



CNECV – NATIONAL COUNCIL OF ETHICS FOR THE LIFE SCIENCES

Prime Minister's Office

Opinion 41/CNECV/2003 on the Additional Protocol to the Convention on Human Rights and Biomedicine concerning transplantation of organs and tissues of human origin

Rapporteurs:
Dr. Rita Amaral Cabral
and Prof. Daniel Pinto Serrão

1. The aim of the Protocol Concerning Transplantation of Organs and Tissues of Human Origin is to protect the dignity, identity and integrity of all human beings with regard to the transplantation of organs and tissues of human origin (Article 1).
2. The Protocol calls on the several Countries to guarantee to all patients equitable access to transplantation services (Article 3).
3. The Protocol lays down rules enabling the use of living donors while requiring that the national law define what constitutes a close personal relationship between the potential donor and the effective recipient. It also requires information to the donor and the latter's free, informed and specific consent. Furthermore, it lays down clear and objective rules for the protection of living donors who do not have the capacity to consent (Chapter III, Articles 9 to 15).
4. The Protocol also defines rules for the removal of organs and tissues from bodies of deceased persons, leaving to the national law the issue of opting in or opting out, and limiting itself in this regard to setting down in Article 17 that such removal may not be carried out if the deceased person, in life, had objected to it (a doctrine already established in Portugal by the Law that created the National Registry of Non-Donors [*Registo Nacional de Não Dadores*]).
5. The Protocol also sets down the principles of non-commercialisation (Chapter VI) and of confidentiality (Chapter VII).
6. Considering the values upheld in the Protocol and the formulation of the ethical norms that protect such values, the National Council of Ethics for the Life Sciences pronounces its favourable opinion on the ratification of the Protocol by Parliament [*Assembleia da República*].

Approved in the 102nd Plenary Meeting of the National Council of Ethics for the Life Sciences.

Lisbon, the 11th of November 2003

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President of the
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**ADDITIONAL PROTOCOL
TO THE CONVENTION
ON HUMAN RIGHTS AND BIOMEDICINE
CONCERNING TRANSPLANTATION
OF ORGANS AND TISSUES
OF HUMAN ORIGIN¹**

Strasbourg, 24.I.2002

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;

¹ <http://conventions.coe.int/Treaty/en/Treaties/Word/186.doc>



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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.



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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



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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



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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



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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.



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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,



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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.