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PART A

COMMITTEE OF MINISTERS

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.

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APPENDIX TO RESOLUTION (78) 29

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.

COUNCIL OF EUROPE

COMMITTEE OF MINISTERS

RECOMMENDATION NO. R (79) 5

of the Committee of Ministers to member States

*concerning international exchange
and transportation of human substances*

*(Adopted by the Committee of Ministers on 14 March 1979
at the 301st 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 a greater unity between its members, in particular through common action in social, scientific, legal and administrative fields;

Considering that the substantial increase in recent years in the treatment of patients by transplantation or grafting of removed or collected human organs, tissues or other substances and the increasing demand for such organs, tissues and substances, has also increased the need for wider international co-operation in this field;

Considering that the increasing demand for human substances, as well as information as to the demand for them and their availability, must be further facilitated by common action of the member states in order to make them available in due time and condition;

Considering Resolution (78) 29 on harmonisation of legislation of member states relating to removal, grafting and transplantation of human substances,

A. Recommends to the governments of member states:

I. to take all appropriate measures:

1. to facilitate the international exchange and transportation of substances indicated under paragraph II below;

2. to ensure the safe, speedy and priority transport of these substances. For these reasons all containers of substances shall clearly indicate their contents and purposes, the name and address of the sender and addressee and the name, address and telephone number of the person to whom any query should be made;

3. to ensure the exchange of information on the demand for and the availability of substances and on all matters pertaining to their preservation, transportation and processing;

4. to exempt substances and their containers from all duties and taxes at importation and exportation; this exemption shall also extend to the return of used containers;

II. to apply the measures mentioned in paragraph I above to any international exchange or transportation of substances of human origin removed or collected with a view to transplantation or other use for therapeutic or diagnostic purposes for the benefit of persons other than the donor and for research purposes. The international exchange and transportation of human blood and its derivatives, which are covered by the European Agreement on the Exchange of Therapeutic Substances of Human Origin, as well as the international exchange and transportation of embryos, testicles, ovaries, ova and sperm are excluded from the field of application of this recommendation;

III. to require, if they are the sending state, only payment of expenses for removing (or collecting), preserving, processing and transporting the substances mentioned in paragraph II above and, if the substances are sent by a private body, to endeavour to ensure that only payment of those expenses will be requested;

B. 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 this recommendation.

COUNCIL OF EUROPE
COMMITTEE OF MINISTERS

RECOMMENDATION NO. R (81) 1

*of the Committee of Ministers to member States
on regulations for automated medical data banks*

*(Adopted by the Committee of Ministers on 23 January 1981,
at the 328th 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 a greater unity between its members;

Aware of the increasing use of computers for medical care, medical research, hospital management and public health records;

Convinced that it is desirable to ensure the confidentiality, security and ethical use of personal information contained in those records;

Recalling the general principles on data protection in the private and public sectors as set out in its Resolutions (73) 22 and (74) 29 and the guarantees on the protection of health data of a personal nature provided by the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data;

Observing also that in several member states, guarantees are provided with the same purpose under existing or draft legislation on data protection and on medical and professional secrecy;

Considering that it is desirable to provide the persons responsible for medical data banks with further guidance as to the best way in which these principles can be implemented with regard to their specific type of computerised records,

Recommends the governments of member states:

a. to take steps in order to ensure that every automated medical data bank set up in their territory will be subject to regulations which reflect the principles laid down in the appendix to this recommendation ;

b. to bring this, recommendation to the notice of all services, authorities and institutions, both public and private, which operate automated data banks;

c. to promote awareness and information about the protection of medical data among members of the medical profession and data processing specialists and encourage close co-operation in the matter between these two professional groups;

Instructs the Secretary General of the Council of Europe to bring the contents of this recommendation to the notice of the governments of Australia, Canada, Finland, Japan, the United States of America and Yugoslavia, as well as the Director General of the World Health Organisation.

Appendix to Recommendation No. R (81) 1

PRINCIPLES APPLYING TO AUTOMATED MEDICAL DATA BANKS

1. Scope and purpose of the regulations

1.1. The following principles apply to automated data banks set up for purposes of medical care, public health, management of medical or public health services or medical research, in which are stored medical data and, as the case may be, related social or administrative data pertaining to identified or identifiable individuals (automated medical data banks).

1.2. Every automated medical data bank should be subject to its own specific regulations, in conformity with the laws of the state in whose territory it is established.

The regulations of medical data banks used for purposes of public health, management of medical and health services, or for the advancement of medical science should have due regard to the pre-eminence of individual rights and freedoms.

1.3. The regulations should be sufficiently specific to provide ready answers to those questions likely to arise in the operation of the particular medical data bank.

1.4. Where a medical data bank combines several sets of medical records or sub-systems of medical data, each of these elements may require separate supplementary regulations relating to its special features.

1.5. The requirements and obligations following from this recommendation are to be taken duly into account not only with regard to medical data banks which are operational, but also those which are in the development phase.

2. Public notice of automated medical data banks

2.1. Plans for the establishment of automated medical data banks as well as plans for the fundamental modification of existing banks should be brought to the notice of the public in advance.

2.2. When an automated medical data bank becomes operational a public notice thereof should be given, relating at the very least to the following features:

a. the name of the medical data bank;

b. reference to the instrument pursuant to which the medical data bank has been established;

c. a summary of the data bank's regulations and an indication of how the complete regulations can be obtained or consulted.

3. Minimum contents of the data bank's regulations

3.1. The data bank's regulations should at least contain provisions on:

- a.* its specific purpose(s);
- b.* the categories of information recorded;
- c.* the body or person for whom the data bank is operated and who is competent to decide which categories of data should be processed;
- d.* the person(s) in charge of its day-to-day running;
- e.* the categories of persons who are entitled to cause data to be placed in storage, modified and erased ("originators of the data");
- f.* the person or body
 - to whom certain decisions must be submitted for approval;
 - who supervises the use of the data bank;
 - to whom appeal may be made in the event of dispute;
- g.* the categories of persons who have access to the data bank in the course of their work and the categories of data to which they are entitled to have access;
- h.* the disclosure of information to third parties;
- i.* the disclosure of information to the individuals concerned ("data subjects");
- j.* the long-term conservation of data;
- k.* the procedure concerning requests for use of data for purposes other than those for which they have been collected;
- l.* the security of data and installations;
- m.* whether and on which conditions linking with other data banks is permitted.

4. Recording of data

4.1. The person or body responsible for establishing and/or managing a medical data bank should ensure that:

- a.* data are collected by lawful and fair means;
- b.* no data are collected other than those which are relevant and appropriate to the declared purpose(s);
- c.* so far as is practicable the accuracy of the data is verified; and
- d.* the contents of the record are kept up to date as appropriate.

4.2. In order to ensure on the one hand selective access to the information in conformity with paragraph 5.1. and on the other hand the security of the data, the records must as a general rule be so designed as to enable the separation of:

- a.* identifiers and data relating to the identity of persons;
- b.* administrative data;
- c.* medical data;
- d.* social data.

A distinction between objective and subjective data is to be made with regard to the data mentioned under *c* and *d* above.

Where, however, it is unnecessary or impossible to achieve such separation, other measures must be taken in order to protect the privacy of individuals and confidentiality of the information.

4.3. A person from whom medical information is collected should be informed of its intended use(s).

5. Access to and use of information

5. 1. As a general rule access to the information may be given only to medical staff and, as far as national law or practice permits, to other health care staff, each person having access to those data which he needs for his specific duties.

5.2. When a person mentioned in the previous paragraph ceases to exercise his functions, he may no longer store, modify, erase or gain access to the data, save by special agreement with the person or body mentioned in paragraph 3.1.f.

5.3. A person referred to in paragraph 5.1 who has access to data in the course of his work may not use such data for a purpose different from that for which he originally had access to those data, unless:

- a.* he puts the information in such a form that the data subject cannot be identified, or
- b.* such different use has been authorised by the person or body referred to in paragraph 3.1.f., or
- c.* such different use is imposed by a provision of law,

it being understood that national law or practice may impose an additional obligation to obtain the consent of the data subject (or, should he be deceased, of his family) or his physician.

5.4. Without the data subject's express and informed consent, the existence and content of his medical record may not be communicated to persons or bodies outside the fields of medical care, public health or medical research, unless such a communication is permitted by the rules on medical professional secrecy.

5.5. Linking or bringing together information on the same individual contained in different medical data banks is permitted for purposes of medical care, public health or medical research, provided it is in accordance with the specific regulations.

6. The data subject and his medical record

6.1. Measures should be taken to enable every person to know of the existence and content of the information about him held in a medical data bank.

This information shall, if the national law so provides, be communicated to the data subject through the intermediary of his physician.

No exception to this principle shall be allowed unless it is prescribed by law or regulation and concerns:

a. data banks which are used only for statistics or scientific research purposes and when there is obviously no risk of an infringement of the privacy of the data subject;

b. information the knowledge of which might cause serious harm to the data subject.

6.2. The data subject may ask for amendment of erroneous data concerning him and, in case of refusal, he may appeal to the person or body referred to in paragraph 3.1.f.

When the information is amended, it may nevertheless be provided that a record will be kept of the erroneous data so far as knowledge of the error may be relevant to further medical treatment or useful for research purposes.

7. Long-term conservation of data

7.1. As a general rule, data relatable to an individual should be kept on record only during a period reasonably useful for reaching their main purpose(s).

7.2. Where, in the interest of public health, medical science, or for historical or statistical purposes it proves desirable to conserve medical data that have no longer any immediate use, technical provision is to be made for their correct conservation and safekeeping.

8. Professional obligations

In addition to the members of the health care staff, the data processing personnel and any other persons participating in the design, operation, use or maintenance of a medical data bank, must respect the confidential nature of the information and ensure the correct use of the medical data bank.

9. Extended protection

None of the principles in this appendix shall be interpreted as limiting the possibility for a member state to introduce legal provisions granting a wider measure of protection to the persons to whom medical data refer.

COUNCIL OF EUROPE
COMMITTEE OF MINISTERS

RECOMMENDATION NO. R (83) 2
of the Committee of Ministers to member States

*concerning the legal protection of persons suffering
from mental disorder placed as involuntary patients¹*

*(Adopted by the Committee of Ministers on 22 February 1983
at the 356th 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 a greater unity between its members, in particular through harmonising the laws on matters of common interest;

Having regard to the Convention for the Protection of Human Rights and Fundamental Freedoms and to its application by the organs established under that convention;

Having regard to Recommendation 818 (1977) of the Consultative Assembly of the Council of Europe on the situation of the mentally ill;

Considering that common action at European level will promote the desired better protection of persons suffering from mental disorder,

Recommends that the governments of the member states should adapt their laws to the rules annexed to this recommendation or adopt provisions in accordance with those rules when introducing new legislation.

¹When this recommendation was adopted and in application of Article 10.2.c of the Rules of Procedure for the meetings of the Ministers' Deputies, the Representatives of the following member states reserved the right of their governments to comply or not with the provisions indicated below of the rules appended hereto:

- The Federal Republic of Germany: Articles 3.a and 6.b;
- Ireland: Articles 4.2 last sentence and 3 last sentence, and 9.2;
- Liechtenstein: Articles 4.2 last sentence and 3 first sentence, and 6.b;
- The Netherlands: Articles 3.a, 4.4 and 6;
- Sweden: Article 6.b;
- Switzerland: Articles 4.1 last sentence, final phrase, and 2 last sentence, and 6.b;
- The United Kingdom: Articles 4.2 last sentence and 3 last sentence, and 6.b.

RULES

Article 1

1. These rules concern the involuntary placement of persons suffering from mental disorder. Placement decided pursuant to criminal proceedings is not covered by these rules; however, Rules 5, 9, 10 and 11 apply to such a placement.
2. Involuntary placement (hereinafter referred to as "placement") means the admission and detention for treatment of a person suffering from mental disorder (hereinafter referred to as "patient") in a hospital, other medical establishment or appropriate place (hereinafter referred to as "establishment"), the placement not being at his own request.
3. The admission of a patient to an establishment for treatment at his own request does not fall within the field of application of these rules. However, these rules apply to cases where a patient who has originally been admitted at his own request is to be detained in an establishment in spite of his wish to be discharged.

Article 2

Psychiatrists and other doctors, in determining whether a person is suffering from a mental disorder and requires placement, should do so in accordance with medical science. Difficulty in adapting to moral, social, political or other values, in itself, should not be considered a mental disorder.

Article 3

In the absence of any other means of giving the appropriate treatment

a. a patient may be placed in an establishment only when, by reason of his mental disorder, he represents a serious danger to himself or to other persons

b. states may, however, provide that a patient may also be placed when, because of the serious nature of his mental disorder, the absence of placement would lead to a deterioration of his disorder or prevent the appropriate treatment being given to him.

Article 4

1. A decision for placement should be taken by a judicial or any other appropriate authority prescribed by law. In an emergency, a patient may be admitted and retained at once in an establishment on the decision of a doctor who should thereupon immediately inform the competent judicial or other authority which should make its decision. Any decision of the competent judicial or other authority mentioned in this paragraph should be taken on medical advice and under a simple and speedy procedure.
2. Where a decision for placement is taken by a non-judicial body or person, that body or person should be different from that which originally requested or recommended placement. The patient should immediately be informed of his rights and should have the right of appeal to a court which should decide under a simple and speedy procedure. Moreover, a person whose duty it is to assist the patient to decide whether to appeal should be designated by an appropriate authority, without prejudice to the right of appeal of any other interested person.

3. When the decision is taken by a judicial authority or when an appeal is made before a judicial authority against the decision of placement by an administrative body, the patient should be informed of his rights and should have the effective opportunity to be heard personally by a judge except where the judge, having regard to the patient's state of health, decides to hear him through sole form of representation. He should be informed of his right to appeal against the decision ordering or confirming the placement and, if he requests it or the judge considers that it would be appropriate, have the benefit of the assistance of a counsel or of another person.

4. The judicial decisions referred to in paragraph 3 should be open to appeal.

Article 5

1. A patient put under placement has a right to be treated under the same ethical and scientific conditions as any other sick person and under comparable environmental conditions. In particular, he has the right to receive appropriate treatment and care.

2. A treatment which is not yet generally recognised by medical science or presents a serious risk of causing permanent brain damage or adversely altering the personality of the patient may be given only if the doctor considers it indispensable and if the patient, after being informed, has given his express consent. If the patient is not capable of understanding the nature of the treatment, the doctor should submit the matter for decision to an appropriate independent authority prescribed by law which should consult the patient's legal representative, if any.

3. Clinical trials of products and therapies not having a psychiatric therapeutic purpose on persons suffering from mental disorder, subject to placement, should be forbidden. Clinical trials having a psychiatric therapeutic purpose are a matter for national legal provisions.

Article 6

The restrictions on personal freedom of the patient should be limited only to those which are necessary because of his state of health and for the success of the treatment; however, the right of a patient:

a. to communicate with any appropriate authority, the person mentioned in Article 4 and a lawyer, and

b. to send any letter unopened, should not be restricted.

Article 7

A patient should not be transferred from one establishment to another unless his therapeutical interest and, as far as possible, his wishes are taken into account.

Article 8

1. A placement should be for a limited period or, at least, the necessity for placement should be examined at regular intervals. The patient can request that the necessity for placement should be considered by a judicial authority at reasonable intervals. The rules in Article 4, paragraph 3, apply.

2. The placement may be terminated at any moment on the decision:

a. of a doctor, or

b. of a competent authority, acting on his own initiative or at the request of the patient or any other interested person.

3. The termination of the placement does not necessarily imply the end of treatment which may continue on a voluntary basis.

Article 9

1. The placement, by itself, cannot constitute, by operation of law, a reason for the restriction of the legal capacity of the patient.

2. However, the authority deciding a placement should see, if necessary, that adequate measures are taken in order to protect the material interests of the patient.

Article 10

In all circumstances, the patient's dignity should be respected and adequate measures to protect his health taken.

Article 11

These rules do not limit the possibility for a member state to adopt provisions granting a wider measure of legal protection to persons suffering from mental disorder subject to placement.

COUNCIL OF EUROPE

COMMITTEE OF MINISTERS

RECOMMENDATION NO. R (84) 16

of the Committee of Ministers to member States

*concerning notification of work
involving recombinant deoxyribonucleic acid (DNA)*

*(Adopted by the Committee of Ministers on 25 September 1984
at the 375th 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 a greater unity between its members by common action in economic, social, cultural, scientific, legal and administrative matters, in particular through harmonisation of laws on matters of common interest;

Having regard to the Consultative Assembly Recommendation 934 (1982) on Genetic Engineering;

Considering and welcoming the great progress realised in recent years as to the safety in recombinant DNA work;

Being informed that not all member states possess legislation or regulations concerning safety in DNA work;

Considering that the European Communities Council Recommendation of 30 June 1982 (82/472/EEC) concerning the registration of work involving recombinant deoxyribonucleic acid, which is applicable only to the ten member states of the European Communities, is a good basis for the harmonisation of the rules on notification and registration of recombinant DNA work;

Convinced that this result should be extended to all the member states of the Council of Europe,

Recommends that the governments of the member states, if they have not yet done so:

a. adopt, by the means they consider appropriate, a system of notification in accordance with the principles contained in the appendix to the present recommendation;

b. provide, in order to safeguard scientific and industrial secrecy and to protect intellectual property, that each notification, its contents and accompanying documents shall be kept confidential unless the notifying laboratory agrees otherwise.

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* *

APPENDIX

The following principles apply to work involving recombinant DNA which may present a biohazard of a category which will be determined by each state. The use of recombinant DNA techniques for transfer into human subjects shall be dealt with by specific provisions.

I

Any laboratory wishing to undertake, in the territory of a member state, work involving recombinant DNA notifies the competent national or regional authority.

II

Such notification is given, for each of the research projects envisaged, before the date on which it is begun or, where the competent authorities so decide and in the case of work falling within a category of very low risk potential, if possible within six months and not later than twelve months after the date on which the project is begun.

III

Such notification is accompanied, for each of the projects which is subject to prior notification, by the following documents:

- the portion of the experimental protocol which is required for the evaluation of safety at the site where the proposed activities are to be carried out,
- a list of the protective and supervisory measures to be applied throughout the duration of the experimental work,
- a description of the general education in recombinant DNA research and of the training received by the members of the team which will participate in the proposed activities or will be responsible for supervision, monitoring or safety.

IV

Each notification and the accompanying documents are classified and stored by the national authorities or regional authorities for safety and health protection to which they have been submitted.

V

Each notification and its accompanying documents may be consulted by national experts authorised to that effect by the national authorities.

VI

Work involving recombinant DNA is defined as the formation of new combinations of genetic material by the insertion of nucleic acid molecules produced by whatever means outside the cell, into any virus, bacterial plasmid or other vector system so as to allow their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation.

COUNCIL OF EUROPE

COMMITTEE OF MINISTERS

RECOMMENDATION NO. R (90) 3

*of the Committee of Ministers to member States
concerning medical research on human beings¹*

*(Adopted by the Committee of Ministers on 6 February 1990
at the 433rd 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 a greater unity between its members, in particular by the adoption of minimum common rules on matters of common interest;

Having regard to the Convention for the Protection of Human Rights and Fundamental Freedoms, in particular its Articles 2.1, 3 and 8; to Article 7 of the United Nations International Covenant on Civil and Political Rights; to the European Convention for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment; to Recommendation 874 (1979) of the Parliamentary Assembly of the Council of Europe on a European Charter on the Rights of the Child; to Recommendation No. R (83) 2 of the Committee of Ministers concerning the legal protection of persons suffering from mental disorder placed as involuntary patients, and to the Declaration of Helsinki, adopted at the 18th World Medical Assembly (1964) and amended by the 29th Assembly in Tokyo (1975), the 35th Assembly in Venice (1983) and the 41st Assembly in Hong Kong (1989), concerning recommendations guiding physicians in biomedical research involving human subjects;

Being aware of the fact that the advancement of medical science and practice is dependent on knowledge and discovery which necessitate, as a last resort, experimentation on human beings;

Being convinced that medical research should never be carried out contrary to human dignity;

Considering the paramount concern to be the protection of the person undergoing medical research;

Considering that particular protection should be given to certain groups of persons;

Considering that every person has a right to accept or to refuse to undergo medical research and that no one should be forced to undergo it;

¹When this recommendation was adopted, the Representative of the Federal Republic of Germany, in application of Article 10.2.c of the Rules of Procedure for the meetings of the Ministers' Deputies, reserved the right of his Government to comply with it or not.

Considering that medical research on human beings should take into account ethical principles, and should also be subject to legal provisions;

Realising that in member states existing legal provisions are either divergent or insufficient in this field;

Noting the wish and the need to harmonise legislation,

Recommends the governments of member states;

a. to adopt legislation in conformity with the principles appended to this recommendation, or to take any other measures in order to ensure their implementation;

b. to ensure that the provisions so adopted are brought to the knowledge of all persons concerned.

Principles concerning medical research on human beings

Scope and definition

For the purpose of application of these principles, medical research means any trial and experimentation carried out on human beings, the purpose of which or one of the purposes of which is to increase medical knowledge.

Principle 1

Any medical research must be carried out within the framework of a scientific plan and in accordance with the following principles.

Principle 2

1. In medical research the interests and well-being of the person undergoing medical research must always prevail over the interests of science and society.
2. The risks incurred by a person undergoing medical research must be kept to a minimum. The risks should not be disproportionate to the benefits to that person or the importance of the aims pursued by the research.

Principle 3

1. No medical research may be carried out without the informed, free, express and specific consent of the person undergoing it. Such consent may be freely withdrawn at any phase of the research and the person undergoing the research should be informed, before being included in it, of his right to withdraw his consent.
2. The person who is to undergo medical research should be given information on the purpose of the research and the methodology of the experimentation. He should also be informed of the foreseeable risks and inconveniences to him of the proposed research. This information should be sufficiently clear and suitably adapted to enable consent to be given or refused in full knowledge of the relevant facts.
3. The provisions of this principle should apply also to a legal representative and to a legally incapacitated person having the capacity of understanding, in the situations described in Principles 4 and 5.

Principle 4

A legally incapacitated person may only undergo medical research where authorised by Principle 5 and if his legal representative, or an authority or an individual authorised or designated under his national law, consents. If the legally incapacitated person is capable of understanding, his consent is also required and no research may be undertaken if he does not give his consent.

Principle 5

1. A legally incapacitated person may not undergo medical research unless it is expected to produce a direct and significant benefit to his health.

2. However, by way of exception, national law may authorise research involving a legally incapacitated person which is not of direct benefit to his health when that person offers no objection, provided that the research is to the benefit of persons in the same category and that the same scientific results cannot be obtained by research on persons who do not belong to this category.

Principle 6

Pregnant or nursing women may not undergo medical research where their health and/or that of the child would not benefit directly unless this research is aimed at benefiting other women and children who are in the same position and the same scientific results cannot be obtained by research on women who are not pregnant or nursing.

Principle 7

Persons deprived of liberty may not undergo medical research unless it is expected to produce a direct and significant benefit to their health.

Principle 8

In an emergency situation, notwithstanding Principle 3, where a patient is unable to give a prior consent, medical research can be carried out only when the following conditions are fulfilled:

- the research must have been planned to be carried out in the emergency in question;
- the systematic research plan must have been approved by an ethics committee;
- the research must be intended for the direct health benefit of the patient.

Principle 9

Any information of a personal nature obtained during medical research should be treated as confidential.

Principle 10

Medical research may not be carried out unless satisfactory evidence as to its safety for the person undergoing research is furnished.

Principle 11

Medical research that is not in accordance with scientific criteria in its design and cannot answer the question posed is unacceptable even if the way it is to be carried out poses no risk to the person undergoing research.

Principle 12

1. Medical research must be carried out under the responsibility of a doctor or a person who exercises full clinical responsibility and who possesses appropriate knowledge and qualifications to meet any clinical contingency.

2. The responsible doctor or other person referred to in the preceding paragraph should enjoy full professional independence and should have the power to stop the research at any time.

Principle 13

1. Potential subjects of medical research should not be offered any inducement with compromises free consent. Persons undergoing medical research should not gain any financial benefit. However, expenses and any financial loss may be refunded and in appropriate cases a modest allowance may be given for any inconvenience inherent in the medical research.

2. If the person undergoing research is legally incapacitated, his legal representatives should not receive any form of remuneration whatever, except for the refund of their expenses.

Principle 14

1. Persons undergoing medical research and/or their dependants should be compensated for injury and loss caused by the medical research.

2. Where there is no existing system providing compensation for the persons concerned, states should ensure that sufficient guarantees for such compensation are provided.

3. Terms and conditions which exclude or limit, in advance, compensation to the victim should be considered to be null and void.

Principle 15

All proposed medical research plans should be the subject of an ethical examination by an independent and multidisciplinary committee.

Principle 16

Any medical research which is:

- unplanned, or
- contrary to any of the preceding principles, or
- in any other way contrary to ethics or law, or

– not in accordance with scientific methods in its design and cannot answer the questions posed should be prohibited or, if it has already begun, stopped or revised, even if it poses no risk to the person(s) undergoing the research.

