

**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.

Each Party shall take in its internal law the necessary measures to give effect to the provisions of this Convention.

Article 2.

PRIMACY OF THE HUMAN BEING

The interests and welfare of the human being shall prevail over the sole interest of society or 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 A 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 assessment of the importance of the aim of the research, and multidisciplinary review of its 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 real and 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, in accordance with the law and with the approval of the competent body,
- v. the potential donor concerned 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-thirds 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., 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, acceptance, approval or accession, 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 Oviedo (Asturias), this 4th day of April 1997., 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.

ADDITIONAL PROTOCOL TO THE CONVENTION FOR THE PROTECTION OF HUMAN RIGHTS AND DIGNITY OF THE HUMAN BEING WITH REGARD TO THE APPLICATION OF BIOLOGY AND MEDICINE, ON THE PROHIBITION OF CLONING HUMAN BEINGS

The member States of the Council of Europe, the other States and the European Community Signatories to this Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine,

Noting scientific developments in the field of mammal cloning, particularly through embryo splitting and nuclear transfer,

Mindful of the progress that some cloning techniques themselves may bring to scientific knowledge and its medical application,

Considering that the cloning of human beings may become a technical possibility,

Having noted that embryo splitting may occur naturally and sometimes result in the birth of genetically identical twins,

Considering however that the instrumentalisation of human beings through the

deliberate creation of genetically identical human beings is contrary to human dignity and thus constitutes a misuse of biology and medicine,

Considering also the serious difficulties of a medical, psychological and social nature that such a deliberate biomedical practice might imply for all the individuals involved, Considering the purpose of the Convention on Human Rights and Biomedicine, in particular the principle mentioned in Article 1 aiming to protect the dignity and identity of all human beings,

Have agreed as follows:

Article 1.

1. Any intervention seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited.

2. For the purpose of this article, the term human being »genetically identical« to another human being means a human being sharing with another the same nuclear gene set.

Article 2.

No derogation from the provisions of this Protocol shall be made under Article 26., paragraph 1., of the Convention.

Article 3.

As between the Parties, the provisions of Articles 1. and 2. of this Protocol shall be regarded as additional articles to the Convention and all the provisions of the Convention shall apply accordingly.

Article 4.

This Protocol shall be open for signature by Signatories to the Convention. It is subject to ratification, acceptance or approval. A Signatory may not ratify, accept or approve this Protocol unless it has previously or simultaneously ratified, accepted or approved the Convention. Instruments of ratification, acceptance or approval shall be deposited with the Secretary General of the Council of Europe.

Article 5.

1. This Protocol 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 Protocol in accordance with the provisions of Article 4.

2. In respect of any Signatory which subsequently expresses its consent to be bound by it, the Protocol 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 the instrument of ratification, acceptance or approval.

Article 6.

1. After the entry into force of this Protocol, any State which has acceded to the Convention may also accede to this Protocol.

2. Accession shall be effected by the deposit with the Secretary General of the Council of Europe of an instrument of accession which shall take effect on the first day of the month following the expiration of a period of three months after the date of its deposit.

Article 7.

1. Any Party may at any time denounce this Protocol 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 such notification by the Secretary General.

Article 8.

The Secretary General of the Council of Europe shall notify the member States of the Council of Europe, the European Community, any Signatory, any Party and any other State which has been invited to accede to the 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 Protocol in accordance with Articles 5. and 6.,
- d. any other act, notification or communication relating to this Protocol.

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

Done at Paris, this twelfth day of January 1998., in English and in 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 Protocol, to any State invited to accede to the Convention and to the European Community.

