing ***[, within their jurisdiction,]*** *equitable access to health care, taking into account* ***health needs and available resources****.*

Article 5 (Consent)

No intervention may be carried out in the health field without the free and informed consent of the person undergoing it.

The person concerned may freely withdraw consent at any time.

Article 6 (Incapacity)

Interventions may be carried out on legally incapacitated persons and those who, though legally capable, have a reduced capacity of understanding, only for their direct benefit and under protective conditions approved by national law.

In exceptional cases and in accordance with national law*, in cases where there is an overriding interest and provided that sufficient protection of the incapacitated person is guaranteed, non-beneficial interventions* ***may be carried out*** *on an incapacitated person in the two following situations:*

- *in the case of medical research where there is a [minimal risk and burden]* ***[negligible risk and minimal burden]*** *for the individual concerned, provided that* ***equally effective research may not be carried out on*** *subjects with full capacity and that there is no equally effective alternative method* ***to research****;*

- *in the case of removal of regenerative tissues for transplantation purposes between persons having close personal or family relations, provided that there is no donor with full capacity nor any equally effective alternative method.*

Article 7 (Consent of incapacitated persons)

The individual undergoing the intervention shall, as far as possible, be involved in the consenting procedure.

The consent of minors shall be regarded as an increasingly determining factor in proportion to their age and capacity for discernment.

If adults, though legally incapacitated, are capable of understanding, their consent is required.

Article 8 (Emergency situation)

When because of an emergency situation the appropriate consent cannot be obtained, any medically necessary intervention may be carried out ***immediately*** *for the benefit of the health of the individual concerned.*

Article 9 (Previously expressed wishes)

The previously expressed wishes relating to a medical intervention by a patient who is not, at the time of the intervention, in a state to express his wishes shall be taken into account.

Article 10 (Mental disorders)

Patients whose ability to decide what is in their best interests is impaired by mental disorders may be subjected, without their consent and on the protective conditions prescribed by national law, to an intervention aimed at treating their mental disorders where, without such treatment, serious harm is likely to result to their health. The protective conditions prescribed by national law shall include supervisory, control and appeal procedures.

Article 11 (Prohibition of financial gain)

The human body and its parts shall not, as such, give rise to financial gain.

Article 12 (Privacy and access to information)

Everyone has the right to privacy in the health field.

Individuals are entitled to know any information collected about their health. However, the wishes of individuals not to be so informed shall be ***followed****.*

[In exceptional cases, restrictions may be placed by national law on the exercise of the rights contained in the preceeding paragraph in the interests of the patient's health.]

Article 13 (Disposal of a removed part of the human body)

When in the course of an intervention any part of a human body is removed, it can only be stored and used for a purpose other than that for which it was removed, provided this is done in conformity with appropriate information and consent procedures.

Article 14 (Scientific research)

Scientific research in the field of biology and medicine shall be carried out freely in accordance with this Convention and with the other legal provisions ensuring the protection of the human being.

Article 15 (Research on embryos in vitro)

1. Where research on embryos in vitro is allowed by law, such research may only be permitted in the case of embryos which have not been developed for more than 14 days.

2. The creation of human embryos solely for research purposes is prohibited.

Article 16 (Human genome)

An intervention on the human genome shall only be undertaken for therapeutic or diagnostic purposes and as long as the aim is not to interfere with the germ cell line.

Article 17 (Genetic tests)

Tests which are predictive of genetic diseases shall only be performed for health purposes or for scientific research linked to health purposes.

Article 18 (Communication of results)

The communication of results of genetic testing outside the health field shall only be allowed if prescribed by law when there is an overriding interest.

Article 19 (Infringements of the principles)

The Parties shall provide appropriate judicial protection to prevent or to put a stop to an unlawful infringement of the principles set forth in this Convention at short notice.

Article 20 (Compensation for undue damage)

The person who has suffered undue damage resulting from an intervention is entitled to fair compensation according to the conditions and procedures **prescribed** by national law.

Article 21 (Sanctions)

Parties shall provide for appropriate sanctions to be applied in the event of infringement of the provisions contained in this [Chapter].

Article 22 (Wider protection)

None of the provisions of this chapter shall be interpreted as limiting or otherwise affecting the possibility for a Party to grant a wider measure of protection than is stipulated in this convention.

CHAPTER II

Article 23

The Parties shall see that the fundamental questions raised by the developments of biology and medicine are appropriately discussed in the light, in particular, of relevant medical, social, economic, ethical and legal implications, and that their possible application is made the subject of appropriate public consultation.

CHAPTER III

Article 24

Protocols may be concluded in pursuance of Article 29, with a view to developing, in specific fields, the principles contained in this Convention.

[Protocols shall be open for signature by Signatories of the Convention. They shall be subject to ratification, acceptance or approval. A signatory may not ratify, accept or approve Protocols without previously or simultaneously ratifying the Convention.]

Chapter IV -

Article 25 - Reports on the application of the Convention

1 *On receipt of a request from the Secretary General of the Council of Europe any Party shall furnish an explanation of the manner in which its internal law ensures the effective implementation of any of the provisions of the Convention. [source: Article 57 of the Human rights Convention]*

2 *The reports presented by the Parties shall be examined by the [Standing Committee]. [source: European Charter for Regional or Minority Languages, Article 16.5]*

3 *The Secretary General of the Council of Europe shall make a two-yearly report to the Committee of Ministers and the Parliamentary Assembly on the application of the Convention. [source: ibidem, Article 16.6]*

Article 26 - [The Standing Committee]

1 *For the purposes of this Convention, a [Standing Committee] is hereby set up.*

2 *The [Standing Committee] shall be composed of one member per Party, appointed by the Committee of Ministers of the Council of Europe from a list of three individuals of the highest integrity and recognised competence in the matters dealt with in the Convention, who shall be nominated by the Party concerned. [source: ibidem, Article 17.1]*

3 *Members of the Committee shall be appointed for a period of six years and shall be eligible for reappointment. A member who is unable to complete a term of office shall be replaced in accordance with the procedure laid down in paragraph 2, and the rplacing member shall complete his predecessor's term of office. [source: ibidem, Article 17.2]*

4 *Any State referred to in Article 30 or invited to accede to the Convention in accordance with the provisions of Article 31 which is not a Party to this Convention may be represented on the [Standing Committee] by an observer. [If the European Economic Community is not a Party it may be represented on the [Standing Committee] by an observer.]*

5 *Unless, at least one month before the meeting, a Party has informed the Secretary General of its objection, the [Standing Committee] may invite the following to attend as observers at all its meetings or one or part of a meeting:*

- *any State not referred to in paragraph 4 above;*
- *any international or national, governmental or non-governmental body technically qualified in the fields covered by this Convention.*

6 *The [Standing Committee] may seek the advice of experts in order to discharge its functions.*

7 *The [Standing Committee] shall be convened by the Secretary General of the Council of Europe. It shall meet whenever one-third of the Parties or the Committee of Ministers or the Secretary General of the Council of Europe so request.*

8 *A majority of members shall constitute a quorum for holding a meeting of the [Standing Committee].*

9 *Subject to Articles 27 and 29 the decisions of the [Standing Committee] shall be taken by a majority of the members present.*

10 *Subject to the provisions of this Convention the [Standing Committee] shall draw up its own rules of procedure.*

11 *The Secretariat of the [Standing Committee] shall be provided by the Secretary General of the Council of Europe.*

Article 27 - Functions of the [Standing Committee]

The [Standing Committee] shall keep under review problems relating to this Convention. It may, in particular:

a *consider any question of a general nature referred to it concerning interpretation or implementation of the Convention. The [Standing Committee]'s conclusions concerning implementation of the Convention may take the form of a recommendation; recommendations shall be adopted by a three quarters majority of the votes cast;*

b *propose any necessary amendments to the Convention including its Protocols and examine those proposed in accordance with Article 29.*

Article 28 - Reports of the [Standing Committee]

After each meeting, the [Standing Committee] shall forward to the Parties and the Committee of Ministers of the Council of Europe a report on its discussions and any decisions taken.

Chapter V - Amendments to the Convention

Article 29

1 Any proposal for an amendment to this Convention, and any proposal for a new Protocol **or for an amendment to a Protocol**, presented by a Party, the Committee **or the Committee of Ministers** shall be communicated to the Secretary General of the Council of Europe and forwarded by him at least two months before the meeting of the Committee to the member States of the Council of Europe, [to the European Community,] to any Signatory, to any Party, to any State invited to sign this Convention in accordance with the provisions of Article 30 and to any State invited to accede to it in accordance with the provisions of Article 31.

[The Committee shall be composed of one member per Party, appointed by the Government of the said Party.]

2 Any proposal presented in accordance with the provisions of the preceding paragraph shall be examined by the Committee which shall submit the text adopted by a three-quarters majority of the votes cast to the Committee of Ministers for approval. After its approval **by a two-thirds majority**, this text shall be forwarded to the Parties for acceptance.

3 Any amendment shall enter into force, in respect of those Parties which have accepted it, on the first day of the month following the expiration of a period of one month after the date on which **five** Parties, including at least **four** member States of the Council of Europe, have informed the Secretary General that they have accepted it.

In respect of any Party which subsequently accepts it, the amendment shall enter into force on the first day of the month following the expiration of a period of one month after the date on which that Party has informed the Secretary General of its acceptance.

Chapter VI - Final clauses

Article 30 - Signature, ratification and entry into force

1 This Convention shall be open for signature by the member States of the Council of Europe, the non-member States which have participated in its elaboration [and by the European Community].

2 This Convention is subject to ratification, acceptance or approval. Instruments of ratification, acceptance or approval shall be deposited with the Secretary General of the Council of Europe.

3 This Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date on which **five** States, including at least **four** member States of the Council of Europe, have expressed their consent to be bound by the Convention in accordance with the provisions of paragraph 2 of the present Article.

4 In respect of any Signatory which subsequently expresses its consent to be bound by it, the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of the deposit of its instrument of ratification, acceptance or approval.

Article 31 - Non-member States

1 After the entry into force of this Convention, the Committee of Ministers of the Council of Europe may of its own initiative or on proposal of the Committee and, after consultation of the Parties, invite any non-member State of the Council of Europe to accede to this Convention by a decision taken by the majority provided for in Article 20, sub-paragraph d of the Statute of the Council of Europe, and by the unanimous vote of the representatives of the Contracting States entitled to sit on the Committee of Ministers.

2 In respect of any acceding State, the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of deposit of the instrument of accession with the Secretary General of the Council of Europe.

Article 32 - Territories

1 Any Signatory may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, specify the territory or territories to which this Convention shall apply. Any other State may formulate the same declaration when depositing its instrument of accession.

2 Any Party may, at any later date, by a declaration addressed to the Secretary General of the Council of Europe, extend the application of this Convention to any other territory specified in the declaration and for whose international relations it is responsible or on whose behalf it is authorised to give undertakings. In respect of such territory the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of receipt of such declaration by the Secretary General.

3 Any declaration made under the two preceding paragraphs may, in respect of any territory specified in such declaration, be withdrawn by a notification addressed to the Secretary General. The withdrawal shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of such notification by the Secretary General.

Article 33 - Reservations

1 Any Signatory may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, make **a reservation to Article 15.2** of this Convention. No other reservation may be made.

Any other State may formulate the same reservation when depositing its instrument of accession.

2 Any Signatory or any other State which makes use of a reservation shall notify the Secretary General of the Council of Europe of the relevant contents of its internal law.

3 Any Party which extends the application of this Convention to a territory mentioned in the declaration referred to in Article 32, paragraph 2, may, in respect of the territory concerned, make a reservation in accordance with the provisions of the preceding paragraphs.

4 Any Party which has made the reservation mentioned in this Article may withdraw it by means of a declaration addressed to the Secretary General of the Council of Europe. The withdrawal shall become effective on the first day of the month following the expiration of a period of one month after the date of its receipt by the Secretary General.

Article 34 - Denunciation

1 Any Party may at any time denounce this Convention by means of a notification addressed to the Secretary General of the Council of Europe.

2 Such denunciation shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of notification by the Secretary General.

Article 35 - Notifications

The Secretary General of the Council of Europe shall notify the member States of the Council, any Signatory, any Party and any other State which has been invited to accede to this Convention of:

a any signature;
b the deposit of any instrument of ratification, acceptance, approval or accession;
c any date of entry into force of this Convention in accordance with Articles 30 or 31;
d any amendment adopted in accordance with Article 29, and the date on which such an amendment enters into force;
e any declaration made under the provisions of Article 32;
f any reservation and withdrawal of reservation made in pursuance of the provisions of Article 33;
g any other act, notification or communication relating to this Convention.

In witness whereof the undersigned, being duly authorised thereto, have signed this Convention.

Done at ....., the ....., in English and French, both texts being equally authentic, in a single copy which shall be deposited in the archives of the Council of Europe. The Secretary General of the Council of Europe shall transmit certified copies to each member State of the Council of Europe, to the non-member States which have participated in the elaboration of this Convention, [to the European Economic Community] and to any State invited to accede to this Convention.

27 June-1 July 1994

DRAFT CONVENTION FOR THE PROTECTION OF HUMAN RIGHTS AND DIGNITY OF THE HUMAN BEING WITH REGARD TO THE APPLICATION OF BIOLOGY AND MEDICINE: BIOETHICS CONVENTION AND EXPLANATORY MEMORANDUM

This draft Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Bioethics Convention has been prepared by the Steering Committee on Bioethics (CDBI).

The draft has been declassified in its present form following the authorisation of the Committee of Ministers to enable the Steering Committee and governments to proceed to the necessary consultations and to take account of any views expressed when preparing the final text.

When the Steering Committee has completed the draft, it will be submitted to the Committee of Ministers of the Council of Europe for adoption.

Declassification at this stage does not imply the agreement of the Committee of Ministers with the contents of the draft Convention nor does it in any way engage the political responsibility of the Committee of Ministers or of the Member States of the Council of Europe.

Directorate of Legal Affairs

Strasbourg, July 1994

DRAFT CONVENTION FOR THE PROTECTION OF HUMAN RIGHTS AND DIGNITY OF THE HUMAN BEING WITH REGARD TO THE APPLICATION OF BIOLOGY AND MEDICINE: BIOETHICS CONVENTION

PREAMBLE

The Member States of the Council of Europe, the other States [and the European Community] signatories hereto,

Bearing in mind the Universal Declaration of Human Rights proclaimed by the General Assembly of the United Nations on 10 December 1948;

Bearing in mind the Convention for the Protection of Human Rights and Fundamental Freedoms of 4 November 1950;

Bearing in mind the International Covenant on Civil and Political Rights of 16 December 1966;

Bearing also in mind the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data of 28 January 1981;

Conscious of the accelerating developments in biology and medicine;

Convinced of the need to respect the human being both as an individual and as a member of the human species and recognising the importance of ensuring the dignity of the human being;

Conscious that the misuse of biology and medicine may lead to acts endangering human dignity;

Affirming that progress in biology and medicine should be used for the benefit of present and future generations;

Considering that the aim of the Council of Europe is the achievement of a greater unity between its members and that one of the methods by which that aim is to be pursued is the maintenance and further realisation of human rights and fundamental freedoms;

Stressing the need for international co-operation so that all humanity may enjoy the benefits of biology and medicine;

Recognising the importance of promoting a public debate on the questions posed by the application of biology and medicine and the responses to be given thereto;

Wishing to remind all members of society of their rights and responsibilities;

Taking account of the work of the Parliamentary Assembly in this field, including Recommendation 1160 (1991) on the preparation of a Convention on bioethics;

Resolving to take such measures as are necessary to safeguard human dignity and the fundamental rights of the individual with regard to the application of biology and medicine;

Have agreed as follows:

CHAPTER I

Article 1 (Purpose and object)

Parties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine.

Article 2 (Primacy of the human being)

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

No restrictions shall be placed on the exercise of the rights 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 disorder or crime, for the protection of public health or for the protection of the rights and freedoms of others.

Article 3 (Professional standards)

Any intervention in the health field, including research, must be carried out in accordance with relevant professional obligations and standards.

Article 4 (Equitable access)

Parties shall take appropriate measures with a view to providing, within their jurisdiction, equitable access to health care, taking into account health needs and available resources.

Article 5 (Consent)

No intervention may be carried out in the health field without the free and informed consent of the person undergoing it.

The person concerned may freely withdraw consent at any time.

Article 6 [*Protection of persons lacking capacity*]

Interventions may be carried out on [*legally incapacitated persons*] [*persons who have no legal capacity to give consent*] and those who, though legally capable [*to give consent*], have a reduced capacity of understanding, only for their direct benefit and under protective conditions approved by law.

[*In exceptional cases and in accordance with the law, in cases where a significant benefit may be derived and provided that sufficient protection of the incapacitated person is guaranteed, [non-beneficial interventions] [interventions with no direct individual benefit] may be carried out on an incapacitated person in the two following situations:*

- *in the case of medical research where there is a negligible risk and minimal burden for the individual concerned, provided that equally effective research may not be carried out on subjects with full capacity and that there is no equally effective alternative method to research;*

- *in the case of removal of regenerative tissues for transplantation purposes between persons having close personal or family relations, provided that there is no donor with full capacity nor any equally effective alternative method.*][3]

[3] It should be pointed out that, while the whole text is still only a draft, the passages in square brackets are considered by the CDBI to need detailed re-examination. Although the CDBI has managed to identify the principles contained therein, the wording has still to be carefully revised.

Article 7 (Consent of incapacitated persons)

The individual undergoing the intervention shall, as far as possible, be involved in the consenting procedure.

The consent of minors shall be regarded as an increasingly determining factor in proportion to their age and capacity for discernment.

If adults, though legally incapacitated, are capable of understanding, their consent is required.

Article 8 (Emergency situation)

When because of an emergency situation the appropriate consent cannot be obtained, any medically necessary intervention may be carried out immediately for the benefit of the health of the individual concerned.

Article 9 (Previously expressed wishes)

The previously expressed wishes relating to a medical intervention by a patient who is not, at the time of the intervention, in a state to express his wishes shall be taken into account.

Article 10 (Mental disorders)

Patients whose ability to decide what is in their best interests is impaired by mental disorders may be subjected, without their consent and on the protective conditions prescribed by law, to an intervention aimed at treating their mental disorders where, without such treatment, serious harm is likely to result to their health. The protective conditions prescribed by law shall include supervisory, control and appeal procedures.

Article 11 (Prohibition of financial gain)

The human body and its parts shall not, as such, give rise to financial gain.

Article 12 (Privacy and access to information)

Everyone has the right to respect for private life in the health field.

Individuals are entitled to know any information collected about their health. However, the wishes of individuals not to be so informed shall be observed.

In exceptional cases, restrictions may be placed by law on the exercise of the rights contained in the preceding paragraph in the interests of the patient.

Article 13 (Disposal of a removed part of the human body)

When in the course of an intervention any part of a human body is removed, it may be stored and used for a purpose other than that for which it was removed, only if this is done in conformity with appropriate information and consent procedures.

Article 14 (Scientific research)

Scientific research in the field of biology and medicine shall be carried out freely in accordance with this Convention and with the other legal provisions ensuring the protection of the human being.

Article 15 (Research on embryos in vitro)

1. Where research on embryos in vitro is allowed by law, such research may only be permitted in the case of embryos which have not been developed for more than 14 days.

2. The creation of human embryos solely for research purposes is prohibited.

Article 16 (Human genome)

An intervention on the human genome may only be undertaken for preventive, therapeutic or diagnostic purposes and as long as the aim is not to interfere with the germ cell line.

Article 17 (Tests predictive of genetic disease)

Tests which are predictive of genetic diseases or that may identify a genetic predisposition to a disease may only be performed for health purposes or for scientific research linked to health purposes.

Article 18 (Communication of results)

The communication of results of genetic testing outside the health field may only be allowed in accordance with the provisions of Article 2 paragraph 2 of this Convention.

Article 19 (Infringements of the principles)

The Parties shall provide appropriate judicial protection to prevent or to put a stop to an unlawful infringement of the rights and principles set forth in this Convention at short notice.

Article 20 (Compensation for undue damage)

The person who has suffered undue damage resulting from an intervention is entitled to fair compensation according to the conditions and procedures prescribed by law.

Article 21 (Sanctions)

Parties shall provide for appropriate sanctions to be applied in the event of infringement of the provisions contained in this Chapter.

Article 22 (Wider protection)

None of the provisions of this chapter 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.

CHAPTER II

Article 23 (Public debate)

The Parties shall see to it that the fundamental questions raised by the developments of biology and medicine are the subject of appropriate public discussion in the light, in particular, of relevant medical, social, economic, ethical and legal implications, and that their possible application is made the subject of appropriate consultation.

CHAPTER III

Article 24 (Protocols)

Protocols may be concluded in pursuance of Article 26, with a view to developing, in specific fields, the principles contained in this Convention.

The Protocols shall be open for signature by Signatories of the Convention. They shall be subject to ratification, acceptance or approval. A signatory may not ratify, accept or approve Protocols without previously or simultaneously ratifying the Convention.

CHAPTER IV

Article 25 - Reports on the application of the Convention

On receipt of a request from the Secretary General of the Council of Europe any Party shall furnish an explanation of the manner in which its internal law ensures the effective implementation of any of the provisions of the Convention.

CHAPTER V

Article 26 Amendments to the Convention

1 For the purposes of this article a Committee is hereby set up.

2 The Committee referred to in the preceding paragraph shall be composed of one delegation per Party, appointed by the Government of the said Party. Each delegation shall have one vote. Any State referred to in Article 27 or invited to accede to the Convention in accordance with the provisions of Article 28 which is not a Party to this Convention may be represented on the Committee by an observer. [If the European Community is not a Party it may be represented on the Committee by an observer.]

3 Any proposal for an amendment to this Convention, and any proposal for a Protocol or for an amendment to a Protocol, presented by a Party, the Committee or the Committee of Ministers shall be communicated to the Secretary General of the Council of Europe and forwarded by him to the member States of the Council of Europe, [to the European Community,] to any Signatory, to any Party, to any State invited to sign this Convention in accordance with the provisions of Article 27 and to any State invited to accede to it in accordance with the provisions of Article 28.

4 The Committee shall meet not earlier than two months after a proposal has been forwarded by the Secretary General in accordance with paragraph 3 and examine the proposal. It shall submit the text adopted by a two-third majority of the votes cast to the Committee of Ministers for approval. After its approval, this text shall be forwarded to the Parties for ratification, acceptance or approval.

5 Any amendment shall enter into force, in respect of those Parties which have accepted it, on the first day of the month following the expiration of a period of one month after the date on which five Parties, including at least four member States of the Council of Europe, have informed the Secretary General that they have accepted it.

In respect of any Party which subsequently accepts it, the amendment shall enter into force on the first day of the month following the expiration of a period of one month after the date on which that Party has informed the Secretary General of its acceptance.

CHAPTER VI - Final clauses

Article 27 - Signature, ratification and entry into force

1 This Convention shall be open for signature by the member States of the Council of Europe, the non-member States which have participated in its elaboration [and by the European Community].

2 This Convention is subject to ratification, acceptance or approval. Instruments of ratification, acceptance or approval shall be deposited with the Secretary General of the Council of Europe.

3 This Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date on which five States, including at least four member States of the Council of Europe, have expressed their consent to be bound by the Convention in accordance with the provisions of paragraph 2 of the present Article.

4 In respect of any Signatory which subsequently expresses its consent to be bound by it, the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of the deposit of its instrument of ratification, acceptance or approval.

Article 28 - Non-member States

1 After the entry into force of this Convention, the Committee of Ministers of the Council of Europe may, after consultation of the Parties, invite any non-member State of the Council of Europe to accede to this Convention by a decision taken by the majority provided for in Article 20, sub-paragraph d of the Statute of the Council of Europe, and by the unanimous vote of the representatives of the Contracting States entitled to sit on the Committee of Ministers.

2 In respect of any acceding State, the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of deposit of the instrument of accession with the Secretary General of the Council of Europe.

Article 29 - Territories

1 Any Signatory may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, specify the territory or territories to which this Convention shall apply. Any other State may formulate the same declaration when depositing its instrument of accession.