COUNCIL OF EUROPE

COMMITTEE OF MINISTERS

RECOMMENDATION NO. R (90) 13

of the Committee of Ministers to member States

*on prenatal genetic screening, prenatal genetic diagnosis
and associated genetic counselling*

*(Adopted by the Committee of Ministers on 21 June 1990
at the 442nd 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 a greater unity between its members, in particular by the adoption of common rules on matters of common interest;

Aware of the Council of Europe's vocation for safeguarding the moral values which are the common heritage of the member states, based essentially on respect for life and human dignity;

Reaffirming its commitment to personal freedom and respect for private and family life;

Having regard to the Convention for the Protection of Human Rights and Fundamental Freedoms (1950), the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (1981) and other relevant international instruments;

Having regard to Recommendation 934 (1982) on genetic engineering of the Parliamentary Assembly of the Council of Europe as well as the World Medical Association's Madrid Statement (1987) on genetic counselling and genetic engineering;

Recognising the continuing relevance of the detailed principles contained in Recommendation No. R(81) 1 on regulations for automated medical data banks for the collection, storage and processing of personal data, but believing nevertheless that it is necessary to make specific provision for such data in the context of prenatal screening and diagnosis and associated genetic counselling;

Noting that in recent decades considerable progress has been achieved in detecting genetic abnormalities in the child to be born through genetic screening and through prenatal diagnosis of pregnant women, but also noting the fears that these procedures arouse;

Considering that women of child-bearing age and couples should be fully informed and educated about the availability of, the reasons for and risks of such procedures;

Convinced that the genetic diagnosis and screening must always be accompanied by appropriate genetic counselling but that such counselling should in no case be of a directive nature and must always leave the woman of child-bearing age fully informed so as to enable her to take a free decision;

Aware of the role that the mass media play in informing and educating the public, and considering therefore that it is appropriate that they should be better and regularly informed about progress, practice, availability, ethical issues and ethical principles relating to prenatal screening and diagnosis and, in particular, procedures used for prenatal genetic screening and diagnosis;

Aware of the fear that prenatal screening and diagnosis could adversely affect social attitudes towards the handicapped and wishing that all necessary measures should be taken to ensure that society's attitude and behaviour is not so affected;

Considering that the use of these procedures should be governed by ethical, medical, legal and social principles in order to prevent any abuse,

Recommends the governments of the member states to adopt legislation in conformity with the principles contained in this recommendation or to take any other measures to ensure their implementation.

Principles

Scope and definitions

For the purpose of these principles, "prenatal genetic screening" is the term used to describe screening tests carried out to identify among the general population of apparently healthy individuals those at risk of transmitting a genetic disorder to their offspring. Prenatal genetic screening may take place during pregnancy and may involve testing people of either sex.

The principles also cover premarital and preconception screening which are undertaken to identify a risk to the health of the future child.

"Prenatal diagnosis" is the term used to describe tests used to determine whether or not an individual embryo or foetus is affected by a specific disorder.

Principle 1

No prenatal genetic screening and/or prenatal genetic diagnosis tests should be carried out if counselling prior to and after the tests is not available.

Principle 2

Prenatal genetic screening and/or prenatal genetic diagnosis tests undertaken for the purpose of identifying a risk to the health of an unborn child should be aimed only at detecting a serious risk to the health of the child.

Principle 3

Prenatal genetic screening and prenatal genetic diagnosis should only be carried out under the responsibility of a physician; laboratory procedures must be carried out in qualified institutions which have been approved by the state or by a competent authority of the state to conduct such procedures.

Principle 4

The counselling must be non-directive; the counsellor should under no condition try to impose his or her convictions on the persons being counselled but inform and advise them on pertinent facts and choices.

Principle 5

The participation of both members of the couple in the counselling sessions should be encouraged.

Principle 6

Prenatal genetic screening and prenatal genetic diagnosis may only take place with the free and informed consent of the person concerned.

Special care is needed for legally incapacitated persons to ensure that they are not denied access to prenatal genetic screening and prenatal genetic diagnosis on account of the legal incapacity and that their legal representative or an authority or person designated under national law is consulted on their behalf. Prenatal genetic screening or prenatal genetic diagnosis should not be carried out when the person to undergo tests objects.

Principle 7

When prenatal genetic screening and prenatal genetic diagnosis are offered routinely, this by no means does away with the requirement of free and informed consent.

Principle 8

The information given during the counselling prior to prenatal genetic screening and prenatal genetic diagnosis must be adapted to the person's circumstances and be sufficient to reach a fully informed decision. This information should in particular cover the purpose of the tests and their nature as well as any risks which these tests present.

Principle 9

In order to protect the woman's freedom of choice, she should not be compelled by the requirements of national law or administrative practice to accept or refuse screening or diagnosis. In particular, any entitlement to medical insurance or social allowance should not be dependent on the undergoing of these tests.

Principle 10

No discriminatory conditions should be applied to those who seek or to those who do not seek prenatal screening or diagnostic testing, where these are appropriate.

Principle 11

In prenatal genetic screening, prenatal genetic diagnosis or associated genetic counselling, personal data may only be collected, processed and stored for the purposes of medical care, diagnosis and prevention of disease, and research closely related to medical care. Such data should be collected, processed and stored in accordance with the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data and the Committee of Ministers' Recommendation No. R (81) 1 on regulations for automated medical data banks.

Principle 12

Any information of a personal nature obtained during prenatal genetic screening and prenatal genetic diagnosis must be kept confidential.

Principle 13

The right of access to personal data collected pursuant to prenatal genetic screening and prenatal genetic diagnosis should be given only to the data subject in the normal manner required for personal health data in accordance with national law and practice. Genetic data which relate to one member of the couple should not be communicated to the other member of the couple without the free and informed consent of the former.

Principle 14

Where there is an increased risk of passing on a serious genetic disorder, access to preconception counselling and, if necessary, premarital and preconception screening and diagnostic services should be readily available and widely known.

COUNCIL OF EUROPE
COMMITTEE OF MINISTERS

RECOMMENDATION NO. R (92) 1

of the Committee of Ministers to member States

*on the use of analysis of deoxyribonucleic acid (DNA)
within the framework of the criminal justice system¹*

*(Adopted by the Committee of Ministers on 10 February 1992
at the 470th 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 a greater unity between its members,

Having regard to 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 of 28 January 1981 ("the Data Protection Convention");

Considering that the fight against crime calls for the use of the most modern and effective methods;

Convinced of the need to pursue a common criminal policy aimed at the protection of individuals and the society in which they live;

Bearing in mind that the techniques of DNA analysis can offer advantages to the criminal justice system, in particular in the determination of innocence or guilt;

Bearing in mind, however, that such techniques, which are continuously evolving, should be carried out in a reliable manner;

Mindful, however, that the introduction and use of these techniques should take full account of and not contravene such fundamental principles as the inherent dignity of the individual and the respect for the human body, the rights of the defence and the principle of proportionality in the carrying out of criminal justice,

Recommends that the governments of member states be guided in their legislation and policy by the principles and recommendations set out below;

¹When this recommendation was adopted and in application of Article 10.2.c of the Rules of Procedure for the meetings of the Ministers' Deputies;

- the Representative of Denmark reserved the right of her government to comply or not with the recommendation as a whole;

- the Representatives of Germany, the Netherlands and Norway reserved the right of their governments to comply or not with Principle 8 of the recommendation.

Instructs the Secretary General to bring the contents of this recommendation to the attention of the non-member states and international organisations which have participated in its preparation.

Principles and recommendations

1. Definitions

For the purposes of this recommendation:

"DNA analysis" refers to any procedure which may be employed in the analysis of deoxyribonucleic acid (DNA), the basic genetic material of human and other living beings.

"Samples" refers to any substance of living origin which may be utilised for the purpose of DNA analysis.

"DNA file" refers to any structured collection of the results of DNA analysis tests whether retained in material form, as manually held records, or on a computerised database.

2. Scope and limitations

This recommendation applies to the collection of samples and use of DNA analysis for the purposes of the identification of a suspect or any other individual within the framework of the investigation and prosecution of criminal offences.

3. Use of samples and information derived therefrom

Samples collected for DNA analysis and the information derived from such analysis for the purposes of the identification of a suspect or any other individual within the framework of the investigation and prosecution of criminal offences.

Samples collected from living persons for DNA analysis for medical purposes, and the information derived from such samples, may not be used for the purposes of investigation and prosecution of criminal offences unless in circumstances laid down expressly by the domestic law.

Samples taken for DNA analysis and the information so derived may be needed for research and statistical purposes. Such uses are acceptable provided the identity of the individual cannot be ascertained. Names or other identifying references must therefore be removed prior to their use for these purposes.

4. Taking of samples for DNA analysis

The taking of samples for the purpose of DNA analysis should only be carried out in circumstances determined by the domestic law; it being understood that in some states this may necessitate specific authorisation from a judicial authority.

Where the domestic law admits that samples may be taken without the consent of the suspect, such sampling should only be carried out if the circumstances of the case warrant such action.

5. Recourse to DNA analysis

Recourse to DNA analysis should be permissible in all appropriate cases, independent of the degree of seriousness of the offence.

6. Accreditation of laboratories and institutions and control of DNA analysis

DNA analysis is a sophisticated scientific procedure which should only be performed by laboratories possessing the appropriate facilities and experience.

The member states should ensure that a list be drawn up of accredited laboratories or institutions which satisfy the following criteria:

- high professional knowledge and skill, coupled with appropriate quality control procedures;
- scientific integrity;
- adequate security of the installations and of the substances under investigation;
- adequate safeguards to ensure absolute confidentiality in respect of the identification of the person to whom the result of the DNA analysis relates; and
- guarantees that the conditions laid down by this recommendation are followed.

The member states should institute a means of exercising regular supervision of their accredited laboratories.

7. Data protection

The collection of samples and the use of DNA analysis must be in conformity with the Council of Europe's standards of data protection as laid down in the Data Protection Convention and the recommendations on data protection, in particular Recommendation No. R (87) 15 regulating the use of personal data in the police sector.

8. Storage of samples and data

Samples or other body tissues taken from individuals for DNA analysis should not be kept after the rendering of the final decision in the case for which they were used, unless it is necessary for purposes directly linked to those for which they were collected.

Measures should be taken to ensure that the results of DNA analysis and the information so derived is deleted when it is no longer necessary to keep it for the purposes for which it was used. The results of DNA analysis and the information so derived may, however, be retained where the individual concerned has been convicted of serious offences against the life, integrity or security of persons. In such cases strict storage periods should be defined by domestic law.

Samples and other body tissues, or the information derived from them, may be stored for longer periods:

- when the person concerned so requests; or
- when the sample cannot be attributed to an individual, for example when it is found at the scene of an offence.

Where the security of the state is involved, the domestic law of the members state may permit retention of the samples, the results of DNA analysis and the information so derived even though the individual concerned has not been charged or convicted of an offence. In such cases strict storage periods should be defined by domestic law.

The establishment and operation of any DNA file for purposes of the investigation and prosecution of criminal offences should be regulated by law.

9. Equality of arms

States should ensure that DNA analysis as a specific means of proof is equally accessible to the defence, either by decision of a judicial authority or through the use of an independent expert.

The establishment and operation of any DNA file for purposes of the investigation and prosecution of criminal offences should be regulated by law.

10. Technical standards

The member states should promote standardisation of the methods of DNA analysis both at national and international levels. This may involve interlaboratory collaboration in validation of the analytical and control procedures.

11. Intellectual property

While acknowledging that the intellectual property rights associated with particular methods of DNA analysis may be vested in certain laboratories, member states should ensure that this does not impede access to the use of DNA analysis.

12. Transborder exchange of information

DNA analysis may be obtained from a laboratory or institution established in another country provided that the laboratory or institution satisfies all the requirements laid down in this recommendation.

Transborder communication of the conclusions of DNA analysis should only be carried out between states complying with the provisions of this recommendation and in particular in accordance with the relevant international treaties on exchange of information in criminal matters and with Article 12 of the Data Protection Convention.

COUNCIL OF EUROPE
COMMITTEE OF MINISTERS

RECOMMENDATION NO. R (92) 3

*of the Committee of Ministers to member States
on genetic testing and screening for health care purposes¹*

*(Adopted by the Committee of Ministers on 10 February 1992
at the 470th 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 a greater unity between its members;

Having regard to the Convention for the Protection of Human Rights and Fundamental Freedoms of 4 November 1950 and the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data of 28 January 1981;

Having regard to the Recommendations of the Committee of Ministers No. R (90) 3 on medical research on human beings, No. R (90) 13 on prenatal genetic screening, prenatal genetic diagnosis and associated genetic counselling, and No. R (92) 1 on the use of analysis of deoxyribonucleic acid (DNA) within the framework of the criminal justice system;

Bearing in mind that recent progress in the field of biomedical science has made it possible to obtain a greater knowledge of the human genome and the nature of genetic disorders;

Recognising the benefits and potential usefulness of these techniques not only for the individual, but also for the family and other relatives, as well as for the population as a whole;

Aware that the introduction of genetic testing and screening also arouses anxiety and that it is therefore desirable to give assurances as to their proper use;

¹When this Recommendation was adopted and in application of Article 10.2.c of the Rules of Procedure for the meetings of the Ministers' Deputies;

– the Representative of the Netherlands reserved the right of his government to comply or not with principle 7 of the recommendation;

– the Representative of Germany reserved the right of his government to comply or not with the words “and/or to avoid giving birth to affected offspring”, in the third indent of sub-paragraph a of the paragraph on “Purpose, scope and definitions” of the recommendation.

Bearing in mind that rules governing the collection and use of medical data also apply to genetic data collected and used for health care purposes, including medical research;

Recognising the need for education of the members of the health care professions and the general public about the importance of genetic factors to health, and for including this subject in curricula for general and further education, both at school and at university level, and in professional training;

Considering that each country must determine its own special needs in order to develop the most appropriate services;

Recognising that it should be the goal of every country to offer its citizens equal opportunity of access to genetic testing and screening services;

Aware of the dangers of discrimination and social stigmatisation which may result from genetic information, and determined to fight such phenomena,

Recommends that the governments of the member states

a. be guided in their legislation and policy by the principles and recommendations set out below;

b. promote in their educational systems the teaching of human genetics.

Principles and recommendations

Purpose, scope and definitions

The purpose of this recommendation is to ensure respect for certain principles in the field of genetic testing and screening for health care purposes, including medical research.¹

For the purposes of this recommendation:

a. the term "genetic tests for health care purposes" refers to tests which serve:

– to diagnose and classify a genetic disease;

– to identify unaffected carriers of a defective gene in order to counsel them about the risk of having affected children;

– to detect a serious genetic disease before the clinical onset of symptoms in order to improve the quality of life using secondary preventive measures and/or to avoid giving birth to affected offspring;

– to identify persons at risk of contracting a disease where both a defective gene and a certain lifestyle are important as causes of the disease;

b. the term "genetic diagnosis" refers to tests carried out to diagnose a presumed ailment on an individual or several members of a family, in the framework of a family study;

c. the term "genetic screening" refers to genetic tests carried out on a population as a whole or a subset of it without previous suspicion that the tested individuals may carry the trait.²

¹Genetic testing and screening can be carried out at different levels, such as on chromosomes, genes (DNA), proteins, organs or a given individual, and can be complemented with aspects of the family history.

²The essential distinction between genetic diagnosis and genetic screening is that the latter is not initiated by the

I. Rules for good practice in genetic testing and screening

Principle 1 – Informing the public

- a. Plans for the introduction of genetic testing and screening should be brought to the notice of individuals, families and the public.
- b. The public should be informed about genetic testing and screening, in particular their availability, purpose and implications - medical, legal, social and ethical - as well as the centres where they are carried out. Such information should start within the school system and be continued by the media.

Principle 2 – Quality of genetic services

- a. Proper education should be provided regarding human genetics and genetic disorders, particularly for health professionals and the paramedical professions, but also for any other profession concerned.
- b. Genetic tests may only be carried out under the responsibility of a duly qualified physician.
- c. It is desirable for centres where laboratory tests are performed to be approved by the state or by a competent authority in the state, and to participate in an external quality assurance.

Principle 3 – Counselling and support

- a. Any genetic testing and screening procedure should be accompanied by appropriate counselling, both before and after the procedure.

Such counselling must be non-directive. The information to be given should include the pertinent medical facts, the results of tests, as well as the consequences and choices. It should explain the purpose and the nature of the tests and point out possible risks. It must be adapted to the circumstances in which individuals and families receive genetic information.

- b. Everything should be done to provide, where necessary, continuing support for the tested persons.

II. Access to genetic tests

Principle 4 – Equality of access – non-discrimination

- a. There should be equality of access to genetic testing, without financial considerations and without preconditions concerning eventual personal choices.
- b. No condition should be attached to the acceptance or the undergoing of genetic tests.
- c. The sale to the public of tests for diagnosing genetic diseases or a predisposition for such diseases, or for the identification of carriers of such diseases, should only be allowed subject to strict licensing conditions laid down by national legislation.

individual who is its subject, but by the provider of the screening service.

Principle 5 – Self-determination

a. The provision of genetic services should be based on respect for the principle of self-determination of the persons concerned. For this reason, any genetic testing, even when offered systematically, should be subject to their express, free and informed consent.

b. The testing of the following categories of persons should be subject to special safeguards:

- minors;
- persons suffering from mental disorders;
- adults placed under limited guardianship.

Testing of these persons for diagnostic purposes should be permitted only when this is necessary for their own health or if the information is imperatively needed to diagnose the existence of a genetic disease in family members.

The consent of the person to be tested is required, except where national law provides otherwise.

Principle 6 – Non-compulsory nature of tests

a. Health service benefits, family allowances, marriage requirements or other similar formalities, as well as the admission to, or the continued exercise of, certain activities, especially employment, should not be made dependent on the undergoing of genetics tests or screening.

Exceptions to this principle must be justified by reasons of direct protection of the person concerned or of a third party and be directly related to the specific conditions of the activity.

b. Only if expressly allowed by law may tests be made compulsory for the protection of individuals or the public.

Principle 7 – Insurance

Insurers should not have the right to require genetic testing or to enquire about results of previously performed tests, as a pre-condition for the conclusion or modification of an insurance contract.

III. Data protection and professional secrecy

Principle 8 – Data protection

a. The collection and storage of substances and of samples, and the processing of information derived therefrom, must be in conformity with the Council of Europe's basic principles of data protection and data security laid down in the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data, European Treaty Series No. 108 of 28 January 1981 and the relevant recommendations of the Committee of Ministers in this field.

In particular in genetic screening and testing or associated genetic counselling personal data may be collected, processed and stored only for the purposes of health care, diagnosis and disease prevention, and for research closely related to these matters, as outlined in Principle 5.

b. Nominative genetic data may be stored as part of medical records and may also be stored in disease-related or test-related registers. The establishment and maintenance of such registers should be subject to national legislation.

Principle 9 – Professional secrecy

Persons handling genetic information should be bound by professional rules of conduct and rules laid down by national legislation aimed at preventing the misuse of such information and, in particular, by the duty to observe strict confidentiality. Personal information obtained by genetic testing is protected on the same basis as other medical data by the rules of medical data protection.

However, in the case of a severe genetic risk for other family members, consideration should be given, in accordance with national legislation and professional rules of conduct, to informing family members about matters relevant to their health or that of their future children.

Principle 10 – Separate storage of genetic information

Genetic data collected for health care purposes, as for all medical data, should as a general rule be kept separate from other personal records.

Principle 11 – Unexpected findings

In conformity with national legislation, unexpected findings may be communicated to the person tested only if they are of direct clinical importance to the person or the family.

Communication of unexpected findings to family members of the person tested should only be authorised by national law if the person tested refuses expressly to inform them even though their lives are in danger.

IV. Research

Principle 12 – Supervision

Research projects involving medical genetic data have to be carried out, in conformity with the standards of medical ethics, under the direct supervision of a responsible physician or, in exceptional circumstances, of a responsible scientist.

Principle 13 – Handling of data

a. Samples collected for a specific medical or scientific purpose may not, without permission of the persons concerned or the persons legally entitled to give permission on their behalf, be used in ways which could be harmful to the persons concerned.

b. The use of genetic data for population and similar studies has to respect rules governing data protection, and in particular concerning anonymity and confidentiality. The same applies to the publishing of such data.

COUNCIL OF EUROPE
COMMITTEE OF MINISTERS

RECOMMENDATION NO. R (93) 4

of the Committee of Ministers to member States

*concerning clinical trials
involving the use of components and fractionated products derived from human blood or
plasma*

*(Adopted by the Committee of Ministers on 22 March 1993
at the 490th meeting of the Ministers' Deputies)*

1. The Committee of Ministers, under the terms of Article 15.b of the Statute of the Council of Europe,
2. Considering that the aim of the Council of Europe is to achieve a greater unity between its members, in particular by the adoption of minimum common rules on matters of common interest;
3. Having regard to the Convention for the Protection of Human Rights and Fundamental Freedoms, in particular its Articles 2.1, 3 and 8; to Article 7 of the United Nations International Covenant on Civil and Political Rights; to the European Convention for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment and to the Declaration of Helsinki, adopted at the 18th World Medical Assembly (1964) and amended by the 29th Assembly in Tokyo (1975), the 35th Assembly in Venice (1983) and the 41st Assembly in Hong Kong (1989), concerning recommendations guiding physicians in biomedical research involving human subjects;
4. Recalling Recommendation No. R (90) 3 of the Committee of Ministers concerning medical research on human beings as well as Resolution (78) 29 on harmonisation of legislations of member States relating to removal, grafting and transplantation of human substances and Recommendation No. R (88) 4 on the responsibilities of health authorities in the field of blood transfusion;
5. Considering the growing importance of blood products in supportive haemotherapy and the need to subject such products to clinical testing and trials to ensure their safety, efficacy and quality as is the case for medicinal products;
6. Considering that such products are of human origin and that hence specific ethical and technical principles have to be taken into account in addition to those, national and international applying to medical research and clinical trials on human beings;
7. Considering the need for harmonisation of such principles in member States,

Recommends the governments of member States to adopt legislation in conformity with the principles appended to this Recommendation and to take any other measures in order to ensure their implementation.

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APPENDIX TO RECOMMENDATION NO. (93) 4

A. FIELD OF APPLICATION

1. The following articles apply to:

1.1 the conducting of clinical trials for the purpose of ensuring the safety, efficacy and quality of blood components before their routine clinical use;

1.2 the conducting of clinical trials for fractionated products before obtaining market authorisation;

1.3 the testing of collecting systems involved in the donation of whole blood or apheresis for the purpose of ensuring that these are safe for the donor and that the products are of acceptable safety, efficacy and quality before the marketing of such systems.

2. The recommendations do not apply to the practice of therapeutic apheresis.

B. ETHICAL PRINCIPLES CONCERNING BLOOD DONORS AND RECIPIENTS TAKING PART IN CLINICAL TRIALS

Article 1

All those responsible for clinical trials of blood components and fractionated products whether they are the investigators in charge of carrying out the trials, or directing the experiment, should take into account the following ethical principles concerning blood donors and recipients as prerequisites to their research activity as blood components and fractionated products differ from other medicinal products in that their source is a human blood donor.

Article 2

Blood donors should be voluntary and non-remunerated. Benefits in cash or kind should not be offered to donors of blood or plasma, although direct expenses of the donor may be reimbursed.

Article 3

Selection of donors should be in conformity with the recommendations of the Council of Europe to ensure that the person is in good health, in order to protect the donor against damage to his/her own health, and to protect the recipient against transmission of diseases or against medicinal products and drugs which could be detrimental to him/her.

Article 4

No clinical trial may be carried out without the informed, free, express and specific consent of the person undergoing it. In this context, the relevant principles set out in Recommendation No. R (90) 3 should be observed.

The said principles apply also to the donor:

- when procedures are to be performed which may have relevance to his/her health and well-being,
- when a new procedure is being used to collect his/her blood.

The donor need not be informed when blood or plasma is collected using established procedures and the blood components or fractionated products derived from the donation are being treated in a novel or modified manner to prepare components or products for the purpose of clinical testing or trial respectively.

Article 5

Principle No. 9 (respect of confidentiality) and Principle No. 14 (damages in case of accident) as set out in Recommendation No. R (90) 3 should be applied to recipients, and to donors, under the conditions defined under Article 4 above.

C. TECHNICAL PRINCIPLES

1. Principles common to clinical trials of blood components and of fractionated products

Article 6

Legislation, regulations and both national and international guidelines directed primarily to those who are involved in the generation of clinical data for the purpose of obtaining market authorisation for medicinal products should be applied in clinical trials of blood components and of fractionated products.

Article 7

The preparation of the blood components and fractionated products for the clinical trials should comply with principles of good manufacturing practice and the safety of the components or fractionated products particularly with regard to virology and vis-a-vis transmissible agents, and should be ensured prior to clinical trials; similarly, quality of the product must be ensured prior to the commencement of the trial and throughout the trial.

