

COUNCIL OF EUROPE

COMMITTEE OF MINISTERS

RECOMMENDATION No. R (94) 1

OF THE COMMITTEE OF MINISTERS TO MEMBER STATES ON HUMAN TISSUE BANKS

*(Adopted by the Committee of Ministers on 14 March 1994
at the 509th meeting of the Ministers' Deputies)*

The Committee of Ministers, under the terms of Article 15.b of the Statute of the Council of Europe,

Considering that the aim of the Council of Europe is to achieve greater unity between its members and that this aim may be pursued, *inter alia*, by the adoption of common action in the health field;

Taking account of the ethical principles set out in Recommendation No. R (88) 4 on responsibilities of health authorities in the field of blood transfusion concerning voluntary, non-remunerated blood donation;

Considering that, in the procurement and distribution of human tissues, the ethical principles concerning organ transplantation as set out in Resolution (78) 29 on the harmonisation of legislation of member States relating to removal, grafting and transplantation of human substances, and agreed at the 3rd Conference of European Health Ministers (Paris, 16-17 November 1987), should be respected under all circumstances and that consent is required for the removal of tissues and their proposed use, whether therapeutic, diagnostic or research;

Taking account of World Health Organisation Resolution WHA 42.5 condemning the purchase and sale of organs of human origin;

Noting the fact that human tissue is donated by the public for altruistic reasons;

Taking note also of the questions of interpretation provided for in the appendix to this recommendation,

Recommends to the governments of member States :

1. That activities related to the banking of human tissue be divided into the following separate functions, it being understood that such functions in no case extend to the collection of such tissue :

- organisation;
- processing;
- preservation;
- internal quality control;
- storage;
- distribution;

2. That these functions be carried out by non profit-making institutions which are officially licensed by national health administrations, or recognised by the competent authorities;

3. That, by way of derogation from paragraph 2, in the case of a public health need, the activities described in paragraph 1 may be carried out by a duly authorised profit-making body;

4. That tissue banks ensure that tissue be tested for transmittable diseases, in compliance with the law and practice of the country concerned;
5. That tissue banks store the tissue safely according to scientifically recognised state-of-the-art techniques and respecting the criteria established by general medical and laboratory practice;
6. That records of all tissues retrieved and issued be kept by the tissue banking organisations in such a way that their source and their destination are clearly identifiable, providing always that access to such records will be restricted to the extent necessary to protect confidentiality of information and individual privacy;
7. That distribution take place in such a way as to permit optimal use of the tissues on an equitable basis in accordance with national law, rules and practice and objective selection criteria;
8. That close mutual co-operation be pursued by all officially recognised exchange and tissue banking organisations and that follow-up data on donor/recipient combinations should be shared between relevant institutions within the framework of national guidelines and legislation providing always that the privacy of the person concerned is fully respected.

Appendix to Recommendation No. R (94) 1

Definition of human tissue (for example skin, bone and cornea)

For the purposes of this recommendation, human tissue includes all constituent parts of the human body, including surgical residues but excluding organs, blood and blood products as well as reproductive tissue, such as sperm, eggs and embryos. Hair, nails, placentas and body waste products are also excluded.