2 Any Party may, at any later date, by a declaration addressed to the Secretary General of the Council of Europe, extend the application of this Convention to any other territory specified in the declaration and for whose international relations it is responsible or on whose behalf it is authorised to give undertakings. In respect of such territory the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of receipt of such declaration by the Secretary General.

3 Any declaration made under the two preceding paragraphs may, in respect of any territory specified in such declaration, be withdrawn by a notification addressed to the Secretary General. The withdrawal shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of such notification by the Secretary General.

Article 30 - Reservations

1 Any Signatory may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, make a reservation to Article[s] ... of this Convention. No other reservation may be made.

Any other State may make the same reservation[s] when depositing its instrument of accession.

2 Any Signatory or any other State which makes a reservation shall notify the Secretary General of the Council of Europe of the relevant contents of its internal law.

3 Any Party which extends the application of this Convention to a territory mentioned in the declaration referred to in Article 29, paragraph 2, may, in respect of the territory concerned, make a reservation in accordance with the provisions of the preceding paragraphs.

4 Any Party which has made the reservation mentioned in this Article may withdraw it by means of a declaration addressed to the Secretary General of the Council of Europe. The withdrawal shall become effective on the first day of the month following the expiration of a period of one month after the date of its receipt by the Secretary General.

Article 31 - Denunciation

1 Any Party may at any time denounce this Convention by means of a notification addressed to the Secretary General of the Council of Europe.

2 Such denunciation shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of the notification by the Secretary General.

Article 32 - Notifications

The Secretary General of the Council of Europe shall notify the member States of the Council, [the European Community,] any Signatory, any Party and any other State which has been invited to accede to this Convention of:

a any signature;
b the deposit of any instrument of ratification, acceptance, approval or accession;
c any date of entry into force of this Convention in accordance with Articles **27** or 28;
d any amendment adopted in accordance with Article 26, and the date on which such an amendment enters into force;
e any declaration made under the provisions of Article 29;
f any reservation and withdrawal of reservation made in pursuance of the provisions of Article 30;
g any other act, notification or communication relating to this Convention.

In witness whereof the undersigned, being duly authorised thereto, have signed this Convention.

Done at ....., the ....., in English and French, both texts being equally authentic, in a single copy which shall be deposited in the archives of the Council of Europe. The Secretary General of the Council of Europe shall transmit certified copies to each member State of the Council of Europe, to the European Community, to the non-member States which have participated in the elaboration of this Convention, and to any State invited to accede to this Convention.

DRAFT EXPLANATORY REPORT
TO THE DRAFT BIOETHICS CONVENTION

In accordance with established Council of Europe practice as applied since 1965, this draft Explanatory Report on the Bioethics Convention was drawn up by the Steering Committee on Bioethics on the basis of the preparatory work on the Convention. Its declassification has been authorised by the Committee of Ministers.

This text, dealing with the salient issues raised in the course of the discussions, should facilitate the application of the provisions of the draft Convention but does not constitute an instrument for its authentic interpretation.

INTRODUCTION

1. For several years now, the Council of Europe, through the work of the Parliamentary Assembly and of the ad hoc Committee of experts on Bioethics (CAHBI), later renamed the Steering Committee on Bioethics (CDBI), has concerned itself with the problems confronting mankind as a result of advances in medicine and biology. At the same time, a number of countries have done their own internal work on these topics, and this work is proceeding. So far, therefore, two types of endeavour have been undertaken, one at a national and the other at international level.

2. Basically, these studies are the fruit of observation and concern: observation of the radical developments in science and their applications to medicine and biology, ie fields in which people are directly involved; concern about the ambivalent nature of many of these advances. The scientists and practitioners behind them have worthy aims and often attain them. But some of the known or alleged developments of their work are taking or could potentially take a dangerous turn, as a result of a distortion of the original objectives. Science, with its new complexity and extensive ramifications, thus presents a dark side or a bright side according to how it is used.

3. It has subsequently become necessary to ensure that the beneficial side prevails by developing awareness of what is at stake and constantly reviewing all the possible consequences. No doubt the ethics committees and other national bodies and legislators, as well as the international organisations, have already applied themselves to this task, but their efforts have remained either restricted to a particular geographical area or incomplete because of their focus on a particular topic. On the other hand, common values are more often than not claimed as a basis for the various texts, opinions and recommendations. But differences may nonetheless become apparent in connection with certain aspects of the problems dealt with. Even simple definitions may give rise to profound differences.

Drafting of a Convention

4. It has thus become apparent that there was a need to make a greater effort to harmonise existing standards. In June 1991, in its Recommendation 1160[4] (Rapporteur: Mr Marcelo PALACIOS), the Parliamentary Assembly recommended that the Committee of Ministers "envisage a framework convention comprising a main text with general principles and additional protocols on specific aspects". In September of the same year the Committee of Ministers instructed the CAHBI "to prepare, in close co-operation with the Steering Committee for Human Rights (CDDH) and the European Health Committee (CDSP) ... a framework Convention, open to non-member States, setting out common general standards for the protection of the human person in the context of the biomedical sciences /and/ Protocols to this Convention, relating to, in a preliminary phase: organ transplants and the use of substances of human origin; medical research on human beings".

5. In March 1992 the CAHBI, which has been chaired in turn by Mrs Paula KOKKONEN (Finland), Mr Octavi QUINTANTA (Spain) and Mrs Johanna KITS NIEUWENKAMP (The Netherlands), set up a Working Party to prepare the draft Convention. The members of the Working Party, which was chaired by Dr Michael ABRAMS (United Kingdom), were: Mr Jean MICHAUD (France) (Rapporteur), Dr Stefan WINTER (Germany), Dr Ferenc OBERFRANK (Hungary), Mr Salvatore PUGLISI (Italy) (Co-ordinator), Dr Henriette ROSCAM ABBING (Netherlands), Dr Göran HERMERÉN (Sweden), Mrs Ruth REUSSER (Switzerland) and the chair of the CDBI.

6. As a result of this work a Convention on Bioethics was prepared. The draft was finalised by the CDBI on ... and adopted by the Committee of Ministers on ...

7. Various international instruments already provide protection and guarantees for mankind: the Universal Declaration of Human Rights, the International Convenant on Civil and Political Rights, the Convention for the Protection of Human Rights and Fundamental Freedoms and the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data.

8. They must now be supplemented by other texts so that full account is taken of the potential implications of scientific actions.

9. The principles enshrined in these instruments remain the basis of our conception of human rights; hence they are set out at the beginning of the preamble to the Convention, of which they are the cornerstone.

[4]See Doc 6449, report of the Committee of science and technology, rapporteur: M. Palacios.

10. Starting with the preamble, however, it was necessary to take account of the actual developments in medicine and biology, while indicating the need for them to be used solely for the benefit of present and future generations. This concern has been affirmed at three levels:

- The first is that of the individual, who had to be shielded from any threat resulting from the improper use of scientific developments. Several articles of the Convention illustrate the wish to make it clear that pride of place ought to be given to the individual:

    - protection against unlawful interference with the human body, prohibition of the use of all or part of the body for financial gain, restriction of the use of genetic testing, etc.

- The second level relates to society. Indeed, in this particular field, to a greater extent than in many others, the individual must also be considered to constitute part of a social corpus. Whenever choices are involved in regard to the application of certain developments, the latter must be recognised and endorsed by the community. This is why public debate is so important and is given a place in the Convention.

Nevertheless, the interests at stake are not equal; they are graded to reflect the priority attached to the interests of the individual as opposed to those of science and society alone. The adjective "alone" makes it clear that care must be taken not to neglect the latter; they must come immediately after the interests of the individual.

- The third and final concern relates to the human species. Many of the current achievements and forthcoming advances are based on genetics. Progress in knowledge of the genome is producing more ways of influencing and acting on it. The risks associated with this growing area of expertise should not be ignored. It is no longer the individual or society that is imperilled but the human species itself. The Convention sets up safeguards, starting with the preamble where reference is made to the benefits to future generations and to all humanity, while provision is made throughout the text for the necessary legal guarantees to protect the identity of the human being.

11. It is in this spirit that a ban is imposed on interventions on the human genome which, if not restricted to somatic therapy, might affect the individual's lineal descent.

12. The discussions leading up to the preparation of the Convention brought to light two contrary requirements for the text:

13. Some of the provisions will not require amendment. They are the ones which refer to previous Conventions and proclaim human rights. There are others which owe their wording to scientific knowledge and in their cas the possibility of revision cannot be ruled out depending on developments in science. However, such developments must in no circumstances weaken the force of the first set of provisions.

14. The problem which the Convention seeks to resolve will arise again in the future, perhaps more acutely. Trying to solve it by placing obstacles in the path of the progress of scientific knowledge would amount to disregarding man's right to knowledge and his freedom to extend it. But some broad guidelines are needed for the application of this knowledge, in order to protect man, society and the species.

15. This Convention is therefore devoted to the enunciation of general principles. The protocols that will be attached to it deal with particular fields of biology and medicine. The first two protocols are concerned with organ transplantation and medical research respectively.

Comments on the provisions of the Convention

Title

16. The title of the instrument is "Convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine: Bioethics Convention".

17. The reference to human rights provided a necessary connection between the Convention and the principles defined in the texts which guarantee protection for such rights. The Convention is, for instance, entirely consistent with the Convention for the Protection of Human Rights and Fundamental Freedoms of 4 November 1950. The two Conventions share not only the same underlying approach but also many ethical principles and legal concepts. The concept of the human being found in the remainder of the text was adopted because of its general character. The idea of dignity, which constitutes the essential value to be upheld, can be considered to cover the other values, which are emphasised subsequently.

18. The phrase "application of biology and medicine", which is also used in Article 1, was preferred to "life sciences" in particular, which was considered too broad. It restricts the scope of the Convention to human medicine and biology, thereby excluding animal and plant biology insofar as they do not concern human medicine or biology. The Convention thus covers all medical and biological applications concerning human beings, including preventive, diagnostic, therapeutic and research applications.

19. The term "bioethics" was used in a supplementary title to give a succinct and convenient indication of the purpose of the text.

Preamble

20. This refers to various international instruments on the protection of human rights, with which the Convention has affinities, and to the work of the Parliamentary Assembly which constituted an important stage in the preparation of the Convention.

21. The preamble refers to the developments in medicine and biology which should be used only for the benefit of present and future generations and not be diverted in ways that run counter to their proper objective. It proclaims the respect due to man as an individual and as a member of the human species. It concludes that progress, human benefit and protection can be reconciled if public awareness is aroused by an international instrument devised by the Council of Europe in line with its vocation. Stress is laid on the need for international co-operation to extend the benefits of progress to the whole of mankind.

Article 1 (Purpose and object)

22. This article defines the Convention's scope and purpose.

23. The aim of the Convention is to guarantee everyone's rights and fundamental freedoms and, in particular, their integrity with regard to the application of biology and medicine. It also sets out to secure the dignity and identity of human beings in this sphere. The Convention does not define the terms "everyone" or "human being". In the absence of unanimous agreement on the definition of these terms among the member States of the Council of Europe, it was decided to allow domestic law to define them. It was noted that the European Convention on Human Rights, which likewise uses the term "everyone", did not define this term either. It was nevertheless acknowledged that it was a generally accepted principle that human dignity had to be respected as soon as life began.

24. Accordingly, although the Convention does not define "human being", it was agreed to construe the expression broadly, covering both the connotation of individuality and that of membership of the human race. The phrase "identity of the human being" thus assumes its full meaning in this context.

Article 2 (Primacy of the human being)

25. In this article the Convention, the aim of which is to protect human rights and dignity, affirms the primacy of the human being over the sole interest of science and society. Priority is given to the former, which must take precedence over the latter in the event of a conflict between them. However, this article is not intended to prohibit all research not beneficial to the person who is the subject of it, but there must be rules setting out the conditions on which such research may be carried out on the persons in question, such as for example those foreseen under Article 6 for research on incapacitated persons.

26. The whole Convention is inspired by the principle of the primacy of the human being, and all its articles must be interpreted in this light.

27. The second paragraph of this article lists possible exceptions to the principle stated in the first paragraph. The restrictions defined therein apply to the rights contained in all the provisions of the Convention, without prejudice to any specific restrictions which this or that article may involve.

28. The wording of this second paragraph largely echoes Article 8 (2) of the European Convention on Human Rights. The exceptions it defines are aimed at protecting collective interests (public safety, the protection of public health and the prevention of disorder or crime) or the rights and freedoms of others .

29. The restriction based on the prevention of disorder makes it possible, for example, for respect for privacy to be restricted by permitting a judicial authority to order a test to be carried out in order to identify the perpetrator of a crime.

30. Compulsory isolation of a patient with a serious infectious disease is a typical example of an exception for reasons of public health.

31. A person who may, due to his or her mental disorder, be a possible source of serious harm to others may, according to the law, be placed as an involuntary patient.

32. Protection of the rights of others may, for example, justify an order by a judicial authority for a test to be carried out to establish parentage.

33. However, the protection of the patient's health is not mentioned in this paragraph as one of the factors justifying an exception to the provisions of the Convention as a whole. In order to clarify its scope, it seemed preferable to define this exception in each of the provisions expressly alluding to it. Article 10, for example, specifies the conditions on which individuals suffering from mental disorders may, without their consent, be given treatment if their health might suffer otherwise.

34. Moreover, defending the economic well-being of the country and national security are not included amongst the general exceptions referred to in the second paragraph of this article, unlike Article 8 of the European Convention on Human Rights. It did not appear desirable, in the context of this Convention, to make the exercise of fundamental rights chiefly concerned with the protection of a person's rights in the health sphere subject to the economic well-being of the country or to national security. The economic aspect is however referred to in Article 4 by the words "available resources"; however, in the context of this article this notion does not represent a reason for allowing for an exception to the rights secured in other provisions of the Convention.

35. The reasons mentioned in this paragraph should not be regarded as justifying an absolute exception to the rights secured by the Convention. To be admissible, restrictions must be prescribed by law and be necessary in a democratic society for the protection of the collective interest in question. These conditions must be interpreted in the light of the criteria established with regard to the same notions by the case law of the European Court of Human Rights. In particular, the restrictions must meet the criteria of necessity and proportionality, taking into account the social and cultural conditions proper to each State. The term "prescribed by law" should be interpreted in accordance with the meaning usually given to them by the European Court of Human Rights, ie a formal law is not required and each State may adopt the form of domestic law it considers most appropriate.

Article 3 (Professional standards)

36. This article lays down a principle applicable to doctors and members of the health care professions generally. From the term "professional standards" it follows that this article does not concern persons other than healthcare professionals called upon to perform medical acts, for example in an emergency.

37. The term "intervention" must be understood here in a general sense; it covers all acts, whether for the purpose of diagnosis, preventive care, treatment or rehabilitation or in a research context.

38. As an intervention is an act performed on a human being, it must be both humane and competently performed. Doctors and, generally speaking, all professionals involved in carrying out a medical act are subject to ethical and legal requirements and must be competent and careful.

39. Competence must primarily be determined in relation to the scientific knowledge and clinical experience appropriate to a profession or speciality at a given time. In this respect, it is explicitly indicated that the administration of care must be consistent with established scientific facts. Nevertheless, it is accepted that professional standards do not necessarily prescribe a line of action as being the only one possible: recognised medical practice may, indeed, allow several possible forms of intervention, thus leaving some freedom of choice as to methods or techniques.

40. Further, a particular course of action must be judged in the light of the specific health problem raised by a given patient. It is acknowledged that an intervention must meet the criteria of relevance and proportionality between the aim pursued and the means used.

41. Professional standards are not identical in all countries. The same medical duties vary slightly from one society to another. Moreover, in some countries certain professional standards may or may not derive from a text (in the form of statutory or professional codes of ethics, for example), whereas no such texts exist in other countries.

42. Professional standards cover not only what is done in the course of an intervention, but also how it is done. In some countries they take the form of professional codes of ethics, in other codes of medical conduct, health law or medical ethics or any other means of ensuring respect for the rights and interests of patients.

Article 4 (Equitable access)

43. This article defines an aim and imposes an obligation on States to use their best endeavours to reach it.

44. The aim is to ensure equitable access to health care in accordance with the person's medical needs. "Health care" means the medical service**s** - diagnostic, preventive, therapeutic and rehabilitative - designed to maintain or improve a person's state of health or alleviate a person's suffering.

45. Access to health care must be equitable. In this context, "equitable" means first and foremost the absence of unjustified discrimination. Although not synonymous with absolute equality, equitable access implies effectively obtaining a satisfactory degree of care.

46. The Parties to the Convention are required to take appropriate steps to achieve this aim as far as the available resources permit. The purpose of this provision is not to create an individual right on which each person may rely in legal proceedings against the State, but rather to prompt the latter to adopt the requisite measures as part of its social policy in order to ensure equitable access to health care.

47. Although States are now making substantial efforts to ensure a satisfactory level of health care, the scale of this effort largely depends on the volume of available resources. Moreover, State measures to ensure equitable access may take many different forms and a wide variety of methods may be employed to this end.

Article 5 (Consent)

48. This article deals with consent and establishes a fundamental legal rule, ie that no one may in principle be forced to undergo an intervention without their consent. Human beings must therefore be able freely to give or refuse their informed consent to any intervention involving their person. This rule makes clear the patient's autonomy in his relationship with health care professionals. The word "intervention" is understood in its widest sense, as in Article 3 - that is to say, it covers any act performed on a person for reasons of health and encompasses diagnosis, preventive care, treatment, rehabilitation and research.

49. In order for their consent to be valid, the persons in question must have been informed about the relevant facts regarding the intervention being contemplated. The information need not always be exhaustive. It must, however, always include the "relevant facts" - that is to say, all the factors that might influence the person's choice, including, possibly, any alternatives to the intervention proposed or the danger of the intervention failing. Moreover, this information must be sufficiently clear and suitably worded for the layman who is to undergo the intervention. The patient must be put in a position, through the use of terms he or she can understand, to weigh up the necessity or usefulness of the aim and methods of the intervention against its risks and the discomfort or pain it will cause.

50. Consent may take various forms. It may be express or implied. Express consent may be either verbal or written. Article 5, which is general and covers very different situations, does not require any particular form of consent. The latter will largely depend on the nature of the intervention. It is agreed that express consent would be inappropriate as regards many routine medical acts. The consent may therefore often be implicit, as long as the patient is sufficiently informed. In some cases, however, eg invasive diagnostic acts or treatments, express consent may be required. Moreover, the patient's express, specific written consent should normally be sought for participation in research.

51. Freedom of consent implies that consent may be withdrawn at any time and that the patient's decision shall be respected once he or she has been fully informed of the consequences. There may however be departures from this principle. For example, it may be permissible in certain States, in accordance with the professional standards applying to a particular case under Article 3, for a doctor not to interrupt an intervention once it has begun if this interruption would seriously harm the patient's health.

52. Furthermore, Article 2 of the Convention, as well as Articles 6, 7, 8, and 10 define the instances in which the exercise of the rights contained in the Convention and hence the need for consent may be limited.

53. Information is the patient's right, but as provided for in Article 12, the patient's possible wish not to be informed must be observed. This does not however obviate the need to seek consent.

Article 6 (Protection of persons lacking capacity)[5]

54. Some individuals may not validly give their consent to an intervention due to either their age or their altered mental state. It is therefore necessary to specify the conditions under which an intervention may be carried out on these incapacitated people in order to ensure their protection.

55. This article deals with cases in which interventions may be carried out on such persons. Three categories of incapacitated persons are concerned: minors, persons of full age who are legally incapable of giving consent and persons of full age who are de facto incapable of giving consent. The article therefore applies not only to persons who are legally incapable in the strict sense of the term, irrespective of whether they are minors or persons of full age who are legally incapable, but also to persons who are de facto incapable, that is to say to persons who are legally capable but whose capacity of understanding is temporarily or permanently seriously reduced.

56. Two principles are adopted: 1. No intervention on an incapacitated person (in the widest sense of the term) may be carried out except on the protective conditions accepted by national law. This protection may take the form of action by persons (parents or guardians) who are entitled to give their authorisation; 2. The intervention must be intended to benefit the incapacitated person.

57. However, the article provides for two situations where national law may authorise non-beneficial interventions on an incapacitated person: medical research of significant value and donation of regenerative tissue for transplants. These two exceptions are nevertheless accompanied by precise conditions. In both instances, refusal by the incapacitated person must always be respected and in such cases the intervention may not take place. It has to be noted that the term "non-beneficial interventions" also includes interventions which may be for the indirect benefit of the individual.

58. As far as research is concerned, a fundamental requirement is that there is no equally effective alternative method. This means, for example, that no research experiment will be allowed if similar results could be achieved from tests using animals. This also means that recourse to an invasive method will not be permitted if a similarly effective non-invasive method exists.

59. Likewise, in the case of research not carried out for the direct benefit of an incapacitated subject, one proviso is that there is no alternative subject with full capacity. The use of incapacitated persons therefore has to be the sole possibility, as it will be, for example, in improving the understanding of say children diseases or of certain psychiatric disorders such as dementia in adults. Such research can only be carried out, respectively, on children or the adults concerned.

60. An additional and as fundamental condition is that the research must represent only a negligible risk and minimal burden for the incapacitated persons, for example the taking of a blood sample from a child.

61. The necessity of such research can only be justified by the expected benefit resulting from the outcome of the research for the category of persons to which the incapacitated patient belongs. For example, minors may take part in research into a disease from which they themselves suffer, whilst it is not foreseen that they will benefit from the results of this research, provided that the benefit which may be derived from the research by children affected by the disease is significant.

62. Another condition is that sufficient protection of the incapacitated person must be guaranteed. In this regard there are two levels of protection: not only must the research be approved by an ethics committee which will, inter alia, consider whether recourse to incapacitated subjects is warranted, but in addition the agreement either of the subject himself or of his legal representative or of an authority is required.

63. When all these conditions are met, the exception contained in the present article appears compatible with the sense of Article 7 of the International Covenant on Civil and Political Rights[6].

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[5] It should be pointed out that, while the whole text is still only a draft, the passages which appear in square brackets in the draft Convention are considered by the CDBI to need detailed re-examination. Although the CDBI has managed to identify the principles contained therein, the wording has still to be carefully revised.

[6] Article 7: No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation.

64. When transplanting regenerative tissue, at least the following conditions must be satisfied before removing such tissue from an incapacitated person.

65. There must be no equally effective alternative method. If tissues are removed from an incapacitated person, it is necessary that the transplant should be vital for the recipient, that no "conventional" treatment should therefore exist and that similar results cannot be obtained with cultured tissues or with tissues of animal origin.

66. Another fundamental condition is that the tissue in question must be regenerative; it must be able to recover its functions and mass after partial ablation, an example being bone marrow and skin; organs such as kidneys are therefore excluded. This limitation is explained by the fact that persons should not be irreversibly deprived of one of their organs if they are unable to consent to the procedure.

67. A further requirement concerns the risk for the incapacitated person. The general principle with regard to transplants is that no organ or tissue (as is the case here) may be removed when the risk to the donor's health is disproportionate to the expected benefit to the recipient. This may for example be the case for removal of parts of certain regenerative tissues. If the donor is an incapacitated person, it is necessary that the benefit to the receiver must not just be proportionate but particularly substantial.

68. Furthermore it is also required, as in the case of research, that sufficient protection of the incapacitated person is guaranteed. Thus the express consent either of the subject himself or of his legal representative or the agreement of an authority is required. Under the condition of sufficient protection one must also check that the incapacitated person or his legal representative have not been improperly influenced, in particular within the family where one could fear that pressures are being exercised because the life of another member of the family is at stake.

69. The lack of a donor with full capacity is also a condition, within reasonable limits.

70. Finally, close personal or family relations must exist between the recipient and the incapacitated donor, in order to prevent tissues being obtained improperly.

Article 7 (Consent of incapacitated persons)

71. This article deals with the participation of incapacitated persons in the process of obtaining consent, which must not be ruled out. This idea is reflected in the obligation (first paragraph) to involve incapacitated persons in the consenting procedure whenever possible. Thus, it will be necessary to explain to them the significance and circumstances of the intervention and then obtain their opinion, even if this is not a determining factor.