Article 8

In many instances placebo controlled clinical trials of blood components and fractionated products cannot be undertaken since it is unethical to withhold treatment. In such circumstances the new or modified blood component or fractionated product has to be compared with an existing blood component or fractionated product. However, with this limitation, clinical trials can be randomised and double blind. An alternative, may be the comparison of a new or modified component or fractionated product with well documented retrospective data obtained using an existing blood component or fractionated product.

Article 9

When a new clinical indication for an existing blood component or fractionated product is proposed, the blood component or fractionated product should be subjected to a clinical trial in the same manner as that for a new or modified medicinal product, keeping in mind the specific characteristics of labile products.

2. *Principles applying to clinical trials of blood components*

Article 10

When a blood component has been subjected to physical or chemical modification which may alter its characteristics it should be subjected to a clinical trial (including autologous survival studies where applicable) following approval by an ethical committee, unless the changes are such that secure in vitro tests demonstrate that there has been no biological change; in such a case the person in charge of preparing such a product assumes responsibility for its safety, efficacy and quality and the blood component may be administered to patients only with the authorisation of the physician(s) in charge.

Article 11

Whenever feasible clinical trials should be performed initially by autologous studies to determine adverse reactions and the half-life of the component(s) under test. Group controls should be used.

Article 12

Since each blood component will constitute a batch, a sufficient number of patients must be included in Phase I/II trials to ensure that batch-to-batch variation can be excluded.

3. *Principles applying to clinical trials of fractionated products*

Article 13

The presence of contaminants, particularly neo-antigens, which may be relevant to the health of the trial subjects must be assessed prior to the commencement of the clinical trial.

Article 14

In Phase III trials, there may be relatively few patients available in a given Centre. In these circumstances, multi-centre trials need to be organised and such trials must be continued for a sufficient period to ensure that all possible factors affecting safety and efficacy of the product have been studied.

GLOSSARY

BLOOD PRODUCTS Products derived from whole blood or plasma; these include both cellular blood components and fractionated products.

BLOOD COMPONENT A labile therapeutic constituent derived by separation from single donation, an apheresis procedure or a small pool of human blood or plasma (ie. 12 or less donations). This will include the cellular components, plasma or simple derivatives derived from plasma, eg. cryoprecipitate.

FRACTIONATED PRODUCTS A medicinal product derived by fractionation from human plasma. This will include in particular albumin, coagulation factors and immunoglobulins of human origin.

MEDICINAL PRODUCT Any substance or combination of substances presented for treating or preventing disease in human beings or animals.
Any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings or in animals is likewise considered a medicinal product.

CLINICAL TRIAL A clinical trial is any systematic study of medicinal products in human subjects whether in patients or non- patient volunteers in order to discover or verify the effects and/or identify any adverse reaction to investigational products, and/or study their absorption, distribution, metabolism and excretion in order to ascertain the efficacy and safety of the product.

For the purpose of this recommendation, the term "clinical trial" includes studies carried out on human blood components, keeping in mind the specific characteristics of labile products. Clinical trials are generally classified into phases I to IV. It is not possible to draw distinct lines between the phases and diverging opinions about details and methodology do exist. Definitions (in brief) of the individual phases, based on their purposes related to clinical development of medicinal products, are given below:

PHASE I

First trials of a new active ingredient in man, often healthy volunteers. The purpose is to establish a preliminary evaluation of safety and of the tolerance in respect of the dose and a first outline of the pharmacokinetic/-dynamic profile of the active ingredient in humans.

PHASE II

Therapeutic pilot studies. The purpose is to demonstrate activity and to assess short-term safety of the active ingredient in patients suffering from a disease or condition for which the active ingredient is intended. The trials are performed in a limited number of subjects and often, at a later stage, in a comparative (e.g. placebo-controlled) design. This phase also aims at the determination of appropriate dose ranges/regimens and (if possible) clarification of dose/response relationships, in order to provide an optimal background for the design of wider therapeutic trials.

PHASE III

Trials in larger (and possibly varied) patient groups with the purpose of determining the short and long-term safety/efficacy balance of formulations of the active ingredient, as well as to assess its overall and relative therapeutic value. The pattern and profile of more frequent adverse reactions must be investigated and special features of the product must be explored (e.g. clinically relevant drug interactions, factors leading to differences such as age, etc.). The design of trials should preferably be randomised double blind, but other designs may be acceptable, e.g. long-term safety studies. Generally the circumstances of the trials should be as close as possible to normal conditions of use.

PHASE IV

Studies performed after marketing of the final medicinal product(s) containing the active ingredient, although definition of this phase is not completely agreed upon. Trials in phase IV are carried out on the basis of instructions given in the marketing authorisation, including post-marketing surveillance, assessment of therapeutic value or strategies. However, clinical trials (after a product has been placed on the market) exploring e.g. new indications, new methods of administration or new combinations, should in practice be considered as trials for new medicinal products having similar objectives as pre-marketing trials. Such studies may consequently - according to the circumstances - require trial conditions as described above for phases I-III.

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.

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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.

COUNCIL OF EUROPE

COMMITTEE OF MINISTERS

RECOMMENDATION NO. R (94) 11

of the Committee of Ministers to member States

on screening as a tool of preventive medicine

*(Adopted by the Committee of Ministers on 10 October 1994
at the 518th 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 and that this aim may be pursued, *inter alia*, by the adoption of common action in the public health field;

Noting that chronic diseases are the major causes of death and a high social and economic burden in developed countries;

Considering that screening for the early detection of some of these diseases, could in principle provide a method for their control;

Considering that, as yet, there is no absolute proof of the value of screening and early treatment in most diseases;

Considering that few, if any, diseases can at the present time be regarded as fulfilling all the desirable criteria for screening, and that the recommended evaluative procedures are not often carried out in full;

Recognising that the implementation of widespread screening programmes raises major ethical, legal, social, medical, organisational and economic problems which require initial and ongoing evaluation;

Taking into account the provisions of the Convention of Human Rights and of the European Social Charter;

Bearing in mind the Convention for the protection of individuals with regard to automatic processing of personal data of 28 January 1981, as well as the provisions of Recommendation No. R (81) 1 on regulations for automated medical banks and Recommendation No. R (83) 10 on the protection of personal data used for purposes of scientific research and statistics,

Recommends to governments of member states that they take account in their national health planning regulations and legislation of the conclusions and recommendations set out in the appendix to this recommendation.

Appendix to Recommendation No. R (94) 11

1. *Introduction*

1.1. For the purposes of this recommendation, screening means applying a test to a defined group of persons in order to identify an early stage, a preliminary stage, a risk factor or a combination of risk factors of a disease. In any case it is a question of detecting phenomena, which can be identified prior to the outbreak of the disease.

1.2. The object of screening as a service is to identify a certain disease or risk factor for a disease before the affected person spontaneously seeks treatment, in order to cure the disease or prevent or delay its progression or onset by (early) intervention.

1.3. The value of existing forms of screening for infectious diseases is fully acknowledged but these established methods are not considered in detail in this recommendation. Emphasis is made on screening for chronic degenerative non-communicable disorders.

1.4. Screening is only one method of controlling disease. It should be viewed in the whole context of reducing the burden of ill health to the individual and the community by, for example, socio-economic, environmental measures, health education and improvement of existing health care and disease prevention systems.

1.5. Environmental factors are recognized as important contributors to disease, but inherited factors may also play an important role. With the advent of new genetic knowledge, an increasing number of genetic diseases and genetic risk factors for disease will be identified and offer the possibility for new screening procedures. As the procedures for genetic screening are not fully established nor fully evaluated, they have not been included in this recommendation.

1.6. The present position is that the implementation of screening in European countries is fragmentary, with few national screening programmes for the total population but many screening schemes restricted to population groups.

1.7. Because there are differences in health needs and health services, as well as in ethical values and in legal norms and rules between countries, the decision to implement a particular screening programme should be taken in co-operation with the medical profession by each country. Nevertheless there are common general principles and problems which are equally relevant to all systems.

1.8. Screening is a tool which is potentially capable of improving the health of the population but it also has adverse effects. Constant care should be taken to ensure that in any screening programme the advantages prevail over the disadvantages.

1.9. The general benefits of screening are often described. It is, however, also important to be aware of the adverse effects which can be :

- stigmatisation and/or discrimination of (non) participants;
- social pressure to participate in the screening and undergo the intended treatment/intervention;
- psychological distress where there is no cure for the disease or where the treatment and/or intervention is morally unacceptable to the individual concerned;
- exposure to physical and psychological risks with limited health gains;

- creation of expectations which probably cannot be fulfilled;
- individuals who are positively screened might experience difficulties such as access to insurance, employment, etc.;
- severe side effects of invasive clinical diagnosis of false positives;
- delay in diagnosing false negatives;
- unfavourable cost-benefit relationship of a screening programme.

1.10. The various problems which are encountered in the introduction and provision of screening services are interrelated.

Nevertheless a distinction may be made between those concerned with:

- i. ethical and legal issues;
- ii. selection of diseases (medically) suitable for screening;
- iii. economic aspects and evaluation of screening;
- iv. quality assurance;
- v. organisation of a screening programme;
- vi. scientific research.

2. *Ethical and legal values*

2.1. Effectiveness is a necessary prerequisite for the screening to be ethical. It should nonetheless be kept in mind that screening can be effective and still unethical.

2.2. Advantages and disadvantages of screening for the target population and the individual must be well balanced, taking into account social and economic costs, equity as well as individual rights and freedoms.

2.3. Failure to make known information on the positive and negative aspects of the screening is unethical and infringes the autonomy of the individual.

2.4. The decision to participate in a screening programme should be taken freely. The diagnoses and treatments which may follow the screening should also require a free and separate consent. No pressure should be used to lead somebody to undergo any of these procedures.

2.5. The right to privacy requires that the results of the tests as a general rule are not communicated to those who do not wish to be informed, are collected, stored, and handled confidentially, and adequately protected. It is preferable not to screen individuals who do not wish to be informed of the results of the screening.

2.6. Neonatal screening can only be justified if the intervention is of direct health benefit to the child. Otherwise screening should be postponed until the child can decide for itself.

2.7. No personal data derived from the screening should be communicated to third parties unless the data subject has given consent to it or in accordance with national law.

2.8. When a screening programme is provided as a service and conducted also for research purposes, the decision to make available personal medical data stemming from the screening programme for research purposes should be taken freely, without undue pressure.

The decision not to take part in the research should not in any way prevent the individual from participating in the screening programme.

3. *Criteria for selecting diseases suitable for screening*

3.1. The disease should be an obvious burden for the individual and/or the community in terms of death, suffering, economic or social costs.

3.2. The natural course of the disease should be well-known and the disease should go through an initial latent stage or be determined by risk factors, which can be detected by appropriate tests. An appropriate test is highly sensitive and specific for the disease as well as being acceptable to the person screened.

3.3. Adequate treatment or other intervention possibilities are indispensable. Adequacy is determined both by proven medical effect and ethical and legal acceptability.

3.4. Screening followed by diagnosis and intervention in an early stage of the disease should provide a better prognosis than intervention after spontaneously sought treatment.

4. *Economic aspects*

4.1. The increasing financial burden of health care makes it necessary to assess the economic aspects of screening. However these aspects should not be the overriding consideration. In all screening programmes human consideration regarding the value and quality of life, life expectancy as well as respect for individual rights are of prime importance.

4.2. Economic assessments are necessary to enable rational decisions to be made on the priority to be given to alternative ways of using health resources.

4.3. Measurement of the economic aspects of screening is not fully mastered. Early detection and treatment may be less expensive than late treatment. However, available studies relate only to present screening costs and further work is necessary to determine possible cost control in the long term.

4.4. Non systematic screening or spontaneous screening results in high marginal costs. Only systematic screening is able to provide means for controlling cost. Therefore, constant care should be taken to ensure that in any screening programme the allocated resources are used in an optimal way.

5. *Quality assurance*

5.1. Screening should aim at the highest possible standards of quality from the medical and organisational point of view.

5.2. Because of the expectations that screening creates as well as its adverse effects, screening should meet the highest quality assurance standards in all its aspects.

5.3. An assessment of the scientific evidence of the effectiveness of screening in the control of a disease should be made by experimental studies before introducing a screening programme as a service. The practical arrangements for a mass screening, which are directly linked to the health structures and systems, should obtain the same effectiveness as that obtained in the randomised trial.

5.4. Having implemented a screening programme, it should be subjected to continuous independent evaluation. Evaluation will facilitate adaptation of the programme, correction of deficiencies noted and verification of achievement of objectives. The adverse effects of the screening programme should not be ignored in the evaluation which should be carried out by independent public health experts.

5.5. If quality assurance standards are not met in the long term it should be possible for the screening programme to be corrected, and, if this is not possible, stopped.

5.6. The programme must evaluate participation, and the percentage of people screened in the target population, the technical quality of testing and the quality of diagnosis and treatment provided as a follow-up for persons with a positive test result.

Severe side effects of false positives should be revealed and evaluated.

5.7. There is a need for more teaching of medical students in epidemiology and its application to measuring the effects of screening. Similarly post-graduate education in this field is also needed to enable practising doctors to understand the principles and evaluation of screening.

5.8. Provision of screening programmes requires that training in techniques and interpretation of screening tests is included in undergraduate and post-graduate medical teaching programmes.

5.9. A screening programme requires resources in both staff and technical facilities for carrying out the screening tests. In many instances tests can be performed by non-medical staff. Provision should be made for initial and further training of the medical and technical staff who will be involved in performing the screening tests and interpreting their results. Technical methods, including automated techniques, are useful in screening for some diseases. Quality of screening methods should be monitored.

6. *Organisation*

6.1. The organising body of a screening programme should be held responsible throughout the programme. The organisation of a screening programme should comply with what is described in national guidelines and protocols.

6.2. Within the organisational framework the target population should be defined (by age or otherwise) as well as the frequency of screening tests and the general and specific objectives and quality assurance guidelines.

6.3. It must be stressed that screening cannot succeed without co-operation between preventive and curative systems. Organisation must be tailored to the structures of the health system. If appropriate structures in the curative health care system are lacking, screening should not be implemented until they are developed (pilot programmes, for example). There are various degrees to which screening services may be integrated with curative services or develop as a separate speciality. The advantages and disadvantages of these should be assessed separately in different health care systems.

6.4. Provisions should be made for the financing of the programme, the cost of organising and evaluating the structure, the cost of testing, the cost of quality assessment and monitoring, and the cost of the follow-up care of those people who screen positively.

6.5. Process and outcome indicators should be constantly evaluated.

6.6. Systematic collection of data is required in screening programmes to serve the needs of the individual and of the health service. To that end, data should be collected on the target population, on persons screened (with dates and the results of the test carried out), and on the results of eventual diagnostic examinations. Access to a morbidity register considerably facilitates evaluation.

6.7. Adequate protection of all data collected by means of a screening programme should be guaranteed.

6.8. Participation of the public in screening programmes is determined by personal factors (for example attitudes, motivation and anxiety) and by situational factors (waiting time and efficient organisation, for example). These can be influenced for instance by health education and by good organisation of the screening procedure.

6.9. In order to ensure optimal participation by the target population, the best possible information should be widely provided and awareness-raising and education programmes should be organised for both the target population and the health professionals.

6.10. Invitations should be accompanied by written information on the purposes and effectiveness of the programme, on the test, on potential advantages and disadvantages, on the voluntary nature of participation and on how data will be protected. An address should be provided for those who require further information.

6.11. Participants should be informed on how, when and where their test results will be available or will be communicated to them.

6.12. The positive results found at screening should always be confirmed by subsequent diagnostic tests before commencing a treatment/intervention, unless the screening test is a diagnostic test. It is absolutely essential that adequate diagnostic facilities are available to confirm or reject the screening finding as soon as possible. Similarly, treatment facilities must be available and easily accessible to the confirmed cases. The work load placed on the health services by screening can be very large, especially since most screening programmes also lead to incidental pathological findings unrelated to the disease at which the programme is aimed.

6.13. Combining screening for several diseases into a multiple screening procedure may seem to be convenient to the individual and economic to the programme, but such a "package deal" may negatively influence the extent to which most of the criteria for screening including age limit and frequency would be met.

7. *Research*

7.1. Research into new, more effective, screening tests must be encouraged and the long-term effects of the various methods of treatment and provision for positive subjects studied. Research must be further developed to answer the numerous social, ethical, legal, medical, organisational and economic questions as well as psychological problems raised by screening, on which evidence is incomplete.

7.2. Quality assurance concerning research programmes should be conducted into the effectiveness of the various screening tests, the practical arrangements for screening, the measures to increase participation, the means of improving test efficiency, follow-up to and provisions for screened positive assessment process and all the economic aspects.

7.3. Information gathered during screening should be available for the purpose of scientific research, for the improvement of health services, and for the benefit of future screening, taking into account full respect of autonomy and confidentiality and the protection of personal privacy.

8. *General remarks*

8.1. It is particularly important that political decision-makers and target groups should be kept informed of the current state of knowledge about the value of screening for particular diseases. Improved communication should be encouraged.

8.2. Governments should promote the research and evaluation necessary for assessing the value of both new and existing programmes. This form of research necessarily means large-scale research which, in some instances, may be designed as international collaborative studies. Scientific evaluation

is the only way in which the positive and negative effects of screening can be assessed in order that a rational decision can be taken on whether a screening programme should be implemented and what resources should be allocated.

Quality assurance (as defined by World Health Organisation):

"All those planned and systematic actions necessary to provide adequate confidence that a structure, system or component will perform satisfactorily in service (ISO 6215-1980). Satisfactory performance in service implies the optimum quality of the entire diagnostic process i.e., the consistent production of adequate diagnostic information with minimum exposure of both patients and personnel."

Quality control (as defined by World Health Organisation):

"The set of operations (programming, co-ordinating, carrying out) intended to maintain or to improve [...] (ISO 3534-1977). As applied to a diagnostic procedure, it covers monitoring, evaluation and maintenance at optimum levels of all characteristics of performance that can be defined, measured, and controlled."

COUNCIL OF EUROPE

COMMITTEE OF MINISTERS

RECOMMENDATION NO. R (97) 5

of the Committee of Ministers to member States

on the protection of medical data

*(Adopted by the Committee of Ministers on 13 February 1997
at the 584th 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 a greater unity between its members;

Recalling the general principles on data protection in the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (European Treaty Series, No. 108) and in particular its Article 6 which stipulates that personal data concerning health may not be processed automatically unless domestic law provides appropriate safeguards;

Aware of the increasing use of automatic processing of medical data by information systems, not only for medical care, medical research, hospital management and public health but also outside the health-care sector;

Convinced of the importance of the quality, integrity and availability of medical data for the health of the data subject and his family;

Aware that progress in medical science is dependent to a great extent on the availability of medical data on individuals;

Convinced that it is desirable to regulate the collection and processing of medical data, to safeguard the confidentiality and security of personal data regarding health, and to ensure that they are used subject to the rights and fundamental freedoms of the individual, and in particular the right to privacy;

Aware that progress made in medical science and developments in information technology since 1981 have made it necessary to revise various provisions in Recommendation No. R (81) 1 on regulations for automated medical data banks,

Recommends that the governments of member states:

– take steps to ensure that the principles contained in the appendix to this recommendation are reflected in their law and practice;

– ensure wide circulation of the principles contained in the appendix to this recommendation among persons professionally involved in the collection and processing of medical data;

Decides that this recommendation will replace Recommendation No. R (81) 1 on regulations for automated medical data banks.

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APPENDIX TO RECOMMENDATION NO. R (97) 5

1. Definitions

For the purposes of this recommendation:

- the expression "personal data" covers any information relating to an identified or identifiable individual. An individual shall not be regarded as "identifiable" if identification requires an unreasonable amount of time and manpower. In cases where the individual is not identifiable, the data are referred to as anonymous;
- the expression "medical data" refers to all personal data concerning the health of an individual. It refers also to data which have a clear and close link with health as well as to genetic data;
- the expression "genetic data" refers to all data, of whatever type, concerning the hereditary characteristics of an individual or concerning the pattern of inheritance of such characteristics within a related group of individuals.

It also refers to all data on the carrying of any genetic information (genes) in an individual or genetic line relating to any aspect of health or disease, whether present as identifiable characteristics or not.

The genetic line is the line constituted by genetic similarities resulting from procreation and shared by two or more individuals.

2. Scope

- 2.1. This recommendation is applicable to the collection and automatic processing of medical data, unless domestic law, in a specific context outside the health-care sector, provides other appropriate safeguards.
- 2.2. A member state may extend the principles set out in this recommendation to cover medical data not processed automatically.

3. Respect for privacy

- 3.1. The respect of rights and fundamental freedoms, and in particular of the right to privacy, shall be guaranteed during the collection and processing of medical data.
- 3.2. Medical data may only be collected and processed if in accordance with appropriate safeguards which must be provided by domestic law.

In principle, medical data should be collected and processed only by health-care professionals, or by individuals or bodies working on behalf of health-care professionals. Individuals or bodies working on behalf of health-care professionals who collect and process medical data should be subject to the same rules of confidentiality incumbent on health-care professionals, or to comparable rules of confidentiality.

Controllers of files who are not health-care professionals should only collect and process medical data subject either to rules of confidentiality comparable to those incumbent upon a health-care professional or subject to equally effective safeguards provided for by domestic law.

4. Collection and processing of medical data

4.1. Medical data shall be collected and processed fairly and lawfully and only for specified purposes.

4.2. Medical data shall in principle be obtained from the data subject. They may only be obtained from other sources if in accordance with Principles 4, 6 and 7 of this recommendation and if this is necessary to achieve the purpose of the processing or if the data subject is not in a position to provide the data.

4.3. Medical data may be collected and processed:

a. if provided for by law for:

i. public health reasons; or

ii. subject to Principle 4.8, the prevention of a real danger or the suppression of a specific criminal offence; or

iii. another important public interest; or

b. if permitted by law:

i. for preventive medical purposes or for diagnostic or for therapeutic purposes with regard to the data subject or a relative in the genetic line; or

ii. to safeguard the vital interests of the data subject or of a third person; or

iii. for the fulfilment of specific contractual obligations; or

iv. to establish, exercise or defend a legal claim; or

c. if the data subject or his/her legal representative or an authority or any person or body provided for by law has given his/her consent for one or more purposes, and in so far as domestic law does not provide otherwise.

4.4. If medical data have been collected for preventive medical purposes or for diagnostic or therapeutic purposes with regard to the data subject or a relative in the genetic line, they may also be processed for the management of a medical service operating in the interest of the patient, in cases where the management is provided by the health-care professional who collected the data, or where the data are communicated in accordance with principles 7.2 and 7.3.

Unborn children

4.5. Medical data concerning unborn children should be considered as personal data and enjoy a protection comparable to the protection of the medical data of a minor.

4.6. Unless otherwise provided for by domestic law, the holder of parental responsibilities may act as the person legally entitled to act for the unborn child, the latter being a data subject.

Genetic data

4.7. Genetic data collected and processed for preventive treatment, diagnosis or treatment of the data subject or for scientific research should only be used for these purposes or to allow the data subject to take a free and informed decision on these matters.

4.8. Processing of genetic data for the purpose of a judicial procedure or a criminal investigation should be the subject of a specific law offering appropriate safeguards.

The data should only be used to establish whether there is a genetic link in the framework of adducing evidence, to prevent a real danger or to suppress a specific criminal offence. In no case should they be used to determine other characteristics which may be linked genetically.

4.9. For purposes other than those provided for in Principles 4.7 and 4.8, the collection and processing of genetic data should, in principle, only be permitted for health reasons and in particular to avoid any serious prejudice to the health of the data subject or third parties.

However, the collection and processing of genetic data in order to predict illness may be allowed for in cases of overriding interest and subject to appropriate safeguards defined by law.

5. Information of the data subject

5.1. The data subject shall be informed of the following elements:

- a.* the existence of a file containing his/her medical data and the type of data collected or to be collected;
- b.* the purpose or purposes for which they are or will be processed;
- c.* where applicable, the individuals or bodies from whom they are or will be collected;
- d.* the persons or bodies to whom and the purposes for which they may be communicated;
- e.* the possibility, if any, for the data subject to refuse his consent, to withdraw it and the consequences of such withdrawal;
- f.* the identity of the controller and of his/her representative, if any, as well as the conditions under which the rights of access and of rectification may be exercised.

5.2. The data subject should be informed at the latest at the moment of collection. However, when medical data are not collected from the data subject, the latter should be notified of the collection as soon as possible, as well as - in a suitable manner - of the information listed under Principle 5.1, unless this is clearly unreasonable or impracticable, or unless the data subject has already received the information.

5.3. Information for the data subject shall be appropriate and adapted to the circumstances. Information should preferably be given to each data subject individually.

5.4. Before a genetic analysis is carried out, the data subject should be informed about the objectives of the analysis and the possibility of unexpected findings.