ADDITIONAL PROTOCOL TO THE CONVENTION ON HUMAN RIGHTS AND BIOMEDICINE CONCERNING TRANSPLANTATION OF ORGANS AND TISSUES OF HUMAN ORIGIN

PREAMBLE

The member States of the Council of Europe, the other States and the European Community signatories to this Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (hereinafter referred to as “Convention on Human Rights and Biomedicine”),

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

Considering that the aim of the Convention on Human Rights and Biomedicine, as defined in Article 1, is to 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,

Considering that progress in medical science, in particular in the field of organ and tissue transplantation, contributes to saving lives or greatly improving their quality,

Considering that transplantation of organs and tissues is an established part of the health services offered to the population,

Considering that, in view of the shortage of organs and tissues, appropriate action should be taken to increase organ and tissue donation, in particular by informing the public of the importance of organ and tissue transplantation and by promoting European co-operation in this field,

Considering moreover the ethical, psychological and socio-cultural problems inherent in the transplantation of organs and tissues,

Considering that the misuse of organ and tissue transplantation may lead to acts endangering human life, well being or dignity,

Considering that organ and tissue transplantation should take place under conditions protecting the rights and freedoms of donors, potential donors and recipients of organs and tissues and that institutions must be instrumental in ensuring such conditions,

Recognising that, in facilitating the transplantation of organs and tissues in the interest of patients in Europe, there is a need to protect individual rights and freedoms and to prevent the commercialisation of parts of the human body involved in organ and tissue procurement, exchange and allocation activities,

Taking into account previous work of the Committee of Ministers and the Parliamentary Assembly of the Council of Europe in this field,

Resolving to take such measures as are necessary to safeguard human dignity and the rights and fundamental freedoms of the individual with regard to organ and tissue transplantation,

Have agreed as follows:

Chapter I.

OBJECT AND SCOPE

Article 1.

OBJECT

Parties to this Protocol shall protect the dignity and identity of everyone and guarantee, without discrimination, respect for his or her integrity and other rights and fundamental freedoms with regard to transplantation of organs and tissues of human origin.

Article 2.

SCOPE AND DEFINITIONS

1. This Protocol applies to the transplantation of organs and tissues of human origin carried out for therapeutic purposes.
2. The provisions of this Protocol applicable to tissues shall apply also to cells, including haematopoietic stem cells.
3. The Protocol does not apply:
 - a. to reproductive organs and tissue,
 - b. to embryonic or foetal organs and tissues,
 - c. to blood and blood derivatives.
4. For the purposes of this Protocol:
 - the term »transplantation« covers the complete process of removal of an organ or tissue from one person and implantation of that organ or tissue into another person, including all procedures for preparation, preservation and storage,
 - subject to the provisions of Article 20., the term »removal« refers to removal for the purposes of implantation.

Chapter II.

GENERAL PROVISIONS

Article 3.

TRANSPLANTATION SYSTEM

Parties shall guarantee that a system exists to provide equitable access to transplantation services for patients.

Subject to the provisions of Chapter III., organs and, where appropriate, tissues

shall be allocated only among patients on an official waiting list, in conformity with transparent, objective and duly justified rules according to medical criteria. The persons or bodies responsible for the allocation decision shall be designated within this framework.

In case of international organ exchange arrangements, the procedures must also ensure justified, effective distribution across the participating countries in a manner that takes into account the solidarity principle within each country.

The transplantation system shall ensure the collection and recording of the information required to ensure traceability of organs and tissues.

Article 4.

PROFESSIONAL STANDARDS

Any intervention in the field of organ or tissue transplantation must be carried out in accordance with relevant professional obligations and standards.

Article 5.

INFORMATION FOR THE RECIPIENT

The recipient and, where appropriate, the person or body providing authorisation for the implantation shall beforehand be given appropriate information as to the purpose and nature of the implantation, its consequences and risks, as well as on the alternatives to the intervention.

Article 6.

HEALTH AND SAFETY

All professionals involved in organ or tissue transplantation shall take all reasonable measures to minimise the risks of transmission of any disease to the recipient and to avoid any action which might affect the suitability of an organ or tissue for implantation.

Article 7.

MEDICAL FOLLOW-UP

Appropriate medical follow-up shall be offered to living donors and recipients after transplantation.

Article 8.

INFORMATION FOR HEALTH PROFESSIONALS AND THE PUBLIC

Parties shall provide information for health professionals and for the public in general on the need for organs and tissues. They shall also provide information on the conditions relating to removal and implantation of organs and tissues, including matters relating to consent or authorisation, in particular with regard to removal from deceased persons.

Chapter III.