72. In the particular case of minors, the second paragraph of the article states that a minor's consent (which is understood here to be assent or refusal) should be regarded as an increasingly determining factor in proportion to their age and capacity for discernment. This means that in certain situations for which provision is made in national law and which take account of the nature and seriousness of the intervention as well as the minor's age and ability to understand, the minor's consent should increasingly carry more weight in the final decision. If the minor's consent is required, there may be a conflict between his or her position and that of the legal representative. It lies with domestic law to decide in these cases. In some cases, for example such as those of young people below the age of majority, the minor's consent may be considered as being not only a necessary but a sufficient condition for certain interventions, as the law prescribes in some States.

73. This provision is consistent with Article 12 of the United Nations Convention on the Rights of the Child, which stipulates that "States Parties shall assure to the child who is capable of forming his or her own views the right to express those views freely in all matters affecting the child, the views of the child being given due weight in accordance with the age and maturity of the child."

74. Lastly, the third paragraph of Article 7 specifies that the consent of adults who are legally incapacitated but capable of understanding is a *sine qua non* condition for the intervention. It must be made clear that such consent is essential, in that the intervention must not be carried out against the wishes of the persons concerned; but their consent alone may not suffice if the opinion of the legal representative or a supervisory authority has to be sought under domestic law. However, Article 10 of the Convention constitutes an exception to Article 7 paragraph 3 by providing that persons suffering from mental disorders may be subjected, without their consent and only on certain conditions, to an intervention aimed at treating their mental disorders.

75. It should be noted that bankrupts, squanderers and prisoners, who are incapacitated in certain respects under the law of several countries, do not as such fall within the category of legally incapacitated persons referred to in Article 6 in so far as they are capable of discernment; consequently, they can as a rule, under Article 7 paragraph 3, validly consent or object to an intervention in the health field when their physical or mental integrity is at stake.

Article 8 (Emergency situations)

76. In emergencies, doctors are faced with a conflict between their duty to provide care and their duty to seek the patient's consent. This article exempts the practitioner in such situations from the obligation to seek the consent of the patient, or of the legal representative where appropriate, and enables them to act immediately. As it departs from the general rule laid down in Articles 5, 6 and 7 it is accompanied by conditions.

77. First, this possibility is restricted to emergencies which prevent the practitioner from obtaining the appropriate consent. The article applies both to persons who are capable and to persons who are unable either de jure or de facto to give consent. An example that might be put forward is that of a patient in a coma who is thus unable to give his consent, or that of a doctor who is unable to contact an incapacitated person's legal representative who would normally have to consent to an urgent intervention.

78. Next, the possibility is limited solely to medically necessary interventions. However, this possibility is not limited to life-saving interventions. Interventions for which a delay is acceptable are excluded.

79. Lastly, the article specifies that the intervention must be carried out for the immediate benefit of the individual concerned.

Article 9 (Previously expressed wishes)

80. Whereas Article 8 obviates the need for consent in emergencies, this article is designed to cover cases where persons capable of understanding have previously expressed their consent (ie either assent or refusal) with regard to foreseeable situations where they would not be in a position to express an opinion about the intervention.

81. The article therefore covers not only the emergencies referred to in Article 8 but also situations where individuals have foreseen that they might be unable to give their valid consent, for example in the event of a progressive disease such as senile dementia.

82. The article lays down that when persons have previously expressed their wishes, these must be taken into account. Nevertheless, taking previously expressed wishes into account does not mean that they should necessarily be followed. For example, when the wishes were expressed a long time before the intervention and science has since progressed, there may be grounds for not heeding the patient's opinion. The practitioner should thus, as far as possible, be satisfied that the wishes of the patient apply to the present situation and are still valid.

Article 10 (Mental disorders)

83. This article deals with the specific question of the treatment of patients suffering from mental disorders which prevent them from deciding what is in their interest. In some circumstances it enables doctors to disregard the patient's refusal to undergo an intervention.

84. The first condition is that the person must be suffering from a mental disorder. The term is not limited to mental diseases in the strict sense; it also includes mental handicap. In order for the article to apply, an impairment of the person's mental faculties must have been observed.

85. The second condition is that treatment of the mental disorders concerned must be involved. In accordance with Article 5 or Article 7 paragraph 3 as the case may be, the practitioner must therefore necessarily seek the consent of the patient, if the latter is capable of discernment, for all interventions apart from those aimed at treating mental disorders, for which they do not need to seek the patient's consent. In other words, if patients capable of understanding refuse an intervention not aimed at treating a mental disorder, their opposition must be respected in the same way as for other patients capable of understanding.

86. The third condition is that, without the treatment, serious harm is likely to result to the patient's health. The article is concerned only with the risk to the patient's own health, whereas Article 2 (2) of the Convention permits

patients to be treated against their will in order to protect other people's rights and freedoms (for example, in the event of violent behaviour).

87. The last condition is that the protective conditions laid down in national law must be observed. The article specifies that these conditions must include appropriate supervisory, control and appeal procedures, such as mediation by a judicial authority. This requirement is understandable in view of the fact that it will be possible for an intervention to be carried out on a person who has not consented to it; it is therefore necessary to provide an arrangement for adequately protecting the rights of that person. In this connection, it should be noted that Recommendation R (83) 2 of the Committee of Ministers of the Council of Europe concerning the legal protection of persons suffering from mental disorder placed as involuntary patients establishes a number of principles which must be respected during psychiatric treatment and placement. The Hawaii Declaration of the World Psychiatric Association of 10 July 1983 and its revised versions, as well as Parliamentary Assembly Recommendation 1235 (1994) on psychiatry and human rights, should also be mentioned.

Article 11 (Prohibition of financial gain)

88. This article applies the principle of human dignity set forth in the preamble and in Article 1.

89. It states in particular that the human body and its parts must not, as such, give rise to financial gain. Under this provision organs and tissues proper, including blood, should not be bought or sold or give rise to financial gain for the person from whom they have been removed or for a third party, whether an individual or a corporate entity such as a hospital. However, technical acts (sampling, testing, storage, culture, transport, etc) which are performed on the basis of these items may legitimately give rise to reasonable remuneration. For instance, this article does not prohibit the sale of tissue which is part of a medical device since the tissue is not sold as such. Further, this article does not prevent a person from whom an organ or tissue has been taken from receiving compensation which, while not constituting remuneration, compensates that person equitably for expenses incurred or loss of income (for example as a result of hospitalisation).

90. The provision does not refer to such tissues as hair and nails, which are discarded tissues, and the sale of which is not an affront to human dignity.

Article 12 (Privacy and access to information)

91. The first paragraph establishes the right to privacy in the health field, thereby reaffirming the principle introduced in Article 8 of the European Convention on Human Rights and reiterated in the Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data. It should be pointed out that, under Article 6 of the latter Convention, personal data concerning health constitute a special category of data and are as such subject to special rules.

92. However, restrictions to the respect of privacy are possible under Article 2 paragraph 2. For example, a judicial authority may thus order that a test be carried out in order to identify the author of a crime (exception based on the prevention of disorder) or to determine the filiation link (exception based on the protection of the rights of others).

93. The first sentence of the second paragraph lays down that individuals are entitled to know any information collected about their health. This right is of fundamental importance in itself but also conditions the effective exercise of other rights such as the right of consent set forth in Article 5.

94. A person's "right to know" encompasses all information collected about his or her health, whether it be a diagnosis, prognosis or any other relevant fact.

95. The right to know goes hand in hand with the "right not to know", which is provided for in the second sentence of the second paragraph. Patient may have their own reasons for not wishing to know about certain aspects of their health. A wish of this kind must be observed. The patient's exercise of the right not to know this or that fact concerning his health is not regarded as an impediment to the validity of his consent to an intervention; for example, he can validly consent to the removal of a cyst despite not wishing to know its nature.

96. In some circumstances, the right to know or not to know may be restricted in the patient's own interest or else on the basis of Article 2 (2) in order to protect the rights of a third party or of society.

97. For example, the last paragraph of this article provides that in exceptional cases domestic law may place restrictions on the right to know or not to know in the interests of the patient's health (eg a prognosis of death which might, in certain cases if passed on to the patient, seriously worsen his or her condition). In these cases, the doctor**'s** duty to provide information conflicts with the interests of the patient's health. It is for domestic law, taking account of the social and cultural background, to solve this conflict. Domestic law may justify the doctor in sometimes withholding information or, at all events, disclosing it with circumspection. This is the meaning of what is commonly referred to as "therapeutic exception", being the restriction of a right, it must be limited to cases where it is strictly necessary, avoiding any paternalistic attitude.

98. Furthermore, it may be of vital importance for patients to know certain facts about their health, even though they have expressed the wish not to know them. For example, the knowledge that they have a predisposition to a disease might enable them to take preventive measures. In this case, a doctor's duty to provide care, as laid down in Article 3, might conflict with the patient's right not to know. Here too it will be for domestic law to indicate whether the doctor, in the light of the circumstances of the particular case, may make an exception to the right not to know.

99. At the same time, certain facts concerning the health of a person who has expressed a wish not be to told about them may be of special interest to a third party, as in the case of a disease transmittable to a partner, for example. In such a case, the seriousness of the risk to the third party might, on the basis of Article 2 (2), warrant his or her right taking precedence over the patient's right not to know.

Article 13 (Disposal of a removed part of the human body)

100. Parts of the human body are often removed in the course of interventions, for example surgery. The aim of this article is to ensure the protection of individuals with regard to parts of their body which are thus removed and then stored or used for a purpose different from that for which they have been removed. Such a provision is necessary in particular because much information on the individual may be derived from any part of his body, however small (blood, hair, bone, skin, organ, etc), and even when the sample is anonymous the analysis may yield information about identity.

101. This provision thus establishes a rule consistent with the general principle in Article 5 on consent, ie that parts of the body which have been removed during an intervention for a specified purpose must not be stored or used for a different purpose unless the relevant conditions governing information and consent have been observed.

102. The information and consent arrangements may vary according to the circumstances, thus allowing for flexibility since the express consent of an individual to the use of parts of his body is not systematically needed. In some cases, it will be sufficient for a patient or his or her representative, who have been duly informed (for instance, by means of leaflets handed to the persons concerned at the hospital), not to express their opposition. In other cases, depending on the nature of the use to which the removed parts are to be put, express and specific consent will be necessary, in particular where sensitive information is collected about identifiable individuals.

Article 14 (Scientific research)

103. Freedom of scientific research in the field of biology and medicine is justified not only by humanity's right to knowledge, but also by the considerable progress its results bring as far as health is concerned.

104. Nevertheless, such freedom is not absolute. In medical research it is limited by the fundamendal rights of individuals expressed in particular by the provisions of the Convention and by other legal provisions which protect the human being, such as those which provide for the submission of research projects to ethics committees. In this connection, it should be pointed out that the first article of the Convention specifies that its aim is to protect the dignity and identity of human beings and guarantee to everyone, without discrimination, respect for their integrity as well as for other rights and fundamental freedoms. Any research will therefore have to observe these principles.

Article 15 (Research on embryos in vitro)

105. The advisibility of research on in vitro embryos leads to great debates within the public and raises many difficult ethical questions[7]. In any case, as it has been mentioned in relation to Article 1, it is a generally accepted

[7] The Committee of Ministers has entrusted the CDBI with the preparation of a Protocol on the protection of the human embryo and foetus.

principle that human dignity has to be respected as soon as life begins. If there is to be research, it must be subject to protective conditions for the embryo.

106. This article does not take a stand about the admissibility of the principle of research on embryos. However, in view of the fact that such research is being conducted in some States, the first paragraph defines a limit which must be respected: national law must not authorise research on embryos which have been developed for more than fourteen days. The expression "developed for more than fourteen days" implies that any period during which the embryo has simply been preserved by freezing or any other method is not included. The fourteen day period constitutes a maximum which States may reduce. When research on embryos is permitted by national law, it will not only be subject to the restrictions contained in the Convention. Like any other research, it will have to respect the dignity and identity of the human being and comply with the legal rules affording such protection. National law will therefore provide for additional protective conditions.

107. Paragraph 2 of the article prohibits the creation of human embryos with the intention to do research on them.

Article 16 (Human genome)

108. The advance of science, in particular in knowledge of the genome and the applications deriving therefrom, have raised questions and even great fears. Whilst developments in this field may lead to great benefit for humanity, there is fear that the misuse of these developments may endanger not only the individual but the species itself. This raises the question of what limits should be set to interventions on the human genome.

109. Interventions in the field of research or application and aimed at modifying the human genome are allowed by this article on two conditions.

110. The first is that the intervention must be undertaken for preventive, therapeutic or diagnostic purposes. Consequently, interventions aimed at modifying genetic characteristics not related to a disease are prohibited, for instance those aiming at modifying behavioural features which do not constitute a disease.

111. The second condition is that the aim of the intervention must not be to interfere with the germ cell line (human reproductive cells) of a person who has already been born or of that of an unborn child. However, it does not rule out interventions for a somatic purpose which might have unforeseen side-effects on the germ cell line. In this respect, it has been pointed out that as these interventions are still at an experimental stage, they must be authorised through appropriate procedures such as, for example, evaluation by ethics committees[8]. It is therefore possible that such committees might not authorise an intervention already known to have side-effects on subsequent generations.

112. The proviso that an intervention must not intentionally interfere with the germ cell line has been discussed at length. The advisability of providing for exceptions to this rule in the light of recent or expected scientific developments in the medical field was examined. However, it was felt that, at the present stage of scientific knowledge, it was impossible to know all the effects that these interventions might have on following generations. Owing to this uncertainty, it was decided to adopt the rule as it appears in Article 16 of the Convention.

Article 17 (Tests predictive of genetic diseases)

113. The possibilities for tests which are predictive of genetic diseases are developing quickly. These tests cover both the detection of the presence of genetic factors for a disease or a predisposition to a multifactorial genetic disease. Sometimes the predisposition is certain to lead to a disease developing, sometimes it only indicates the possibility of the development of a disease. In the latter case early detection allows for preventive measures, such as adapting the lifestyle or environmental conditions. Testing can be predictive for the possible development of a serious disease later on in life. When applied with diligence in the individual health care setting early detection of a genetic disease or predisposition may have advantages for the future health of the individual, in particular when it allows for early measures, which may influence positively one's health.

[8] Article 15 of Recommendation R (90) 3 of the Committee of Ministers to the member States on medical research provides that "all proposed medical research plans should be the subject of an ethical examination by an independent and multidisciplinary committee".

Tests which are predictive of genetic diseases allow also for informed decisions on one's offspring. The right to know as well as the right not to know are of particular importance in this field. Problems for the individual stemming from tests which are predictive of genetic diseases to which medical science has no suitable therapy, can usually be met appropriately in the individual doctor-patient relationship. A complicating factor is that testing generates information not only on the individual concerned, but also on future offspring and on biologically related family member[9]. The right to privacy thus involves more than one individual and calls for particular attention. Hence the importance of appropriate professional standards to be developed in this field, as well as the necessity to fully meet with the informed consent requirement.

114. The situation is even more complicated with predictive testing for serious late onset diseases, when there is at present no treatment available. In such diseases, screening should remain exceptional, including when screening is related to scientific research: It would put too much strain on the free participation and on the privacy of individuals.

115. Because of the particular problems which are related to predictive testing, it is necessary to strictly limit its applicability to health purposes for the individual. Scientific research likewise should be carried out in the context of developing medical treatment. Experimental testing methods, provided they are performed in this context, are as such covered by the present article.

116. Because there is an apparent risk that use is made of genetic testing possibilities outside health care (for instance in the case of medical examination prior to an employment contract) it is of importance to clearly distinguish between health care purposes for the benefit of the individual on the one hand and third parties' interests, which may be commercial, on the other hand.

117. Therefore, predictive genetic testing as part of pre-employment medical examinations, is excluded whenever it does not serve a health purpose. However, national law may allow for the performance of a test predictive of a genetic disease outside the health field for one of the reasons and under the conditions provided for in Article 2 paragraph 2 of the Convention.

118. Article 17 prohibits predictive tests for reasons other than health or health-related research, even with the assent of the person concerned. This covers the field of insurance, for example. An insurance company will not be entitled to subject the conclusion or modification of an insurance policy to the holding of a predictive genetic test. Nor will it be able to refuse the conclusion or modification of such a policy on the ground that the applicant has not submitted to a test, as the conclusion of a policy cannot reasonably be made conditional on the performance of an illegal act.

119. Predictive genetic testing in the case of employment or private insurance contracts does not have a health purpose and would imply a disproportionate infringement on the rights of the individual to privacy.

120. In particular circumstances, when the working environment could have negative consequences on the health of an individual because of a genetic predisposition, predictive genetic testing may be offered in employment situations. This however may be done only in the case where there are no reasonable possibilities to improve on working conditions, provided the tests clearly serve the health condition of the individual and the right not to know is respected.

Article 18 (Communication of results)

121. People should have unhindered access to genetic testing which may serve their health purposes. In order to be able to take advantage of these techniques in the health care setting, external factors which might interfere with people's free choice to use genetic services in health care should be barred. It must be noted that the scope of Article 18 which deals with the results of any genetic test is broader than that of Article 17 which only concerns predictive test of genetic diseases or of genetic predisposition to a disease.

122. Therefore it is important to prevent third parties from making use of genetic information which the individual has acquired by making use of genetic services in health care. This holds in particular when the attainment of social goods is involved (for instance, employment, life, health and disability insurance). Therefore, the

[9]The Committee of Ministers of the Council of Europe has adopted two Recommendations on screening: Recommendation R (90) 13 on prenatal genetic screening, prenatal genetic diagnosis and associated genetic counselling and Recommendation R (92) 3 on genetic testing and screening for health care purposes.

communication of results of genetic testing acquired in the framework of health care for other purposes is forbidden, notwithstanding the free contractual relationship. Otherwise, the individual could refuse to undergo a test and obtain essential information about his or her health because of the fear of consequences. However, the article states that national law may allow for the communication of the results of a genetic test outside the health in certain cases under the conditions provided for in Article 2 paragraph 2. Such communication should thus be a necessary measure in a democratic society and serve one of the purposes referred to in this article.

123. Furthermore, the individual who has knowledge of his or her genetic constitution could try to use this unduly, in particular in the case of private insurance contracts. It is left to national law, taking into account especially the notion of good faith and the general principle forbidding the abuse of law, to specify the appropriate solutions.

Article 19 (Infringements of the principle)

124. This article requires the Parties to provide for the possibility of judicial action to prevent or put a stop to an infringement of the principles set forth in the Convention. It therefore covers not only infringements which have already begun and are ongoing but also the threat of an infringement.

125. The judicial protection requested must be appropriate and proportionate to the infringement or the threats of infringement of the principles. Such is the case, for example, with proceedings initiated by a public prosecutor in cases of infringements affecting several persons unable to defend themselves, in order to put an end to the violation of their rights.

126. Under the Convention, the appropriate protective machinery must be capable of operating rapidly as it has to allow an infringement to be prevented or halted at short notice. This requirement can be explained by the fact that, in many cases, the very integrity of an individual has to be protected and an infringement of this right might have irreversible consequences.

127. The judicial protection thus provided by the Convention applies only to unlawful infringements or to threats thereof. The reason for this qualifying adjective is that the Convention itself, in Article 2 (2), permits restrictions to the free exercise of the rights it recognises.

Article 20 (Compensation for undue damage)

128. This article sets forth the principle that any person who has suffered undue damage resulting from an intervention is entitled to fair compensation. The Convention uses the expression "undue damage" because in medicine some damage, such as amputation, is inherent in the therapeutic intervention itself.

129. The due or undue nature of the damage will have to be determined in the light of the circumstances of each case. The cause of the damage must be an intervention in the widest sense, taking the form of either an act or an omission. The intervention may or may not constitute an offence. In order to give entitlement to compensation, the damage must result from the intervention.

130. Compensation conditions and procedures are prescribed by national law. In many cases, this establishes a system of individual liability based either on fault or on the notion of risk or strict liability. In other cases, the law may provide for a collective system of compensation irrespective of individual liability.

131. On the subject of fair compensation, reference can be made to Article 50 of the European Convention on Human Rights, which allows the Court to afford just satisfaction to the injured party.

Article 21 (Sanctions)

132. This article requires the Parties to prescribe sanctions for any infringements of the principles contained in the Convention. The text specifies that these sanctions must be appropriate. They may therefore be of a professional, civil, administrative or penal nature, depending on the circumstances and legal traditions of each State.

Article 22 (Wider protection)

133. In pursuance of this article, the Parties may apply rules of a more protective nature than those contained in the Convention. In other words, the text lays down a common core of standards with which States must comply,

while allowing them to provide greater protection of the human being and of human rights with regard to applications of biology and medicine.

134. A conflict may arise between the various rights established by the Convention, for example between a scientist's right of freedom of research and the rights of a person submitting to the research (Article 14). However, the expression "wider protection" must be interpreted in the light of the purpose of the Convention, as defined in Article 1, namely the protection of the human being with regard to the application of biology and medicine. In the example quoted, any additional statutory protection can only mean greater protection for a person submitting to research.

Article 23 (Public consultation)

135. The purpose of this article is to prompt the Parties to create greater public awareness of the fundamental questions raised by the application of biology and medicine. Society's views must be ascertained as far as possible with regard to problems concerning its members as a whole. To this end, appropriate public discussion and consultation are recommended. The word "appropriate" leaves the Parties free to select the most suitable procedures.

Article 24 (Protocols)

136. The Convention establishes principles valid for all applications of biology and medicine. This article makes provision for the immediate drawing up of protocols containing rules on specific fields. As the purpose of the protocols is to develop further the principles contained in the Convention, their provisions should not depart from these principles. In particular, they cannot lay down rules affording human beings less protection than that resulting from the principles of the Convention.

137. To be able to sign or ratify a protocol, a State must have simultaneously or previously signed or ratified the Convention. On the other hand, States which have signed or ratified the Convention will not be obliged to sign or ratify a protocol.

13-17 February 1995
27-31 March 1995

DRAFT CONVENTION FOR THE PROTECTION OF HUMAN RIGHTS AND DIGNITY OF THE HUMAN BEING WITH REGARD TO [THE APPLICATION OF] BIOLOGY AND MEDICINE: BIOETHICS CONVENTION

PREAMBLE

The Member States of the Council of Europe, the other States and the European Community signatories hereto,

Bearing in mind the Universal Declaration of Human Rights proclaimed by the General Assembly of the United Nations on 10 December 1948;

Bearing in mind the Convention for the Protection of Human Rights and Fundamental Freedoms of 4 November 1950;

Bearing in mind the International Covenant on Civil and Political Rights of 16 December 1966;

Bearing also in mind the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data of 28 January 1981;

Bearing in mind the Convention on the Rights of the Child of 20 November 1989;

Considering that the aim of the Council of Europe is the achievement of a greater unity between its members and that one of the methods by which that aim is to be pursued is the maintenance and further realisation of human rights and fundamental freedoms;

Conscious of the accelerating developments in biology and medicine;

Convinced of the need to respect the human being both as an individual and as a member of the human species and recognising the importance of ensuring the dignity of the human being;

Conscious that the misuse of biology and medicine may lead to acts endangering human dignity;

Affirming that progress in biology and medicine should be used for the benefit of present and future generations;

Stressing the need for international co-operation so that all humanity may enjoy the benefits of biology and medicine;

Recognising the importance of promoting a public debate on the questions posed by the application of biology and medicine and the responses to be given thereto;

Wishing to remind all members of society of their rights and responsibilities;

Taking account of the work of the Parliamentary Assembly in this field, including Recommendation 1160 (1991) on the preparation of a Convention on bioethics;

Resolving to take such measures as are necessary to safeguard human dignity and the fundamental rights **and freedoms** of the individual with regard to [the application of] biology and medicine;

Have agreed as follows:

CHAPTER I

Article 1 (Purpose and object)

Parties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to [the application of] biology and medicine.