Legally incapacitated persons

5.5. If the data subject is a legally incapacitated person, incapable of free decision and domestic law does not permit the data subject to act on his/her own behalf, the information shall be given to the person recognised as legally entitled to act in the interest of the data subject.

If a legally incapacitated person is capable of understanding, he/she should be informed before his/her data are collected or processed.

Derogations

5.6. Derogations from Principles 5.1, 5.2 and 5.3 may be made in the following cases:

a. information of the data subject may be restricted if the derogation is provided for by law and constitutes a necessary measure in a democratic society:

- i.* to prevent a real danger or to suppress a criminal offence.
- ii.* for public health reasons.
- iii.* to protect the data subject and the rights and freedoms of others;

b. in medical emergencies, data considered necessary for medical treatment may be collected prior to information.

6. Consent

6.1. Where the data subject is required to give his/her consent, this consent should be free, express and informed.

6.2. The results of any genetic analysis should be formulated within the limits of the objectives of the medical consultation, diagnosis or treatment for which consent was obtained.

6.3. Where it is intended to process medical data relating to a legally incapacitated person who is incapable of free decision, and when domestic law does not permit the data subject to act on his/her own behalf, consent is required of the person recognised as legally entitled to act in the interest of the data subject or of an authority or any person or body provided for by law.

If, in accordance with Principle 5.5 above, a legally incapacitated person has been informed of the intention to collect or process his/her medical data, his/her wishes should be taken into account, unless domestic law provides otherwise.

7. Communication

7.1. Medical data shall not be communicated, unless on the conditions set out in this principle and in Principle 12.

7.2. In particular, unless other appropriate safeguards are provided by domestic law, medical data may only be communicated to a person who is subject to the rules of confidentiality incumbent upon a health-care professional, or to comparable rules of confidentiality, and who complies with the provisions of this recommendation.

- 7.3. Medical data may be communicated if they are relevant and:
- a. if the communication is provided for by law and constitutes a necessary measure in a democratic society for:
 - i. public health reasons; or
 - ii. the prevention of a real danger or the suppression of a specific criminal offence; or
 - iii. another important public interest; or
 - iv. the protection of the rights and freedoms of others; or
 - b. if the communication is permitted by law for the purpose of:
 - i. the protection of the data subject or a relative in the genetic line;
 - ii. safeguarding the vital interests of the data subject or a third person; or
 - iii. the fulfilment of specific contractual obligations; or
 - iv. establishing, exercising or defending a legal claim; or
 - c. if the data subject or his/her legal representative, or an authority, or any person or body provided for by law has given his/her consent for one or more purposes, and in so far as domestic law does not provide otherwise; or
 - d. provided that the data subject or his/her legal representative, or an authority, or any person or body provided for by law has not explicitly objected to any non-mandatory communication, if the data have been collected in a freely chosen preventive, diagnostic or therapeutic context, and if the purpose of the communication, in particular the provision of care to the patient or the management of a medical service operating in the interest of the patient, is not incompatible with the purpose of the processing for which they were collected.

8. Rights of the data subject

Rights of access and of rectification

- 8.1. Every person shall be enabled to have access to his/her medical data, either directly or through a health-care professional or, if permitted by domestic law, a person appointed by him/her. The information must be accessible in understandable form.
- 8.2. Access to medical data may be refused, limited or delayed only if the law provides for this and if:
- a. this constitutes a necessary measure in a democratic society in the interests of protecting state security, public safety, or the suppression of criminal offences; or
 - b. knowledge of the information is likely to cause serious harm to the data subject's health; or
 - c. the information on the data subject also reveals information on third parties or if, with respect to genetic data, this information is likely to cause serious harm to consanguine or uterine kin or to a person who has a direct link with this genetic line; or

d. the data are used for statistical or for scientific research purposes where there is clearly no risk of an infringement of the privacy of the data subject, notably the possibility of using the data collected in support of decisions or measures regarding any particular individual.

8.3. The data subject may ask for rectification of erroneous data concerning him/her and, in case of refusal, he/she shall be able to appeal.

Unexpected findings

8.4. The person subjected to genetic analysis should be informed of unexpected findings if the following conditions are met:

- a.* domestic law does not prohibit the giving of such information;
- b.* the person himself has asked for this information;
- c.* the information is not likely to cause serious harm:
 - i.* to his/her health; or
 - ii.* to his/her consanguine or uterine kin, to a member of his/her social family, or to a person who has a direct link with his/her genetic line, unless domestic law provides other appropriate safeguards.

Subject to sub-paragraph *a*, the person should also be informed if this information is of direct importance to him/her for treatment or prevention.

9. Security

9.1. Appropriate technical and organisational measures shall be taken to protect personal data - processed in accordance with this recommendation - against accidental or illegal destruction, accidental loss, as well as against unauthorised access, alteration, communication or any other form of processing.

Such measures shall ensure an appropriate level of security taking account, on the one hand, of the technical state of the art and, on the other hand, of the sensitive nature of medical data and the evaluation of potential risks.

These measures shall be reviewed periodically.

9.2. In order to ensure in particular the confidentiality, integrity and accuracy of processed data, as well as the protection of patients, appropriate measures should be taken:

- a.* to prevent any unauthorised person from having access to installations used for processing personal data (control of the entrance to installations);
- b.* to prevent data media from being read, copied, altered or removed by unauthorised persons (control of data media);
- c.* to prevent the unauthorised entry of data into the information system, and any unauthorised consultation, modification or deletion of processed personal data (memory control);

d. to prevent automated data processing systems from being used by unauthorised persons by means of data transmission equipment (control of utilisation);

e. with a view to, on the one hand, selective access to data and, on the other hand, the security of the medical data, to ensure that the processing as a general rule is so designed as to enable the separation of:

– identifiers and data relating to the identity of persons;

– administrative data;

– medical data;

– social data;

– genetic data (access control);

f. to guarantee the possibility of checking and ascertaining to which persons or bodies personal data can be communicated by data transmission equipment (control of communication);

g. to guarantee that it is possible to check and establish *a posteriori* who has had access to the system and what personal data have been introduced into the information system, when and by whom (control of data introduction);

h. to prevent the unauthorised reading, copying, alteration or deletion of personal data during the communication of personal data and the transport of data media (control of transport);

i. to safeguard data by making security copies (availability control).

9.3. Controllers of medical files should, in accordance with domestic law, draw up appropriate internal regulations which respect the related principles in this recommendation.

9.4. Where necessary, controllers of files processing medical data should appoint an independent person responsible for security of information systems and data protection and competent for giving advice on these issues.

10. Conservation

10.1. In general, medical data shall be kept no longer than necessary to achieve the purpose for which they were collected and processed.

10.2. When, in the legitimate interest of public health, medical science - of the person in charge of the medical treatment or the controller of the file, in order to enable him/her to defend or exercise a legal claim - or for historical or statistical reasons, it proves necessary to conserve medical data that no longer serve their original purpose, technical arrangements shall be made to ensure their correct conservation and security, taking into account the privacy of the patient.

10.3. On the request of the data subject, his/her medical data should be erased - unless they have been made anonymous or there are overriding and legitimate interests, in particular those stated in Principle 10.2 not to do so, or there is an obligation to keep the data on record.

11. Transborder flows

11.1. The principles of this recommendation are applicable to the transborder flow of medical data.

11.2. The transborder flow of medical data to a state which has ratified the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data, and which disposes of legislation which provides at least equivalent protection of medical data, should not be subjected to special conditions concerning the protection of privacy.

11.3. Where the protection of medical data can be considered to be in line with the principle of equivalent protection laid down in the convention, no restriction should be placed on the transborder flow of medical data to a state which has not ratified the convention but which has legal provisions which ensure protection in accordance with the principles of that convention and this recommendation.

11.4. Unless otherwise provided for by domestic law, the transborder flow of medical data to a state which does not ensure protection in accordance with the convention and with this recommendation, should not as a rule occur unless:

a. necessary measures, including those of a contractual nature, to respect the principles of the convention and this recommendation, have been taken, and the data subject has the possibility to object to the transfer; or

b. the data subject has given his consent.

11.5. Unless in the case of emergency or of a transfer to which the data subject has given his informed consent, appropriate measures should be taken to ensure the protection of medical data transferred from one country to another, and in particular:

a. the person responsible for the transfer should indicate to the addressee the specified and legitimate purposes for which the data have been originally collected, as well as the persons or bodies to whom they may be communicated;

b. unless otherwise provided for by domestic law, the addressee should undertake, in respect of the person responsible for the transfer, to honour the specified and legitimate purposes which he/she has accepted, and not to communicate the data to persons or bodies other than those indicated by the person responsible for the transfer.

12. Scientific research

12.1. Whenever possible, medical data used for scientific research purposes should be anonymous. Professional and scientific organisations as well as public authorities should promote the development of techniques and procedures securing anonymity.

12.2. However, if such anonymisation would make a scientific research project impossible, and the project is to be carried out for legitimate purposes, it could be carried out with personal data on condition that:

a. the data subject has given his/her informed consent for one or more research purposes; or

b. when the data subject is a legally incapacitated person incapable of free decision, and domestic law does not permit the data subject to act on his/her own behalf, his/her legal representative or an authority, or any person or body provided for by law, has given his/her consent in the framework of a research project related to the medical condition or illness of the data subject; or

c. disclosure of data for the purpose of a defined scientific research project concerning an important public interest has been authorised by the body or bodies designated by domestic law, but only if:

i. the data subject has not expressly opposed disclosure; and

ii. despite reasonable efforts, it would be impracticable to contact the data subject to seek his consent; and

iii. the interests of the research project justify the authorisation; or

d. the scientific research is provided for by law and constitutes a necessary measure for public health reasons.

12.3. Subject to complementary provisions determined by domestic law, health-care professionals entitled to carry out their own medical research should be able to use the medical data which they hold as long as the data subject has been informed of this possibility and has not objected.

12.4. As regards any scientific research based on personal data, the incidental problems, including those of an ethical and scientific nature, raised by respect of the provisions of the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data should also be examined in the light of other relevant instruments.

12.5. Personal data used for scientific research may not be published in a form which enables the data subjects to be identified, unless they have given their consent for the publication and publication is permitted by domestic law.

COUNCIL OF EUROPE

COMMITTEE OF MINISTERS

RECOMMENDATION NO. R (97) 15

of the Committee of Ministers to member States
on xenotransplantation

*(Adopted by the Committee of Ministers on 30 September 1997
at the 602nd 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 into account Resolution (78) 29 on the harmonisation of legislation of member States relating to removal, grafting and transplantation of human substances, the Final Text of the 3rd Conference of European Health Ministers (Paris, 16-17 November 1987) and Articles 19 and 20 of the Convention on Human Rights and Biomedicine;

Considering that xenotransplantation, that is, the use of living organs, tissues and/or cells from animals, whether genetically modified or not, for transplantation into humans, may become a practicable therapeutic intervention in the very near future.

Aware that there is a risk of transmission of disease as a result of xenotransplantation procedures,

Recommends that Governments of member States should, with a view to minimising the risk of transmission of known or unknown diseases and infections to either the human or animal populations, establish a mechanism for the registration and regulation of the following aspects of xenotransplantation:

- i. basic research and clinical trials;
- ii. the source and care of animals for use in xenotransplantation;
- iii. xenotransplantation programmes;
- iv. long term follow-up and review of xenograft recipients and the xenograft source animals.

SECOND SUMMIT OF THE COUNCIL OF EUROPE

Final Declaration

(Strasbourg, 11 October 1997)

We, Heads of State and Government of the member States of the Council of Europe, meeting in Strasbourg on 10 and 11 October 1997 for our Organisation's Second Summit,

Convinced that the far-reaching changes in Europe and the great challenges to our societies require intensified co-operation between all European democracies,

Encouraged by the significant enlargement of our Organisation which has created the basis for a wider area of democratic security in our continent,

Having reviewed the developments since our First Summit held in Vienna in 1993, as well as the implementation of our decisions concerning the establishment of a single European Court of Human Rights; the protection of national minorities; and the fight against racism, xenophobia, anti-Semitism and intolerance,

Welcoming the achievements of the Council of Europe in preparing candidate countries for membership and ensuring their full integration into the wider European family, and underlining the contribution of the Parliamentary Assembly, as well as that of the Congress of Local and Regional Authorities, to supporting democratic development in member States,

- solemnly reaffirm our attachment to the **fundamental principles of the Council of Europe** - pluralist democracy, respect for human rights, the rule of law - and the commitment of our governments to comply fully with the requirements and meet the responsibilities arising from membership of our Organisation,
- underline the essential **standard-setting role** of the Council of Europe in the field of human rights and its contribution to the development of international law through European Conventions, and affirm our determination to ensure full implementation of these standards and conventions, particularly by strengthening the co-operation programmes for the consolidation of democracy in Europe,
- confirm our goal of achieving a greater unity between our member States, with a view to building a **freer, more tolerant and just European society** based on common values, such as freedom of expression and information, cultural diversity and the equal dignity of all human beings,
- decide consequently to give new impetus to those activities of the Council of Europe aimed at supporting member States in their efforts to respond to the **changes in society** on the threshold of a new century,
- give our full support to the Council of Europe with a view to intensifying its contribution to **cohesion, stability and security in Europe**, and welcome the development of its co-operation with other European and transatlantic organisations, in particular the European Union and the Organisation for Security and Co-operation in Europe,

and, on this basis, declare the following:

CONVINCED THAT THE PROMOTION OF HUMAN RIGHTS AND THE STRENGTHENING OF PLURALIST DEMOCRACY BOTH CONTRIBUTE TO STABILITY IN EUROPE:

- decide to reinforce the **protection of human rights** by ensuring that our institutions are capable of effectively defending the rights of individuals throughout Europe,
- call for the **universal abolition of the death penalty** and insist on the maintenance, in the meantime, of existing moratoria on executions in Europe,
- express our determination to reinforce the means to prevent and combat **torture and inhuman or degrading treatment or punishment**,
- call for the intensification of the fight against **racism, xenophobia, anti-Semitism and intolerance**,
- stress the importance of a more balanced representation of men and women in all sectors of society, including political life, and call for continued progress with a view to achieving effective **equality of opportunities between men and women**,
- assert our determination to step up co-operation in respect of the protection of all persons belonging to **national minorities**,
- acknowledge the fundamental role of the institutions of **local democracy** in the preservation of stability in Europe,
- decide to continue active support for **democratic development** in all member States and to increase our efforts to promote an area of common legal standards throughout Europe;

RECOGNISING THAT SOCIAL COHESION IS ONE OF THE FOREMOST NEEDS OF THE WIDER EUROPE AND SHOULD BE PURSUED AS AN ESSENTIAL COMPLEMENT TO THE PROMOTION OF HUMAN RIGHTS AND DIGNITY:

- decide to promote and make full use of the instruments which are a reference and a means of action for States and for the social partners, in particular the **European Social Charter** in the legal field and the **Social Development Fund** in the financial field,
- agree to review our **legislation in the social field** with a view to combating all forms of exclusion and ensuring better protection for the weakest members of society,
- stress the importance of a common and balanced approach, based on international solidarity, to questions relating to **refugees and asylum seekers**, and in this regard recall the obligation for the State of origin to readmit these persons to its territory, in accordance with international law,
- recall the protection due to **victims of conflicts**, as well as the importance of the respect for humanitarian international law and the knowledge of its rules at national level, in particular among the armed forces and the police,
- affirm our determination to protect the rights of lawfully residing **migrant workers** and to facilitate their integration in the societies in which they live;

SHARING THE CONCERN OF CITIZENS ABOUT THE NEW DIMENSION OF THREATS TO THEIR SECURITY AND THE DANGERS WHICH THESE THREATS CONSTITUTE FOR DEMOCRACY:

- reassert our strong condemnation of **terrorism** and our determination to make full use of the existing machinery to combat all of its manifestations, while ensuring respect for legality and human rights,
- decide to seek common responses to the challenges posed by the growth in **corruption, organised crime** and **drug trafficking** throughout Europe,
- decide to intensify our co-operation aiming at strengthening the **legal protection of children**,
- affirm our determination to combat **violence against women** and all forms of sexual exploitation of women,
- support the efforts of the Council of Europe and of local, regional and national authorities to improve the **quality of life** in disadvantaged areas: urban and industrialised;

AWARE OF THE EDUCATIONAL AND CULTURAL DIMENSION OF THE MAIN CHALLENGES TO BE FACED BY EUROPE IN THE FUTURE AS WELL AS OF THE ESSENTIAL ROLE OF CULTURE AND EDUCATION IN STRENGTHENING MUTUAL UNDERSTANDING AND CONFIDENCE BETWEEN OUR PEOPLES:

- express our desire to develop **education for democratic citizenship** based on the rights and responsibilities of citizens, and the participation of young people in civil society,
- reaffirm the importance we attach to the protection of our **European cultural and natural heritage** and to the promotion of awareness of this heritage,
- decide to seek common responses to the development of the **new information technologies**, based on the standards and values of the Council of Europe, while ensuring a proper balance between the right to information and respect for private life,
- recognise the role of **sport** in promoting social integration, particularly among young people,
- encourage **understanding between the citizens of the North and the South**, in particular through information and civic education for young people, as well as initiatives aimed at promoting mutual respect and solidarity among peoples.

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Having in mind the need to redefine our priorities and adapt the functions of our Organisation to the new European context, we have drawn up an **Action Plan**. This document, appended to the present **Declaration**, seeks to define the main tasks for the Council of Europe in the coming years, particularly in the period leading to its 50th Anniversary.

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ACTION PLAN

The Heads of State and Government, meeting in Strasbourg on 10 and 11 October 1997, have outlined an **Action Plan** to strengthen **democratic stability** in the member States, and have accordingly defined four main areas where there is scope for immediate advances and practical measures, together with a fifth field concerning structural reforms.

I. DEMOCRACY AND HUMAN RIGHTS

1. **Single Court of Human Rights:** the Heads of State and Government welcome the ratification of Protocol No. 11 to the European Convention on Human Rights by all contracting parties, making it possible to establish the new single Court of Human Rights, and instruct the Committee of Ministers to take the necessary steps to set it up on 1 November 1998.
2. **Commissioner for Human Rights:** the Heads of State and Government welcome the proposal to create an office of Commissioner for Human Rights to promote respect for human rights in the member States and instruct the Committee of Ministers to study arrangements for its implementation, while respecting the competences of the single Court.
3. **Compliance with member States' commitments:** the Heads of State and Government resolve to ensure that the commitments accepted by the member States are effectively honoured, on the basis of a confidential, constructive, non-discriminatory dialogue carried on within the Committee of Ministers and taking into account the monitoring procedures of the Parliamentary Assembly; they reiterate their determination to work together to solve the problems faced by member States and consider that this monitoring process must be supported, where necessary, by practical assistance from the Council of Europe.
4. **Prohibition of the cloning of human beings:** the Heads of State and Government undertake to prohibit all use of cloning techniques aimed at creating genetically identical human beings and instruct to this end the Committee of Ministers to adopt an additional protocol to the Oviedo Convention on Human Rights and Biomedicine as soon as possible.
5. **Combating racism, xenophobia, anti-Semitism and intolerance:** the Heads of State and Government welcome the action taken in this field by the Council of Europe since the Vienna Summit and resolve to intensify, for this purpose, the activities of the European Commission against Racism and Intolerance, while stressing the importance of close co-operation with the European Union.
6. **Protection of national minorities:** the Heads of State and Government, taking into account the imminent entry into force of the Framework Convention for the Protection of National Minorities, resolve to complement the Council of Europe's standard-setting achievements in this field through practical initiatives, such as confidence-building measures and enhanced co-operation, involving both governments and civil society.

II. SOCIAL COHESION

1. **Promotion of social rights:** the Heads of State and Government undertake to promote social standards as embodied in the Social Charter and in other Council of Europe instruments, and call for the widest possible adherence to these instruments; they resolve to improve the exchange of good practice and information between member States and to intensify their co-operation in this field.
2. **New strategy for social cohesion:** the Heads of State and Government instruct the Committee of Ministers to define a social strategy to respond to the challenges in society and to carry out the appropriate structural reforms within the Council of Europe, including the setting up of a specialised unit for monitoring, comparing and handling issues linked to social cohesion.
3. **Programme for children:** the Heads of State and Government encourage the adoption of a programme to promote the interests of children, in partnership with the international and non-governmental organisations concerned.

4. Social Development Fund: the Heads of State and Government decide to reinforce the activities of the Social Development Fund, invite it to participate actively in the Council of Europe's action for social cohesion, and urge it to increase its investment effort in the social field and in job creation.

III. SECURITY OF CITIZENS

1. Combating terrorism: the Heads of State and Government call for the adoption of further measures to prevent terrorism and to strengthen international co-operation in combating terrorism, in accordance with the relevant provisions of international law, including international standards on human rights, and in the light of the recommendations adopted at the ministerial conference on terrorism held in Paris on 30 July 1996; they note with interest the forthcoming holding of a parliamentary conference to study the phenomenon of terrorism in democratic society.

2. Fighting corruption and organised crime: in order to promote co-operation between member States in the fight against corruption, including its links with organised crime and money-laundering, the Heads of State and Government instruct the Committee of Ministers:

- to adopt, before the end of the year, guiding principles which are to be applied in the development of domestic legislation and practice;
- to secure the rapid completion of international legal instruments pursuant to the Council of Europe's Programme of Action against Corruption;
- to establish without delay an appropriate and efficient mechanism for monitoring observance of the guiding principles and implementation of the said international legal instruments.

They call on all States to ratify the Convention on Laundering, Search, Seizure and Confiscation of the Proceeds from Crime.

3. Prevention of drug abuse: the Heads of State and Government decide to strengthen their co-operation, through the Pompidou Group, with a view to tackling the problems relating to the use and trafficking of illicit drugs ; they note with approval the new work programme of the Group and welcome in particular those activities designed to prevent drug abuse among young people and to facilitate the reintegration of drug addicts and users into society.

4. Protection of children: the Heads of State and Government decide to review national legislation with the aim of ensuring common standards for the protection of children suffering from or at risk of inhuman treatment; they agree to extend their co-operation, within the Council of Europe, with a view to preventing all forms of exploitation of children, including through the production, sale, marketing and possession of pornographic material involving children.

IV. DEMOCRATIC VALUES AND CULTURAL DIVERSITY

1. Education for democratic citizenship: the Heads of State and Government decide to launch an initiative for education for democratic citizenship with a view to promoting citizens' awareness of their rights and responsibilities in a democratic society, activating existing networks, and including a new youth exchange programme.

2. Enhancement of the European heritage: the Heads of State and Government decide to launch a campaign in 1999 on the theme “Europe, a common heritage”, respecting cultural diversity, based on existing or prospective partnerships between government, educational and cultural institutions, and industry.

3. New information technologies: the Heads of State and Government resolve to develop a European policy for the application of the new information technologies, with a view to ensuring respect for human rights and cultural diversity, fostering freedom of expression and information and maximising the educational and cultural potential of these technologies; they invite the Council of Europe to seek, in this respect, suitable partnership arrangements.

V. STRUCTURES AND WORKING METHODS

1. Structural reform: the Heads of State and Government, looking ahead to the 50th Anniversary of the Council of Europe in 1999, instruct the Committee of Ministers to carry out the structural reforms needed to adapt the Organisation to its new tasks and its enlarged membership and to improve its decision-making process.

2. Implementation of the Action Plan: the Heads of State and Government instruct the Committee of Ministers to take the appropriate steps to ensure that this Action Plan is speedily implemented by the various Council of Europe bodies, in co-operation with European and other international organisations.

COUNCIL OF EUROPE
COMMITTEE OF MINISTERS

RECOMMENDATION NO. R (99) 3

of the Committee of Ministers to member States

on the harmonisation of medico-legal autopsy rules¹

*(Adopted by the Committee of Ministers on 2 February 1999
at the 658th 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 a greater unity between its members;

Having regard to the principles laid down in the Convention for the Protection of Human Rights and Fundamental Freedoms and, in particular, the prohibition of torture or inhuman or degrading treatment or punishment, and the right to life;

Conscious that it is normal practice for autopsies to be carried out in all Council of Europe member States to establish the cause and manner of death for medico-legal or other reasons or to establish the identity of the deceased;

Considering the importance of compensation for victims and families in criminal and civil proceedings;

Underlining the need for investigation, description, photographic documentation and sampling during medico-legal autopsy to follow primarily medical and scientific principles and simultaneously consider legal requirements and procedures;

Conscious that the increasing mobility of the population throughout Europe and the world, as well as the increasing internationalisation of judicial proceedings, require the adoption of uniform guidelines on the way autopsies are to be carried out and on the way autopsy reports are to be established;

¹ When this recommendation was adopted the Representatives of Denmark and the Netherlands, in application of Article 10.2c of the Rules of Procedure for the meeting of the Ministers' Deputies, reserved the right of their Governments to comply or not with paragraph 2 (scope of the recommendation) of the present recommendation.

When this recommendation was adopted the Representative of Germany, in application of Article 10.2c of the Rules of Procedure for the meeting of the Ministers' Deputies, reserved the right of his Government to comply or not with paragraph 2 *f* and *h* of the present recommendation.