ORGAN AND TISSUE REMOVAL FROM LIVING PERSONS

Article 9.

GENERAL RULE

Removal of organs or tissue from a living person 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.

Article 10.

POTENTIAL ORGAN DONORS

Organ removal from a living donor may be carried out for the benefit of a recipient with whom the donor has a close personal relationship as defined by law, or, in the absence of such relationship, only under the conditions defined by law and with the approval of an appropriate independent body.

Article 11.

EVALUATION OF RISKS FOR THE DONOR

Before organ or tissue removal, appropriate medical investigations and interventions shall be carried out to evaluate and reduce physical and psychological risks to the health of the donor. The removal may not be carried out if there is a serious risk to the life or health of the donor.

Article 12.

INFORMATION FOR THE DONOR

The donor and, where appropriate, the person or body providing authorisation according to Article 14., paragraph 2., of this Protocol, shall beforehand be given appropriate information as to the purpose and nature of the removal as well as on its consequences and risks.

They shall also be informed of the rights and the safeguards prescribed by law for the protection of the donor. In particular, they shall be informed of the right to have access to independent advice about such risks by a health professional having appropriate experience and who is not involved in the organ or tissue removal or subsequent transplantation procedures.

Article 13.

CONSENT OF THE LIVING DONOR

Subject to Articles 14. and 15. of this Protocol, an organ or tissue may be removed from a living donor only after the person concerned has given free, informed and specific consent to it either in written form or before an official body.

The person concerned may freely withdraw consent at any time.

Article 14.

Protection of persons not able to consent to organ or tissue removal

1. No organ or tissue removal may be carried out on a person who does not have the capacity to consent under Article 13 of this Protocol.

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 has the potential to be life-saving for the recipient,
- iv. the authorisation of his or her representative or an authority or a person or body provided for by law has been given specifically and in writing and with the approval of the competent body,
- v. the potential donor concerned does not object.

Article 15.

CELL REMOVAL FROM A LIVING DONOR

The law may provide that the provisions of Article 14, paragraph 2, indents ii and

iii, shall not apply to cells insofar as it is established that their removal only implies minimal risk and minimal burden for the donor.

Chapter IV.

ORGAN AND TISSUE REMOVAL FROM DECEASED PERSONS

Article 16.

CERTIFICATION OF DEATH

Organs or tissues shall not be removed from the body of a deceased person unless that person has been certified dead in accordance with the law.

The doctors certifying the death of a person shall not be the same doctors who participate directly in removal of organs or tissues from the deceased person, or subsequent transplantation procedures, or having responsibilities for the care of potential organ or tissue recipients.

Article 17.

CONSENT AND AUTHORISATION

Organs or tissues shall not be removed from the body of a deceased person unless consent or authorisation required by law has been obtained.

The removal shall not be carried out if the deceased person had objected to it.

Article 18.

RESPECT FOR THE HUMAN BODY

During removal the human body must be treated with respect and all reasonable measures shall be taken to restore the appearance of the corpse.

Article 19.

PROMOTION OF DONATION

Parties shall take all appropriate measures to promote the donation of organs and tissues.

Chapter V.

IMPLANTATION OF AN ORGAN OR TISSUE REMOVED FOR A PURPOSE OTHER THAN DONATION FOR IMPLANTATION

Article 20.

IMPLANTATION OF AN ORGAN OR TISSUE REMOVED FOR A PURPOSE OTHER THAN DONATION FOR IMPLANTATION

1. When an organ or tissue is removed from a person for a purpose other than donation for implantation, it may only be implanted if the consequences and possible risks have been explained to that person and his or her informed consent, or appropriate authorisation in the case of a person not able to consent, has been obtained.

2. All the provisions of this Protocol apply to the situations referred to in paragraph 1, except for those in Chapter III. and IV.

Chapter VI.

PROHIBITION OF FINANCIAL GAIN

Article 21.

PROHIBITION OF FINANCIAL GAIN

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

The aforementioned provision shall not prevent payments which do not constitute a financial gain or a comparable advantage, in particular:

- compensation of living donors for loss of earnings and any other justifiable expenses caused by the removal or by the related medical examinations,
- payment of a justifiable fee for legitimate medical or related technical services rendered in connection with transplantation,
- compensation in case of undue damage resulting from the removal of organs or tissues from living persons.