Article 2 (Primacy of the human being)

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

Article 3 (Former Article 2 paragraph 2) (Restrictions on the exercise of the rights)

No restrictions shall be placed on the exercise of the rights 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 [disorder or] crime, for the protection of public health or for the protection of the rights and freedoms of others. **These restrictions shall be interpreted in accordance with the case-law of the European Court of Human Rights.**

Article 4 (Equitable access to health care)

Parties shall take appropriate measures with a view to providing, within their jurisdiction, equitable access to health care **of appropriate quality**, taking into account health needs and available resources.

Article 5 (Former Article 3) (Professional standards)

Any intervention in the health field, including research, must be carried out in accordance with relevant professional obligations and standards.

Article 6 (Former Article 5) (Consent in general)

No intervention may be carried out in the health field without the free and informed consent of the person undergoing it.

The person concerned may freely withdraw consent at any time.

Article 7 (Protection of persons not able to consent)

1. <u>Alternative</u>

Alternative a: Interventions under this Article may only be carried out, subject to Articles 16 and 18 paragraph 4 below, for the direct benefit of the individual concerned.

<u>or</u>

Alternative b: Interventions under this Article may only be carried out under protective conditions approved by law. The degree of protection has to correspond to the seriousness of the intervention[10].

2. An intervention may not be carried out on an adult who does not have the capacity to consent to the intervention, without the authorisation of the representative or an authority or any person or body provided for by law. The individual shall so far as possible take part in the authorisation procedure.

3. Where the consent of a minor to an intervention is not required by law, an intervention may not be carried out on a minor without the authorisation of the representative or an authority or any person or body

[10] If this alternative were adopted, it might prove to be necessary to reconsider the order of the paragraphs.

provided for by law. The opinion of the minor shall be taken into consideration as an increasingly determining factor in proportion to his or her age of maturity.

4. The law shall allow for an appeal against any decision taken under this Article.

Article 8 (Former Article 10) (Mental disorder)

A patient whose ability to decide what is in his or her best interests is **severely** impaired by mental disorder may be subjected, without his or her consent and on the protective conditions prescribed by law, to an intervention aimed at treating his or her mental disorders **only** where, without such treatment, serious harm is likely to result to his or her health. The protective conditions prescribed by law shall include supervisory, control and appeal procedures.

Article 9 (Former Article 8) (Emergency situation)

When because of an emergency situation the appropriate consent cannot be obtained, any medically necessary intervention may be carried out immediately for the benefit of the health of the individual concerned.

Article 10 (Former Article 9) (Previously expressed wishes)

The previously expressed wishes relating to a medical intervention by a patient who is not, at the time of the intervention, in a state to express his wishes shall be taken into account.

Article 11 (Former Article 12) (Private life and access to information)

Everyone has the right to respect for private life **in relation to information about their health**.

Individuals are entitled to know any information collected about their health. However, the wishes of individuals not to be so informed shall be observed.

In exceptional cases, restrictions may be placed by law on the exercise of the rights contained in the preceding paragraph in the interests of the patient.

Article 12 (Former Article 17) (Tests predictive of genetic disease)

Tests which are predictive of genetic diseases or which serve **either to identify the subject as a carrier of a gene responsible for a [recessive] disease** or to detect a genetic predisposition or **susceptibility** to a disease may be performed only for health purposes or for scientific research linked to health purposes.

Article 13 (Former Article 18) (Communication of results)

The communication outside the health field of results of genetic testing may only be allowed **when there is an overriding interest and subject to the consent of the person concerned and the safeguards defined by law, including those relating to data protection.**

Article 14 (Former Article 16) (Human genome)

An intervention on the human genome may only be undertaken for preventive, therapeutic or diagnostic purposes and as long as the aim is not to **modify** the germ cell line.

Article 15 (Former Article 14) (Scientific Research)

1. Scientific research in the field of biology and medicine shall be carried out freely, [in accordance with] [subject to the provisions of][11] this Convention and [with] the other legal provisions ensuring the protection of the human being.

2. No research on human beings may be undertaken unless

[11] ecretariat proposal

i) there has been an independent examination of its ethical acceptability and scientific merit

ii) there is no equally effective alternative to research on humans

iii) the risks which may be incurred have been kept to a minimum and are proportionate to the expected benefits and the importance of the aims pursued by the research

iv) the researchers observe the highest professional standards of conduct.

Article 16 (Protection of those undergoing research)

1. A person who is not able to consent according to Article 6 may not undergo research unless it is expected to produce a significant benefit to his or her health. Exceptionally research which does not have the potential for direct benefit may be permitted on such an individual where this research may significantly improve the understanding of disease or disorder, subject to the following additional conditions:

i) any refusal by the individual or his or her representative must always be respected

ii) there is negligible risk and minimum burden for the individual concerned

iii) equally effective research cannot be carried out on individuals capable of giving consent.

2. No research may be carried out under this Article unless the necessary consent or authorisation as provided for under Article 7 has been given expressly and in writing. Such consent or authorisation may be freely withdrawn at any time.

Article 17 (Former Article 15) (Research on embryos in vitro)

[~~Where research on embryos in vitro is allowed by law, such research may only be permitted in the case of embryos which have not been developed for more than 14 days.~~]

The creation of human embryos [solely] for research purposes is prohibited.

Article 18 (Organ transplantation from living donors)

1. Living donors should only be the source of organs for transplantation when there is no suitable cadaveric organ available.

2. The removal of an organ from a living donor may only be carried out

a. for the benefit of a recipient with whom the donor has a close personal or family relationship, or

b. in the absence of such a relationship, with the approval of an appropriate independent authority.

3. The free, informed, specific and written consent of the donor is required.

4. No removal may be carried out on an individual who does not have the capacity to consent under Article 6. Exceptionally, within the protection prescribed by law, the removal of bone marrow from an individual who does not have the capacity to consent may be authorised for the benefit of a recipient having a close family relationship with the donor, provided there is no compatible donor available who has full legal capacity nor any equally effective alternative therapeutic method. The refusal of the individual must always be respected. The removal cannot procede without the written authorisation or consent provided for under paragraphs 2 and 3 of Article 7.

Article 19 (Former Article 13) (Disposal of a removed part of the human body)

When in the course of an intervention any part of a human body is removed, it may be stored and used for a purpose other than that for which it was removed, only if this is done in conformity with appropriate information and consent procedures.

Article 20 (Former Article 11) (Prohibition of financial gain)

The human body and its parts shall not, as such, give rise to financial gain.

Article 21 (Former Article 19) (Infringements of the rights or principles)

The Parties shall provide appropriate judicial protection to prevent or to put a stop to an unlawful infringement of the rights and principles set forth in this Convention at short notice.

Article 22 (Former Article 20) (Compensation for undue damage)

The person who has suffered undue damage resulting from an intervention is entitled to fair compensation ~~[according to the conditions and procedures prescribed by law]~~.

Article 23 (Former Article 21) (Sanctions)

Parties shall provide for appropriate sanctions to be applied in the event of infringement of the provisions contained in this Chapter.

Article 24 (Former Article 22) (Wider protection)

None of the provisions of this chapter 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.

Article 25 (Former Article 23) (Public debate)

The Parties shall see to it that the fundamental questions raised by the developments of biology and medicine are the subject of appropriate public discussion in the light, in particular, of relevant medical, social, economic, ethical and legal implications, and that their possible application is made the subject of appropriate consultation.

CHAPTER II

Article 26 (Former Article 24) (Protocols)

Protocols may be concluded in pursuance of Article 26, with a view to developing, in specific fields, the principles contained in this Convention.

The Protocols shall be open for signature by Signatories of the Convention. They shall be subject to ratification, acceptance or approval. A signatory may not ratify, accept or approve Protocols without previously or simultaneously ratifying the Convention.

CHAPTER III

Article 27 (Former Article 25) (Reports on the application of the Convention)

On receipt of a request from the Secretary General of the Council of Europe any Party shall furnish an explanation of the manner in which its internal law ensures the effective implementation of any of the provisions of the Convention.

Article 28

Parties to this Convention member States of the Council of Europe [and the European Community] may declare at any time that they accept the jurisdiction of the European Court of Human Rights to give a ruling on the interpretation of [certain provisions of] the present Convention at the request of :

- the Government of a Party [or of the European Commission if the Community is a Party]

- any court or tribunal of a Party for a preliminary ruling

- the Committee of Ministers of the Council of Europe

CHAPTER IV

Article 29 (Former Article 26) (Amendments to the Convention)

1 For the purposes of this article a Committee is hereby set up.

2 The Committee referred to in the preceding paragraph shall be composed of one delegation per Party, appointed by the Government of the said Party. Each delegation shall have one vote. Any State referred to in Article 27 or invited to accede to the Convention in accordance with the provisions of Article 28 which is not a Party to this Convention may be represented on the Committee by an observer. [If the European Community is not a Party it may be represented on the Committee by an observer.]

3 Any proposal for an amendment to this Convention, and any proposal for a Protocol or for an amendment to a Protocol, presented by a Party, the Committee or the Committee of Ministers shall be communicated to the Secretary General of the Council of Europe and forwarded by him to the member States of the Council of Europe, [to the European Community,] to any Signatory, to any Party, to any State invited to sign this Convention in accordance with the provisions of Article 27 and to any State invited to accede to it in accordance with the provisions of Article 28.

4 The Committee shall meet not earlier than two months after a proposal has been forwarded by the Secretary General in accordance with paragraph 3 and examine the proposal. It shall submit the text adopted by a two-third majority of the votes cast to the Committee of Ministers for approval. After its approval, this text shall be forwarded to the Parties for ratification, acceptance or approval.

5 Any amendment shall enter into force, in respect of those Parties which have accepted it, on the first day of the month following the expiration of a period of one month after the date on which five Parties, including at least four member States of the Council of Europe, have informed the Secretary General that they have accepted it.

In respect of any Party which subsequently accepts it, the amendment shall enter into force on the first day of the month following the expiration of a period of one month after the date on which that Party has informed the Secretary General of its acceptance.

CHAPTER V - Final clauses

Article 30 (Former Article 27) (Signature, ratification and entry into force)

1 This Convention shall be open for signature by the member States of the Council of Europe, the non-member States which have participated in its elaboration [and by the European Community].

2 This Convention is subject to ratification, acceptance or approval. Instruments of ratification, acceptance or approval shall be deposited with the Secretary General of the Council of Europe.

3 This Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date on which five States, including at least four member States of the Council of Europe, have

expressed their consent to be bound by the Convention in accordance with the provisions of paragraph 2 of the present Article.

4 In respect of any Signatory which subsequently expresses its consent to be bound by it, the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of the deposit of its instrument of ratification, acceptance or approval.

Article 31 (Former Article 28) (Non-member States)

1 After the entry into force of this Convention, the Committee of Ministers of the Council of Europe may, after consultation of the Parties, invite any non-member State of the Council of Europe to accede to this Convention by a decision taken by the majority provided for in Article 20, sub-paragraph d of the Statute of the Council of Europe, and by the unanimous vote of the representatives of the Contracting States entitled to sit on the Committee of Ministers.

2 In respect of any acceding State, the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of deposit of the instrument of accession with the Secretary General of the Council of Europe.

Article 32 (Former Article 29) (Territories)

1 Any Signatory may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, specify the territory or territories to which this Convention shall apply. Any other State may formulate the same declaration when depositing its instrument of accession.

2 Any Party may, at any later date, by a declaration addressed to the Secretary General of the Council of Europe, extend the application of this Convention to any other territory specified in the declaration and for whose international relations it is responsible or on whose behalf it is authorised to give undertakings. In respect of such territory the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of receipt of such declaration by the Secretary General.

3 Any declaration made under the two preceding paragraphs may, in respect of any territory specified in such declaration, be withdrawn by a notification addressed to the Secretary General. The withdrawal shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of such notification by the Secretary General.

Article 33 (Former Article 30) (Reservations)

1 Any State may, when signing this Convention or when depositing its instrument of ratification, make a reservation in respect of any particular provision of the Convention to the extent that any law then in force in its territory is not in conformity with the provision. Reservations of a general character shall not be permitted under this article[12].

2 Any reservation made under this article shall contain a brief statement of the relevant law[3].

3 Any Party which extends the application of this Convention to a territory mentioned in the declaration referred to in Article 29, paragraph 2, may, in respect of the territory concerned, make a reservation in accordance with the provisions of the preceding paragraphs.

4 Any Party which has made the reservation mentioned in this Article may withdraw it by means of a declaration addressed to the Secretary General of the Council of Europe. The withdrawal shall become effective on the first day of the month following the expiration of a period of one month after the date of its receipt by the Secretary General.

[12.] Text taken from Article 64 of the European Convention on Human Rights.

Article 34 (Former Article 31) (Denunciation)

1 Any Party may at any time denounce this Convention by means of a notification addressed to the Secretary General of the Council of Europe.

2 Such denunciation shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of the notification by the Secretary General.

Article 35 (Former Article 32) (Notifications)

The Secretary General of the Council of Europe shall notify the member States of the Council, [the European Community,] any Signatory, any Party and any other State which has been invited to accede to this Convention of:

a any signature;
b the deposit of any instrument of ratification, acceptance, approval or accession;
c any date of entry into force of this Convention in accordance with Articles **27** or 28;
d any amendment adopted in accordance with Article 26, and the date on which such an amendment enters into force;
e any declaration made under the provisions of Article 29;
f any reservation and withdrawal of reservation made in pursuance of the provisions of Article 30;
g any other act, notification or communication relating to this Convention.

In witness whereof the undersigned, being duly authorised thereto, have signed this Convention.

Done at ....., the ....., in English and French, both texts being equally authentic, in a single copy which shall be deposited in the archives of the Council of Europe. The Secretary General of the Council of Europe shall transmit certified copies to each member State of the Council of Europe, to the European Community, to the non-member States which have participated in the elaboration of this Convention, and to any State invited to accede to this Convention.

26-30 June 1995

DRAFT CONVENTION FOR THE PROTECTION OF HUMAN RIGHTS AND DIGNITY OF THE HUMAN BEING WITH REGARD TO THE APPLICATION OF BIOLOGY AND MEDICINE: BIOETHICS CONVENTION[13]

PREAMBLE

The Member States of the Council of Europe, the other States and the European Community signatories hereto,

Bearing in mind the Universal Declaration of Human Rights proclaimed by the General Assembly of the United Nations on 10 December 1948;

Bearing in mind the Convention for the Protection of Human Rights and Fundamental Freedoms of 4 November 1950;

Bearing in mind the International Covenant on Civil and Political Rights of 16 December 1966;

Bearing also in mind the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data of 28 January 1981;

Bearing in mind the Convention on the Rights of the Child of 20 November 1989;

Considering that the aim of the Council of Europe is the achievement of a greater unity between its members and that one of the methods by which that aim is to be pursued is the maintenance and further realisation of human rights and fundamental freedoms;

Conscious of the accelerating developments in biology and medicine;

Convinced of the need to respect the human being both as an individual and as a member of the human species and recognising the importance of ensuring the dignity of the human being;

Conscious that the misuse of biology and medicine may lead to acts endangering human dignity;

Affirming that progress in biology and medicine should be used for the benefit of present and future generations;

Stressing the need for international co-operation so that all humanity may enjoy the benefits of biology and medicine;

Recognising the importance of promoting a public debate on the questions posed by the application of biology and medicine and the responses to be given thereto;

Wishing to remind all members of society of their rights and responsibilities;

Taking account of the work of the Parliamentary Assembly in this field, including Recommendation 1160 (1991) on the preparation of a Convention on bioethics;

Resolving to take such measures as are necessary to safeguard human dignity and the fundamental rights and freedoms of the individual with regard to the application of biology and medicine;

Have agreed as follows:

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[13] The distribution and the wording of the chapters, proposed by the Secretariat, have not yet been discussed by the CDBI.

CHAPTER I General provisions

Article 1 (Purpose and object)

Parties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine.

Article 2 (Primacy of the human being)

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

Article 3 (Former Article 2 paragraph 2) (Restrictions on the exercise of the rights)

No restrictions shall be placed on the exercise of the rights 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.

Article 4 (Equitable access to health care)

Parties shall take appropriate measures with a view to providing, within their jurisdiction, taking into account health needs and available resources, equitable access to health care of appropriate quality **[having regard to its assessment].**

Article 5 (Former Article 3) (Professional standards)

Any intervention in the health field, including research, must be carried out in accordance with relevant professional obligations and standards.

CHAPTER II Consent

Article 6 (Former Article 5) (General rule)

An intervention in the health field may only be carried out after the person concerned has given free consent to it.

This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks.

The person concerned may freely withdraw consent at any time.

Article 7 (Persons not able to consent)

1. Where, **according to law**, a minor does not have the capacity to consent to an intervention, the intervention may not be carried out without the authorisation of his or her representative or an authority or any person or body provided for by law.

The opinion of the minor shall be taken into consideration as an increasingly determining factor in proportion to his or her age and degree of maturity.

2. Where, **according to law,** an adult does not have the capacity to consent to an intervention **because of a mental disability, a disease or for similar reasons**, **the intervention may not be carried out** without the authorisation of his or her representative or an authority or any person or body provided for by law.

The individual concerned shall as far as possible take part in the [decision] [authorisation procedure]. **[The consent of an adult who is capable of understanding is required even if he or she is legally incapacitated.]**

3. The representative or authority mentioned in the preceding paragraphs shall be given, under the same conditions, the information referred to in Article 6. [They shall act in the [best] interests of the person concerned.][14]

Article 7 bis (Protection of persons not able to consent)

No intervention may be carried out, subject to Articles 16 and 18 bis below, on a person who does not have the capacity to consent, except for his or her [direct] personal benefit.

Article 8 (Former Article 10) (Mental disorder)

A patient whose ability to decide what is in his or her best interests is **severely** impaired by mental disorder may be subjected, without his or her consent and on the protective conditions prescribed by law, to an intervention aimed at treating his or her mental disorders **only** where, without such treatment, serious harm is likely to result to his or her health. The protective conditions prescribed by law shall include supervisory, control and appeal procedures.

Article 9 (Former Article 8) (Emergency situation)

When because of an emergency situation the appropriate consent cannot be obtained, any medically necessary intervention may be carried out immediately for the benefit of the health of the individual concerned.

Article 10 (Former Article 9) (Previously expressed wishes)

The previously expressed wishes relating to a medical intervention by a patient who is not, at the time of the intervention, in a state to express his wishes shall be taken into account.

CHAPTER III Private life and access to information

Article 11 (Former Article 12) (Private life and access to information)

Everyone has the right to respect for private life **in relation to information about their health**.

Individuals are entitled to know any information collected about their health. However, the wishes of individuals not to be so informed shall be observed.

In exceptional cases, restrictions may be placed by law on the exercise of the rights contained in the preceding paragraph in the interests of the patient.

CHAPTER IV Human genome

Article 12 (Former Article 17) (Tests predictive of genetic disease)

Tests which are predictive of genetic diseases or which serve **either to identify the subject as a carrier of a gene responsible for a [recessive] disease** or to detect a genetic predisposition or **susceptibility** to a disease may be performed only for health purposes or for scientific research linked to health purposes.

Article 13 (Former Article 18) (Communication of results)

The communication outside the health field of results of genetic testing may only be allowed **when there is an overriding interest and subject to the consent of the person concerned and the safeguards defined by law, including those relating to data protection.**

Article 14 (Former Article 16) (Human genome)

[14] Bold type is used for words not appearing in the version proposed by CDBI-CO-RED. Phrases in square brackets were suggested by one or more delegations and have not yet been decided upon by the CDBI.

An intervention on the human genome may only be undertaken for preventive, therapeutic or diagnostic purposes and as long as the aim is not to **modify** the germ cell line.

CHAPTER V - Scientific research

Article 15 (Former Article 14) (General rule)

1. Scientific research in the field of biology and medicine shall be carried out freely, [in accordance with] [subject to the provisions of][15] this Convention and [with] the other legal provisions ensuring the protection of the human being.

2. A research on human beings may only be undertaken if [**the following conditions are met**][3]**:**

i) **the research project has been approved [by the competent authority]** after independent examination of its ethical acceptability and scientific merit,

[ii) there is no equally effective alternative to research on humans,]

iii) **the person concerned has given free, informed, express and specific consent. [Such consent may be freely withdrawn at any time.]**[3]

Article 16 (Protection of sujects incapable of consenting to research)

1. A person who is not able to consent according to Article 6 may not undergo research unless it [is expected to] **[could potentially]** produce a significant benefit to his or her health.

2. Exceptionally **[the law may allow for [additional]]** research which does not have the potential for direct benefit [may be permitted] on such an individual where this research may **[be beneficial to persons with the same age, disease or disability profile]** [significantly improve the understanding of disease or disorder], subject to the following additional conditions:

i) the necessary [consent or][16] authorisation as provided for under Article 7 has been given expressly and in writing. Such [consent or][4] authorisation may be freely withdrawn at any time,

ii) any refusal by the individual or his or her representative must always be respected,

iii) there is negligible risk and minimum burden for the individual concerned,

[iv) the individual is not subjected to more than one type of research at a time,]

v) equally effective research cannot be carried out on individuals capable of giving consent.

Article 17 (Former Article 15) (Research on embryos in vitro)

[~~Where research on embryos in vitro is allowed by law, such research may only be permitted in the case of embryos which have not been developed for more than 14 days.~~]

The creation of human embryos [solely] for research purposes is prohibited.

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15 Secretariat proposal

16 In the Secretariat's opinion, this is not necessary since this situation is covered by the following indent.

CHAPTER VI - Organ [or tissue] removal from living donors for transplantion purposes

Article 18 (General rule)

1. Removal of organs **[or tissues]** from a living person for transplantation purposes may be carried out solely **[for the direct therapeutic benefit of the recipient]** and when there is no suitable organ **[or tissue]** available from a deceased person **[or through an alternative method].**

2. No organ **[or tissue]** may be removed from a living donor except

   a. for the benefit of a recipient with whom the donor has a close family relationship, or

   b. in the absence of such a relationship, with the approval of an appropriate independent authority.

3. The free, informed, specific and written consent of the donor is required.

[4. Immunological analyses shall be carried out before any [removal] [transplantation].]

Article 18 bis (Protection of persons incapable to consent to organ [or tissue] removal)

1. No removal may be carried out on an individual who does not have the capacity to consent under Article 6.

2. Exceptionally and within the protection prescribed by law, the removal of bone marrow **[or other regenerative tissues]** from an individual who does not have the capacity to consent may be authorised for the benefit of a recipient having a close family relationship with the donor, provided there is no compatible donor available who has full legal capacity [nor any equally effective alternative therapeutic method][17]. The removal cannot procede without the written authorisation [or consent] provided for under paragraphs 1 and 2 of Article 7. The refusal of the individual must always be respected.

Article 19 (Former Article 13) (Disposal of a removed part of the human body)[18]

When in the course of an intervention any part of a human body is removed, it may be stored and used for a purpose other than that for which it was removed, only if this is done in conformity with appropriate information and consent procedures.

CHAPTER VII Prohibition of financial gain

Article 20 (Former Article 11) (Prohibition of financial gain)

The human body and its parts shall not, as such, give rise to financial gain.

CHAPTER VIII Infringements of the provisions of the Convention

Article 21 (Former Article 19) (Infringement of the rights or principles)

The Parties shall provide appropriate judicial protection to prevent or to put a stop to an unlawful infringement of the rights and principles set forth in this Convention at short notice.

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[17] The Secretariat is of the opinion that this would not be necessary if it appeared, as proposed, under Article 18.1.

[18] The Secretariat proposes to move this article to the chapter dealing with consent, after Article 10, as it does not deal with organ transplantation but consent.

Article 22 (Former Article 20) (Compensation for undue damage)

The person who has suffered undue damage resulting from an intervention is entitled to fair compensation ~~[according to the conditions and procedures prescribed by law]~~.

Article 23 (Former Article 21) (Sanctions)

Parties shall provide for appropriate sanctions to be applied in the event of infringement of the provisions contained in this **Convention**.