Considering the Council of Europe Agreement on the Transfer of Corpses (European Treaty Series No. 80) and having regard to the difficulties often experienced by the receiving country when a dead body is repatriated from one member state to another;

Aware of the importance of proper autopsy procedures, in particular with a view to bringing to light illegal executions, and murders perpetrated by authoritarian regimes;

Underlining the need to protect the independence and impartiality of medico-legal experts, as well as to make available the necessary legal and technical facilities for them to carry out their duties in an appropriate way and to promote their training;

Considering the importance of national quality control systems to ensure the proper performance of medico-legal autopsies;

Underlining the need to strengthen international co-operation with a view to the progressive harmonisation of medico-legal autopsy procedures at a European level;

Having regard to Recommendation 1159 (1991) on the harmonisation of autopsy rules adopted, at its 43rd Ordinary Session, by the Parliamentary Assembly of the Council of Europe;

Having regard to the Model Autopsy Protocol of the United Nations, endorsed by the General Assembly of the United Nations in 1991;

Taking into account the "guide on disaster victim identification" adopted by the International Criminal Police Organisation (Interpol) General Assembly in 1997,

1. Recommends the governments of member states:
 - i. to adopt as their internal standards the principles and rules contained in this recommendation;
 - ii. to take or reinforce, as the case may be, all appropriate measures with a view to the progressive implementation of the principles and rules contained in this recommendation;
 - iii. to set up a quality assurance programme to ensure the proper implementation of the principles and rules contained in this recommendation.
2. Invites the governments of member states to inform the Secretary General of the Council of Europe upon his or her request of the measures taken to follow up the principles and rules contained in this recommendation.

Principles and rules relating to medico-legal autopsy procedures

Scope of the recommendation

1. In cases where death may be due to unnatural causes, the competent authority, accompanied by one or more medico-legal experts, should where appropriate investigate the scene, examine the body and decide whether an autopsy should be carried out.
2. Autopsies should be carried out in all obvious or suspected unnatural death, even where there is a delay between causative events and death, in particular:

- a. homicide or suspected homicide;
 - b. sudden, unexpected death, including sudden infant death;
 - c. violation of human rights such as suspicion of torture or any other form of ill treatment;
 - d. suicide or suspected suicide;
 - e. suspected medical malpractice;
 - f. accidents, whether transportation, occupational or domestic;
 - g. occupational disease and hazards;
 - h. technological or environmental disasters;
 - i. death in custody or death associated with police or military activities;
 - j. unidentified or skeletalised bodies.
3. Medico-legal experts must exercise their functions with total independence and impartiality. They should not be subject to any form of pressure and they should be objective in the exercise of their functions, in particular in the presentation of their results and conclusions.

Principle I – Scene investigation

a. *General principles*

- 1. In case of obvious or suspected unnatural death, the physician who first attended the dead body should report to the competent authorities, the latter deciding whether an examination should be carried out by a qualified medico-legal expert or by a physician familiar with medico-legal examination.
- 2. Particularly in cases of homicide or suspicious death, medico-legal experts should be informed without delay and, where appropriate, go immediately to the place where the body is found and have immediate access there. In this respect, there should be an adequate structure of co-ordination among all persons involved and, in particular, among judicial bodies, medico-legal experts and police.

b. *Examination of the body*

1. Role of the police

The following tasks, among others, should be carried out by police officers:

- a. record the identities of all persons at the scene;
- b. photograph the body as it is found;
- c. make sure that all relevant artifacts are noted, and that all exhibits, such as weapons and projectiles, are seized for further examination;
- d. in agreement with the medico-legal expert, obtain identification of the body and other pertinent information from scene witnesses, including those who last saw the decedent alive, where

available;

e. protect the deceased's hands and head with paper bags, under the control of the medico-legal expert;

f. preserve the integrity of the scene and surroundings;

2. Role of the medico-legal expert

The medico-legal expert should without delay:

a. be informed of all relevant circumstances relating to the death;

b. ensure that photographs of the body are properly taken;

c. record the body position and its relation to the state of the clothing and to the distribution pattern of rigor mortis and hypostasis, as well as the state of *post-mortem* decomposition;

d. examine and record the distribution and pattern of any blood stains on the body and at the scene, as well as other biological evidence;

e. proceed to a preliminary examination of the body;

f. except where the body is decomposed or skeletal, note the ambient temperature and deep-rectal temperature of the body, and estimate the time of death by recording the degree, location and fixation of rigor mortis and hypostasis, as well as other findings;

g. make sure that the body is transported and stored in a secure and refrigerated location in an undisturbed state.

Principle II – Autopsy physicians

Medico-legal autopsies should be performed, whenever possible, by two physicians, of whom at least one should be qualified in forensic pathology.

Principle III – Identification

In order to ensure that proper identification of the body is carried out in accordance with the disaster victim identification guide adopted by the General Assembly of Interpol in 1997, the following criteria should be considered: visual recognition, personal effects, physical characteristics, dental examination, anthropological identification, finger prints and genetic identification.

1. Visual identification

Visual identification of a body should be carried out by relatives or persons who knew and have recently seen the decedent.

2. Personal effects

A description of clothing, jewellery and pocket contents should be recorded. These may assist correct identification.

3. Physical characteristics

Physical characteristic should be recorded through an external and an internal examination.

4. Dental examination

Where appropriate, the examination of teeth and jaws should be carried out by a dentist with medico-legal experience.

5. Anthropological identification

Whenever human material is skeletised or in an advanced stage of decomposition, an anthropological identification should be carried out, if necessary.

6. Fingerprints

Where appropriate, fingerprints should be taken by police officers.

A close collaboration should exist between all experts involved.

7. Genetic identification

Where appropriate, genetic identification should be carried out by an expert in forensic genetics.

It is appropriate to take biological samples from the deceased in order to assist genetic identification. Measures should be taken in order to avoid contamination and guarantee appropriate storage of biological samples.

Principle IV - General considerations

1. Medico-legal autopsies and all related measures must be carried out in a manner consistent with medical ethics and respecting the dignity of the deceased.

2. Where appropriate, the closest relatives should be given an opportunity to see the corpse.

3. Before beginning the autopsy, the following minimum rules should be applied:

a. record the date, time and place of autopsy;

b. record the name(s) of the medico-legal expert(s), assistant(s) and all other persons present at the autopsy with indication as to the position and role of each one in the autopsy;

c. take colour photographs or video, where appropriate, of all relevant findings and of the dressed and undressed body;

d. undress the body, examine and record clothing and jewellery, verify the correspondence between injuries on the body and clothing;

e. where appropriate, take X-rays, particularly in cases of suspected child abuse, and for identification and location of foreign objects.

4. Where appropriate, before beginning the autopsy, body orifices should be appropriately swabbed for the recovery and identification of biological trace evidence.

5. If the decedent was hospitalised prior to death, admission blood specimens and any X-rays should be obtained as well as hospital records.

Principle V – Autopsy procedures

I. External examination

1. The examination of the clothing is an essential part of the external examination and all findings therein are to be clearly described. This is especially important in those cases where the clothing has been damaged or soiled: each area of recent damage must be described fully and relevant findings are to be related to the site of injuries on the corpse. Discrepancies in such findings are also to be described.

2. The description of the body following an external examination must include:

a. age, sex, build, height, ethnic group and weight, nutritional state, skin colour and special characteristics (such as scars, tattoos or amputations);

b. post-mortem changes, including details relating to rigor and post mortem hypostasis – distribution, intensity, colour and reversibility – and putrefaction and environmentally induced changes;

c. findings on a primary external inspection and description which, if required, include sampling of stains and other trace evidence on the body surface and a reinspection after removal and cleaning of the body;

d. inspection of the skin of the posterior surfaces of the corpse;

e. description and careful investigation of the head and the facial orifices includes: colour, length, density and distribution of hair (and beard); nasal skeleton; oral mucosa, dentition and tongue; ears, retro-auricular areas and external meati; eyes: colour of irises and sclerae, regularity and appearance of pupils, sclerae, conjunctivae; skin (presence and absence of petechiae to be described); if fluids have been evacuated from facial orifices, their colour and odour;

f. neck: checking for excessive mobility, presence and absence of abrasions, other marks and bruising (including petechiae) over the entire circumference of the neck;

g. thorax: shape and stability; breasts; aspect, nipples and pigmentation;

h. abdomen: external bulging, pigmentation, scars, abnormalities and bruising;

i. anus and genitals;

j. extremities: shape and abnormal mobility, abnormalities; injection marks and scars; palmar surfaces, finger and toe nails;

k. material findings under fingernails.

3. All injuries, including abrasions, bruises, lacerations and other marks have to be described by shape, exact measurement, direction, edges, angles and location relative to anatomical landmarks. Photographs should be taken. Bite marks shall be swabbed, and casts made where necessary.

4. Signs of vital reaction around wounds, foreign particles inside wounds and in their surroundings and secondary reactions, such as discolouration, healing and infections must also be described.

5. The investigation of cutaneous and sub-cutaneous bruising may require local skin incision.
6. Where appropriate, specimens from wounds must be removed for further investigations, such as histology and histochemistry.
7. All signs of recent or old medical and surgical intervention and resuscitation must be described. Medical devices must not be removed from the body before the intervention of the medico-legal expert.
8. A decision has to be taken at this stage as to the strategies of investigation and the necessity of documentation by X-rays and other imaging procedures.

II. *Internal examination*

A. *General*

1. All relevant artifacts produced by the dissection and from sampling procedures, must be documented.
2. All three body cavities – head, thorax and abdomen – must be opened layer by layer. Where appropriate, the vertebral canal and joint cavities should be examined.
3. Examination and description of body cavities include: an examination for the presence of gas (pneumothorax), measurement of volume of fluids and blood, appearance of internal surfaces, intactness of anatomical boundaries, external appearance of organs and their location; adhesion and cavity obliterations, injuries and haemorrhage.
4. The demonstration and dissection of the soft tissues and musculature of the neck have to be components of all medico-legal autopsies (see the paragraph concerning special procedures).
5. All organs must be examined and sliced following established guidelines of pathological anatomy. This includes opening of all relevant vessels, for example, intracranial arteries, sinuses, carotid arteries, coronary arteries, pulmonary arteries and veins, aorta and vessels of the abdominal organs, femoral arteries and lower limb veins. Relevant ducts have to be dissected, for example, central and peripheral airways, biliary ducts and ureters. All hollow organs have to be opened and their content described by colour, viscosity, volume (samples should be retained, where appropriate). All organs have to be sliced and the appearance of the cut surface described. If injuries are present, the dissection procedure may have to vary from the normal one: this should be appropriately described and documented.
6. All internal lesions and injuries must be precisely described by size and location. Injury tracks must be described in order to include their direction as regards the organ anatomy.
7. The weight of all major organs must be recorded.

B. *Detailed*

1. *Head*

a. Before opening the skull, the periosteum must be scraped off in order to display or exclude any fractures.

b. The head examination procedure must allow the inspection and description of the scalp, external and internal surfaces of the skull and of the temporal muscles.

c. The thickness and appearances of the skull and sutures, the appearances of the meninges, the cerebrospinal fluid (CSF), the wall structure and contents of cerebral arteries and sinuses must be described. The description of the bones must also include an examination of their intactness, including the connection between the skull and the first two vertebrae.

d. In obvious or suspected head injury (for example, if a detailed examination is required or if autolysis or putrefaction is present) fixation of the whole brain is recommended before its dissection.

e. Middle ears must be always opened and nasal sinuses where indicated.

f. The soft tissue and skeleton of the face is dissected only in relevant cases, using a cosmetically acceptable technique.

2. *Thorax and neck*

The opening of the thorax must be performed using a technique which allows the demonstration of the presence of pneumothorax and the inspection of the thorax walls, including the postero-lateral regions. *In situ* dissection of the neck must display the details of its anatomy.

3. *Abdomen*

The opening procedure of the abdomen must allow an accurate examination of all layers of the walls, including the postero-lateral regions. *In situ* dissection is necessary in certain cases, particularly for the demonstration of injury tracks and evacuation of fluids. Dissection of organs should observe anatomical continuity of systems, where possible. The whole intestine must be dissected and its contents described.

4. *Skeleton*

a. The examination of the thoracic cage, the spine and the pelvis must be part of the autopsy procedure.

b. Where appropriate traumatic deaths need a precise dissection of the extremities, possibly complemented by X-ray examination.

5. *Special procedures*

a. If there is any suspicion of neck trauma, the brain and thoracic organs are to be removed prior to the dissection of the neck, to enable detailed dissection to take place in a bloodless field.

b. If there is a suspicion of air embolism, pre-autopsy radiology of the thorax must be performed. The first stage of the autopsy in such a case must be a careful partial opening of the thorax and dislocation of the lower three-quarters of the sternum with the subsequent opening of the heart under water, allowing the measurement and sampling of escaping air or gas.

c. For the demonstration of particular injury patterns, deviation from the normal procedure of dissection has to be accepted, provided that such procedures are specifically described in the autopsy report.

d. The dissection in traumatic deaths must include a full exposure of the soft tissues and musculature on the back of the body. The same procedure must be applied to the extremities (so called "peel-off" procedure).

e. In suspected or overt sexual assaults, the sexual organs are to be removed *en bloc* together with the external genitalia, rectum and anus, before they are dissected. Relevant swabs of orifices and cavities must be taken prior to this procedure.

6. *Sampling*

The scope of the sampling procedure is to be case-dependent. However, the following minimum rules should be applied:

a. in all autopsies, the basic sampling scheme includes specimens from the main organs for histology and peripheral blood sampling (such as for alcohol and drug analyses and genetic identification), urine and gastric contents. All blood samples must be peripheral blood and not heart or thoracic;

b. if the cause of death cannot be established with the necessary degree of certainty, sampling includes additional specimens and fluids for metabolic studies and thorough toxicology. This includes blood, vitreous humour, CSF, bile, hair samples and further relevant tissues;

c. if death is related to physical violence, sampling includes the injuries, for example to determine wound age and any foreign materials in the wounds;

d. if reconstructions are desirable, the removal of bones and osseous compartments may become necessary;

e. if identification is the predominant aim, the removal of jaws and other bones may be necessary;

f. if strangulation or the application of physical force to the neck is suspected or diagnosed, the entire neck structures, musculature and neurovascular bundles must be preserved for histology. The hyoid bone and the laryngeal cartilages must be dissected very carefully;

g. biological samples must be collected in tightly closed jars, properly preserved and placed under seal and transported to the laboratory in perfect safety;

h. certain specimens and fluids need to be sampled in a special way and analysed without delay.

7. *Release of the body*

After a medico-legal autopsy has been carried out, medico-legal experts should ensure that the body is returned in a dignified condition.

Principle VI – Autopsy report

1. The autopsy report is as important as the autopsy itself, as the latter is of little value if the findings and opinions of the medico-legal expert are not communicated in a clear, accurate and permanent document. The autopsy report should be an integral part of the autopsy procedure and be drafted carefully.

2. The report should therefore be:

a. full, detailed, comprehensive and objective;

- b.* clear and comprehensible not only to other doctors, but also to non-medical readers;
 - c.* written in a logical sequence, well-structured and easy to refer to in various sections of the report;
 - d.* be in a legible and permanent form, with hard paper copy even if it is retained in electronic storage;
 - e.* be written in a discursive "essay" style;
3. When drafting an autopsy report, the following minimum content should be included:
- a.* legal preface to fulfil statutory requirements, if needed;
 - b.* serial number, computer retrieval coding and International Classification of Disease Code (ICD) code;
 - c.* full personal details of deceased (including name, age, sex, address and occupation) unless unidentified;
 - d.* date, place and time of death, where known;
 - e.* date, place and time of autopsy;
 - f.* name, qualifications and status of medico-legal expert(s);
 - g.* persons present at the autopsy and their function;
 - h.* name of the authority commissioning the autopsy;
 - i.* person(s) identifying the body to the medico-legal expert;
 - j.* name and address of the medical attendant of the deceased;
 - k.* a synopsis of the history and circumstances of the death, as given to the medico-legal expert by the police, judges, relatives or other persons, as well as information contained in the file, where available;
 - l.* description of the scene of death, if attended by the medico-legal expert; reference should be made to the provisions contained in Principle I above;
 - m.* external examination; reference should be made to the provisions of Principle V above;
 - n.* internal examination by anatomic systems, together with a comment on every organ. Reference should be made to the provisions of Principle V above;
 - o.* a list of all samples retained for toxicology, genetic identification, histology, microbiology and other investigations should be included; all such specimens should be identified and attested by the medico-legal expert according to the legal system of the state concerned, for continuity of evidence;
 - p.* results of ancillary investigations, such as radiology, odontology, entomology and anthropology should be included, when such results are available;

q. one of the most important parts of the autopsy report is the evaluation of the significance of the accumulated results by the medico-legal expert. After termination of the autopsy, evaluation is usually provisional because later findings and later knowledge of other circumstantial facts can necessitate alteration and modification. Medico-legal experts must interpret the overall findings so that the maximum information and opinion can be offered. Also questions that have not been raised by the competent authority must be addressed if they could be of significance;

r. based on the final interpretation, the cause of death (in the International Classification of Disease should be given. Where several alternatives for the cause of death exist and the facts do not allow a differentiation between them, the medico-legal expert should describe the alternatives and, if possible, rank them in order of probability. If this is not possible, then the cause of death should be certified as "Unascertained";

s. the report should be finally checked, dated and signed by the medico-legal expert(s).

4. The date of the autopsy and the date of the provisional report should never be more than a day or two apart. The date of the autopsy and the date of the final report should be as close together as possible.

Appendix to Recommendation No. R (99) 3

Specific procedures (selected examples)

1. *Constriction of neck (hanging, manual and ligature strangulation)*

The examination of the scene where the body was found is extremely important: for example the presence of a chair or similar platform; fastening of the strangulation device; technique of tying of the knot; adhesive taping of hands and objects for trace evidence:

– Strangulation marks: depth, width, intermediate rings, direction, suspension point, raised ridges of skin, zones of hyperaemia, presence of duplicate strangulation marks; further specific neck injuries: dried excoriations due to slippage of the implement, marks due to textile weave pattern and structure, distribution of petechiae in the skin, bruising, scratch marks, blisters in the strangulation mark.

– Bleeding from facial orifices. Differences in widths of the pupils, localization of hypostasis, presence and distribution of congestion.

– Injuries due to convulsions, defensive injuries, injuries due to being held forcibly.

Dissection of the soft tissues, of the musculature and of the organs of the neck in a bloodless field is essential .

2. *Drowning / Immersion*

Note carefully the following findings: foam at the mouth, cutis anserina, maceration, mud and algae, lesions due to water animals, injuries due to surroundings (for example rocks and ships), loss of nails, skin, localization of livor mortis.

Technique: sampling of gastric contents, precise description of the lungs (weight, measurement, extent of emphysema), sampling, lung fluid, liver and other tissues, for the possible demonstration of diatoms and other contaminants.

If required, sampling of drowning medium (for example river, bath water) should be carried out.

3. *Sexually motivated murder*

The inspection and documentation of the scene of crime, e.g. relative to the injury pattern, is especially important. All injuries must be photographed together with a scale. If required, the body surfaces must be investigated under UV light and taped. Search for and sampling of foreign biological material must include pubic hairs and secretions on the body surface as for instance originating from bites. Such material must be preserved carefully for DNA investigation and protected against contamination. "En bloc" dissection of the genital organs is strongly recommended. It is also necessary to proceed to the careful removal and sampling of material under the fingernails and control hairs.

4. *Death from child abuse and neglect*

State of nutrition and general care, thorough description and documentation of external injuries and scars, thorough examination for bone fractures (X-ray), must be evaluated.

Consider the removal of a variety of tissues: for example all injuries, regional lymph nodes in malnutrition, endocrine organs, immuno-competent tissues, specimens from different parts of the intestine.

5. *Infanticide / still-birth*

Special techniques of dissection are necessary to expose the falx cerebri and the tentorium cerebelli; describe the site of caput succedaneum; remove all fractures "en bloc"; investigate all bone centres of ossification (size and presence). Special care is to be applied to the thoracic organs: degree of inflation of the lungs, flotation test "en bloc" and "en detail". However, the limitations of the flotation test must be appreciated. All malformations must be described. As regards abdominal organs, gas content of the intestine must be investigated. The umbilical cord and the placenta must be subject to morphological and histological examination.

6. *Sudden death*

A subdivision into three main categories relative to the further strategy after gross examination is useful:

a. findings that obviously explain the sudden occurrence of death (for example haemopericardium, aortic rupture). Cases belonging to this category can usually be regarded as sufficiently solved;

b. findings that could explain the death but allow other explanations. Cases belonging to this category necessitate the exclusion of, for example, poisoning and possibly histological proof of recent or chronic alterations relative to the cause of death;

c. findings are either nil/minimal or do not explain the occurrence of death. Cases belonging to this category will usually require extensive further investigations. This is especially so with sudden infant death cases. In such cases a more comprehensive investigative scheme is essential.

7. *Shooting fatalities*

The following should be carried out:

- extensive account on the scene of the incident, of weapons involved, of types of bullets, of sites of "environmental" damage, of cartridge cases and of relative positions of persons involved;
- thorough examination of the clothing and description of relevant damage and careful sampling;
- thorough investigation and documentation of any blood (splashes) on the body surfaces (including clothing and hands);
- precise description of bullet entry and exit wounds relative to anatomical landmarks and distances from the soles of the feet and bullet tracks within the body;
- description of any impression marks of the muzzle;
- excision of uncleaned skin specimens surrounding entry and exit wounds;
- X-ray before and/or during autopsy (where necessary);
- determination of bullet tracks and their direction(s);
- final determination of direction(s) of fire, of the succession of shots, of intra-vital occurrence, of the victim's position (s).

8. *Death caused by explosive devices*

- a. As well as evaluating the cause of death, autopsy is essential to assist in reconstructing the nature of the explosion and identifying the type and maker of the explosive device, especially in aircraft sabotage or other terrorist actions.
- b. Full X-ray of the body must be made to detect and localise any metallic objects, such as detonator components, which may lead to the identification of the explosive device.
- c. The pattern of injury may indicate that the dead person was a perpetrator of the explosion, for example maximum injury in the lower abdominal region suggests that he or she carried the device on his or her lap during a premature explosion.
- d. At autopsy, all foreign objects in the tissues, identified on X-rays, must be carefully preserved for forensic examination.
- e. Samples of tissues, clothing, etc., must be retained for chemical analysis to identify the type of explosive.

9. *Blunt and/or sharp force injuries*

The following should be carried out:

- examination of the weapons or objects that are possibly involved (especially their dimensions);

- extensive examination and inspection of clothing (including damage, stains);
- careful dissection and description of all tracks (layer by layer) including their dimensions and weapon-related traces, signs of vitality.

10. *Fire Deaths*

The following should be carried out:

- examination of remains of clothing, - specific types and shapes of skin combustions;
- search for heat-related alterations and peculiarities;
- demonstration/exclusion of fire accelerants.;
- search for signs of vitality: carbon monoxide, HCN, soot inhalation, skin lesions.

11. *Suspicion of intoxication (General Outlines)*

11.1 Where anatomical findings do not reveal a cause of death and/or there is vague suspicion of poisoning, basic sampling should include peripheral blood, urine, stomach contents, bile, liver and kidney.

11.2 If specific suspicion arises, sampling should be group-related as follows:

- hypnotics, sedatives, psycho-active drugs, cardiac drugs and analgesics, pesticides: as aforementioned under (11.1);
- drugs of abuse: as aforementioned under (11.1) and additionally cerebrospinal fluid, brain tissue, injection marks, hairs;
- volatile fat-soluble substances such as fire accelerant and solvents: as aforementioned under (11.1) and in addition: blood from left ventricle, brain tissue, subcutaneous fat tissue, lung tissue, clothing;
- nutritional intoxication: as aforementioned under (11.1) and in addition: intestinal contents, if possible taken from 3 different sites;
- suspicion of chronic intoxication (heavy metals, drugs, pesticides etc.) as aforementioned under (11.1) and in addition: hairs (tufts), bones, fat tissue, intestinal contents.

12. *Decomposed bodies*

The presence of decomposition does not remove the need for a full autopsy.

Radiological examination will exclude bony injury, the presence of foreign bodies, for example bullets.

Toxicological studies (particularly estimation of alcohol concentrations) should be carried out but interpreted with great caution.

COUNCIL OF EUROPE

COMMITTEE OF MINISTERS

RECOMMENDATION NO. R (99) 4¹

of the Committee of Ministers to member States

on principles concerning the legal protection of incapable adults

*(Adopted by the Committee of Ministers on 23 February 1999
at the 660th meeting of the Ministers' Deputies)*

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

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 and the International Covenant on Economic, Social and Cultural Rights of 16 December 1966;

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

Bearing in mind the 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 of 4 April 1997;

Considering that the aim of the Council of Europe is to achieve a greater unity between its members, in particular by promoting the adoption of common rules in legal matters;

Noting that demographic and medical changes have resulted in an increased number of people who, although of full age, are incapable of protecting their interests by reason of an impairment or insufficiency of their personal faculties;

Noting also that social changes have resulted in an increased need for adequate legislation to ensure the protection of such people;

¹ When adopting this decision, the Representative of Ireland indicated that, in accordance with Article 10.2c of the Rules of Procedure for the meetings of the Ministers' Deputies, he reserved the right of his Government to comply or not with principles 5 and 6 of the Recommendation.