2. Advertising the need for, or availability of, organs or tissues, with a view to offering or seeking financial gain or comparable advantage, shall be prohibited.

Article 22.

PROHIBITION OF ORGAN AND TISSUE TRAFFICKING

Organ and tissue trafficking shall be prohibited.

Chapter VII.

CONFIDENTIALITY

Article 23.

CONFIDENTIALITY

1. All personal data relating to the person from whom organs or tissues have been removed and those relating to the recipient shall be considered to be confidential. Such data may only be collected, processed and communicated according to the rules relating to professional confidentiality and personal data protection.

2. The provisions of paragraph 1 shall be interpreted without prejudice to the provisions making possible, subject to appropriate safeguards, the collection, processing and communication of the necessary information about the person from whom organs or tissues have been removed or the recipient(s) of organs and tissues in so far as this is required for medical purposes, including traceability, as provided for in Article 3 of this Protocol.

Chapter VIII.

INFRINGEMENTS OF THE PROVISIONS OF THE PROTOCOL

Article 24.

INFRINGEMENTS OF RIGHTS OR PRINCIPLES

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 Protocol at short notice.

Article 25.

COMPENSATION FOR UNDUE DAMAGE

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

Article 26.

SANCTIONS

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

Chapter IX.

CO-OPERATION BETWEEN PARTIES

Article 27.

CO-OPERATION BETWEEN PARTIES

Parties shall take appropriate measures to ensure that there is efficient co-operation between them on organ and tissue transplantation, *inter alia* through information exchange.

In particular, they shall undertake appropriate measures to facilitate the rapid and safe transportation of organs and tissues to and from their territory.

Chapter X.

RELATION BETWEEN THIS PROTOCOL AND THE CONVENTION, AND RE-EXAMINATION OF THE PROTOCOL

Article 28.

RELATION BETWEEN THIS PROTOCOL AND THE CONVENTION

As between the Parties, the provisions of Articles 1. to 27. of this Protocol shall be regarded as additional articles to the Convention on Human Rights and Biomedicine, and all the provisions of that Convention shall apply accordingly.

Article 29.

RE-EXAMINATION OF THE PROTOCOL

In order to monitor scientific developments, the present Protocol shall be examined within the Committee referred to in Article 32. of the Convention on Human Rights and Biomedicine no later than five years from the entry into force of this Protocol and thereafter at such intervals as the Committee may determine.

Chapter XI.

FINAL CLAUSES

Article 30.

SIGNATURE AND RATIFICATION

This Protocol shall be open for signature by Signatories to the Convention. It is subject to ratification, acceptance or approval. A Signatory may not ratify, accept or approve this Protocol unless it has previously or simultaneously ratified, accepted or approved the Convention. Instruments of ratification, acceptance or approval shall be deposited with the Secretary General of the Council of Europe.

Article 31.

ENTRY INTO FORCE

1. This Protocol 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 Protocol in accordance with the provisions of Article 30.

2. In respect of any Signatory which subsequently expresses its consent to be bound by it, the Protocol 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 the instrument of ratification, acceptance or approval.

Article 32.

ACCESSION

1. After the entry into force of this Protocol, any State which has acceded to the Convention may also accede to this Protocol.

2. Accession shall be effected by the deposit with the Secretary General of the Council of Europe of an instrument of accession which shall take effect on the first day of the month following the expiration of a period of three months after the date of its deposit.

Article 33.

DENUNCIATION

1. Any Party may at any time denounce this Protocol 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 such notification by the Secretary General.

Article 34.

NOTIFICATION

The Secretary General of the Council of Europe shall notify the member States of the Council of Europe, the European Community, any Signatory, any Party and any other State which has been invited to accede to the 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 Protocol in accordance with Articles 31. and 32.,
- d. any other act, notification or communication relating to this Protocol.

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

Done at Strasbourg, this 24th day of January 2002., in English and in 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 Protocol, to any State invited to accede to the Convention and to the European Community.