CHAPTER IX Relation between this Convention and other provisions

Article 24 (Former Article 22) (Wider protection)

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.

Article 25 (Former Article 23) (Public debate)

The Parties shall see to it that the fundamental questions raised by the developments of biology and medicine are the subject of appropriate public discussion in the light, in particular, of relevant medical, social, economic, ethical and legal implications, and that their possible application is made the subject of appropriate consultation.

CHAPTER X Protocols[19]

Article 26 (Former Article 24) (Protocols)

Protocols may be concluded in pursuance of Article 26, with a view to developing, in specific fields, the principles contained in this Convention.

The Protocols shall be open for signature by Signatories of the Convention. They shall be subject to ratification, acceptance or approval. A signatory may not ratify, accept or approve Protocols without previously or simultaneously ratifying the Convention.

CHAPTER XI Interpretation and follow-up of the Convention

Article 27 (Former Article 25) (Reports on the application of the Convention)

On receipt of a request from the Secretary General of the Council of Europe any Party shall furnish an explanation of the manner in which its internal law ensures the effective implementation of any of the provisions of the Convention.

Article 28

Parties to this Convention member States of the Council of Europe [and the European Community] may declare at any time that they accept the jurisdiction of the European Court of Human Rights to give a ruling on the interpretation of [certain provisions of] the present Convention at the request of :

- the Government of a Party [or of the European Commission if the Community is a Party]

- any court or tribunal of a Party for a preliminary ruling

- the Committee of Ministers of the Council of Europe

[19] The Secretariat proposes to move this chapter before chapter XII (amendments)

CHAPTER XII Amendments to the Convention

Article 29 (Former Article 26) (Amendments to the Convention)

1 For the purposes of this article a Committee is hereby set up.

2 The Committee referred to in the preceding paragraph shall be composed of one delegation per Party, appointed by the Government of the said Party. Each delegation shall have one vote. Any State referred to in Article 30 or invited to accede to the Convention in accordance with the provisions of Article 31 which is not a Party to this Convention may be represented on the Committee by an observer. If the European Community is not a Party it may be represented on the Committee by an observer.

3 Any proposal for an amendment to this Convention, and any proposal for a Protocol or for an amendment to a Protocol, presented by a Party, the Committee or the Committee of Ministers shall be communicated to the Secretary General of the Council of Europe and forwarded by him to the member States of the Council of Europe, [to the European Community,] to any Signatory, to any Party, to any State invited to sign this Convention in accordance with the provisions of Article 30 and to any State invited to accede to it in accordance with the provisions of Article 31.

4 The Committee shall meet not earlier than two months after a proposal has been forwarded by the Secretary General in accordance with paragraph 3 and examine the proposal. It shall submit the text adopted by a two-third majority of the votes cast to the Committee of Ministers for approval. After its approval, this text shall be forwarded to the Parties for ratification, acceptance or approval.

5 Any amendment shall enter into force, in respect of those Parties which have accepted it, on the first day of the month following the expiration of a period of one month after the date on which five Parties, including at least four member States of the Council of Europe, have informed the Secretary General that they have accepted it.

In respect of any Party which subsequently accepts it, the amendment shall enter into force on the first day of the month following the expiration of a period of one month after the date on which that Party has informed the Secretary General of its acceptance.

CHAPTER… Final clauses

Article 30 (Former Article 27) (Signature, ratification and entry into force)

1 This Convention shall be open for signature by the member States of the Council of Europe, the non-member States which have participated in its elaboration [and by the European Community].

2 This Convention is subject to ratification, acceptance or approval. Instruments of ratification, acceptance or approval shall be deposited with the Secretary General of the Council of Europe.

3 This Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date on which five States, including at least four member States of the Council of Europe, have expressed their consent to be bound by the Convention in accordance with the provisions of paragraph 2 of the present Article.

4 In respect of any Signatory which subsequently expresses its consent to be bound by it, the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of the deposit of its instrument of ratification, acceptance or approval.

Article 31 (Former Article 28)(Non-member States)

1 After the entry into force of this Convention, the Committee of Ministers of the Council of Europe may, after consultation of the Parties, invite any non-member State of the Council of Europe to accede to this Convention by a decision taken by the majority provided for in Article 20, sub-paragraph d of the Statute of the Council of Europe, and by the unanimous vote of the representatives of the Contracting States entitled to sit on the Committee of Ministers.

2 In respect of any acceding State, the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of deposit of the instrument of accession with the Secretary General of the Council of Europe.

Article 32 (Former Article 29) (Territories)

1 Any Signatory may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, specify the territory or territories to which this Convention shall apply. Any other State may formulate the same declaration when depositing its instrument of accession.

2 Any Party may, at any later date, by a declaration addressed to the Secretary General of the Council of Europe, extend the application of this Convention to any other territory specified in the declaration and for whose international relations it is responsible or on whose behalf it is authorised to give undertakings. In respect of such territory the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of receipt of such declaration by the Secretary General.

3 Any declaration made under the two preceding paragraphs may, in respect of any territory specified in such declaration, be withdrawn by a notification addressed to the Secretary General. The withdrawal shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of such notification by the Secretary General.

Article 33 (Former Article 30) (Reservations)

1 Any State may, when signing this Convention or when depositing its instrument of ratification, make a reservation in respect of any particular provision of the Convention to the extent that any law then in force in its territory is not in conformity with the provision. Reservations of a general character shall not be permitted under this article[20].

2 Any reservation made under this article shall contain a brief statement of the relevant law[3].

3 Any Party which extends the application of this Convention to a territory mentioned in the declaration referred to in Article 32, paragraph 2, may, in respect of the territory concerned, make a reservation in accordance with the provisions of the preceding paragraphs.

4 Any Party which has made the reservation mentioned in this Article may withdraw it by means of a declaration addressed to the Secretary General of the Council of Europe. The withdrawal shall become effective on the first day of the month following the expiration of a period of one month after the date of its receipt by the Secretary General.

Article 34 (Former Article 31) (Denunciation)

1 Any Party may at any time denounce this Convention by means of a notification addressed to the Secretary General of the Council of Europe.

2 Such denunciation shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of the notification by the Secretary General.

Article 35 (Former Article 32) (Notifications)

The Secretary General of the Council of Europe shall notify the member States of the Council, [the European Community,] any Signatory, any Party and any other State which has been invited to accede to this Convention of:

[20] Text taken from Article 64 of the European Convention on Human Rights.

a any signature;
b the deposit of any instrument of ratification, acceptance, approval or accession;
c any date of entry into force of this Convention in accordance with Articles 30 or 31;
d any amendment adopted in accordance with Article 29, and the date on which such an amendment enters into force;
e any declaration made under the provisions of Article 32;
f any reservation and withdrawal of reservation made in pursuance of the provisions of Article 33;
g any other act, notification or communication relating to this Convention.

In witness whereof the undersigned, being duly authorised thereto, have signed this Convention.

Done at ....., the ....., in English and French, both texts being equally authentic, in a single copy which shall be deposited in the archives of the Council of Europe. The Secretary General of the Council of Europe shall transmit certified copies to each member State of the Council of Europe, to the European Community, to the non-member States which have participated in the elaboration of this Convention, and to any State invited to accede to this Convention.

5-8 September 1995

DRAFT CONVENTION FOR THE PROTECTION OF HUMAN RIGHTS AND DIGNITY OF THE HUMAN BEING WITH REGARD TO THE APPLICATION OF BIOLOGY AND MEDICINE: BIOETHICS CONVENTION

PREAMBLE

The Member States of the Council of Europe, the other States and the European Community signatories hereto,

Bearing in mind the Universal Declaration of Human Rights proclaimed by the General Assembly of the United Nations on 10 December 1948;

Bearing in mind the Convention for the Protection of Human Rights and Fundamental Freedoms of 4 November 1950;

Bearing in mind the International Covenant on Civil and Political Rights of 16 December 1966;

Bearing also in mind the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data of 28 January 1981;

Bearing in mind the Convention on the Rights of the Child of 20 November 1989;

Considering that the aim of the Council of Europe is the achievement of a greater unity between its members and that one of the methods by which that aim is to be pursued is the maintenance and further realisation of human rights and fundamental freedoms;

Conscious of the accelerating developments in biology and medicine;

Convinced of the need to respect the human being both as an individual and as a member of the human species and recognising the importance of ensuring the dignity of the human being;

Conscious that the misuse of biology and medicine may lead to acts endangering human dignity;

Affirming that progress in biology and medicine should be used for the benefit of present and future generations;

Stressing the need for international co-operation so that all humanity may enjoy the benefits of biology and medicine;

Recognising the importance of promoting a public debate on the questions posed by the application of biology and medicine and the responses to be given thereto;

Wishing to remind all members of society of their rights and responsibilities;

Taking account of the work of the Parliamentary Assembly in this field, including Recommendation 1160 (1991) on the preparation of a Convention on bioethics;

Resolving to take such measures as are necessary to safeguard human dignity and the fundamental rights and freedoms of the individual with regard to the application of biology and medicine;

Have agreed as follows:

CHAPTER I General provisions

Article 1 (Purpose and object)

Parties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine.

Article 2 (Primacy of the human being)

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

Article 3 (Restrictions on the exercise of the rights)

No restrictions shall be placed on the exercise of the rights 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.

Article 4 (Equitable access to health care)

Parties, taking into account health needs and available resources, shall take appropriate measures with a view to providing, within their jurisdiction, equitable access to health care of appropriate quality**.**

Article 5 (Professional standards)

Any intervention in the health field, including research, must be carried out in accordance with relevant professional obligations and standards.

CHAPTER II Consent

Article 6 (General rule)

An intervention in the health field may only be carried out after the person concerned has given free **and informed** consent to it.

This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks.

The person concerned may freely withdraw consent at any time.

Article 7 (Protection of persons not able to consent)

1. Subject to Articles 16 and 19 below, an intervention may only be carried out on a person who does not have the capacity to consent, for his or her **direct** benefit.

2. Where, according to law, a minor does not have the capacity to consent to an intervention, the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law.

The opinion of the minor shall be taken into consideration as an increasingly determining factor in proportion to his or her age and degree of maturity.

3. Where, according to law, an adult does not have the capacity to consent to an intervention because of a mental disability, a disease or for similar reasons, the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law.

The individual concerned shall as far as possible take part in the authorisation procedure.

4. The representative**, the** authority**, the person or the body** mentioned in paragraphs 2 and 3 above shall be given, under the same conditions, the information referred to in Article 6.

5. The authorisation referred to in paragraphs 2 and 3 above may be withdrawn at any time in the best interests of the person concerned.

Article 8 (Protection of persons who have mental disorder)

[Only] **subject to** protective conditions prescribed by law, including supervisory, control and appeal procedures, [may] a **person** who has a mental disorder **of a serious nature** [may] be subjected, without his or her consent, to an intervention aimed at treating his or her mental disorder [only] where, without such treatment, serious harm is likely to result to his or her health.

Article 9 (Emergency situation)

When because of an emergency situation the appropriate consent cannot be obtained, any medically necessary intervention may be carried out immediately for the benefit of the health of the individual concerned.

Article 10 (Previously expressed wishes)

The previously expressed wishes relating to a medical intervention by a patient who is not, at the time of the intervention, in a state to express his wishes shall be taken into account.

CHAPTER III Private life and access to information

Article 11 (Private life and access to information)

Everyone has the right to respect for private life **in relation to information about their health**.

Everyone is entitled to know any information collected about their health. However, the wishes of individuals not to be so informed shall be observed.

In exceptional cases, restrictions may be placed by law on the exercise of the rights contained in the preceding paragraph in the interests of the patient.

CHAPTER IV Human genome

Article 12 (Tests predictive of genetic disease)

Tests which are predictive of genetic diseases or which serve **either to identify the subject as a carrier of a gene responsible for a [recessive] disease** or to detect a genetic predisposition or **susceptibility** to a disease may be performed only for health purposes or for scientific research linked to health purposes.

Article 13 (Communication of results)

The communication outside the health field of results of genetic testing may only be allowed **when there is an overriding interest and subject to the consent of the person concerned and the safeguards defined by law, including those relating to data protection.**

Article 14 (Interventions on the human genome)

An intervention on the human genome may only be undertaken for preventive, therapeutic or diagnostic purposes and as long as the aim is not to **modify** the germ cell line.

CHAPTER V Scientific research

Article 15 (General rule)

1. Scientific research in the field of biology and 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. **[Individuals undergoing research shall be informed of their rights and the safeguards prescribed by law for their protection.]**

2. Research on human beings may only be undertaken if all the following conditions are met:

i) the research project has been approved by the competent **body** after independent examination of its scientific merit and ethical acceptability,

ii) there is no alternative of comparable effectiveness to research on humans,

iii) the necessary consent as provided for under Article 6 has been given expressly and specifically. Such consent may be freely withdrawn at any time.

Article 16 (Protection of persons not able of consenting to research)

1. A person who is not able to consent according to Article 6 may not undergo research unless it **has the potential to** produce a significant benefit to his or her health.

2. **Exceptionally, under the protective conditions prescribed by law, research without direct benefit may be permitted on an individual who is not able to consent where this research may significantly improve the understanding of his or her health condition, disease or disorder and aims to benefit to persons with the same age, growth, disease or disorder profile, provided that, in addition to those contained in Article 15, the following conditions are met**:

i) research of **comparable** effectiveness cannot be carried out on individuals capable of giving consent,

ii) there is only negligible risk and minimum burden for the individual concerned,

iii) the necessary authorisation as provided for under Article 7 has been given expressly and in writing. Such authorisation may be freely withdrawn at any time,

iv) any refusal by the individual must always be observed..

Article 17 (Research on embryos in vitro)

[~~Where research on embryos in vitro is allowed by law, such research may only be permitted in the case of embryos which have not been developed for more than 14 days.~~]

The creation of human embryos [solely] for research purposes is prohibited.

CHAPTER VI Organ removal from living donors for transplantion purposes

Article 18 (General rule)

1. Removal of organs, **including bone marrow,** from a living person for transplantation purposes may be carried out solely **for the direct therapeutic benefit of the recipient** and where there is no suitable organ available from a deceased person **and no other alternative therapeutic method of comparable effectiveness.**

2. The free, informed and specific consent of the donor **shall be given in written form or before an official body**.

Article 19 (Protection of persons not capable to consent to organ removal)

1. No **organ** removal may be carried out on an individual who does not have the capacity to consent under Article 6.

2. Exceptionally and within the protection prescribed by law, the removal of bone marrow from an individual who does not have the capacity to consent may be authorised for the benefit of a recipient having a close family relationship with the donor, provided there is no compatible donor available who **is able to consent**. The removal cannot procede unless the authorisation provided for under paragraphs 1 and 2 of Article 7 has been given in written form. The refusal of the individual must always be observed.

CHAPTER VII - Prohibition of financial gain and disposal of a part of the human body

Article 20 (Prohibition of financial gain)

The human body and its parts shall not, as such, give rise to financial gain.

Article 21 (Disposal of a removed part of the human body)

When in the course of an intervention any part of a human body is removed, it may be stored and used for a purpose other than that for which it was removed, only if this is done in conformity with appropriate information and consent procedures.

CHAPTER VIII Infringements of the provisions of the Convention

Article 22 (Infringement of the rights or principles)

The Parties shall provide appropriate judicial protection to prevent or to put a stop to an unlawful infringement of the rights and principles set forth in this Convention at short notice.

Article 23 (Compensation for undue damage)

The person who has suffered undue damage resulting from an intervention is entitled to fair compensation ~~[according to the conditions and procedures prescribed by law]~~.

Article 24 (Sanctions)

Parties shall provide for appropriate sanctions to be applied in the event of infringement of the provisions contained in this Convention.

CHAPTER IX - Relation between this Convention and other provisions

Article 25 (Wider protection)

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.

CHAPTER X - Public debate

Article 26 (Public debate)

The Parties shall see to it that the fundamental questions raised by the developments of biology and medicine are the subject of appropriate public discussion in the light, in particular, of relevant medical, social, economic, ethical and legal implications, and that their possible application is made the subject of appropriate consultation.

CHAPTER XI - Interpretation and follow-up of the Convention

Article 27

Parties to this Convention member States of the Council of Europe [and the European Community] may declare at any time that they accept the jurisdiction of the European Court of Human Rights to give a ruling on the interpretation of [certain provisions of] the present Convention at the request of :

- the Government of a Party [or of the European Commission if the Community is a Party]

- any court or tribunal of a Party for a preliminary ruling

- the Committee of Ministers of the Council of Europe

Article 28 (Reports on the application of the Convention)

On receipt of a request from the Secretary General of the Council of Europe any Party shall furnish an explanation of the manner in which its internal law ensures the effective implementation of any of the provisions of the Convention.

CHAPTER XII - Protocols

Article 29 (Protocols)

Protocols may be concluded in pursuance of Article 30, with a view to developing, in specific fields, the principles contained in this Convention.

The Protocols shall be open for signature by Signatories of the Convention. They shall be subject to ratification, acceptance or approval. A signatory may not ratify, accept or approve Protocols without previously or simultaneously ratifying the Convention.

CHAPTER XIII - Amendments to the Convention

Article 30 (Amendments to the Convention)

1 For the purposes of this article a Committee is hereby set up.

2 The Committee referred to in the preceding paragraph shall be composed of one delegation per Party, appointed by the Government of the said Party. Each delegation shall have one vote. Any State referred to in Article 31 or invited to accede to the Convention in accordance with the provisions of Article 32 which is not a Party to this Convention may be represented on the Committee by an observer. If the European Community is not a Party it may be represented on the Committee by an observer.

3 Any proposal for an amendment to this Convention, and any proposal for a Protocol or for an amendment to a Protocol, presented by a Party, the Committee or the Committee of Ministers shall be communicated to the Secretary General of the Council of Europe and forwarded by him to the member States of the Council of Europe, [to the European Community,] to any Signatory, to any Party, to any State invited to sign this Convention in accordance with the provisions of Article 31 and to any State invited to accede to it in accordance with the provisions of Article 32.

4 The Committee shall meet not earlier than two months after a proposal has been forwarded by the Secretary General in accordance with paragraph 3 and examine the proposal. It shall submit the text adopted by a two-third majority of the votes cast to the Committee of Ministers for approval. After its approval, this text shall be forwarded to the Parties for ratification, acceptance or approval.

5 Any amendment shall enter into force, in respect of those Parties which have accepted it, on the first day of the month following the expiration of a period of one month after the date on which five Parties, including at least four member States of the Council of Europe, have informed the Secretary General that they have accepted it.

In respect of any Party which subsequently accepts it, the amendment shall enter into force on the first day of the month following the expiration of a period of one month after the date on which that Party has informed the Secretary General of its acceptance.

CHAPTER XIV - Final clauses

Article 31 (Signature, ratification and entry into force)

1 This Convention shall be open for signature by the member States of the Council of Europe, the non-member States which have participated in its elaboration [and by the European Community].

2 This Convention is subject to ratification, acceptance or approval. Instruments of ratification, acceptance or approval shall be deposited with the Secretary General of the Council of Europe.

3 This Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date on which five States, including at least four member States of the Council of Europe, have expressed their consent to be bound by the Convention in accordance with the provisions of paragraph 2 of the present Article.

4 In respect of any Signatory which subsequently expresses its consent to be bound by it, the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of the deposit of its instrument of ratification, acceptance or approval.

Article 32 (Non-member States)

1 After the entry into force of this Convention, the Committee of Ministers of the Council of Europe may, after consultation of the Parties, invite any non-member State of the Council of Europe to accede to this Convention by a decision taken by the majority provided for in Article 20, sub-paragraph d of the Statute of the Council of Europe, and by the unanimous vote of the representatives of the Contracting States entitled to sit on the Committee of Ministers.

2 In respect of any acceding State, the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of deposit of the instrument of accession with the Secretary General of the Council of Europe.

Article 33 (Territories)

1 Any Signatory may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, specify the territory or territories to which this Convention shall apply. Any other State may formulate the same declaration when depositing its instrument of accession.

2 Any Party may, at any later date, by a declaration addressed to the Secretary General of the Council of Europe, extend the application of this Convention to any other territory specified in the declaration and for whose international relations it is responsible or on whose behalf it is authorised to give undertakings. In respect of such territory the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of receipt of such declaration by the Secretary General.

3 Any declaration made under the two preceding paragraphs may, in respect of any territory specified in such declaration, be withdrawn by a notification addressed to the Secretary General. The withdrawal shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of such notification by the Secretary General.

Article 34 (Reservations)

1 Any State may, when signing this Convention or when depositing its instrument of ratification, make a reservation in respect of any particular provision of the Convention to the extent that any law then in force in its territory is not in conformity with the provision. Reservations of a general character shall not be permitted under this article[1].

2 Any reservation made under this article shall contain a brief statement of the relevant law[21].

3 Any Party which extends the application of this Convention to a territory mentioned in the declaration referred to in Article 33, paragraph 2, may, in respect of the territory concerned, make a reservation in accordance with the provisions of the preceding paragraphs.

4 Any Party which has made the reservation mentioned in this Article may withdraw it by means of a declaration addressed to the Secretary General of the Council of Europe. The withdrawal shall become effective on the first day of the month following the expiration of a period of one month after the date of its receipt by the Secretary General.Article 35 (Denunciation)

1 Any Party may at any time denounce this Convention by means of a notification addressed to the Secretary General of the Council of Europe.

2 Such denunciation shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of the notification by the Secretary General.

Article 36 (Notifications)

The Secretary General of the Council of Europe shall notify the member States of the Council, [the European Community,] any Signatory, any Party and any other State which has been invited to accede to this Convention of:

a any signature;
b the deposit of any instrument of ratification, acceptance, approval or accession;
c any date of entry into force of this Convention in accordance with Articles 31 or 32;
d any amendment or Protocol adopted in accordance with Article 30, and the date on which such an amendment or Protocol enters into force;
e any declaration made under the provisions of Article 33;
f any reservation and withdrawal of reservation made in pursuance of the provisions of Article 34;
g any other act, notification or communication relating to this Convention.

In witness whereof the undersigned, being duly authorised thereto, have signed this Convention.

Done at ....., the ....., in English and French, both texts being equally authentic, in a single copy which shall be deposited in the archives of the Council of Europe. The Secretary General of the Council of Europe shall transmit certified copies to each member State of the Council of Europe, to the European Community, to the non-member States which have participated in the elaboration of this Convention, and to any State invited to accede to this Convention.

[21] Text taken from Article 64 of the European Convention on Human Rights.

20-22 November 1995

DRAFT CONVENTION FOR THE PROTECTION OF HUMAN RIGHTS AND DIGNITY OF THE HUMAN BEING WITH REGARD TO THE APPLICATION OF BIOLOGY AND MEDICINE: BIOETHICS CONVENTION[22]

PREAMBLE

The Member States of the Council of Europe, the other States and the European Community signatories hereto,

Bearing in mind the Universal Declaration of Human Rights proclaimed by the General Assembly of the United Nations on 10 December 1948;

Bearing in mind the Convention for the Protection of Human Rights and Fundamental Freedoms of 4 November 1950;

Bearing in mind the International Covenant on Civil and Political Rights of 16 December 1966;

Bearing also in mind the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data of 28 January 1981;

Bearing in mind the Convention on the Rights of the Child of 20 November 1989;

Considering that the aim of the Council of Europe is the achievement of a greater unity between its members and that one of the methods by which that aim is to be pursued is the maintenance and further realisation of human rights and fundamental freedoms;

Conscious of the accelerating developments in biology and medicine;

Convinced of the need to respect the human being both as an individual and as a member of the human species and recognising the importance of ensuring the dignity of the human being;

Conscious that the misuse of biology and medicine may lead to acts endangering human dignity;

Affirming that progress in biology and medicine should be used for the benefit of present and future generations;

Stressing the need for international co-operation so that all humanity may enjoy the benefits of biology and medicine;

Recognising the importance of promoting a public debate on the questions posed by the application of biology and medicine and the responses to be given thereto;

Wishing to remind all members of society of their rights and responsibilities;

Taking account of the work of the Parliamentary Assembly in this field, including Recommendation 1160 (1991) on the preparation of a Convention on bioethics;

Resolving to take such measures as are necessary to safeguard human dignity and the fundamental rights and freedoms of the individual with regard to the application of biology and medicine;

Have agreed as follows:

[22] Texts adopted by the CDBI appear in italics.