When adopting this decision, the Representative of France indicated that, in accordance with Article 10.2c of the Rules of Procedure for the meetings of the Ministers' Deputies, the following reservation should be made: France considers that the application of principle 23, para. 3 should be subject to a request by the person concerned.

Noting that legislative reforms on the protection, by representation or assistance, of incapable adults have been introduced or are under consideration in a number of member states and that these reforms have common features;

Recognising, however, that wide disparities in the legislation of member states in this area still exist;

Convinced of the importance in this context of respect for human rights and for the dignity of each person as a human being,

Recommends the governments of member states to take or reinforce, in their legislation and practice, all measures they consider necessary with a view to the implementation of the following principles:

PRINCIPLES

Part I – Scope of application

1. The following principles apply to the protection of adults who, by reason of an impairment or insufficiency of their personal faculties, are incapable of making, in an autonomous way, decisions concerning any or all of their personal or economic affairs, or understanding, expressing or acting upon such decisions, and who consequently cannot protect their interests.
2. The incapacity may be due to a mental disability, a disease or a similar reason.
3. The principles apply to measures of protection or other legal arrangements enabling such adults to benefit from representation or assistance in relation to those affairs.
4. In these principles "adult" means a person who is treated as being of full age under the applicable law on capacity in civil matters.
5. In these principles "intervention in the health field" means any act performed professionally on a person for reasons of health. It includes, in particular, interventions for the purposes of preventive care, diagnosis, treatment, rehabilitation or research.

Part II – Governing principles

Principle 1 – Respect for human rights

In relation to the protection of incapable adults the fundamental principle, underlying all the other principles, is respect for the dignity of each person as a human being. The laws, procedures and practices relating to the protection of incapable adults shall be based on respect for their human rights and fundamental freedoms, taking into account any qualifications on those rights contained in the relevant international legal instruments.

Principle 2 – Flexibility in legal response

1. The measures of protection and other legal arrangements available for the protection of the personal and economic interests of incapable adults should be sufficient, in scope or flexibility, to enable a suitable legal response to be made to different degrees of incapacity and various situations.
2. Appropriate measures of protection or other legal arrangements should be available in cases

of emergency.

3. The law should provide for simple and inexpensive measures of protection or other legal arrangements.
4. The range of measures of protection should include, in appropriate cases, those which do not restrict the legal capacity of the person concerned.
5. The range of measures of protection should include those which are limited to one specific act without requiring the appointment of a representative or a representative with continuing powers.
6. Consideration should be given to the inclusion of measures under which the appointed person acts jointly with the adult concerned, and of measures involving the appointment of more than one representative.
7. Consideration should be given to the need to provide for, and regulate, legal arrangements which a person who is still capable can take to provide for any subsequent incapacity.
8. Consideration should be given to the need to provide expressly that certain decisions, particularly those of a minor or routine nature relating to health or personal welfare, may be taken for an incapable adult by those deriving their powers from the law rather than from a judicial or administrative measure.

Principle 3 – Maximum preservation of capacity

1. The legislative framework should, so far as possible, recognise that different degrees of incapacity may exist and that incapacity may vary from time to time. Accordingly, a measure of protection should not result automatically in a complete removal of legal capacity. However, a restriction of legal capacity should be possible where it is shown to be necessary for the protection of the person concerned.
2. In particular, a measure of protection should not automatically deprive the person concerned of the right to vote, or to make a will, or to consent or refuse consent to any intervention in the health field, or to make other decisions of a personal character at any time when his or her capacity permits him or her to do so.
3. Consideration should be given to legal arrangements whereby, even when representation in a particular area is necessary, the adult may be permitted, with the representative's consent, to undertake specific acts or acts in a specific area.
4. Whenever possible the adult should be enabled to enter into legally effective transactions of an everyday nature.

Principle 4 – Publicity

The disadvantage of automatically giving publicity to measures of protection or similar legal arrangements should be weighed in the balance against any protection which might be afforded to the adult concerned or to third parties.

Principle 5 – Necessity and subsidiarity

1. No measure of protection should be established for an incapable adult unless the measure is necessary, taking into account the individual circumstances and the needs of the person concerned. A

measure of protection may be established, however, with the full and free consent of the person concerned.

2. In deciding whether a measure of protection is necessary, account should be taken of any less formal arrangements which might be made, and of any assistance which might be provided by family members or by others.

Principle 6 – Proportionality

1. Where a measure of protection is necessary it should be proportional to the degree of capacity of the person concerned and tailored to the individual circumstances and needs of the person concerned.
2. The measure of protection should interfere with the legal capacity, rights and freedoms of the person concerned to the minimum extent which is consistent with achieving the purpose of the intervention.

Principle 7 – Procedural fairness and efficiency

1. There should be fair and efficient procedures for the taking of measures for the protection of incapable adults.
2. There should be adequate procedural safeguards to protect the human rights of the persons concerned and to prevent possible abuses.

Principle 8 – Paramountcy of interests and welfare of the person concerned

1. In establishing or implementing a measure of protection for an incapable adult the interests and welfare of that person should be the paramount consideration.
2. This principle implies, in particular, that the choice of any person to represent or assist an incapable adult should be governed primarily by the suitability of that person to safeguard and promote the adult's interests and welfare.
3. This principle also implies that the property of the incapable adult should be managed and used for the benefit of the person concerned and to secure his or her welfare.

Principle 9 – Respect for wishes and feelings of the person concerned

1. In establishing or implementing a measure of protection for an incapable adult the past and present wishes and feelings of the adult should be ascertained so far as possible, and should be taken into account and given due respect.
2. This principle implies, in particular, that the wishes of the adult as to the choice of any person to represent or assist him or her should be taken into account and, as far as possible, given due respect.
3. It also implies that a person representing or assisting an incapable adult should give him or her adequate information, whenever this is possible and appropriate, in particular concerning any major decision affecting him or her, so that he or she may express a view.

Principle 10 – Consultation

In the establishment and implementation of a measure of protection there should be consultation, so far as reasonable and practicable, with those having a close interest in the welfare of the adult concerned, whether as representative, close family member or otherwise. It is for national law to determine which persons should be consulted and the effects of consultation or its absence.

Part III – Procedural principles

Principle 11 – Institution of proceedings

1. The list of those entitled to institute proceedings for the taking of measures for the protection of incapable adults should be sufficiently wide to ensure that measures of protection can be considered in all cases where they are necessary. It may, in particular, be necessary to provide for proceedings to be initiated by a public official or body, or by the court or other competent authority on its own motion.
2. The person concerned should be informed promptly in a language, or by other means, which he or she understands of the institution of proceedings which could affect his or her legal capacity, the exercise of his or her rights or his or her interests unless such information would be manifestly without meaning to the person concerned or would present a severe danger to the health of the person concerned.

Principle 12 – Investigation and assessment

1. There should be adequate procedures for the investigation and assessment of the adult's personal faculties.
2. No measure of protection which restricts the legal capacity of an incapable adult should be taken unless the person taking the measure has seen the adult or is personally satisfied as to the adult's condition and an up-to-date report from at least one suitably qualified expert has been submitted. The report should be in writing or recorded in writing.

Principle 13 – Right to be heard in person

The person concerned should have the right to be heard in person in any proceedings which could affect his or her legal capacity.

Principle 14 – Duration, review and appeal

1. Measures of protection should, whenever possible and appropriate, be of limited duration. Consideration should be given to the institution of periodical reviews.
2. Measures of protection should be reviewed on a change of circumstances and, in particular, on a change in the adult's condition. They should be terminated if the conditions for them are no longer fulfilled.
3. There should be adequate rights of appeal.

Principle 15 – Provisional measures in case of emergency

If a provisional measure is needed in a case of emergency, principles 11 to 14 should be

applicable as far as possible according to the circumstances.

Principle 16 – Adequate control

There should be adequate control of the operation of measures of protection and of the acts and decisions of representatives.

Principle 17 – Qualified persons

1. Steps should be taken with a view to providing an adequate number of suitably qualified persons for the representation and assistance of incapable adults.

2. Consideration should be given, in particular, to the establishment or support of associations or other bodies with the function of providing and training such people.

Part IV – The role of representatives

Principle 18 – Control of powers arising by operation of law

1. Consideration should be given to the need to ensure that any powers conferred on any person by operation of law, without the intervention of a judicial or administrative authority, to act or take decisions on behalf of an incapable adult are limited and their exercise controlled.

2. The conferment of any such powers should not deprive the adult of legal capacity.

3. Any such powers should be capable of being modified or terminated at any time by a measure of protection taken by a judicial or administrative authority.

4. Principles 8 to 10 apply to the exercise of such powers as they apply to the implementation of measures of protection.

Principle 19 – Limitation of powers of representatives

1. It is for national law to determine which juridical acts are of such a highly personal nature that they can not be done by a representative.

2. It is also for national law to determine whether decisions by a representative on certain serious matters should require the specific approval of a court or other body.

Principle 20 – Liability

1. Representatives should be liable, in accordance with national law, for any loss or damage caused by them to incapable adults while exercising their functions.

2. In particular, the laws on liability for wrongful acts, negligence or maltreatment should apply to representatives and others involved in the affairs of incapable adults.

Principle 21 – Remuneration and expenses

1. National law should address the questions of the remuneration and the reimbursement of expenses of those appointed to represent or assist incapable adults.

2. Distinctions may be made between those acting in a professional capacity and those acting in other capacities, and between the management of personal matters of the incapable adult and the management of his or her economic matters.

Part V – Interventions in the health field

Principle 22 – Consent

1. Where an adult, even if subject to a measure of protection, is in fact capable of giving free and informed consent to a given intervention in the health field, the intervention may only be carried out with his or her consent. The consent should be solicited by the person empowered to intervene.

2. Where an adult is not in fact capable of giving free and informed consent to a given intervention, the intervention may, nonetheless, be carried out provided that:

– it is for his or her direct benefit, and

– authorisation has been given by his or her representative or by an authority or a person or body provided for by law.

3. Consideration should be given to the designation by the law of appropriate authorities, persons or bodies for the purpose of authorising interventions of different types, when adults who are incapable of giving free and informed consent do not have a representative with appropriate powers. Consideration should also be given to the need to provide for the authorisation of a court or other competent body in the case of certain serious types of intervention.

4. Consideration should be given to the establishment of mechanisms for the resolution of any conflicts between persons or bodies authorised to consent or refuse consent to interventions in the health field in relation to adults who are incapable of giving consent.

Principle 23 – Consent (alternative rules)

If the government of a member state does not apply the rules contained in paragraphs 1 and 2 of Principle 22, the following rules should be applicable:

Where an adult is subject to a measure of protection under which a given intervention in the health field can be carried out only with the authorisation of a body or a person provided for by law, the consent of the adult should nonetheless be sought if he or she has the capacity to give it.

2. Where, according to the law, an adult is not in a position to give free and informed consent to an intervention in the health field, the intervention may nonetheless be carried out if:

– it is for his or her direct benefit, and

– authorisation has been given by his or her representative or by an authority or a person or body provided for by law.

3. The law should provide for remedies allowing the person concerned to be heard by an independent official body before any important medical intervention is carried out.

Principle 24 – Exceptional cases

1. Special rules may be provided by national law, in accordance with relevant international instruments, in relation to interventions which, because of their special nature, require the provision of additional protection for the person concerned.
2. Such rules may involve a limited derogation from the criterion of direct benefit provided that the additional protection is such as to minimise the possibility of any abuse or irregularity.

Principle 25 – Protection of adults with a mental disorder

Subject to protective conditions prescribed by law, including supervisory, control and appeal procedures, an adult 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.

*Principle 26 – Permissibility of intervention
in emergency situation*

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

*Principle 27 – Applicability of certain principles
applying to measures of protection*

1. Principles 8 to 10 apply to any intervention in the health field concerning an incapable adult as they apply to measures of protection.
2. In particular, and in accordance with principle 9, 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 should be taken into account.

Principle 28 – Permissibility of special rules on certain matters

Special rules may be provided by national law, in accordance with relevant international instruments, in relation to interventions which 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 freedom of others.

COUNCIL OF EUROPE
COMMITTEE OF MINISTERS

RECOMMENDATION NO. REC(2001)5
of the Committee of Ministers to member States
on the management of organ transplant
waiting lists and waiting times

*(Adopted by the Committee of Ministers on 7 March 2001
at the 744th 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 public health field;

Bearing in mind Article 11 of the European Social Charter on the right to the protection of health;

Recalling that Article 3 of the Convention on Human Rights and Biomedicine requires that Contracting Parties provide “equitable access to health care of appropriate quality”;

Taking into account Resolution (78) 29 on the harmonisation of legislations of member states relating to removal, grafting and transplantation of human substances, the final text of the 3rd Conference of European Health Ministers (Paris, 16-17 November 1987) and Articles 19 and 20 of the Convention on Human Rights and Biomedicine;

Having regard to Recommendation No. R (99) 21 on criteria for the management of waiting lists and waiting times in health care;

Considering that the collection of medical data raises special concerns with regard to data protection, especially where the data are to be collected or used for purposes other than immediate health benefits to the individual;

Having regard to the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (ETS No. 108) and to Recommendation No. R (97) 5 on the protection of medical data;

Aware that waiting lists and waiting times may appear when the demand for organs exceeds availability;

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

Considering that organ transplantation is severely restricted by the availability of organs for transplantation and that a properly managed waiting list is essential to ensure equality of access to organ transplantation,

Recommends that governments of member states conform to the following rules:

1. Member states should guarantee that a system exists to provide equitable access to transplantation services for patients which ensures that organs and tissues are allocated in conformity with transparent and duly justifiable rules according to medical criteria.
2. There should be a mechanism, enforceable by law or regulations, for establishing and managing an officially recognised regional, national or international waiting list for each of the main types of organ transplantation.
3. Cadaveric organs should only be allocated to patients registered on the official waiting list. Patients receiving organs from a living donor should also be registered if there is any possibility that they might need an organ from a deceased person.
4. Patients may only be registered on one official transplant waiting list be it regional, national or international. Individual transplant units may have their own local waiting list but only as a subset of the official waiting list.
5. Criteria for registration on the waiting list should be established by a process of consensus based on medical criteria. Registration should include the data essential to identify patients individually, their location and the criteria for their inclusion on the waiting list. The criteria for inclusion should ensure there is no discrimination on the grounds of race, religion, disability or any other non-medical factor. Priority on the waiting list such as “urgent” or “very-urgent” categories should be based solely on medical factors relating to the severity of risk for the individual patient. If patients are registered who do not normally reside in the area covered by the official waiting list, then those managing the waiting list should make all reasonable efforts to check with other transplant organisations that the patient is only on one waiting list.
6. Only transplant units recognised by the official waiting list should be able to register patients in their charge on the waiting list and should do so directly with the organisation managing the official waiting list. Patients should be informed that they are on the waiting list and notified if for any reason they are subsequently suspended or removed.
7. There should be a nationally recognised organisation responsible for the management of the waiting list and the allocation of organs. Organs should be allocated on behalf of the transplant units on the basis of objective rules. The allocation rules should be agreed by all the relevant transplant organisations within the geographical area covered by the waiting list.
8. The waiting list should be regularly updated in conjunction with the transplant units. In particular, the situation of suspended patients or those who have been on the list for a long time should be reviewed to make sure they still meet the registration criteria.
9. Allocation rules should ensure that, as far as possible, no group of patients waits longer than another group waiting for the same type of organ. Waiting times should be analysed regularly to ensure that no patient group is disadvantaged. The allocation rules should be changed when necessary to ensure similar waiting times for all groups of similar patients on the waiting list.
10. The organisation responsible for managing the waiting list should provide information, on at least an annual basis, for health professionals and the public. Information should include:
 - i. the criteria for registration, the allocation rules and any changes thereto;
 - ii. the numbers and flows of patients registered;

iii. the waiting times on the various transplant lists including:

- a.* the actual waiting time for patients who have been transplanted;
- b.* the time patients still on the list have waited; and
- c.* the average time patients in any group on any organ transplant list can expect to wait.

11. All organisations managing transplant waiting lists should exchange information with comparable organisations to help improve practice. Research should be promoted to analyse and improve the quality of organ transplant waiting lists and waiting time management.

12. Member states should guarantee that a system is put in place for implementing, monitoring and supervising the rules set out in this recommendation.

COUNCIL OF EUROPE
COMMITTEE OF MINISTERS

RECOMMENDATION NO. REC(2002)9

of the Committee of Ministers to member States

on the protection of personal data collected and processed for insurance purposes

*(Adopted by the Committee of Ministers on 18 September 2002
at the 808th meeting of the Ministers' Deputies)*

Preamble

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

1. Considering that the aim of the Council of Europe is to achieve greater unity among its members;
2. Recalling the general principles relating to data protection of the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (ETS No. 108), and in particular Article 6, which states that personal data categorised as sensitive may not be processed unless domestic law provides appropriate safeguards;
3. Aware of the fact that automated processing of personal data for insurance purposes is increasingly widespread, not only for the preparation, conclusion, implementation and termination of insurance, but also to facilitate rational and economic management of insurance and to fight against fraud;
4. Aware of the fact that insurance is provided by various economic entities, in particular by insurance companies;
5. Convinced of the importance that the quality, integrity and availability of personal data have for insured persons;
6. Noting that virtually the entire population of the member states is affected by one or more insurance contract and that, for this reason, insurance professionals are in possession of a large volume of personal data, some of which are sensitive;
7. Convinced that it is desirable to regulate the collection and processing of personal data for insurance purposes, to guarantee their confidential character and data security and to ensure that the use to which they are put respects fundamental human rights and freedoms, notably the right to privacy;
8. Taking into account the fact that the mobility of individuals and the globalisation of markets and commercial activities necessitate a transborder exchange of information in the insurance sector also and require equivalent data protection in all the member states of the Council of Europe,

Recommends that governments of member states:

1. take measures to ensure that the principles contained in the appendix to this recommendation are reflected in their law and practice;
2. ensure wide circulation of the principles contained in the appendix to this recommendation among persons, public authorities and public or private bodies that collect and process personal data for insurance purposes, as well as to bodies with competence in data protection;
3. promote the acceptance and implementation of the principles contained in the appendix to this recommendation, notably by adopting legal provisions or encouraging the drafting of a code of ethics.

Appendix to Recommendation Rec(2002)9

1. Definitions

For the purposes of this recommendation:

- a.* "Personal data" covers any information relating to an identified or identifiable individual ("data subject"). An individual should not be regarded as "identifiable" if identification requires an unreasonable amount of time and manpower.
- b.* "Sensitive data" means personal data revealing racial origin, political opinions, religious or other beliefs, as well as personal data concerning health and sexual life. Data concerning criminal proceedings and convictions and other data defined as sensitive by domestic law are also considered to be sensitive data.
- c.* "For insurance purposes" comprises any operation involving the collection and processing of personal data relating to cover for a risk, in particular under a policy or an insurance contract.
- d.* "Processing" means any operation or set of operations carried out partly or completely with the help of automated processes and applied to personal data, such as recording, conservation or alteration, extraction, consultation, utilisation, communication, matching or interconnection and erasure or destruction.
- e.* "Communication" refers to the act of making personal data accessible to third parties, regardless of the means or media used.
- f.* "Controller" means the natural or legal person, public authority, agency, or any other body which, alone, or in collaboration with others, determines the purposes of and means used in the collection and processing of personal data.
- g.* "Processor" means a natural or legal person, public authority, agency or any other body which processes personal data on behalf of the controller.

2. Scope

2.1. This Recommendation applies to personal data collected and processed for insurance purposes. It does not apply to the collection and processing of personal data used for social security purposes.

2.2. Member states are encouraged to extend the application of this recommendation to non-automated processing of personal data for insurance purposes.

2.3. No personal data should be processed in a non-automated manner in order to avoid applying the principles of this Recommendation.

2.4. Member states may extend the application of the principles set out in this Recommendation to the collection and processing of data relating to groups of persons, associations, foundations, companies, corporations and any other bodies consisting directly or indirectly of individuals, whether or not such bodies possess legal personality.

2.5. Member states may extend the principles set out in this recommendation to the protection of personal data used for social security purposes.

3. Respect for privacy

3.1. Respect for fundamental rights and freedoms, particularly the right to private life, must be safeguarded when personal data are collected and processed for insurance purposes.

3.2. Persons who, in the course of an insurance activity, have access to personal data must, in accordance with domestic law and practice, be subject to rules of confidentiality. Moreover, the collection and processing of medical data must only be undertaken by health professionals or in conformity either with confidentiality rules comparable to those applicable to health-care professionals or with equally effective safeguards provided for in domestic law.

4. Collection and processing of personal data for insurance purposes

Essential conditions for the collection and processing of personal data

4.1. The collection and processing (including communication) of personal data should be carried out fairly and lawfully and for specified and lawful purposes,

Personal data should be

- adequate, relevant and not excessive in relation to the purposes for which they are collected or for which they are to be further processed;
- accurate and, if necessary, kept up to date.

Source of personal data

4.2. Personal data collected and processed for insurance purposes should, in principle, be collected from the data subject or his/her legal representative.

Lawfulness

4.3. Personal data may be collected and processed for insurance purposes:

- a. if provided for by law;
- b. for the performance of an insurance contract to which the data subject is party, as well as for the preparation of such a contract at the request of the data subject;
- c. if the data subject or his/her legal representative or an authority or any other person or body provided for by law has given his/her consent as provided for in Chapter 6; or

d. if the data are necessary in the pursuit of the controller's legitimate interests, provided that these are not overridden by the interests of the data subject.

Purpose

4.4. Subject to the provisions of Principles 4.6 to 4.8, 8.1 and 13.1, personal data may only be collected and processed for the purposes of:

- a.* preparing and issuing insurance;
- b.* collecting premiums and submitting other bills;
- c.* settling claims or paying other benefits;
- d.* reinsurance;
- e.* co-insurance;
- f.* preventing, detecting and/or prosecuting insurance fraud;
- g.* establishing, exercising or defending a legal claim;
- h.* meeting another specific legal or contractual obligation;
- i.* prospecting new insurance markets;
- j.* internal management;
- k.* actuarial activities.

These data may not be processed further for purposes incompatible with the original purpose of the collection.

Unborn children

4.5. Personal data concerning unborn children should enjoy a protection comparable to the protection of the personal data of a minor.

Unless otherwise provided for by domestic law, the holder of the parental responsibilities may act as the person legally entitled to act for the unborn child, the latter being a data subject.

Sensitive data

4.6. The collection and processing of sensitive data should be prohibited, unless, for one of the purposes set out in Principles 4.4, 4.8, 8.1 and 13.1:

- a.* the data subject or his/her legal representative or an authority or any other person or body appointed by law has explicitly given his/her consent as provided for in Chapter 6; or
- b.* it is permitted by law and
 - i.* subject to appropriate safeguards, processing is necessary for the purpose of complying with the controller's other legal or contractual obligations; or
 - ii.* processing is necessary for establishing, exercising or defending a legal claim; or
 - iii.* the processing is necessary to protect the vital interests of the data subject or another person where the data subject is physically or legally incapable of giving his/her consent.
- c.* collection and processing are permitted, subject to appropriate safeguards, on grounds of an important public interest, and provided for by law or by virtue of a decision of an authority within the

meaning of Principle 15.1.

Criminal data

4.7. By way of derogation from Principle 4.6, the collection and processing of data concerning criminal proceedings and convictions may be carried out for insurance purposes only if suitable specific safeguards are provided for by domestic law, and if the data are necessary to combat insurance fraud, for the granting of insurance or the payment of claims or any other insurance benefit.

Direct marketing

4.8. Provided that the data subject has been informed and has not objected, the controller may use, for the purposes of marketing and promoting its range of services, the data collected and recorded for insurance purposes. If, however, processing concerns sensitive data, the explicit consent of the data subject is required provided that this is not contrary to domestic law.

The data subject should be informed of the fact that if he/she refuses to consent to or objects to his/her data being used for marketing purposes this will not prejudice the decision to provide him/her with insurance cover or to allow him/her to continue benefiting from insurance cover already issued.

5. Information for the data subject

5.1. Data subjects should be informed of the following:

- a. the purpose or purposes for which data are or will be processed;
- b. the identity of the controller;
- c. any other information which is necessary to ensure the fairness of processing, such as:
 - the categories of data collected or to be collected;
 - the categories of external persons or bodies to whom, and the purposes for which, the data may be communicated;
 - the possibility, if any, for data subjects to refuse their consent or to withdraw it and the consequences of such withdrawal;
 - the conditions under which the rights of access and of rectification may be exercised;
 - the individuals or bodies from whom the data are or will be collected;
 - the obligatory or optional character of the reply to the questions which are the object of the collection and the consequences of a defective response with regard to the person.

