

COUNCIL OF EUROPE

COMMITTEE OF MINISTERS

RESOLUTION (78) 29

ON HARMONISATION OF LEGISLATIONS OF MEMBER STATES RELATING TO REMOVAL, GRAFTING AND TRANSPLANTATION OF HUMAN SUBSTANCES

*(Adopted by the Committee of Ministers on 11 May 1978
at the 287th meeting of the Ministers' Deputies)*

The Committee of Ministers,

Considering that the aim of the Council of Europe is to achieve a greater unity between its members, in particular through harmonising legislations on matters of common interest ;

Considering that because of the substantial increase in recent years in the treatment of patients by transplantation or grafting of removed human organs, tissues, or other substances, the need for new and more specific legislation was felt in all member states ;

Considering that harmonisation of legislations of member states on removal, grafting and transplantation of human substances will ensure better protection of donors, prospective donors and recipients of human substances and enhance the progress of medical science and therapeutics ;

Recommends to the governments of member states :

- A. to conform their laws to the rules annexed to this resolution or adopt provisions conforming to these rules when introducing new legislation ;
- B. to introduce appropriate sanctions to ensure the application of the rules adopted when implementing this resolution ;
- C. to study the desirability and the possibility of inserting in an appropriate document a statement so that the wish of the deceased person as mentioned in Article 10 of the rules might be determined more easily ;
- D. to intensify, by appropriate means, their efforts to inform the public and arouse the interest of doctors in the need and importance of donations of substances, while keeping the confidential character of individual operations ;
- E. to provide, or to encourage the preparation of practical guidelines for those entitled to decide according to paragraph 1 of Article 11 that a substance may be removed from a deceased person ;
- F. to apply the rules annexed to this resolution, in particular Articles 9 and 14, to substances originating from states which are not members of the Council of Europe.

Invites the governments of member states to inform the Secretary General of the Council of Europe in due course and at any rate every five years, of the action taken on the recommendations contained in this resolution.

RULES

Chapter I - Field of application

Article 1

1. These rules apply to removals, graftings, transplantations and other use of substances of human origin removed or collected for therapeutic or diagnostic purposes for the benefit of persons other than the donor and for research purposes.
2. The transfer of embryos, the removal and transplantation of testicles and ovaries and utilisation of ova and sperm are excluded from the field of application of these rules.

Chapter II - Removals, graftings and transplantations of substances from living persons

Article 2

1. The donor and his legal representative in the case of a minor or otherwise legally incapacitated person (both hereafter referred to as "legally incapacitated person"), must be given appropriate information before the removal about the possible consequences of this removal, in particular medical, social and psychological, as well as the importance of the donation for the recipient.
2. The anonymity of the donor and of the recipient must be respected except where there are close personal or family relations between the two.

Article 3

A removal must not be effected without the consent of the donor. This consent must be given freely. In cases of removal of substances which can regenerate which presents risks for the donor and of removal of substances which cannot regenerate, this consent must be given in writing.

Article 4

Removal of substances which cannot regenerate must be confined to transplantation between genetically related persons except in exceptional cases where there are good chances of success.

Article 5

Where removal of substances presents a foreseeable substantial risk to the life or the health of the donor, a removal may only be permitted exceptionally when it is justified by the motivations of the donor, the family relationship with the recipient and the medical requirements of the case. However a state can prohibit such removal.

Article 6

1. For legally incapacitated persons removals of substances which can regenerate must be limited to exceptional cases. Such a removal may be permitted when it is necessary for therapeutic or diagnostic reasons. It may only be effected with the consent of the legal representative of the incapacitated person if the incapacitated person does not, himself, object to it. If the removal represents a risk to the health of the incapacitated person, prior authorisation must also be obtained from an appropriate authority.
2. The removal of substances which cannot regenerate, from legally incapacitated persons is forbidden. However, a state may permit such a removal in a special case justified for therapeutic or diagnostic reasons if the donor, having the capacity of understanding, has given his consent, if his legal representative and an appropriate authority have authorised removal and if the donor and the recipient are closely genetically related.
3. A removal of substances which presents foreseeable substantial risk to the life or the health of the donor who is a legally incapacitated person is forbidden.

Article 7

Before the removal and transplantation appropriate medical examinations must be made to evaluate and reduce the risks to the health and life of both donor and recipient.

Article 8

1. Substances must be removed under conditions representing the least possible risk to the donor.
2. Removals, graftings and transplantations of substances which cannot regenerate must take place in properly equipped and staffed institutions.

Article 9

No substance may be offered for profit. However, loss of earnings and any expenses caused by the removal or preceding examination may be refunded. The donor, or potential donor, must be compensated, independently of any possible medical responsibility, for any damage sustained as a result of a removal procedure or preceding examination, under a social security or other insurance scheme.

Chapter III - Removals, graftings and transplantations of substances from deceased persons

Article 10

1. No removal must take place when there is an open or presumed objection on the part of the deceased, in particular, taking into account his religious and philosophical convictions.
2. In the absence of the explicit or implicit wish of the deceased the removal may be effected. However, a state may decide that the removal must not be effected if, after such reasonable inquiry as may be practicable has been made into the views of the family of the deceased and in the case of a surviving legally incapacitated person those of his legal representative, an objection is apparent ; when the deceased was a legally incapacitated person the consent of his legal representative may also be required.

Article 11

1. Death having occurred a removal may be effected even if the function of some organ other than the brain may be artificially preserved.
2. A removal can be effected if it does not interfere with a forensic examination or autopsy as required by law. A state may, when such requirement exists, decide that a removal can only be effected with the approval of a competent authority.

Article 12

1. Removals for therapeutic, diagnostic or research purposes must be effected in appropriate places and under suitable conditions.
2. Grafting and transplantations must take place in public or private institutions which possess proper staff and equipment.
3. Death must be established by a doctor who does not belong to the team which will effect the removal, grafting or transplantation. However, this doctor can effect a removal in cases of minor operations when no other suitable doctor is available.

Article 13

The identity of the donor must not be disclosed to the recipient and the identity of the recipient to the family of the donor.

Article 14

Substances must not be offered for any profit.