CHAPTER I
General provisions

Article 1 (Purpose and object)

Parties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine.

Article 2 (Primacy of the human being)

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

Article 3 (Restrictions on the exercise of the rights)

No restrictions shall be placed on the exercise of the rights 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.

Article 4 (Equitable access to health care)

Parties, taking into account health needs and available resources, shall take appropriate measures with a view to providing, within their jurisdiction, equitable access to health care of appropriate quality.

Article 5 (Professional standards)

Any intervention in the health field, including research, must be carried out in accordance with relevant professional obligations and standards.

CHAPTER II
Consent

Article 6 (General rule)

An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it.

This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks.

The person concerned may freely withdraw consent at any time.

Article 7 (Protection of persons not able to consent)

1. Subject to Articles 16 and 19 below, an intervention may only be carried out on a person who does not have the capacity to consent, for his or her direct benefit.

2. Where, according to law, a minor does not have the capacity to consent to an intervention, the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law.

The opinion of the minor shall be taken into consideration as an increasingly determining factor in proportion to his or her age and degree of maturity.

3. Where, according to law, an adult does not have the capacity to consent to an intervention because of a mental disability, a disease or for similar reasons, the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law.

The individual concerned shall as far as possible take part in the authorisation procedure.

4. The representative, the authority, the person or the body mentioned in paragraphs 2 and 3 above shall be given, under the same conditions, the information referred to in Article 6.

5. The authorisation referred to in paragraphs 2 and 3 above may be withdrawn at any time in the best interests of the person concerned.

Article 8 (Protection of persons who have mental disorder)

Subject to protective conditions prescribed by law, including supervisory, control and appeal procedures, a person who has a mental disorder of a serious nature may be subjected, without his or her consent, to an intervention aimed at treating his or her mental disorder only where, without such treatment, serious harm is likely to result to his or her health.

Article 9 (Emergency situation)

When because of an emergency situation the appropriate consent cannot be obtained, any medically necessary intervention may be carried out immediately for the benefit of the health of the individual concerned.

Article 10 (Previously expressed wishes)

The previously expressed wishes relating to a medical intervention by a patient who is not, at the time of the intervention, in a state to express his or her wishes shall be taken into account.

CHAPTER III
Private life and right to information

Article 11 (Private life and right to information)

1. Everyone has the right to respect for private life in relation to information about his or her health.

2. Everyone is entitled to know any information collected about his or her health. However, the wishes of individuals not to be so informed shall be observed.

3. In exceptional cases, restrictions may be placed by law on the exercise of the rights contained in paragraph 2 in the interests of the patient.

CHAPTER IV - Human genome

Article 12 (Tests predictive of genetic disease)[23]

Tests which are predictive of genetic diseases **or which serve either to identify the subject as a carrier of a gene responsible for a [recessive] disease or** to detect

a genetic predisposition **or susceptibility** to a disease may be performed only for health purposes or for scientific research linked to health purposes.

Article 13 (Communication of results)[8]

The communication outside the health field of results of genetic testing may only be allowed **when there is an overriding interest and subject to the consent of the person concerned and the safeguards defined by law, including those relating to data protection**.

[23] This article has been examined by the CDBI at this meeting but has not yet been agreed upon.

Article 14 (Interventions on the human genome)[24]

An intervention on the human genome may only be undertaken for preventive, therapeutic or diagnostic purposes and as long as the aim is not to **modify** the germ cell line.

CHAPTER V - Scientific research

Article 15 (General rule)

Scientific research in the field of biology and 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.

Article 15 bis (Protection of persons undergoing research)

*Research on **a person** may only be undertaken if all the following conditions are met:*

i) there is no alternative of comparable effectiveness to research on humans,

ii) the risks which may be incurred by that person are not disproportionate to the potential benefits of the research,

*iii) the research project has been approved by the competent body after independent examination of its scientific merit, **including the importance of the aim of the research,** and ethical acceptability,*

iv) the persons undergoing research have been informed of their rights and the safeguards prescribed by law for their protection,

*v) the necessary consent as provided for under Article 6 has been given expressly, specifically **and is documented**. Such consent may be freely withdrawn at any time.*

Article 16 (Protection of persons not able to consent to research)[25]

1. A person who is not able to consent according to Article 6 may not undergo research unless **the results thereof** ha**ve** the potential to produce a significant **direct** benefit to his or her health.

The necessary authorisation as provided for under Article 7 has to have been given expressly and in writing. Such authorisation may be freely withdrawn at any time. Any refusal by the individual must always be observed.

2. Exceptionally, under the protective conditions prescribed by law, research may be permitted on an individual who is not able to consent where this research may **[have a significant indirect benefit for the individual's health or]** improve knowledge of his or her health condition, disease or disorder **[and] [or]** aims to benefit persons **in the same group or those with the same disease or disorder. In addition to the conditions contained in paragraph 1, sub-paragraph 2 of this article and in Article 15 bis, the following conditions have to be satisfied:**

i) research of comparable effectiveness cannot be carried out on individuals capable of giving consent,

ii) there is only minimum risk **and** burden for the individual concerned.

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[24] The CDBI proceeded to a first examination of this article.

[25] This article has been examined by the CDBI at this meeting but has not yet been agreed upon.

The Secretariat has been entrusted with the preparation of a new version of the article, which will appear in document CDBI/RAP. 9, taking into account the remarks made during the discussions.

Article 17 (Research on embryos ~~in vitro~~)[26]

Alternative 1

Where research on embryo in vivo or in vitro is allowed by law, it must always be based on prevalent national existential and cultural values pertaining to the earliest stages of human life.

Alternative 2

1. Any research on the human embryo shall respect the dignity of the embryo and the legal rules affording such protection.

2. The creation of human embryos for research purposes is prohibited.

Alternative 3

Where the law allows research on embryos *in vivo* or *in vitro*, it shall ensure adequate protection of the embryo.

CHAPTER VI - Organ removal from living donors for transplantation purposes

Article 18 (General rule)

1. Removal of organs, **including bone marrow,** from a living person for transplantation purposes may be carried out solely **for the direct therapeutic benefit of the recipient** and where there is no suitable organ available from a deceased person **and no other alternative therapeutic method of comparable effectiveness.**

2. The free, informed and specific consent of the donor **shall be given in written form or before an official body**.

Article 19 (Protection of persons not capable to consent to organ removal)

1. No **organ** removal may be carried out on an individual who does not have the capacity to consent under Article 6.

2. Exceptionally and within the protection prescribed by law, the removal of bone marrow from an individual who does not have the capacity to consent may be authorised for the benefit of a recipient having a close family relationship with the donor, provided there is no compatible donor available who **is able to consent**. The removal cannot proceed unless the authorisation provided for under paragraphs 2 and 3 of Article 7 has been given in written form. The refusal of the individual must always be observed.

CHAPTER VII - Prohibition of financial gain and disposal of a part of the human body

Article 20 (Prohibition of financial gain)

The human body and its parts shall not, as such, give rise to financial gain.

Article 21 (Disposal of a removed part of the human body)

When in the course of an intervention any part of a human body is removed, it may be stored and used for a purpose other than that for which it was removed, only if this is done in conformity with appropriate information and consent procedures.

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[26] This article has been examined by the CDBI at this meeting but has not yet been agreed upon.

CHAPTER VIII - Infringements of the provisions of the Convention

Article 22 (Infringement of the rights or principles)

The Parties shall provide appropriate judicial protection to prevent or to put a stop to an unlawful infringement of the rights and principles set forth in this Convention at short notice.

Article 23 (Compensation for undue damage)

Alternative 1

The person who has suffered undue damage resulting from an intervention is entitled to fair compensation ~~[according to the conditions and procedures prescribed by law]~~.

Alternative 2 (proposed by the Secretariat)

The person who has suffered a damage resulting from an infringement of the provisions of this Convention is entitled to fair compensation.

Article 24 *(Sanctions)*

Parties shall provide for appropriate sanctions to be applied in the event of infringement of the provisions contained in this Convention.

CHAPTER IX - Relation between this Convention and other provisions

Article 25 (Wider protection)

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.

CHAPTER X - Public debate

Article 26 (Public debate)

The Parties shall see to it that the fundamental questions raised by the developments of biology and medicine are the subject of appropriate public discussion in the light, in particular, of relevant medical, social, economic, ethical and legal implications, and that their possible application is made the subject of appropriate consultation.

CHAPTER XI - Interpretation and follow-up of the Convention

Article 27[27]

Parties to this Convention member States of the Council of Europe [and the European Community if it is a Party] may declare at any time that they accept the jurisdiction of the European Court of Human Rights to give, **without direct reference to any specific proceedings pending in the national courts [or, where appropriate, in the Court of Justice of the European Communities], advisory opinions on legal questions concerning** the interpretation of the present Convention at the request of:

- the Government of a Party [, or of the European Commission if the Community is a Party]

- the Committee of Ministers of the Council of Europe**, by a decision adopted by majority vote of the representatives entitled to sit on the Committee**

[27] This article has been examined by the CDBI at this meeting but has not yet been agreed upon.

- the Committee set up by Article 30 of this Convention by a decision adopted by a majority vote of the Parties.

Article 28 (Reports on the application of the Convention)

On receipt of a request from the Secretary General of the Council of Europe any Party shall furnish an explanation of the manner in which its internal law ensures the effective implementation of any of the provisions of the Convention.

CHAPTER XII - Protocols

Article 29 (Protocols)

Protocols may be concluded in pursuance of Article 30, with a view to developing, in specific fields, the principles contained in this Convention.

The Protocols shall be open for signature by Signatories of the Convention. They shall be subject to ratification, acceptance or approval. A signatory may not ratify, accept or approve Protocols without previously or simultaneously ratifying the Convention.

CHAPTER XIII - Amendments to the Convention

Article 30 (Amendments to the Convention)

1 For the purposes of this article a Committee is hereby set up.

2 The Committee referred to in the preceding paragraph shall be composed of one delegation per Party, appointed by the Government of the said Party. Each delegation shall have one vote. Any State referred to in Article 31 or invited to accede to the Convention in accordance with the provisions of Article 32 which is not a Party to this Convention may be represented on the Committee by an observer. If the European Community is not a Party it may be represented on the Committee by an observer.

3 Any proposal for an amendment to this Convention, and any proposal for a Protocol or for an amendment to a Protocol, presented by a Party, the Committee or the Committee of Ministers shall be communicated to the Secretary General of the Council of Europe and forwarded by him to the member States of the Council of Europe, [to the European Community,] to any Signatory, to any Party, to any State invited to sign this Convention in accordance with the provisions of Article 31 and to any State invited to accede to it in accordance with the provisions of Article 32.

4 The Committee shall meet not earlier than two months after a proposal has been forwarded by the Secretary General in accordance with paragraph 3 and examine the proposal. It shall submit the text adopted by a two-third majority of the votes cast to the Committee of Ministers for approval. After its approval, this text shall be forwarded to the Parties for ratification, acceptance or approval.

5 Any amendment shall enter into force, in respect of those Parties which have accepted it, on the first day of the month following the expiration of a period of one month after the date on which five Parties, including at least four member States of the Council of Europe, have informed the Secretary General that they have accepted it.

In respect of any Party which subsequently accepts it, the amendment shall enter into force on the first day of the month following the expiration of a period of one month after the date on which that Party has informed the Secretary General of its acceptance.

CHAPTER XIV - Final clauses

Article 31 (Signature, ratification and entry into force)

1 This Convention shall be open for signature by the member States of the Council of Europe, the non-member States which have participated in its elaboration [and by the European Community].

2 This Convention is subject to ratification, acceptance or approval. Instruments of ratification, acceptance or approval shall be deposited with the Secretary General of the Council of Europe.

3 This Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date on which five States, including at least four member States of the Council of Europe, have expressed their consent to be bound by the Convention in accordance with the provisions of paragraph 2 of the present Article.

4 In respect of any Signatory which subsequently expresses its consent to be bound by it, the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of the deposit of its instrument of ratification, acceptance or approval.

Article 32 (Non-member States)

1 After the entry into force of this Convention, the Committee of Ministers of the Council of Europe may, after consultation of the Parties, invite any non-member State of the Council of Europe to accede to this Convention by a decision taken by the majority provided for in Article 20, sub-paragraph d of the Statute of the Council of Europe, and by the unanimous vote of the representatives of the Contracting States entitled to sit on the Committee of Ministers.

2 In respect of any acceding State, the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of deposit of the instrument of accession with the Secretary General of the Council of Europe.

Article 33 (Territories)

1 Any Signatory may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, specify the territory or territories to which this Convention shall apply. Any other State may formulate the same declaration when depositing its instrument of accession.

2 Any Party may, at any later date, by a declaration addressed to the Secretary General of the Council of Europe, extend the application of this Convention to any other territory specified in the declaration and for whose international relations it is responsible or on whose behalf it is authorised to give undertakings. In respect of such territory the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of receipt of such declaration by the Secretary General.

3 Any declaration made under the two preceding paragraphs may, in respect of any territory specified in such declaration, be withdrawn by a notification addressed to the Secretary General. The withdrawal shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of such notification by the Secretary General.

Article 34 (Reservations)[28] [29]

1 Any State [and the European Community] may, when signing this Convention or when depositing the instrument of ratification, make a reservation in respect of any particular provision of the Convention to the extent that any law then in force in its territory is not in conformity with the provision. Reservations of a general character shall not be permitted under this article.

2 Any reservation made under this article shall contain a brief statement of the relevant law.

3 Any Party which extends the application of this Convention to a territory mentioned in the declaration referred to in Article 33, paragraph 2, may, in respect of the territory concerned, make a reservation in accordance with the provisions of the preceding paragraphs.

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[28] This article has been examined by the CDBI at this meeting but has not yet been agreed upon.

[29] Text taken from Article 64 of the European Convention on Human Rights.

4 Any Party which has made the reservation mentioned in this Article may withdraw it by means of a declaration addressed to the Secretary General of the Council of Europe. The withdrawal shall become effective on the first day of the month following the expiration of a period of one month after the date of its receipt by the Secretary General.

Article 35 (Denunciation)

1 Any Party may at any time denounce this Convention by means of a notification addressed to the Secretary General of the Council of Europe.

2 Such denunciation shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of the notification by the Secretary General.

Article 36 (Notifications)

The Secretary General of the Council of Europe shall notify the member States of the Council, [the European Community,] any Signatory, any Party and any other State which has been invited to accede to this Convention of:

a any signature;
b the deposit of any instrument of ratification, acceptance, approval or accession;
c any date of entry into force of this Convention in accordance with Articles 31 or 32;
d any amendment or Protocol adopted in accordance with Article 30, and the date on which such an amendment or Protocol enters into force;
e any declaration made under the provisions of Article 33;
f any reservation and withdrawal of reservation made in pursuance of the provisions of Article 34;
g any other act, notification or communication relating to this Convention.

In witness whereof the undersigned, being duly authorised thereto, have signed this Convention.

Done at ....., the ....., in English and French, both texts being equally authentic, in a single copy which shall be deposited in the archives of the Council of Europe. The Secretary General of the Council of Europe shall transmit certified copies to each member State of the Council of Europe, to the European Community, to the non-member States which have participated in the elaboration of this Convention, and to any State invited to accede to this Convention.

26 February-1 March 1996

DRAFT CONVENTION FOR THE PROTECTION OF HUMAN RIGHTS AND DIGNITY OF THE HUMAN BEING WITH REGARD TO THE APPLICATION OF BIOLOGY AND MEDICINE: BIOETHICS CONVENTION[30] [31]

PREAMBLE

The Member States of the Council of Europe, the other States and the European Community signatories hereto,

Bearing in mind the Universal Declaration of Human Rights proclaimed by the General Assembly of the United Nations on 10 December 1948;

Bearing in mind the Convention for the Protection of Human Rights and Fundamental Freedoms of 4 November 1950;

Bearing in mind the International Covenant on Civil and Political Rights of 16 December 1966;

Bearing also in mind the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data of 28 January 1981;

Bearing in mind the Convention on the Rights of the Child of 20 November 1989;

Considering that the aim of the Council of Europe is the achievement of a greater unity between its members and that one of the methods by which that aim is to be pursued is the maintenance and further realisation of human rights and fundamental freedoms;

Conscious of the accelerating developments in biology and medicine;

Convinced of the need to respect the human being both as an individual and as a member of the human species and recognising the importance of ensuring the dignity of the human being;

Conscious that the misuse of biology and medicine may lead to acts endangering human dignity;

Affirming that progress in biology and medicine should be used for the benefit of present and future generations;

Stressing the need for international co-operation so that all humanity may enjoy the benefits of biology and medicine;

Recognising the importance of promoting a public debate on the questions posed by the application of biology and medicine and the responses to be given thereto;

Wishing to remind all members of society of their rights and responsibilities;

Taking account of the work of the Parliamentary Assembly in this field, including Recommendation 1160 (1991) on the preparation of a Convention on bioethics;

Resolving to take such measures as are necessary to safeguard human dignity and the fundamental rights and freedoms of the individual with regard to the application of biology and medicine;

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[30] Texts provisionally adopted by the CDBI appear in italics.

[31] Where the result of the vote does not appear the articles in italic have been adopted by consensus. The meeting during which the Article was adopted is mentionned below the Article.

Have agreed as follows:

CHAPTER I - General provisions

Article 1 (Purpose and object)

Parties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine.

VOTE: 27 FOR, 1 AGAINST, 1 ABSTENTION (7th meeting)

Article 2 (Primacy of the human being)

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

(7th meeting)

Article 3 (Restrictions on the exercise of the rights)[32]

No restrictions shall be placed on the exercise of the rights 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.

Article 4 (Equitable access to health care)

Parties, taking into account health needs and available resources, shall take appropriate measures with a view to providing, within their jurisdiction, equitable access to health care of appropriate quality.

(8th meeting)

Article 5 (Professional standards)

Any intervention in the health field, including research, must be carried out in accordance with relevant professional obligations and standards.

(7th meeting)

CHAPTER II - Consent

Article 6 (General rule)

An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it.

This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks.

The person concerned may freely withdraw consent at any time.

(8th meeting)

[32] The formal adoption of this Article, examined at the 7th meeting, has been postponed.

Article 7 (Protection of persons not able to consent)

1. Subject to Articles 16 and 19 below, an intervention may only be carried out on a person who does not have the capacity to consent, for his or her direct benefit.

2. Where, according to law, a minor does not have the capacity to consent to an intervention, the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law.

The opinion of the minor shall be taken into consideration as an increasingly determining factor in proportion to his or her age and degree of maturity.

3. Where, according to law, an adult does not have the capacity to consent to an intervention because of a mental disability, a disease or for similar reasons, the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law.

The individual concerned shall as far as possible take part in the authorisation procedure.

4. The representative, the authority, the person or the body mentioned in paragraphs 2 and 3 above shall be given, under the same conditions, the information referred to in Article 6.

5. The authorisation referred to in paragraphs 2 and 3 above may be withdrawn at any time in the best interests of the person concerned.

VOTE: 30 FOR, 0 AGAINST, 2 ABSTENTIONS (9th meeting)

Article 8 (Protection of persons who have mental disorder)

Subject to protective conditions prescribed by law, including supervisory, control and appeal procedures, a person who has a mental disorder of a serious nature may be subjected, without his or her consent, to an intervention aimed at treating his or her mental disorder only where, without such treatment, serious harm is likely to result to his or her health.

(9th meeting)

Article 9 (Emergency situation)

When because of an emergency situation the appropriate consent cannot be obtained, any medically necessary intervention may be carried out immediately for the benefit of the health of the individual concerned.

(8th meeting)

Article 10 (Previously expressed wishes)

The previously expressed wishes relating to a medical intervention by a patient who is not, at the time of the intervention, in a state to express his or her wishes shall be taken into account.

(7th meeting)

CHAPTER III - Private life and right to information

Article 11 (Private life and right to information)

1. Everyone has the right to respect for private life in relation to information about his or her health.

2. Everyone is entitled to know any information collected about his or her health. However, the wishes of individuals not to be so informed shall be observed.

3. In exceptional cases, restrictions may be placed by law on the exercise of the rights contained in paragraph 2 in the interests of the patient.

VOTE: 22 FOR, 1 AGAINST, 9 ABSTENTIONS (9th meeting)

CHAPTER IV - Human genome

Article 11a (Non-discrimination)[33]

Discrimination against an individual on grounds of his or her genetic heritage is prohibited.

VOTE: 29 FOR, 2 AGAINST, 2 ABSTENTIONS (10th meeting)

Article 11b (Non-selection of sex)

The CDBI adopted the principle of prohibiting the predetermination of the sex of a future child. No decision was taken on a concrete wording.

VOTE ON THE PRINCIPLE: 27 FOR, 0 AGAINST, 3 ABSTENTIONS (10th meeting)

Article 12 (Tests predictive of genetic disease)

1. Tests which are predictive of genetic diseases or 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 a disease may be performed only for health purposes or for scientific research linked to health purposes, and subject to appropriate genetic counselling.

VOTE: 28 FOR, 2 AGAINST, 1 ABSTENTION (10th meeting)

2. The use of the results of these genetic tests is allowed, subject to receiving the free and informed consent of the person, only for the purposes mentioned in the preceding paragraph.

VOTE: 23 FOR, 4 AGAINST, 5 ABSTENTIONS (10th meeting)

Article 13 (Communication of results)

Article 14 (Interventions on the human genome)

An intervention seeking to modify the human genome may only be undertaken if its aim is not to modify the genetic characteristics of descendants and only for preventive, diagnostic or therapeutic purposes.

PROVISIONAL VOTE: 30 FOR, 0 AGAINST, 3 ABSTENTIONS (10th meeting)

CHAPTER V - Scientific research

Article 15 (General rule)

Scientific research in the field of biology and 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.

VOTE: 32 FOR, 0 AGAINST, 1 ABSTENTION (9th meeting)

[33] The CDBI adopted the principle of prohibiting discrimination but it did not take a formal stand on the wording of the Article.

Article 15 bis (Protection of persons undergoing research)

Research on a person may only be undertaken if all the following conditions are met:

i) there is no alternative of comparable effectiveness to research on humans,

ii) the risks which may be incurred by that person are not disproportionate to the potential benefits of the research,

iii) the research project has been approved by the competent body after independent examination of its scientific merit, including the importance of the aim of the research, and ethical acceptability,

iv) the persons undergoing research have been informed of their rights and the safeguards prescribed by law for their protection,

v) the necessary consent as provided for under Article 6 has been given expressly, specifically and is documented. Such consent may be freely withdrawn at any time.

VOTE: 33 FOR, 0 AGAINST, 0 ABSTENTIONS (9th meeting)

Article 16 (Protection of persons not able to consent to research)

1. Research on a person without the capacity to consent as stipulated in Article 6 may be undertaken only if all the following conditions are met:

i. the conditions laid down in Article 15 bis, sub-paragraphs (i) to (iv), are fulfilled;

ii. the results of the research have the potential to produce direct benefit to his or her health;

iii. research of comparable effectiveness cannot be carried out on individuals capable of giving consent;

iv. the necessary authorisation provided for under Article 7 has been given specifically and in writing, and

v. the person concerned does not object.

VOTE: 30 FOR, 0 AGAINST, 2 ABSTENTIONS (10th meeting)

2. Exceptionally and under the protective conditions prescribed by law, where the research has not the potential to produce results of direct benefit to the health of the person concerned, such research may be authorised subject to the conditions laid down in paragraph 1, sub-paragraphs (i), (iii), (iv) and (v) above, and to the following additional conditions:

i. the research has the aim of contributing, through significant improvement in the scientific understanding of the individual's condition, disease or disorder, to the ultimate attainment of results capable of conferring benefit to the person concerned or to other persons in the same age category or afflicted with the same disease or disorder or having the same condition.

ii. the research entails only minimal risk and minimal burden for the individual concerned.