5.2. Where the data are collected from the data subject, the controller should give data subjects the information listed in Principle 5.1 above at the latest at the time of collection, except where the data subject has already been informed.

5.3. Where personal data are not collected from data subjects, the controller should give the data subjects the information listed in Principle 5.1, as soon as the data are recorded or, if it is planned to communicate the data to a third party, at the latest when the data are first communicated.

The obligation to inform the data subject does not apply if:

- a.* the data subject has already been informed;
- b.* it proves impossible to provide the information or if it would involve disproportionate effort;
- c.* the processing or communication of the data for insurance purposes is expressly provided for by domestic law.

In the cases set out in *b* and *c*, appropriate safeguards must be provided for.

5.4. Information for the data subject must be appropriate and adapted to the circumstances.

5.5. If data subjects have no legal capacity and are unable to make their own decisions freely, and if domestic law does not permit them to act on their own behalf, the information must be provided to the persons legally empowered to act on behalf of those data subjects.

5.6. The provision of information to data subjects may be restricted if this is provided for by law and is necessary to prevent, investigate or prosecute a criminal offence or to guarantee the rights and liberties of others.

6. Consent

6.1. When data subjects are asked to give their consent, it must be freely given, specific and informed. Moreover, it must be unambiguous or, in the case of sensitive data, explicit.

However, there may be circumstances in which domestic law does not permit consent to be considered as a sufficient basis for lawfulness of collection or processing.

6.2. When personal data concern persons with no legal capacity and when domestic law does not permit the data subject to act on his/her own behalf, consent is required of his/her legal representative or an authority or any other person or body appointed by law.

6.3. If, in accordance with Principle 5.5 above, data subjects with no legal capacity have been informed of the intention to collect and process data concerning them, their wishes should be taken into consideration, provided that this is not contrary to domestic law.

7. Collection and processing by processors

7.1. In accordance with the provisions of domestic law, controllers may contract out the collection and processing of personal data for a specific purpose, in so far as they are authorised to collect and process these data and the processor undertakes to act solely on instruction from the controller and to respect the provisions of domestic law which implement Chapter 11 of the Appendix to this Recommendation.

7.2. Controllers should choose processors who offer adequate safeguards regarding the technical and organisational aspects of the processing to be carried out. They must ensure that these safeguards are observed and that, in particular, the processing is in accordance with their instructions.

7.3. The collection and processing of personal data by processors should be governed by a contract or legal instrument binding the processor to the controller and specifying that the processor will only act within the terms of reference issued by the controller and the provisions of domestic law concerning the obligations of processors.

8. Communication of data for other purposes

8.1. Personal data may only be communicated for purposes other than those laid down in Principle 4.4 if:

- a.* this is provided for in domestic law and constitutes a necessary measure in a democratic society for preventing, investigating and prosecuting a criminal offence or for guaranteeing another important public interest, or
- b.* data subjects or their legal representatives or an authority or any other person or body appointed by law have given their consent as provided for in Chapter 6; or
- c.* communication is for purposes of direct marketing, provided that the data subject has been informed and has no objection. However, the data subject's explicit consent should be required if the data to be communicated are of a sensitive nature as provided for in Chapter 6; or
- d.* the data are necessary in the pursuit of the controller's legitimate interests, provided that these are not overridden by the interests of the data subject. However the data subject's explicit consent should be required if the data to be communicated are of a sensitive nature as provided for in Chapter 6.

9. Individual automated decisions

9.1. Insurance decisions which have a legal effect on data subjects or affect them significantly should not be taken solely on the basis of automated data processing intended to evaluate certain personal aspects relating to them according to pre-established criteria or statistical results.

9.2. Such decisions may nevertheless be taken if they satisfy a request made by the data subjects with a view to the conclusion or execution of an insurance contract, or if the data subjects are permitted to put their point of view in order to guarantee protection of their legitimate interests. Such decisions may also be taken if they are authorised by a law which safeguards the legitimate interests of the data subject.

10. Rights of access and rectification

10.1. All data subjects should, on request, be able to obtain confirmation as to whether data relating to them are being processed or not and, in an intelligible form, to obtain all of the data concerning them, as well as information at least as to the purposes of the processing operation, the categories of data concerned by the processing, the recipients or categories of recipients to whom the data are communicated, and the source of the data. They should also be informed, on request, of the logic underlying the automated processing of data concerning them, at least in the case of individual automated decisions.

10.2. The rights of data subjects to obtain data concerning them should not be restricted unless this is provided for by law and is necessary:

- a.* for preventing, investigating or prosecuting a criminal offence;
- b.* to guarantee the rights and liberties of data subjects or others.

In that case, the right of access may be restricted only for as long as the reason for the restriction remains.

10.3. Data subjects should be entitled to have their data rectified, blocked or erased as appropriate where they have been collected or processed in disregard of the provisions of domestic law implementing the principles of this Recommendation and, in particular, where they are found to be inaccurate, irrelevant or excessive.

10.4. Reasons for restriction of the rights of access, rectification, erasure and blocking should be given in writing. Where the data subject's rights of access, rectification, erasure and blocking of data are restricted, the data subject should be informed of his/her right to ask the competent authority to check the lawfulness of data processing.

10.5. Third parties to whom data have been communicated should be informed of the rectification, erasure or blocking carried out unless this is manifestly unreasonable or unfeasible.

10.6. Controllers should communicate at reasonable intervals and without excessive delay or expense to persons who exercise the right of access to personal data concerning them, as well as any information referred to in Principle 10.1 for which access is requested.

11. Security of data

11.1. Appropriate technical and organisational measures should be taken to protect personal data – processed in accordance with the provisions of domestic law giving effect to the principles of this Recommendation – against accidental or unlawful destruction, accidental loss, as well as against unauthorised access, alteration or communication or any other form of unlawful processing.

Such measures should ensure an appropriate level of security taking account, on the one hand, of the technical state of the art and, on the other hand, of the sensitive nature of data collected and processed for insurance purposes and the evaluation of potential risks. These measures should be reviewed periodically.

11.2. In order to ensure, in particular, the confidentiality, integrity and availability of processed data, as well as the protection of data subjects, the controller should take appropriate measures:

- a.* to prevent any unauthorised person from having access to installations used for processing personal data (control at the entrance to installations);
- b.* to prevent data media from being read, copied, altered or removed by unauthorised persons (control of data media);
- c.* to prevent the unauthorised entry of data into the information system, and any unauthorised consultation, modification or deletion of memorised personal data (memory control);
- d.* to prevent automated data processing systems from being used by unauthorised persons by means of data transmission equipment (control of utilisation);
- e.* with a view to, on the one hand, selective access to data and, on the other hand, the security of the personal data, to ensure that the processing as a general rule is so designed as to enable the separation of:
 - identifiers and data relating to the identity of persons,
 - administrative data,
 - sensitive data (access control);

- f. to guarantee the possibility of checking and ascertaining to which persons or bodies personal data can be communicated by data transmission equipment (control of communication);
- g. to guarantee that it is possible to check and establish, *a posteriori*, who has had access to the system and what personal data have been introduced into the information system, when and by whom (control of data introduction);
- h. to prevent the unauthorised reading, copying, alteration or deletion of personal data during the communication of personal data and the transport of data media (control of transport);
- i. to safeguard data by making security copies (availability control).

11.3. Controllers should, in accordance with domestic law, draw up appropriate internal regulations which respect the related principles in this Recommendation.

11.4. Where necessary, controllers should appoint an independent person responsible for information systems security and data protection and competent for giving advice on these issues.

12. Transborder data flows

12.1. The principles of this Recommendation are applicable to the transborder flow of personal data collected and processed for insurance purposes.

12.2. The transborder flow of personal data to a state which has ratified the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (ETS No. 108), and which has legislation which provides at least equivalent data protection, should not be subjected to special conditions concerning the protection of privacy.

12.3. No restriction should be placed on the transborder flow of data to a state which has not ratified the Convention but which ensures an adequate level of protection.

12.4. Unless otherwise provided for by domestic law, the transborder flow of data to a state which does not ensure an adequate level of protection should not as a rule occur unless:

- a. the data subject has given his/her consent as provided for in Chapter 6, or
- b. measures, including those of a contractual nature, necessary to respect the provisions of domestic law giving effect to the principles of the Convention and this Recommendation, have been taken, and the data subject has the possibility to object to the transfer.

13. Conservation of data

13.1. Where personal data are no longer necessary for the accomplishment of the purposes for which they were collected and processed by the controller, they should be deleted. This principle also applies where a decision is taken to refuse insurance coverage. If they must nevertheless be conserved for purposes of scientific research or statistics, or other purposes provided for by law, they should be conserved separately and be accessible only for these purposes subject to appropriate safeguards.

13.2. In determining the period of conservation of data, account should be taken in particular of the need to retain data for the period necessary for the purpose of defending legal actions or for furnishing proof of transactions or for justifying a decision to refuse insurance coverage.

14. Remedies

Domestic law should provide appropriate sanctions and remedies in cases of breach of the provisions of domestic law giving effect to the principles laid down in this Recommendation.

15. Ensuring respect for the principles

15.1. Member states should give one or more authorities responsibility for ensuring in complete independence the application of the provisions of domestic law giving effect to the principles laid down in this Recommendation.

15.2. The following information should be publicised appropriately and be readily available to all:

- a.* the name and address of the controller and of his representative, if any;
- b.* the purpose or purposes of the processing;
- c.* the category or categories of data subject and of the data;
- d.* the recipient or categories of recipient to whom the data might be disclosed;
- e.* any proposed transfers of data to third countries.

COUNCIL OF EUROPE
COMMITTEE OF MINISTERS

RECOMMENDATION NO. REC(2003)10
of the Committee of Ministers to member States
on xenotransplantation

*(Adopted by the Committee of Ministers on 19 June 2003
at the 844th meeting of the Ministers' Deputies)*

Preamble

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 a greater unity between its members;

Having regard to the European Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine and its Additional Protocol Concerning Transplantation of Organs and Tissues of Human Origin;

Having regard to the European Convention for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes;

Having regard to the Resolution of the Committee of Ministers (78) 29 on the harmonisation of legislation of member states relating to removal, grafting and transplantation of human substances, the Final Text of the 3rd Conference of European Health Ministers (Paris, 16-17 November 1987) and the Recommendation R (97) 15 of the Committee of Ministers to member states on xenotransplantation;

Bearing in mind Recommendation 1399 (1999) of the Parliamentary Assembly on xenotransplantation;

Bearing in mind recent reports from the OECD, the WHO and other national and international organisations;

Taking into account the shortage of organs and tissues of human origin available for transplantation;

Considering that xenotransplantation might be one of the possible therapeutic responses to this shortage;

Noting that xenotransplantation remains largely an experimental activity and that research is essential for the achievement of progress in this field;

Aware of the risks of rejection and illness xenotransplantation may cause in the recipient patient;

Mindful of the considerable risks which might arise from xenotransplantation in the field of public health and the transmission of diseases;

Considering that it is the responsibility of each member state to adopt adequate measures in order to address them and conscious that in some countries no appropriate regulations exist;

Considering that public health concerns require common provisions applicable in all the member states of the Council of Europe in which xenotransplantation is envisaged;

Considering that worldwide cooperation between states in this field is necessary;

Considering that no clinical xenotransplantation research should take place unless sufficient efficacy and safety is demonstrated through pre-clinical research;

Conscious that the need for such a demonstration will considerably limit the number of xenotransplantations in the coming years, thus allowing for an appropriate risk assessment;

Considering that xenotransplantation of cells and tissues is already being carried out in a number of states and that stringent regulations are thus urgently required;

Mindful of the social, ethical, cultural, legal and psychological problems which might be associated with xenotransplantation;

Mindful of the ethical and welfare issues associated with the use of animals for xenotransplantation and the associated research;

Noting the public concern over the issues related to xenotransplantation and stressing the importance of undertaking a public debate on this subject,

A. Recommends that the governments of member states:

- take the necessary measures to put their legislation and practice in the field of xenotransplantation in conformity with the following principles and guidelines with a view to minimising the risk of transmission of known or unknown diseases and infections to populations;
- co-operate in the setting-up of world-wide surveillance procedures and agreements;
- ensure a wide dissemination of this recommendation, in particular among all persons, organisations and bodies, public or private, responsible for organising and carrying out xenotransplantation;
- take steps to make the provisions of this recommendation subject to public debate.

B. Decides that this recommendation will be re-examined at appropriate intervals and not later than in three years' time.

C. Instructs the Secretary General to bring the contents of this recommendation to the attention of the non-member states and international organisations which have participated in its preparation and to invite them to participate in the setting-up of an international surveillance network.

GUIDELINES

Chapter I - Object, scope and definitions

Article 1 - Object of the recommendation

This recommendation aims

- to protect, in both the short and long term, public health, patients, their close personal contacts and the professional staff involved in xenotransplantation, and
- to provide adequate protection for the animals used in xenotransplantation.

Article 2 – Scope of the recommendation

This recommendation covers all xenotransplantation activities involving human beings as recipients.

Article 3 - Definition

For the purpose of this recommendation, xenotransplantation is defined as any procedure that involves the transplantation or infusion into a human recipient of:

- live animal cells, tissues or organs, or
- human body fluids, cells, tissues or organs that have had *ex vivo* contact with live animal cells, tissues or organs.

Chapter II - General provisions

Article 4 – Xenotransplantation - the setting

No xenotransplantation should be carried out in a member state that does not provide regulation for xenotransplantation activities in conformity with the provisions of this recommendation.

Article 5 – Xenotransplantation authorisation

No xenotransplantation activity should be carried out in a member state unless authorisation is given by a body officially recognised as competent for this purpose, in accordance with the provisions contained in the following two paragraphs:

1. Authorisation for clinical xenotransplantation research should only be given if:
 - a. pre-clinical research has demonstrated, in accordance with internationally accepted scientific standards, that:
 - i. in the light of current scientific knowledge it is highly probable that there is no risk, in particular of infection, for public health;
 - ii. the potential level of efficacy and safety for the patient may justify the intervention having regard to the risks incurred;
 - b. all substantive and procedural conditions generally applicable to clinical research are fulfilled.

2. Xenotransplantation should not be authorised other than in clinical research unless, on the basis of clinical data:

i. there is adequate evidence, in accordance with internationally accepted scientific standards, that no risks, in particular of infection, to the general population exist, and

ii. the therapeutic benefit of the xenotransplantation has been established.

Article 6 – Xenotransplantation teams and centres

No xenotransplantation should be carried out unless it is undertaken by an accredited team in an authorised centre.

a. The teams carrying out the xenotransplantation should be appropriately qualified and comprise all the necessary scientific and medical expertise.

b. The centres should have received an authorisation by the competent bodies prior to beginning the xenotransplantation.

Chapter III – Protection of Public Health

Article 7 – Public Health protection plan

Member states should have a plan in place to address any events, in particular of infection, possibly related to a xenotransplantation which could compromise public health.

In particular, public authorities should take appropriate measures, in conformity with the principles of necessity and proportionality, to respond to events of transmissible or previously unknown illness related to xenotransplantation. These measures, if exceptional circumstances so require, might include isolation.

Article 8 – Collection and storage of biological samples and information

Information and biological samples concerning the source animals used in xenotransplantation and the recipients should be collected and stored in order to ensure traceability and long-term monitoring.

Article 9 - Follow-up

1. All protocols for clinical research should be accompanied by a plan to ensure the traceability and monitoring of the recipients, their close personal contacts and the professional staff involved in xenotransplantation in order to detect and deal with any adverse events, in particular of infection, possibly related to xenotransplantation.

The plan should include communication without delay to the competent body at national level of any such events.

2. Any xenotransplantation other than in clinical research should be accompanied by a plan to:

- ensure the traceability of the recipient as well as, depending on the circumstances, of other persons mentioned in paragraph 1;

- monitor, wherever necessary, the persons mentioned in paragraph 1.

The plan should include communication without delay to national public health authorities of any events, in particular of infection, possibly related to xenotransplantation and which could be of relevance to public health.

Article 10 – Precautions relating to the transmission of disease

All appropriate measures, in accordance with internationally recognised criteria, should be taken to prevent the risk of transmission of infectious agents from source animals.

Only animals bred specifically for xenotransplantation should be used. An appropriate Quality Assurance system encompassing all the stages from the production of the source animals to the final collection of the xenotransplants should be set up.

Article 11 - Prohibition relating to the use of non-human primates

1. Non-human primates should not be used as source animals for xenotransplantation.
2. Exceptionally, authorisation for the xenotransplantation of cell lines obtained from non-human primates may be given if :
 - the conditions under Article 5 are fulfilled, and
 - specific protective measures for these animals have been addressed. This implies that Great Apes should not be used as source animals in xenotransplantation.

Chapter IV - Protection of patients and close personal contacts

Article 12 – Conditions for patient participation

No xenotransplantation should be carried out unless the following specific conditions are fulfilled:

- i. There is no other appropriate therapeutic method of comparable effectiveness available for the patient.
- ii. The data resulting from pre-clinical research suggest or, where appropriate, the data resulting from prior clinical research indicate a clear therapeutic benefit for the xenotransplantation patient. In particular these data should:
 - have demonstrated an adequate function of the xenotransplant in relevant models for an appropriate period of time through a clinically applicable methodology,
 - provide sufficient reasons to believe that rejection can be overcome and that the xenotransplant can function adequately in humans.
- iii. The risks which may be incurred by the patient are not disproportionate to the potential therapeutic benefit of the procedure.

In particular, the evaluation through pre-clinical research of the risks for adverse events and transmission of infectious agents to the recipient, as based on international standards for laboratory results and diagnostic assays, should have demonstrated sufficient safety.

Article 13 – Information to be given to patients

1. Patients participating in a xenotransplantation should be adequately informed in a comprehensible manner of the nature, objectives, possible benefits, potential risks and consequences of the procedure, as well as of any constraints that may be linked to it.

2. In particular patients should also be made aware of the constraints of monitoring and precautionary measures that may become necessary subsequent to xenotransplantation. Such measures will, according to the principles of necessity and proportionality, be adapted to the circumstances and adjusted in accordance with the assessment, based on current scientific and medical knowledge, of the risks generated by each of the procedures involved, and may in particular include:

- a.* the collection of personal data and inclusion in a register;
- b.* the provision by the medical team, in accordance with Article 14, of information concerning the risks of infection and the constraints associated thereto;
- c.* long-term medical monitoring including repeated biological samples being taken and archived;
- d.* reporting any significant unexplained symptoms or illness that may arise after the xenotransplantation;
- e.* maintaining contact with the medical team;
- f.* taking precautions with respect to sexual activity;
- g.* the need for the patient to agree that information is provided by a medical team to any future close personal contacts, in accordance with Article 14, concerning the risks of infection and the constraints associated thereto;
- h.* the other constraints which might be applicable if circumstances so require, in particular the possibility of isolation which may become necessary in the event of a contagious or previously unknown illness occurring.

3. Patients should be informed that, in accordance with Article 21, constraints mentioned hereinabove may be imposed if the person concerned refuses to comply with them.

Article 14 – Information to be given to close personal contacts of the patient

To protect close personal contacts and warn of the possible risks they might pose to the general public, the patient's close personal contacts should, with his or her consent, be informed by the medical team of the patient's envisaged participation in a xenotransplantation, of the risks of infection and of the consequences for them of such participation, and in particular, of the constraints which may be applicable.

The patient should also ensure that such information is provided to any future close personal contacts.

Article 15 – Information to be given to the professional staff involved in xenotransplantation

Professional staff involved in xenotransplantation should be fully aware of the risks of infection as well as the possible consequences and constraints which may derive from their participation in

xenotransplantation.

Article 16 – Consent to xenotransplantation

1. No xenotransplantation should be carried out without:
 - i. the documented, specific, free and informed consent of the patient to the procedure and any necessary specific constraints; and
 - ii. the provision by the patient to the medical team of the necessary information concerning his or her current close personal contacts and the acceptance by the patient that his or her current and future close personal contacts be given information in accordance with Article 14.
2. Prior to xenotransplantation, the consent to carry out the intervention may be freely withdrawn at any time.

Article 17 - Counselling and support

The patients and their close personal contacts should be given proper information and have access to counselling and support by experts outside the team both before and after the xenotransplantation. This informing and counselling process should include the biomedical, ethical, psychological and social aspects of xenotransplantation.

Article 18 – Right to medical care

A refusal to participate, or a withdrawal of consent prior to the xenotransplantation, should not prejudice the patient's right to receive all other appropriate medical care in due course. The patient's consent to participate in a xenotransplantation should not prejudice his or her right to benefit from an allotransplant that becomes available while awaiting xenotransplantation, if medically indicated.

Article 19 – Patients not able to consent

1. Where xenotransplantation has been authorised for use other than in clinical research according to Article 5 paragraph 2, it may be carried out on a person not able to consent only if the following conditions are fulfilled:
 - there is no therapeutic alternative of comparable effectiveness available to the patient,
 - taking into account the constraints and conditions to which the person will or may be subjected according to Articles 13 and 14, the intervention is expected to result in a direct and important benefit for the patient, and
 - the representative or an authority or a person or body provided for by law, after receiving the information referred to in Article 13, has authorised both the intervention and the provision of the necessary information to the present and future close personal contacts of the patient.
2. Patients unable to consent should not undergo clinical xenotransplantation research as referred to in Article 5, paragraph 1.

Exceptionally, a patient unable to consent may participate in a clinical xenotransplantation research intervention if the following specific conditions are fulfilled:

- there is adequate indication, on the basis of prior clinical research, that the xenotransplantation might be lifesaving,
- there is no alternative means of saving the life of the patient,
- taking into account the constraints and conditions to which the person will or may be subjected according to Articles 13 and 14, the intervention is expected to result in a direct and important benefit for the patient, and
- the representative or an authority or a person or body provided for by law, after receiving the information referred to in Article 13, has authorised both the patient's participation in the clinical xenotransplantation research and the provision of the necessary information to the present and future close personal contacts of the patient.

Article 20 - Confidentiality

All personal data relating to the recipient person and, where such data exist, their close personal contacts should be considered to be confidential.

Without prejudice to the provision of Article 8, such data should be collected, processed and communicated according to the rules relating to professional confidentiality and personal data protection.

Article 21 – Compulsory constraints

If, after the xenotransplantation has been carried out, the recipient or his or her close personal contacts refuse to comply with the constraints associated with xenotransplantation, public authorities should intervene and take appropriate measures, where public health protection so requires, in conformity with principles of necessity and proportionality.

Depending on the circumstances and in accordance with the procedures provided for by national law, such measures might include registration, compulsory medical follow-up and sampling.

Chapter V - Protection of animals

Article 22 – Compliance with animal protection regulations

All animal use in xenotransplantation should comply with the provisions of the *European Convention for the protection of vertebrate animals used for experimental and other scientific purposes* including the principles of Appendix A and *Council Directive 86/609/EEC on the approximation of laws, regulations and administrative provisions of member states regarding the protection of animals used for experimental and other scientific purposes* including Annex II.

These provisions should apply to source animals in addition to their sires and dams in source production units, pre-transplantation holding facilities, tissue harvest areas and during transport.

Article 23 – Husbandry, care, use and requirements of animals

The husbandry and care for all animals used in xenotransplantation should take account of their physiological, social and behavioural needs and should be designed to ensure their well being, particularly where breeding animals are maintained for long periods. The pain, suffering or distress and the number of animals used should be minimised.

Article 24 – Responsibility for husbandry and care of animals

There should be clearly assigned and documented responsibilities for husbandry and care of the animals used in xenotransplantation from birth to death, with a sufficient number of appropriately trained and competent staff available to inspect and care for them.

Article 25 – Surgical derivation and early weaning techniques

Surgical derivation and segregated/medicated early weaning production techniques should only be used where essential to produce animals of appropriate health status for use in xenotransplantation.

Article 26 – Transport of animals

Transport of animals for xenotransplantation should be kept to a minimum. If transportation is necessary, adequate arrangements should be made for the dispatch, receipt, acclimatisation and quarantine of animals in order to minimise the associated stress. The relevant national and international legislation/regulations (including European Union *Directive 95/29/EEC* modifying *Directive 91/628/EEC* on the protection of animals during transport, and the European Convention for the Protection of Animals During International Transport (revised)) should be complied with.

Article 27 – Organ and tissue procurement from animals

Analgesia or anaesthesia should be used for the procurement of organs, tissues and cells for xenotransplantation, where it is necessary to minimise pain, suffering and distress of the animals.

If, as a result of the procurement, the subsequent health and welfare of the animals would be compromised, the animals should be killed by an appropriate method.

Sequential harvest of solid organs from individual animals should not be permitted.

Article 28 – Collection of animal records

Detailed records should be maintained of the derivation, source, use and final disposal of all animals bred for or used in xenotransplantation. Any unusual or unexpected traits or events should be recorded.