VOTE: 27 FOR, 4 AGAINST, 2 ABSTENTIONS (10th meeting)

Article 17 (Research on embryos in vitro)[34]

1. Where the law allows research on embryos in vitro, it shall ensure adequate protection of the embryo.

VOTE: 24 FOR, 3 AGAINST, 5 ABSTENTIONS (10th meeting)

2. The creation of human embryos for research purposes is prohibited.

VOTE: 21 FOR, 8 AGAINST, 4 ABSTENTIONS (10th meeting)

CHAPTER VI - Organ removal from living donors for transplantation purposes[35]

Article 18 (General rule)

1. Removal of organs *or tissues* from a living person for transplantation purposes may be carried out solely for the direct therapeutic benefit of the recipient and where there is no suitable organ available from a deceased person and no other alternative therapeutic method of comparable effectiveness.

2. The free, informed and specific consent of the donor shall be given in written form or before an official body.

Article 19 (Protection of persons not able to consent to organ removal)

1. No organ removal may be carried out on an individual who does not have the capacity to consent under Article 6.

2. Exceptionally and within the protection prescribed by law, the removal of bone marrow *or other regenerative tissue* from an individual who does not have the capacity to consent may be authorised for the benefit of a recipient having a close family relationship with the donor, provided there is no compatible donor available who is able to consent. The removal cannot proceed unless the authorisation provided for under paragraphs 2 and 3 of Article 7 has been given in written form. The refusal of the individual must always be observed.

CHAPTER VII - Prohibition of financial gain and disposal of a part of the human body

Article 20 (Prohibition of financial gain)

The human body and its parts shall not, as such, give rise to financial gain.

(10th meeting)

Article 21 (Disposal of a removed part of the human body)

When in the course of an intervention any part of a human body is removed, it may be stored and used for a purpose other than that for which it was removed, only if this is done in conformity with appropriate information and consent procedures.

(10th meeting)

[34] A separate vote on each of the two paragraphs reached a majority of 2/3, but a vote on draft Article 17 as a whole did not reach a 2/3 majority. VOTE: 17 FOR, 11 AGAINST, 3 ABSTENTIONS

[35] Articles 18 and 19 have not yet been decided upon. The CDBI-CO-RED has been entrusted with submitting new draft Articles 18 and 19.

CHAPTER VIII - Infringements of the provisions of the Convention

Article 22 (Infringement of the rights or principles)

The Parties shall provide appropriate judicial protection to prevent or to put a stop to an unlawful infringement of the rights and principles set forth in this Convention at short notice.

(8th meeting)

Article 23 (Compensation for undue damage)

The person who has suffered undue damage resulting from an intervention is entitled to fair compensation according to the conditions and procedures prescribed by law.

VOTE: ADOPTED UNANIMOUSLY (10th meeting)

Article 24 (Sanctions)

Parties shall provide for appropriate sanctions to be applied in the event of infringement of the provisions contained in this Convention.

(8th meeting)

CHAPTER IX - Relation between this Convention and other provisions

Article 25 (Wider protection)

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.

(10th meeting)

CHAPTER X - Public debate

Article 26 (Public debate)

Parties to this Convention shall see to it that the fundamental questions raised by the developments of biology and medicine are the subject of appropriate public discussion in the light, in particular, of relevant medical, social, economic, ethical and legal implications, and that their possible application is made the subject of appropriate consultation.

(10th meeting)

CHAPTER XI - Interpretation and follow-up of the Convention

Article 27 (Interpretation of the Convention)[36]

Parties to this Convention member States of the Council of Europe and the European Community if it is a Party may declare at any time that they accept the jurisdiction of the European Court of Human Rights to give, without direct reference to any specific proceedings pending in the national courts or, where appropriate, in the Court of Justice of the European Communities, advisory opinions on legal questions concerning the interpretation of the present Convention at the request of:

[- the Government of a Party, or of the European Commission if the Community is a Party,]

[36] This article was examined by the CDBI but has not yet been agreed upon.

[- the Committee of Ministers of the Council of Europe, by a decision adopted by majority vote of the representatives entitled to sit on the Committee,]

[- the Committee set up by Article 30 of this Convention by a decision adopted by a majority vote of the Parties.]

Article 28 (Reports on the application of the Convention)

On receipt of a request from the Secretary General of the Council of Europe any Party shall furnish an explanation of the manner in which its internal law ensures the effective implementation of any of the provisions of the Convention.

(10th meeting)

CHAPTER XII - Protocols

Article 29 (Protocols)

Protocols may be concluded in pursuance of Article 30, with a view to developing, in specific fields, the principles contained in this Convention.

The Protocols shall be open for signature by Signatories of the Convention. They shall be subject to ratification, acceptance or approval. A signatory may not ratify, accept or approve Protocols without previously or simultaneously ratifying the Convention.

(10th meeting)

CHAPTER XIII - Amendments to the Convention

Article 30 (Amendments to the Convention)[37]

1 For the purposes of this article a Committee is hereby set up.

2 The Committee referred to in the preceding paragraph shall be composed of one delegation per Party, appointed by the Government of the said Party. Each delegation shall have one vote. Any State referred to in Article 31 or invited to accede to the Convention in accordance with the provisions of Article 32 which is not a Party to this Convention may be represented on the Committee by an observer. If the European Community is not a Party it may be represented on the Committee by an observer.

3 Any proposal for an amendment to this Convention, and any proposal for a Protocol or for an amendment to a Protocol, presented by a Party, the Committee or the Committee of Ministers shall be communicated to the Secretary General of the Council of Europe and forwarded by him to the member States of the Council of Europe, to the European Community, to any Signatory, to any Party, to any State invited to sign this Convention in accordance with the provisions of Article 31 and to any State invited to accede to it in accordance with the provisions of Article 32.

4 The Committee shall meet not earlier than two months after a proposal has been forwarded by the Secretary General in accordance with paragraph 3 and examine the proposal. It shall submit the text adopted by a two-third majority of the votes cast to the Committee of Ministers for approval. After its approval, this text shall be forwarded to the Parties for ratification, acceptance or approval.

5 Any amendment shall enter into force, in respect of those Parties which have accepted it, on the first day of the month following the expiration of a period of one month after the date on which five Parties, including at least four member States of the Council of Europe, have informed the Secretary General that they have accepted it.

[37] This article was examined by the CDBI but it was decided to postpone the vote. Furthermore, the Secretariat was asked to submit a provision containing a general clause for revision of the Convention at regular intervals.

In respect of any Party which subsequently accepts it, the amendment shall enter into force on the first day of the month following the expiration of a period of one month after the date on which that Party has informed the Secretary General of its acceptance.

CHAPTER XIV - Final clauses

Article 31 (Signature, ratification and entry into force)

1 This Convention shall be open for signature by the member States of the Council of Europe, the non-member States which have participated in its elaboration and by the European Community.

2 This Convention is subject to ratification, acceptance or approval. Instruments of ratification, acceptance or approval shall be deposited with the Secretary General of the Council of Europe.

3 This Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date on which five States, including at least four member States of the Council of Europe, have expressed their consent to be bound by the Convention in accordance with the provisions of paragraph 2 of the present Article.

4 In respect of any Signatory which subsequently expresses its consent to be bound by it, the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of the deposit of its instrument of ratification, acceptance or approval.

(10th meeting)

Article 32 (Non-member States)

1 After the entry into force of this Convention, the Committee of Ministers of the Council of Europe may, after consultation of the Parties, invite any non-member State of the Council of Europe to accede to this Convention by a decision taken by the majority provided for in Article 20, sub-paragraph d of the Statute of the Council of Europe, and by the unanimous vote of the representatives of the Contracting States entitled to sit on the Committee of Ministers.

2 In respect of any acceding State, the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of deposit of the instrument of accession with the Secretary General of the Council of Europe.

(10th meeting)

Article 33 (Territories)

1 Any Signatory may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, specify the territory or territories to which this Convention shall apply. Any other State may formulate the same declaration when depositing its instrument of accession.

2 Any Party may, at any later date, by a declaration addressed to the Secretary General of the Council of Europe, extend the application of this Convention to any other territory specified in the declaration and for whose international relations it is responsible or on whose behalf it is authorised to give undertakings. In respect of such territory the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of receipt of such declaration by the Secretary General.

3 Any declaration made under the two preceding paragraphs may, in respect of any territory specified in such declaration, be withdrawn by a notification addressed to the Secretary General. The withdrawal shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of such notification by the Secretary General.

(10th meeting)

Article 34 (Reservations)[38] [39]

1 Any State and the European Community may, when signing this Convention or when depositing the instrument of ratification, make a reservation in respect of any particular provision of the Convention to the extent that any law then in force in its territory is not in conformity with the provision. Reservations of a general character shall not be permitted under this article.

2 Any reservation made under this article shall contain a brief statement of the relevant law.

3 Any Party which extends the application of this Convention to a territory mentioned in the declaration referred to in Article 33, paragraph 2, may, in respect of the territory concerned, make a reservation in accordance with the provisions of the preceding paragraphs.

4 Any Party which has made the reservation mentioned in this Article may withdraw it by means of a declaration addressed to the Secretary General of the Council of Europe. The withdrawal shall become effective on the first day of the month following the expiration of a period of one month after the date of its receipt by the Secretary General.

Article 35 (Denunciation)

1 Any Party may at any time denounce this Convention by means of a notification addressed to the Secretary General of the Council of Europe.

2 Such denunciation shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of the notification by the Secretary General.

(10th meeting)

Article 36 (Notifications)

The Secretary General of the Council of Europe shall notify the member States of the Council, the European Community, any Signatory, any Party and any other State which has been invited to accede to this Convention of:

a any signature;
b the deposit of any instrument of ratification, acceptance, approval or accession;
c any date of entry into force of this Convention in accordance with Articles 31 or 32;
d any amendment or Protocol adopted in accordance with Article 30, and the date on which such an amendment or Protocol enters into force;
e any declaration made under the provisions of Article 33;
f any reservation and withdrawal of reservation made in pursuance of the provisions of Article 34;
g any other act, notification or communication relating to this Convention.

In witness whereof the undersigned, being duly authorised thereto, have signed this Convention.

Done at ....., the ....., in English and French, both texts being equally authentic, in a single copy which shall be deposited in the archives of the Council of Europe. The Secretary General of the Council of Europe shall transmit certified copies to each member State of the Council of Europe, to the European Community, to the non-member States which have participated in the elaboration of this Convention, and to any State invited to accede to this Convention.

(10th meeting)

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[38] This article was examined by the CDBI but has not yet been agreed upon.

[39] Text taken from Article 64 of the European Convention on Human Rights.

24-26 April 1996

DRAFT CONVENTION FOR THE PROTECTION OF HUMAN RIGHTS AND DIGNITY OF THE HUMAN BEING WITH REGARD TO THE APPLICATION OF BIOLOGY AND MEDICINE[40] [41] [42]

PREAMBLE

The Member States of the Council of Europe, the other States and the European Community signatories hereto,

Bearing in mind the Universal Declaration of Human Rights proclaimed by the General Assembly of the United Nations on 10 December 1948;

Bearing in mind the Convention for the Protection of Human Rights and Fundamental Freedoms of 4 November 1950;

Bearing in mind the International Covenant on Civil and Political Rights of 16 December 1966;

Bearing in mind the International Covenant on Economic, Social and Cultural Rights of 16 December 1966;

Bearing also in mind the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data of 28 January 1981;

Bearing in mind the Convention on the Rights of the Child of 20 November 1989;

Considering that the aim of the Council of Europe is the achievement of a greater unity between its members and that one of the methods by which that aim is to be pursued is the maintenance and further realisation of human rights and fundamental freedoms;

Conscious of the accelerating developments in biology and medicine;

Convinced of the need to respect the human being both as an individual and as a member of the human species and recognising the importance of ensuring the dignity of the human being;

Conscious that the misuse of biology and medicine may lead to acts endangering human dignity;

Affirming that progress in biology and medicine should be used for the benefit of present and future generations;

Stressing the need for international co-operation so that all humanity may enjoy the benefits of biology and medicine;

Recognising the importance of promoting a public debate on the questions posed by the application of biology and medicine and the responses to be given thereto;

Wishing to remind all members of society of their rights and responsibilities;

Taking account of the work of the Parliamentary Assembly in this field, including Recommendation 1160 (1991) on the preparation of a Convention on bioethics;

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[40] Texts provisionally adopted by the CDBI appear in italics.

[41] Where the result of the vote does not appear the articles in italic have been adopted by consensus. The meeting during which the Article was adopted is mentionned below the Article.

[42] The changes appearing in bold are those proposed by the CDBI-CO-RED.

Resolving to take such measures as are necessary to safeguard human dignity and the fundamental rights and freedoms of the individual with regard to the application of biology and medicine;

Have agreed as follows:

CHAPTER I - General provisions

Article 1 (Purpose and object)

Parties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine.

VOTE: 27 FOR, 1 AGAINST, 1 ABSTENTION (7th meeting)

Article 2 (Primacy of the human being)

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

(7th meeting)

Article 3 (Restrictions on the exercise of the rights) (The CDBI-CO-RED proposes to put this Article before the present Article 25)

1. No restrictions shall be placed on the exercise of the rights 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.

2. The restrictions set out in the preceding paragraph shall not apply to Articles 11a, 11b, 14, 15bis, 16, 18, 19 and 20.

Article 4 (Equitable access to health care)

Parties, taking into account health needs and available resources, shall take appropriate measures with a view to providing, within their jurisdiction, equitable access to health care of appropriate quality.

(8th meeting)

Article 5 (Professional standards)

Any intervention in the health field, including research, must be carried out in accordance with relevant professional obligations and standards.

(7th meeting)

CHAPTER II - Consent

Article 6 (General rule)

An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it.

This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks.

The person concerned may freely withdraw consent at any time.

(8th meeting)

Article 7 (Protection of persons not able to consent)

1. Subject to Articles 16 and 19 below, an intervention may only be carried out on a person who does not have the capacity to consent, for his or her direct benefit.

2. Where, according to law, a minor does not have the capacity to consent to an intervention, the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law.

The opinion of the minor shall be taken into consideration as an increasingly determining factor in proportion to his or her age and degree of maturity.

3. Where, according to law, an adult does not have the capacity to consent to an intervention because of a mental disability, a disease or for similar reasons, the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law.

The individual concerned shall as far as possible take part in the authorisation procedure.

4. The representative, the authority, the person or the body mentioned in paragraphs 2 and 3 above shall be given, under the same conditions, the information referred to in Article 6.

5. The authorisation referred to in paragraphs 2 and 3 above may be withdrawn at any time in the best interests of the person concerned.

VOTE: 30 FOR, 0 AGAINST, 2 ABSTENTIONS (9th meeting)

Article 8 (Protection of persons who have mental disorder)

Subject to protective conditions prescribed by law, including supervisory, control and appeal procedures, a person who has a mental disorder of a serious nature may be subjected, without his or her consent, to an intervention aimed at treating his or her mental disorder only where, without such treatment, serious harm is likely to result to his or her health.

(9th meeting)

Article 9 (Emergency situation)

When because of an emergency situation the appropriate consent cannot be obtained, any medically necessary intervention may be carried out immediately for the benefit of the health of the individual concerned.

(8th meeting)

Article 10 (Previously expressed wishes)

The previously expressed wishes relating to a medical intervention by a patient who is not, at the time of the intervention, in a state to express his or her wishes shall be taken into account.

(7th meeting)

CHAPTER III - Private life and right to information

Article 11 (Private life and right to information)

1. Everyone has the right to respect for private life in relation to information about his or her health.

2. Everyone is entitled to know any information collected about his or her health. However, the wishes of individuals not to be so informed shall be observed.

3. In exceptional cases, restrictions may be placed by law on the exercise of the rights contained in paragraph 2 in the interests of the patient.

VOTE: 22 FOR, 1 AGAINST, 9 ABSTENTIONS (9th meeting)

CHAPTER IV - Human genome

Article 11a (Non-discrimination)

Any form of discrimination against an individual on grounds of his or her genetic heritage is prohibited.

VOTE ON THE PRINCIPLE: 29 FOR, 2 AGAINST, 2 ABSTENTIONS (10th meeting)

Article 11b (Non-selection of sex)
(The CDBI-CO-RED proposes to put this Article after the present Article 14)

The use of techniques of medically assisted procreation shall not be allowed for the purpose of choosing a future child's sex, except where serious hereditary sex-related disease is to be avoided.

VOTE ON THE PRINCIPLE: 27 FOR, 0 AGAINST, 3 ABSTENTIONS (10th meeting)

Article 12 (Tests predictive of genetic disease)

Tests which are predictive of genetic diseases or 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 a disease may be performed only for health purposes or for scientific research linked to health purposes, and subject to appropriate genetic counselling.

VOTE: 28 FOR, 2 AGAINST, 1 ABSTENTION (10th meeting)

Article 13 (Use of results)

*The use of the results of the genetic tests **referred to in Article 12** is allowed, subject to receiving the free and informed consent of the person, only for the purposes mentioned in **that** Article.*

VOTE: 23 FOR, 4 AGAINST, 5 ABSTENTIONS (10th meeting)

Article 14 (Interventions on the human genome)

An intervention seeking to modify the human genome may only be undertaken if its aim is not to modify **any** genetic characteristics of descendants and only for preventive, diagnostic or therapeutic purposes.

PROVISIONAL VOTE: 30 FOR, 0 AGAINST, 3 ABSTENTIONS (10th meeting)

CHAPTER V - Scientific research

Article 15 (General rule)

Scientific research in the field of biology and 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.

VOTE: 32 FOR, 0 AGAINST, 1 ABSTENTION (9th meeting)

Article 15 bis (Protection of persons undergoing research)

Research on a person may only be undertaken if all the following conditions are met:

i) there is no alternative of comparable effectiveness to research on humans,

ii) the risks which may be incurred by that person are not disproportionate to the potential benefits of the research,

iii) the research project has been approved by the competent body after independent examination of its scientific merit, including the importance of the aim of the research, and ethical acceptability,

iv) the persons undergoing research have been informed of their rights and the safeguards prescribed by law for their protection,

v) the necessary consent as provided for under Article 6 has been given expressly, specifically and is documented. Such consent may be freely withdrawn at any time.

VOTE: 33 FOR, 0 AGAINST, 0 ABSTENTIONS (9th meeting)

Article 16 (Protection of persons not able to consent to research)

1. Research on a person without the capacity to consent as stipulated in Article 6 may be undertaken only if all the following conditions are met:

i. the conditions laid down in Article 15 bis, sub-paragraphs (i) to (iv), are fulfilled;

ii. the results of the research have the potential to produce direct benefit to his or her health;

iii. research of comparable effectiveness cannot be carried out on individuals capable of giving consent;

iv. the necessary authorisation provided for under Article 7 has been given specifically and in writing, and

v. the person concerned does not object.

VOTE: 30 FOR, 0 AGAINST, 2 ABSTENTIONS (10th meeting)

2. Exceptionally and under the protective conditions prescribed by law, where the research has not the potential to produce results of direct benefit to the health of the person concerned, such research may be authorised subject to the conditions laid down in paragraph 1, sub-paragraphs (i), (iii), (iv) and (v) above, and to the following additional conditions:

i. the research has the aim of contributing, through significant improvement in the scientific understanding of the individual's condition, disease or disorder, to the ultimate attainment of results capable of conferring benefit to the person concerned or to other persons in the same age category or afflicted with the same disease or disorder or having the same condition.

ii. the research entails only minimal risk and minimal burden for the individual concerned.

VOTE: 27 FOR, 4 AGAINST, 2 ABSTENTIONS (10th meeting)

Article 17 (Research on embryos in vitro)[43]

1. Where the law allows research on embryos in vitro, it shall ensure adequate protection of the embryo.

VOTE: 24 FOR, 3 AGAINST, 5 ABSTENTIONS (10th meeting)

2. The creation of human embryos for research purposes is prohibited.

VOTE: 21 FOR, 8 AGAINST, 4 ABSTENTIONS (10th meeting)

[43] A separate vote on each of the two paragraphs reached a majority of 2/3, but a vote on draft Article 17 as a whole did not reach a 2/3 majority. VOTE: 17 FOR, 11 AGAINST, 3 ABSTENTIONS

CHAPTER VI - Organ removal from living donors for transplantation purposes

Article 18 (General rule)

1. Removal of organs or tissues from a living person for transplantation purposes may be carried out solely for the therapeutic benefit of the recipient and where there is no suitable organ or tissue available from a deceased person and no other alternative therapeutic method of comparable effectiveness.

2. The necessary consent as provided for under Article 6 must have been given expressly and specifically either in written form or before an official body.

Article 19 (Protection of persons not able to consent to organ removal)

1. No organ or tissue removal may be carried out on an individual who does not have the capacity to consent under Article 6.

2. Exceptionally and under the protective conditions prescribed by law, the removal of regenerative tissue from an individual who does not have the capacity to consent may be authorised provided the following conditions are met :

i. there is no compatible donor available who has the capacity to consent,

ii. the recipient is a sibling with the same parents as the donor,

iii. the donation must have the potential to be life-saving for the recipient,

iv. the authorisation provided for under paragraphs 2 and 3 of Article 7 has been given specifically and in writing, as provided for by law,

v. the person concerned does not object.

CHAPTER VII - Prohibition of financial gain and disposal of a part of the human body

Article 20 (Prohibition of financial gain)

The human body and its parts shall not, as such, give rise to financial gain.

(10th meeting)

Article 21 (Disposal of a removed part of the human body)

When in the course of an intervention any part of a human body is removed, it may be stored and used for a purpose other than that for which it was removed, only if this is done in conformity with appropriate information and consent procedures.

(10th meeting)

CHAPTER VIII - Infringements of the provisions of the Convention

Article 22 (Infringement of the rights or principles)

The Parties shall provide appropriate judicial protection to prevent or to put a stop to an unlawful infringement of the rights and principles set forth in this Convention at short notice.

(8th meeting)

Article 23 (Compensation for undue damage)

The person who has suffered undue damage resulting from an intervention is entitled to fair compensation according to the conditions and procedures prescribed by law.

VOTE: ADOPTED UNANIMOUSLY (10th meeting)

Article 24 (Sanctions)

Parties shall provide for appropriate sanctions to be applied in the event of infringement of the provisions contained in this Convention.

(8th meeting)

CHAPTER IX - Relation between this Convention and other provisions

Article 25 (Wider protection)

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.

(10th meeting)

CHAPTER X - Public debate

Article 26 (Public debate)

Parties to this Convention shall see to it that the fundamental questions raised by the developments of biology and medicine are the subject of appropriate public discussion in the light, in particular, of relevant medical, social, economic, ethical and legal implications, and that their possible application is made the subject of appropriate consultation.

(10th meeting)

CHAPTER XI - Interpretation and follow-up of the Convention

Article 27 (Interpretation of the Convention)[44]

Parties to this Convention member States of the Council of Europe and the European Community if it is a Party may declare at any time that they accept the jurisdiction of the European Court of Human Rights to give, without direct reference to any specific proceedings pending in the national courts or, where appropriate, in the Court of Justice of the European Communities, advisory opinions on legal questions concerning the interpretation of the present Convention at the request of:

[- the Government of a Party, or of the European Commission if the Community is a Party,]

[- the Committee of Ministers of the Council of Europe, by a decision adopted by majority vote of the representatives entitled to sit on the Committee,]

[- the Committee set up by Article 30 of this Convention by a decision adopted by a majority vote of the Parties.]

[44] This article was examined by the CDBI but has not yet been agreed upon.

Article 28 (Reports on the application of the Convention)

On receipt of a request from the Secretary General of the Council of Europe any Party shall furnish an explanation of the manner in which its internal law ensures the effective implementation of any of the provisions of the Convention.

(10th meeting)

Article 28 bis (Re-examination of the Convention)

The present Convention shall be re-examined within the Committee referred to in Article 30 no later than five years from its entry into force and thereafter at such intervals as the Committee may determine.

CHAPTER XII - Protocols

Article 29 (Protocols)

Protocols may be concluded in pursuance of Article 30, with a view to developing, in specific fields, the principles contained in this Convention.

The Protocols shall be open for signature by Signatories of the Convention. They shall be subject to ratification, acceptance or approval. A signatory may not ratify, accept or approve Protocols without previously or simultaneously ratifying the Convention.

(10th meeting)

CHAPTER XIII - Amendments to the Convention

Article 30 (Amendments to the Convention)

Alternative 1 :

1 For the purposes of this article a Committee is hereby set up.

2 The Committee referred to in the preceding paragraph shall be composed of one delegation per Party, appointed by the Government of the said Party. Each delegation shall have one vote. Any State referred to in Article 31 or invited to accede to the Convention in accordance with the provisions of Article 32 which is not a Party to this Convention may be represented on the Committee by an observer. If the European Community is not a Party it may be represented on the Committee by an observer.

3 Any proposal for an amendment to this Convention, and any proposal for a Protocol or for an amendment to a Protocol, presented by a Party, the Committee or the Committee of Ministers shall be communicated to the Secretary General of the Council of Europe and forwarded by him to the member States of the Council of Europe, to the European Community, to any Signatory, to any Party, to any State invited to sign this Convention in accordance with the provisions of Article 31 and to any State invited to accede to it in accordance with the provisions of Article 32.

4 The Committee shall meet not earlier than two months after a proposal has been forwarded by the Secretary General in accordance with paragraph 3 and examine the proposal. It shall submit the text adopted by a two-third majority of the votes cast to the Committee of Ministers for approval. After its approval, this text shall be forwarded to the Parties for ratification, acceptance or approval.

5 Any amendment shall enter into force, in respect of those Parties which have accepted it, on the first day of the month following the expiration of a period of one month after the date on which five Parties, including at least four member States of the Council of Europe, have informed the Secretary General that they have accepted it.

In respect of any Party which subsequently accepts it, the amendment shall enter into force on the first day of the month following the expiration of a period of one month after the date on which that Party has informed the Secretary General of its acceptance.

Alternative 2 :

(Version proposed by the CDBI-CO-RED foreseeing the CDBI replacing the Conventional Committee):

1. The tasks assigned to "the Committee" in the present article, [and] in article 27 [and article 28 bis] shall be carried out by the Steering Committee on Bioethics (CDBI), or by any other committee designated to do so by the Committee of Ministers.

2. In the Committee, when carrying out the tasks assigned to it by the present Convention, each member State of the Council of Europe as well as each Party to the present Convention which is not a member, may be represented and have one vote.

3. Any State referred to in Article 31 or invited to accede to the Convention in accordance with the provisions of Article 32 which is not Party to this Convention may be represented on the Committee by an observer. If the European Community is not a Party it may be represented on the Committee by an observer.

4. Any proposal for an amendment to this Convetion, and any proposal for a Protocol or for an amendment to a Protocol, presented by a Party, the Committee or the Committee of Ministers shall be communicated to the Secretary General of the Council of Europe and forwarded by him to the member States of the Council of Europe, to the European Community, to any Signatory, to any Party, to any State invited to sign this Convention in accordance with the provisions of Article 31 and to any State invited to accede to it in accordance with the provisions of Article 32.

5. The Committee shall **examine the proposal** not earlier than two months after a proposal has been forwarded by the Secretary General in accordance with paragraph **4**. It shall submit the text adopted by a two-thirds majority of the votes cast to the Committee of Ministers for approval. After its approval, this text shall be forwarded to the Parties for ratification, acceptance or approval.

6. Any amendment shall enter into force, in respect of those Parties which have accepted it, on the first day of the month following the expiration of a period of one month after the date on which five Parties, including at least four member States of the Council of Europe, have informed the Secretary General that they have accepted it.

In respect of any Party which subsequently accepts it, the amendment shall enter into force on the first day of the month following the expiration of a period of one month after the date on which that Party has informed the Secretary General of its acceptance.

CHAPTER XIV - Final clauses

Article 31 (Signature, ratification and entry into force)

1 This Convention shall be open for signature by the member States of the Council of Europe, the non-member States which have participated in its elaboration and by the European Community.

2 This Convention is subject to ratification, acceptance or approval. Instruments of ratification, acceptance or approval shall be deposited with the Secretary General of the Council of Europe.

3 This Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date on which five States, including at least four member States of the Council of Europe, have expressed their consent to be bound by the Convention in accordance with the provisions of paragraph 2 of the present Article.

4 In respect of any Signatory which subsequently expresses its consent to be bound by it, the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of the deposit of its instrument of ratification, acceptance or approval.

(10th meeting)

Article 32 (Non-member States)

1 After the entry into force of this Convention, the Committee of Ministers of the Council of Europe may, after consultation of the Parties, invite any non-member State of the Council of Europe to accede to this Convention by a decision taken by the majority provided for in Article 20, sub-paragraph d of the Statute of the Council of Europe, and by the unanimous vote of the representatives of the Contracting States entitled to sit on the Committee of Ministers.

2 In respect of any acceding State, the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of deposit of the instrument of accession with the Secretary General of the Council of Europe.

(10th meeting)

Article 33 (Territories)

1 Any Signatory may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, specify the territory or territories to which this Convention shall apply. Any other State may formulate the same declaration when depositing its instrument of accession.

2 Any Party may, at any later date, by a declaration addressed to the Secretary General of the Council of Europe, extend the application of this Convention to any other territory specified in the declaration and for whose international relations it is responsible or on whose behalf it is authorised to give undertakings. In respect of such territory the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of receipt of such declaration by the Secretary General.

3 Any declaration made under the two preceding paragraphs may, in respect of any territory specified in such declaration, be withdrawn by a notification addressed to the Secretary General. The withdrawal shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of such notification by the Secretary General.

(10th meeting)

Article 34 (Reservations)[45] [46]

1 Any State and the European Community may, when signing this Convention or when depositing the instrument of ratification, make a reservation in respect of any particular provision of the Convention to the extent that any law then in force in its territory is not in conformity with the provision. Reservations of a general character shall not be permitted under this article.

2 Any reservation made under this article shall contain a brief statement of the relevant law.

3 Any Party which extends the application of this Convention to a territory mentioned in the declaration referred to in Article 33, paragraph 2, may, in respect of the territory concerned, make a reservation in accordance with the provisions of the preceding paragraphs.

4 Any Party which has made the reservation mentioned in this Article may withdraw it by means of a declaration addressed to the Secretary General of the Council of Europe. The withdrawal shall become effective on the first day of the month following the expiration of a period of one month after the date of its receipt by the Secretary General.

Article 35 (Denunciation)

1 Any Party may at any time denounce this Convention by means of a notification addressed to the Secretary General of the Council of Europe.

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45 This article was examined by the CDBI but has not yet been agreed upon.

46 Text taken from Article 64 of the European Convention on Human Rights.

2 Such denunciation shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of the notification by the Secretary General.

(10th meeting)

Article 36 (Notifications)

The Secretary General of the Council of Europe shall notify the member States of the Council, the European Community, any Signatory, any Party and any other State which has been invited to accede to this Convention of:

a any signature;
b the deposit of any instrument of ratification, acceptance, approval or accession;
c any date of entry into force of this Convention in accordance with Articles 31 or 32;
d any amendment or Protocol adopted in accordance with Article 30, and the date on which such an amendment or Protocol enters into force;
e any declaration made under the provisions of Article 33;
f any reservation and withdrawal of reservation made in pursuance of the provisions of Article 34;
g any other act, notification or communication relating to this Convention.

In witness whereof the undersigned, being duly authorised thereto, have signed this Convention.

Done at ....., the ....., in English and French, both texts being equally authentic, in a single copy which shall be deposited in the archives of the Council of Europe. The Secretary General of the Council of Europe shall transmit certified copies to each member State of the Council of Europe, to the European Community, to the non-member States which have participated in the elaboration of this Convention, and to any State invited to accede to this Convention.

4-7 June 1996

DRAFT CONVENTION FOR THE PROTECTION OF HUMAN RIGHTS AND DIGNITY OF THE HUMAN BEING WITH REGARD TO THE APPLICATION OF BIOLOGY AND MEDICINE: CONVENTION ON HUMAN RIGHTS AND BIOMEDICINE

PREAMBLE

The Member States of the Council of Europe, the other States and the European Community signatories hereto,

Bearing in mind the Universal Declaration of Human Rights proclaimed by the General Assembly of the United Nations on 10 December 1948;

Bearing in mind the Convention for the Protection of Human Rights and Fundamental Freedoms of 4 November 1950;

Bearing in mind the European Social Charter of 18 October 1961;

Bearing in mind the International Covenant on Civil and Political Rights and the International Covenant on Economic, Social and Cultural Rights of 16 December 1966;

Bearing in mind the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data of 28 January 1981;

Bearing also in mind the Convention on the Rights of the Child of 20 November 1989;

Considering that the aim of the Council of Europe is the achievement of a greater unity between its members and that one of the methods by which that aim is to be pursued is the maintenance and further realisation of human rights and fundamental freedoms;

Conscious of the accelerating developments in biology and medicine;

Convinced of the need to respect the human being both as an individual and as a member of the human species and recognising the importance of ensuring the dignity of the human being;

Conscious that the misuse of biology and medicine may lead to acts endangering human dignity;

Affirming that progress in biology and medicine should be used for the benefit of present and future generations;

Stressing the need for international co-operation so that all humanity may enjoy the benefits of biology and medicine;

Recognising the importance of promoting a public debate on the questions posed by the application of biology and medicine and the responses to be given thereto;

Wishing to remind all members of society of their rights and responsibilities;

Taking account of the work of the Parliamentary Assembly in this field, including Recommendation 1160 (1991) on the preparation of a Convention on bioethics;

Resolving to take such measures as are necessary to safeguard human dignity and the fundamental rights and freedoms of the individual with regard to the application of biology and medicine;

Have agreed as follows:

CHAPTER I - General provisions

Article 1 (Purpose and object)

Parties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine.

Article 2 (Primacy of the human being)

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

Article 3 (Equitable access to health care)

Parties, taking into account health needs and available resources, shall take appropriate measures with a view to providing, within their jurisdiction, equitable access to health care of appropriate quality.

Article 4 (Professional standards)

Any intervention in the health field, including research, must be carried out in accordance with relevant professional obligations and standards.

CHAPTER II - Consent

Article 5 (General rule)

An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it.

This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks.

The person concerned may freely withdraw consent at any time.

Article 6 (Protection of persons not able to consent)

1. Subject to Articles 17 and 20 below, an intervention may only be carried out on a person who does not have the capacity to consent, for his or her direct benefit.

2. Where, according to law, a minor does not have the capacity to consent to an intervention, the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law.

The opinion of the minor shall be taken into consideration as an increasingly determining factor in proportion to his or her age and degree of maturity.

3. Where, according to law, an adult does not have the capacity to consent to an intervention because of a mental disability, a disease or for similar reasons, the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law.

The individual concerned shall as far as possible take part in the authorisation procedure.

4. The representative, the authority, the person or the body mentioned in paragraphs 2 and 3 above shall be given, under the same conditions, the information referred to in Article 5.

5. The authorisation referred to in paragraphs 2 and 3 above may be withdrawn at any time in the best interests of the person concerned.

Article 7 (Protection of persons who have mental disorder)

Subject to protective conditions prescribed by law, including supervisory, control and appeal procedures, a person who has a mental disorder of a serious nature may be subjected, without his or her consent, to an intervention aimed at treating his or her mental disorder only where, without such treatment, serious harm is likely to result to his or her health.

Article 8 (Emergency situation)

When because of an emergency situation the appropriate consent cannot be obtained, any medically necessary intervention may be carried out immediately for the benefit of the health of the individual concerned.

Article 9 (Previously expressed wishes)

The previously expressed wishes relating to a medical intervention by a patient who is not, at the time of the intervention, in a state to express his or her wishes shall be taken into account.

CHAPTER III - Private life and right to information

Article 10 (Private life and right to information)

1. Everyone has the right to respect for private life in relation to information about his or her health.

2. Everyone is entitled to know any information collected about his or her health. However, the wishes of individuals not to be so informed shall be observed.

3. In exceptional cases, restrictions may be placed by law on the exercise of the rights contained in paragraph 2 in the interests of the patient.

CHAPTER IV - Human genome

Article 11 (Non-discrimination)

Any form of discrimination against a person on grounds of his or her genetic heritage is prohibited.

Article 12 (Predictive genetic tests)

Tests which are predictive of genetic diseases or 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 a disease may be performed only for health purposes or for scientific research linked to health purposes, and subject to appropriate genetic counselling.

Article 13 (Interventions on the human genome)

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.

Article 14 (Non-selection of sex)

The use of techniques of medically assisted procreation shall not be allowed for the purpose of choosing a future child's sex, except where serious hereditary sex-related disease is to be avoided.

CHAPTER V - Scientific research

Article 15. (General rule)

Scientific research in the field of biology and 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.

Article 16 (Protection of persons undergoing research)

Research on a person may only be undertaken if all the following conditions are met:

i) there is no alternative of comparable effectiveness to research on humans,

ii) the risks which may be incurred by that person are not disproportionate to the potential benefits of the research,

iii) the research project has been approved by the competent body after independent examination of its scientific merit, including the importance of the aim of the research, and ethical acceptability,

iv) the persons undergoing research have been informed of their rights and the safeguards prescribed by law for their protection,

v) the necessary consent as provided for under Article 5 has been given expressly, specifically and is documented. Such consent may be freely withdrawn at any time.

Article 17 (Protection of persons not able to consent to research)

1. Research on a person without the capacity to consent as stipulated in Article 5 may be undertaken only if all the following conditions are met:

   i. the conditions laid down in Article 16, sub-paragraphs (i) to (iv), are fulfilled;

   ii. the results of the research have the potential to produce direct benefit to his or her health;

   iii. research of comparable effectiveness cannot be carried out on individuals capable of giving consent;

   iv. the necessary authorisation provided for under Article 6 has been given specifically and in writing, and

   v. the person concerned does not object.

2. Exceptionally and under the protective conditions prescribed by law, where the research has not the potential to produce results of direct benefit to the health of the person concerned, such research may be authorised subject to the conditions laid down in paragraph 1, sub-paragraphs (i), (iii), (iv) and (v) above, and to the following additional conditions:

   i. the research has the aim of contributing, through significant improvement in the scientific understanding of the individual's condition, disease or disorder, to the ultimate attainment of results capable of conferring benefit to the person concerned or to other persons in the same age category or afflicted with the same disease or disorder or having the same condition.

   ii. the research entails only minimal risk and minimal burden for the individual concerned.

Article 18 (Research on embryos in vitro)

1. Where the law allows research on embryos in vitro, it shall ensure adequate protection of the embryo.

2. The creation of human embryos for research purposes is prohibited.

CHAPTER VI - Organ and tissue removal from living donors for transplantation purposes

Article 19 (General rule)

1. Removal of organs or tissue from a living person for transplantation purposes may be carried out solely for the therapeutic benefit of the recipient and where there is no suitable organ or tissue available from a deceased person and no other alternative therapeutic method of comparable effectiveness.

2. The necessary consent as provided for under Article 5 must have been given expressly and specifically either in written form or before an official body.

Article 20 (Protection of persons not able to consent to organ removal)

1. No organ or tissue removal may be carried out on a person who does not have the capacity to consent under Article 5.

2. Exceptionally and under the protective conditions prescribed by law, the removal of regenerative tissue from a person who does not have the capacity to consent may be authorised provided the following conditions are met :

i. there is no compatible donor available who has the capacity to consent,

ii. the recipient is a brother or sister of the donor,

iii. the donation must have the potential to be life-saving for the recipient,

iv. the authorisation provided for under paragraphs 2 and 3 of Article 6 has been given specifically and in writing, as provided for by law,

v. the potential donor does not object.

CHAPTER VII - Prohibition of financial gain and disposal of a part of the human body

Article 21 (Prohibition of financial gain)

The human body and its parts shall not, as such, give rise to financial gain.

Article 22 (Disposal of a removed part of the human body)

When in the course of an intervention any part of a human body is removed, it may be stored and used for a purpose other than that for which it was removed, only if this is done in conformity with appropriate information and consent procedures.

CHAPTER VIII - Infringements of the provisions of the Convention

Article 23 (Infringement of the rights or principles)

The Parties shall provide appropriate judicial protection to prevent or to put a stop to an unlawful infringement of the rights and principles set forth in this Convention at short notice.

Article 24 (Compensation for undue damage)

The person who has suffered undue damage resulting from an intervention is entitled to fair compensation according to the conditions and procedures prescribed by law.

Article 25 (Sanctions)

Parties shall provide for appropriate sanctions to be applied in the event of infringement of the provisions contained in this Convention.

CHAPTER IX - Relation between this Convention and other provisions

Article 26 (Restrictions on the exercise of the rights)

1. 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.

2. The restrictions contemplated in the preceding paragraph may not be placed on Articles 11, 13, 14, 16, 17, 19, 20 and 21.

Article 27 (Wider protection)

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.

CHAPTER X - Public debate

Article 28 (Public debate)

Parties to this Convention shall see to it that the fundamental questions raised by the developments of biology and medicine are the subject of appropriate public discussion in the light, in particular, of relevant medical, social, economic, ethical and legal implications, and that their possible application is made the subject of appropriate consultation.

CHAPTER XI - Interpretation and follow-up of the Convention

Article 29 (Interpretation of the Convention)

The European Court of Human Rights may give, without direct reference to any specific proceedings pending in a court, advisory opinions on legal questions concerning the interpretation of the present Convention at the request of:

- the Government of a Party, after having informed the other Parties,

- the Committee set up by Article 32, with membership restricted to the Representatives of the Parties to this Convention, by a decision adopted by a two-third majority of votes cast.

Article 30 (Reports on the application of the Convention)

On receipt of a request from the Secretary General of the Council of Europe any Party shall furnish an explanation of the manner in which its internal law ensures the effective implementation of any of the provisions of the Convention.

CHAPTER XII - Protocols

Article 31 (Protocols)

Protocols may be concluded in pursuance of Article 32, with a view to developing, in specific fields, the principles contained in this Convention.

The Protocols shall be open for signature by Signatories of the Convention. They shall be subject to ratification, acceptance or approval. A signatory may not ratify, accept or approve Protocols without previously or simultaneously ratifying accepting or approving the Convention.

CHAPTER XIII - Amendments to the Convention

Article 32 (Amendments to the Convention)

1. The tasks assigned to "the Committee" in the present Article and in Article 29 shall be carried out by the Steering Committee on Bioethics (CDBI), or by any other committee designated to do so by the Committee of Ministers.

2. Without prejudice to the specific provisions of Article 29, each member State of the Council of Europe, as well as each Party to the present Convention which is not a member of the Council of Europe, may be represented and have one vote in the Committee when the Committee carries out the tasks assigned to it by the present Convention.

3. Any State referred to in Article 33 or invited to accede to the Convention in accordance with the provisions of Article 34 which is not Party to this Convention may be represented on the Committee by an observer. If the European Community is not a Party it may be represented on the Committee by an observer.

4. In order to monitor scientific developments, the present Convention shall be examined within the Committee no later than five years from its entry into force and thereafter at such intervals as the Committee may determine.

5. Any proposal for an amendment to this Convention, and any proposal for a Protocol or for an amendment to a Protocol, presented by a Party, the Committee or the Committee of Ministers shall be communicated to the Secretary General of the Council of Europe and forwarded by him to the member States of the Council of Europe, to the European Community, to any Signatory, to any Party, to any State invited to sign this Convention in accordance with the provisions of Article 33 and to any State invited to accede to it in accordance with the provisions of Article 34.

6. The Committee shall examine the proposal not earlier than two months after it has been forwarded by the Secretary General in accordance with paragraph 5. The Committee shall submit the text adopted by a two-thirds majority of the votes cast to the Committee of Ministers for approval. After its approval, this text shall be forwarded to the Parties for ratification, acceptance or approval.

7. Any amendment shall enter into force, in respect of those Parties which have accepted it, on the first day of the month following the expiration of a period of one month after the date on which five Parties, including at least four member States of the Council of Europe, have informed the Secretary General that they have accepted it.

In respect of any Party which subsequently accepts it, the amendment shall enter into force on the first day of the month following the expiration of a period of one month after the date on which that Party has informed the Secretary General of its acceptance.

CHAPTER XIV - Final clauses

Article 33 (Signature, ratification and entry into force)

1. This Convention shall be open for signature by the member States of the Council of Europe, the non-member States which have participated in its elaboration and by the European Community.

2. This Convention is subject to ratification, acceptance or approval. Instruments of ratification, acceptance or approval shall be deposited with the Secretary General of the Council of Europe.

3. This Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date on which five States, including at least four member States of the Council of Europe, have

expressed their consent to be bound by the Convention in accordance with the provisions of paragraph 2 of the present Article.

4. In respect of any Signatory which subsequently expresses its consent to be bound by it, the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of the deposit of its instrument of ratification, acceptance or approval.

Article 34 (Non-member States)

1. After the entry into force of this Convention, the Committee of Ministers of the Council of Europe may, after consultation of the Parties, invite any non-member State of the Council of Europe to accede to this Convention by a decision taken by the majority provided for in Article 20, sub-paragraph d of the Statute of the Council of Europe, and by the unanimous vote of the representatives of the Contracting States entitled to sit on the Committee of Ministers.

2. In respect of any acceding State, the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of deposit of the instrument of accession with the Secretary General of the Council of Europe.

Article 35 (Territories)

1. Any Signatory may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, specify the territory or territories to which this Convention shall apply. Any other State may formulate the same declaration when depositing its instrument of accession.

2. Any Party may, at any later date, by a declaration addressed to the Secretary General of the Council of Europe, extend the application of this Convention to any other territory specified in the declaration and for whose international relations it is responsible or on whose behalf it is authorised to give undertakings. In respect of such territory the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of receipt of such declaration by the Secretary General.

3. Any declaration made under the two preceding paragraphs may, in respect of any territory specified in such declaration, be withdrawn by a notification addressed to the Secretary General. The withdrawal shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of such notification by the Secretary General.

Article 36 (Reservations)

1. Any State and the European Community may, when signing this Convention or when depositing the instrument of ratification, make a reservation in respect of any particular provision of the Convention to the extent that any law then in force in its territory is not in conformity with the provision. Reservations of a general character shall not be permitted under this article.

2. Any reservation made under this article shall contain a brief statement of the relevant law.

3. Any Party which extends the application of this Convention to a territory mentioned in the declaration referred to in Article 35, paragraph 2, may, in respect of the territory concerned, make a reservation in accordance with the provisions of the preceding paragraphs.

4. Any Party which has made the reservation mentioned in this Article may withdraw it by means of a declaration addressed to the Secretary General of the Council of Europe. The withdrawal shall become effective on the first day of the month following the expiration of a period of one month after the date of its receipt by the Secretary General.

Article 37 (Denunciation)

1. Any Party may at any time denounce this Convention by means of a notification addressed to the Secretary General of the Council of Europe.

2. Such denunciation shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of the notification by the Secretary General.

Article 38 (Notifications)

The Secretary General of the Council of Europe shall notify the member States of the Council, the European Community, any Signatory, any Party and any other State which has been invited to accede to this Convention of:

a. any signature;
b. the deposit of any instrument of ratification, acceptance, approval or accession;
c. any date of entry into force of this Convention in accordance with Articles 33 or 34;
d. any amendment or Protocol adopted in accordance with Article 32, and the date on which such an amendment or Protocol enters into force;
e. any declaration made under the provisions of Article 35;
f. any reservation and withdrawal of reservation made in pursuance of the provisions of Article 36;
g. any other act, notification or communication relating to this Convention.

In witness whereof the undersigned, being duly authorised thereto, have signed this Convention.

Done at ....., the ....., in English and French, both texts being equally authentic, in a single copy which shall be deposited in the archives of the Council of Europe. The Secretary General of the Council of Europe shall transmit certified copies to each member State of the Council of Europe, to the European Community, to the non-member States which have participated in the elaboration of this Convention, and to any State invited to accede to this Convention.