Article 29 – Pre-clinical research

The provisions of Articles 22 to 28 should also apply to animals used in pre-clinical research carried out to support clinical xenotransplantation research.

Chapter VI – Provisions relating to the ethical, social and psychological acceptability of xenotransplantation

Article 30 – Public debate

In accordance with the principles stated in Article 28 of the Convention on Human Rights and Biomedicine, member states should take active steps to ensure that the fundamental questions raised by xenotransplantation are the subject of appropriate public discussion particularly in light of relevant medical, psychological, cultural, ethical, legal, social and economic implications.

Chapter VII – Co-operation between parties

Article 31- International co-operation in medical research

Member states should co-operate through international surveillance procedures and agreements. They should also take appropriate steps to facilitate the co-ordination of research in xenotransplantation in order to improve its efficacy and safety, to avoid unnecessary duplication and to minimise animal use and suffering.

Article 32 – International co-operation in public health

Every member state should communicate without delay to national public health authorities of other member states and other concerned states any events, in particular of infection, possibly related to a xenotransplantation which could compromise public health.

Chapter VIII – Compensation for undue damage

Article 33 - Compensation for undue damage

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

Chapter IX – Reports on the implementation of the recommendation

Article 34 – Implementation of the recommendation

On receipt of a request from the Secretary General of the Council of Europe any member state should furnish an explanation on the manner in which its legislation and practice in the field of xenotransplantation integrate the principles and guidelines of this recommendation, on any xenotransplantation activity and on any adverse event as referred to in Article 9.

COUNCIL OF EUROPE

COMMITTEE OF MINISTERS

RECOMMENDATION NO. REC(2003)12

of the Committee of Ministers to member States

on organ donor registers

*(Adopted by the Committee of Ministers on 19 June 2003
at the 844th 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 regulations in the health field;

Having regard to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (the Convention on Human Rights and Biomedicine) (ETS No.164);

Having regard to the Additional Protocol to the Convention on Human Rights and Biomedicine concerning the Transplantation of Organs and Tissues of Human Origin (ETS No. 186);

Bearing in mind that:

- the Protocol concerning the Transplantation of Organ and Tissues of Human Origin requires member states to have a legally recognised system specifying the conditions under which removal of organs or tissues is authorised;
- by virtue of Article 8 of the said protocol, member states should take appropriate measures to inform the public, namely about matters relating to consent or authorisation with regard to the removal of organs or tissues from deceased persons;
- Article 17 of the said protocol prohibits the removal of any organ or tissue unless the consent or authorisation required by national law has been obtained by the person proposing to remove the organ or tissue;

Recalling the general principles relating to data protection of the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (ETS No. 108),

Recommends to governments of member states to conform with the principles contained in the appendix to this recommendation as regards organ donor registries:

Appendix to Recommendation Rec(2003)12

1. Careful consideration should be given to the need for, and purpose of, an organ donor register.
2. In those member states with a legal framework for organ donation which assumes people are willing to donate their organs or tissues unless they have registered their refusal (opt-out system),

states must provide an effective means for people to register their decision. A national register can be an effective means of recording such decisions.

3. For member states in which consent to donation is actively sought from the donor and/or those close to them prior to organ donation (opt-in system), an organ donor register may also fulfil important functions:

- as a means of registering the wishes of people willing to donate their organs;
- as a means of improving the efficiency of the organ and tissue donation process by making those wishes available rapidly after the death of a potential donor has been confirmed;
- as a means of publicising organ donation, and of involving people and organisations in realising the benefits of organ donations for themselves and for others in society;

4. Consideration should be given to the primary function of the organ donor register. Organ donor registers may:

- be opt-out only;
- be opt-in only;
- register both choices, or even a third choice, such as “ask my relatives”;
- allow simply a general agreement to donate organs and/or tissues;
- allow wishes about the donation of particular organs and/or tissues to be specified;
- allow registration of wishes with respect to other sensitive procedures, such as post-mortem examinations or the donation of organs/tissue for medical research.

5. Organ donor registers should ensure, that:

- people wishing to register their wishes can do so easily and reliably;
- people can, if they wish, specify organs and tissues they do/do not wish to donate;
- people can revoke their entry at any time;
- all information on people who die is removed from the organ donor registry.

6. If the organ donor register is intended to facilitate organ donation it must:

- have details of a high proportion of potential donors/non-donors. If enquiries about potential donors give no results, health professionals will consider it a waste of time trying to access the register;
- enable easy and rapid twenty-four hour access by health professionals needing information about a potential donor.

7. Careful consideration should be given to the costs and benefits of setting up and maintaining an organ donor register:

- member states operating an opt-out system should, as a minimum, have a central register for those who do not wish to donate organs or tissues or any particular organ or tissue;
- a centrally-run information technology-based organ donor register offers the greatest flexibility in terms of content, updating and rapidity of access, but data security has to be ensured;
- everyone should be able to register their wishes;
- registration must be easy, preferably by both written and/or electronic means;
- written confirmation should be sent to all who register;
- people should have a simple means of checking and amending their entry
- specified healthcare professionals such as intensive care staff and/or transplant co-ordinators must have twenty-four-hours-a-day access to check the wishes of potential donors by phone, fax or electronically. Such checks should normally be made only after the death of a potential donor;
- checking the register could be made mandatory as a condition of donation.

8. Member states with organ donor registers should consider whether their register is designed and operated in a way which best meets the needs of their population and transplant service. Those member states which have an organ donor register are advised to consider the purposes and the likely advantages and disadvantages before establishing a new organ donor register.

COUNCIL OF EUROPE

COMMITTEE OF MINISTERS

RECOMMENDATION NO. REC(2003)24

of the Committee of Ministers to member States

on the organisation of palliative care

*(Adopted by the Committee of Ministers on 12 November 2003
at the 860th 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 rules in the health field;

Recalling Article 11 of the European Social Charter on the right to health protection, and recalling that Article 3 of the Convention on Human Rights and Biomedicine (ETS No.164) requires that contracting parties provide equitable access to health care of appropriate quality, that Article 4 requests that any intervention in the health field, including research, must be carried out in accordance with relevant professional obligations and standards, and that Article 10 emphasises the right of everyone to know any information about his or her health;

Recognising that a health care system should be patient-oriented and that citizens should necessarily participate in decisions regarding their health care;

Recalling in this context the recommendation of the Committee of Ministers to member states, Recommendation No. R (2000) 5 on the development of structures for citizen and patient participation in the decision-making process affecting health care;

Convinced that the respect and protection of the dignity of a terminally ill or a dying person implies above all the provision of appropriate care in a suitable environment, enabling him or her to die with dignity;

Recalling in this context Recommendation 1418 (1999) of the Parliamentary Assembly on protection of the human rights and dignity of the terminally ill and the dying;

Further recalling Recommendation No. R (89) 13, on the organisation of multidisciplinary care for cancer patients;

Recognising that palliative care needs to be further developed in European countries;

Recalling in this respect the 1998 Poznan Declaration on palliative care in Eastern Europe;

Recognising that the right to health care is aimed at the patient's enjoyment of the highest attainable sense of well-being, irrespective of age, ethnicity, economic or social status, and the nature of any

disease or infirmity;

Considering that there is a growing number of people in need of palliative care;

Considering that the differences in the availability and quality of palliative care throughout Europe need to be addressed through increased co-operation between countries;

Conscious that palliative care is the active, total care of patients with advanced, progressive diseases, aiming at the control of pain and other symptoms, and offering psychological, social, and spiritual support;

Aware that the goal of palliative care is the achievement of the best possible quality of life for patients and their families;

Aware that palliative care aims to help men, women and children with advanced, progressive diseases to enjoy the best possible quality of life until the end, and intends neither to hasten nor postpone death;

Considering that palliative care affirms life and regards dying as a normal process, and is not guided by hopelessness or fatalism;

Considering that palliative care is an integral part of the health care system and an inalienable element of a citizen's right to health care, and that therefore it is a responsibility of the government to guarantee that palliative care is available to all who need it;

Considering that it is necessary to pursue the development of quality care, carried out humanely, in order to make it an essential part of health care for patients near the end of life;

Recognising that all people near the end of life desire to be treated as valued persons by health care professionals and to have skilled attention directed at maintaining dignity and fostering independence, relieving symptoms and maximising comfort;

Recognising that palliative care, like all medical care, should be patient-oriented, guided by the needs of the patient, taking into account his or her values and preferences, and that dignity and autonomy are central issues for patients in need of palliative care,

Recommends that the governments of member states:

1. adopt policies, legislative and other measures necessary for a coherent and comprehensive national policy framework for palliative care;
2. take to this end, whenever feasible, the measures presented in the appendix to this recommendation, taking account of their respective national circumstances;
3. promote international networking between organisations, research institutions and other agencies that are active in the palliative care field;
4. support an active, targeted dissemination of this recommendation and its explanatory memorandum, where appropriate accompanied by a translation.

Appendix to Recommendation Rec(2003)24

General considerations

While in many countries the greater part of health care budgets is spent on people in their final years of life, they do not always receive the care that is most appropriate to their needs.

Palliative care does not address a specific disease and spans the period from the diagnosis of advanced disease until the end of bereavement; this may vary from years to weeks or (rarely) days. It is not synonymous with terminal care, but encompasses it.

The creation, in member states, of a climate in which the importance of palliative care is recognised is crucial.

The public, including patients and their families, needs to be educated regarding the importance of palliative care, and of what it can offer.

Several recent studies, providing data in a total of thirty-five countries across Europe, have pointed out differences between countries with regard to palliative care, among which are variations in reimbursement (where applicable), in health care system organisation and in the place of palliative care within it; differing ethical and cultural factors; the role of national organisations, and international collaboration in palliative care development; opioid availability; and questions of workforce training and development.

I. Guiding principles

Palliative care policies should be based on values propounded by the Council of Europe: human rights and patients' rights, human dignity, social cohesion, democracy, equity, solidarity, equal gender opportunities, participation and freedom of choice.

Palliative care has the following core dimensions:

- symptom control;
- psychological, spiritual, and emotional support;
- support for the family;
- bereavement support.

The following principles underpin the recommendation:

1. Palliative care is a vital and integral part of health services. Provisions for its development and functional integration should be incorporated into national health strategies.
2. Any person who is in need of palliative care should be able to access it without undue delay, in a setting which is, as far as reasonably feasible, consistent with his or her needs and preferences.
3. Palliative care has as its objective the achievement and maintenance of the best possible quality of life for patients.
4. Palliative care seeks to address physical, psychological and spiritual issues associated with advanced disease. Therefore, it requires a co-ordinated input from a highly-skilled and adequately resourced interdisciplinary and multi-professional team.
5. Acute intervening problems should be treated if the patient so wishes, but should be left untreated, while the best palliative care continues to be provided, if the patient prefers.
6. Access to palliative care should be based on need, and must not be influenced by disease type, geographical location, socio-economic status or other such factors.
7. Programmes of palliative care education should be incorporated into the training of all

- concerned health care professionals.
8. Research aimed at improving the quality of care should be undertaken. All palliative care interventions should be supported to the greatest possible extent by relevant research data.
 9. Palliative care should receive an adequate and equitable level of funding.
 10. As in all sectors of medical care, health care providers involved in palliative care should fully respect patients' rights, comply with professional obligations and standards, and, in that context, act in the best interest of the patients.

II. Settings and services

1. Palliative care is an interdisciplinary and multi-professional undertaking which attends to the needs of the patient, while not neglecting the informal caregivers, such as family members.
2. Palliative care services and policies must offer a wide range of resources, such as home care, in-patient care in specific or conventional units, day hospital and out-patient clinics, emergency call-out and respite care facilities. These should be comprehensive and appropriate to the health care system and culture, and should focus on the changing needs and wishes of patients.
3. Informal caregivers should be supported in their caregiving, and should not incur major social setbacks, such as job loss, as a consequence of caregiving. A formal right to "care leave" may be desirable.
4. All professionals involved in the care of patients with advanced, progressive disease should have easy access to specific expertise if and when they need it.
5. Specialist palliative care should be available for all patients when they need it, at any time and in any situation.
6. It should be ensured that there is leadership in the development of palliative care at national level and proper co-ordination of services with a clear allocation of responsibilities. The formation of regional networks is recommended as a good means to reach this goal.
7. Patients should be guaranteed access to palliative care without undue financial barriers. Financial and other arrangements should be such that continuity in palliative care is guaranteed, and is adapted to the needs of the patient.
8. There should be sufficient respite care facilities to offer temporary relief when caregivers in the home become overburdened.

III. Policy and organisation

1. Palliative care must be an integral part of a country's health care system, and as such it must be an element of comprehensive health care plans, and of specific programmes concerning, for instance, cancer, Aids or geriatrics.
2. Governments should have a needs assessment study performed that addresses the need for services, for personnel of different levels of expertise, and for training of different professions (including volunteers).
3. On the basis of a needs assessment, national or regional governments need to design and implement comprehensive rational palliative care strategies in close collaboration with professionals and patients and families, or their representatives.
4. As part of such strategies, governments should identify legal, social, economic, cultural, administrative and/or physical barriers in access to palliative care services. Initiatives and programmes should be implemented in order to reduce such barriers, which often lead to inequalities.
5. Legislation should make opioids and other drugs accessible in a range of formulations and dosages for medical use. The fear of abuse should not hinder access to necessary and effective medication. Countries may wish to consider whether this will require new legislation or an amendment to existing legislation.
6. It is recommended that, both at national and at regional and local level, interdisciplinary focal

- groups or councils devoted to palliative care involving patients, families and others be constituted in order to maintain political and social attention. Preferably, such groups cooperate with governments and other bodies in putting in place the necessary policies.
7. In order to facilitate the monitoring of the quality of palliative care, the constitution of a uniform “minimum data set” (MDS) is necessary, at least at national level.
 8. Because of the importance of equity, special attention should be paid to palliative care for underprivileged groups (for instance, prisoners those with learning disabilities, the homeless, refugees) and to cultural and ethnic differences related to the needs of patients. Equally importantly, special attention should be paid to palliative care for children.
 9. Professional caregivers are entitled to a fair remuneration, and to recognition for the work they do and for their competence.
 10. A national annual report on organisation and functioning of palliative care should be published.

IV. Quality improvement and research

1. The definition and adoption of indicators of good palliative care assessing all dimensions of care from the perspective of the patient should be encouraged.
2. Clinical practice guidelines for palliative care, based on the best available evidence, should be developed in a systematic way, with the participation of patients.
3. Continuous feedback on practices in the form of an audit is essential to quality control.
4. Even though scientific research in palliative care may pose specifically pressing ethical problems, care services and medical intervention should be evaluated using proven scientific methods, both qualitative and quantitative in nature. The focus of such studies should be patient-related.
5. Collaborative research, both at national and at European level, should be encouraged.
6. An observatory should be set up at national and regional level to collect, process and disseminate reliable information on developments in and quality of palliative care.

V. Education and training

1. Both for research and for education, academic recognition of palliative care is important.
2. Palliative care should be included in all undergraduate training of doctors and nurses. Standard curricula should be established, as well as postgraduate training and education, and there should be training programmes for experts in palliative care.
3. International co-operation on education should be encouraged, for example by establishing a directory of palliative care units wishing to participate in twinning programmes.
4. All professionals and non-professionals involved in palliative care should be trained appropriately for their task; they should receive at all levels of training concrete, insightful and culturally sensitive instruction in palliative care.
5. Education in palliative care should be both monodisciplinary and interdisciplinary.
6. Education in palliative care should be regularly followed up, for instance in the form of supervision.
7. Centres of reference should be set up in each country for teaching and training in palliative care.
8. Ideally, there should be the following three levels of (continuing) education for professionals: basic, intermediary and advanced education.
9. It is recommended that countries devote specific attention to educating the general public about all relevant aspects of palliative care.
10. The unjustified negative images concerning opioids among patients, families, professionals and the public should be corrected, with the essential differences between the clinical applications and the potential for abuse being stressed, both in public campaigns and professional education.

VI. The family

1. The aim and the principle, in helping those close to patients (principally family members), are to put to good use and to develop their ability to bring emotional and practical support to patients, to adapt to the process, and to cope with grief and loss. Particular attention must be paid to the prevention of and the treatment of depression from exhaustion.

VII. Communicating with patient and family

1. Palliative care demands a climate, an attitude and a caregiver-patient relationship which encourage openness in information to patients and families.
2. Professionals should take into account the extent to which patients wish to be informed about their situation; in this regard, attention should be paid to cultural differences.
3. Professionals should adapt the way in which they give information to patients to the emotional or cognitive barriers that are often associated with having an advanced and progressive illness.
4. Where children are involved, either because of their own illness or because of the illness of a parent, communication should be adapted to their needs.

VIII. Teams, teamwork and care planning

1. Palliative care is an interdisciplinary and multiprofessional undertaking, most often involving a physician and a nurse and other health care workers who have the expertise needed to respond to the physical, psychological, and spiritual needs of the patient and the family. The functioning of such teams should be facilitated.
2. Decision-making, especially the making, monitoring and regular reviewing of individual anticipatory care plans, should be shared between the patient, the family and the team, whenever this is appropriate, and complies fully with the patients' wishes. Appropriate communication between the various services involved (curative and palliative) should be ensured.
3. Volunteers can be an important part of the team. They do not take over the work of professionals, but have their own contribution and expertise. The setting-up of volunteer services, and the process of becoming a volunteer, should be facilitated.
4. All team members should be competent in their roles and aware of the possibilities and limitations of both their own role and that of the other members.
5. Receiving coherent messages from different care providers is crucial for the patient and the family. Therefore, optimal information flows between care providers are essential in order to avoid misunderstandings or discrepancies. It is advisable to establish a leading co-ordinator, preferably, depending on circumstances, the primary physician.
6. All communication between professionals concerning patients and families is subject to professional secrecy, fully respecting the patient's right to medical secrecy and the families' right to privacy.
7. Palliative care is usually very rewarding, but equally it can be very demanding. Therefore, caring for the caregivers is an essential part of palliative care, and the occupational health of those working in palliative care should be a focus of policies.

IX. Bereavement

1. Bereavement care services should be offered to those who are in need of support.
2. All professional workers in palliative care should be attentive to signs of complicated or disturbed bereavement.

COUNCIL OF EUROPE

COMMITTEE OF MINISTERS

RECOMMENDATION NO. REC(2004)7

of the Committee of Ministers to member States

on organ trafficking

*(Adopted by the Committee of Ministers on 19 May 2004
at the 884th 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 field of health;

Taking into account Resolution (78) 29 on harmonisation of legislation of member states relating to removal, grafting and transplantation of human substances and the final text of the 3rd Conference of European Health Ministers (Paris, 16-17 November 1987), and the World Health Organisation Resolution WHA 42.5 condemning the purchase and sale of organs of human origin;

Having regard to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (ETS No. 164) and in particular to Articles 19 and 20 thereof;

Bearing in mind the requirements of the Additional Protocol to the above convention on Transplantation of Organs and Tissues of Human Origin, and in particular that Article 22 requires the prohibition of organ and tissue trafficking; that Article 3 requires member states to have a transplant system in place which allocates organs, and where appropriate tissues, only to those on the official waiting list; that Article 26 requires member states to provide for appropriate sanctions to be applied in the event of any infringement of the provisions contained in the aforementioned protocol; that Article 21 requires that the human body and its parts shall not, as such, give rise to financial gain or comparable advantage,

Considering that:

The universal shortage of organs and tissues can lead patients to a desperate search for a transplant which may involve unacceptable practices from a legal or ethical point of view;

Organ shortage can also encourage illegal organisations to traffic human beings for the purpose of organ transplantation, or to traffic organs obtained as a result of inducement or coercion;

Organ trafficking may undermine public confidence in organ and tissue transplantation services, decreasing the public's disposition to legitimate organ donation, thereby exacerbating the shortage of organs and tissues for transplantation,

Recommends that the governments of member states conform with the requirements set out in the appendix to this recommendation.

Appendix to Recommendation Rec(2004)7

Article 1 – Object

Member states should protect the dignity and identity of all persons and guarantee without discrimination their fundamental rights and freedoms with regard to organ and tissue transplantation.

Member states should make it clear to all that organ trafficking exploits human beings and is illegal, and should take all possible measures to prevent organ trafficking (see Article 4).

Article 2 – Scope and definitions

1. The provisions of this recommendation shall apply to all living persons and to the removal of organs, tissues and cells from those recently deceased.
2. The provisions of this recommendation applicable to tissues shall apply also to cells, including haematopoietic stem cells.
3. The provisions of this recommendation do not apply to blood or blood derivatives.
4. For the purposes of this recommendation the term “organ and tissue trafficking” applies to:
 - the transportation of a person to a place for the removal of organs or tissues without his or her valid consent;
 - the transportation of a person to a place for the removal of organs or tissues with his or her consent but in contravention of legislation or other controls in operation in the relevant jurisdiction;
 - the transplantation of removed organs and tissues, whether transported or not, in contravention of legislation or other regulations in operation in the relevant jurisdiction or in contravention of international legal instruments.
5. For the purposes of this recommendation:
 - 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, storage and transportation;
 - the term “removal” refers to removal from the body of an organ or tissue intended for transplantation, by a surgical procedure or by other means.

Article 3 – Prevention

Prevention of organ trafficking should be undertaken in an integrated way by:

- Improving organ and tissue availability by well-established means such as those described in the Council of Europe consensus document “Meeting the organ shortage: current status and strategies for improvement of organ donation” (1999);
- Approving a legal framework which strictly forbids any kind of commercialisation of the human body and its parts consistent with the Convention for the Protection of Human Rights

and Dignity of the Human Being with regard to the Application of Biology and Medicine (ETS No. 164). Legislation should be extended to citizens going abroad. However, medical care should not be denied;

- Assuring the traceability of human organs and tissues through the accreditation and control of centres for procurement and/or transplantation, tissue banks, and the follow up of patients;
- In the case of a living donor transplant, member states should provide for official authorisation of all such transplants;
- In all cases where the living donor is a foreign citizen, the relevant officially recognised bodies in the country of transplantation and in the home country of the living donor must be informed;
- In the case of a living donor, all payments to the donor should be strictly prohibited and considered a criminal offence.

This provision should not apply to 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 related medical examinations;
- payment of a justifiable fee for legitimate medical or related technical services rendered in connection with transplantation;
- compensation in case of unjustified harm resulting from the removal of organs or tissues from living donors.

Article 4 – Legal instruments

1. Member states should ensure that there are legal instruments in place which prohibit the trafficking of persons for the purpose of organ or tissue transplantation and the trafficking of organs and tissues themselves.
2. Member states should ensure that those legal instruments prohibit:
 - the removal of organs and tissues except in centres or circumstances recognised for the purpose and by health professionals with appropriate training and experience;
 - the implantation of organs and tissues except in centres or circumstances recognised for the purpose and by health professionals with appropriate training and experience;
 - financial gain from the human body or parts of the body intended for transplantation;
 - advertising with the intention of securing persons or organs or tissues for trafficking or for financial gain;
 - organising or running an organisation or service involved in organ or tissue trafficking.
3. Member states shall ensure that legislation provides for appropriate sanctions to be applied in the event of any infringement of the provisions of this recommendation.

Article 5 – The transplantation system

1. Member states shall ensure the provision of a nationally recognised transplantation system which guarantees equitable access to transplant services.
2. National transplant waiting lists should be established in compliance with the Committee of Ministers' Recommendation Rec(2001)5 on the management of organ transplant waiting lists and

waiting times.

3. The system shall ensure that:

- appropriate information is recorded on all organs and tissues removed for the purposes of transplantation;
- all organs, and where appropriate tissues, are only allocated to persons who are on a nationally recognised waiting list;
- appropriate information is recorded on all organs and tissues used for implantation or other purposes;
- information on the risks associated with organs obtained illegally is provided.

4. The information provided should ensure traceability from donor to recipient but shall be collected, processed and communicated in accordance with regulations relating to confidentiality and personal data protection.

Article 6 – International co-operation

1. Organ trafficking is a universal problem. Therefore international co-operation is required to combat it.
2. Member states should ensure full co-operation with all other states and with international agencies, including law enforcement agencies, in order to combat organ trafficking, and apply the sanctions provided for in this recommendation to any person or entity involved in organ trafficking.
3. Member states should present a full report of any allegations or instances of organ trafficking within their territory to the Secretary General of the Council of Europe.

Article 7 – Information for the general public

Member states should ensure that the general public is fully informed about organ trafficking and the penalties which may be incurred. In particular:

- accurate information about organ and tissue donation and transplantation should be provided;
- organ and tissue donation should be promoted as positive behaviour that contributes to saving lives and improving the health of many people;
- false reports on organ trafficking may alarm the general public and adversely affect organ and tissue donation and should be refuted.

COUNCIL OF EUROPE

COMMITTEE OF MINISTERS

RECOMMENDATION NO. REC(2004)8

of the Committee of Ministers to member States

on autologous cord blood banks

*(Adopted by the Committee of Ministers on 19 May 2004
at the 88th 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 field of health;

Taking into account Resolution (78) 29 on harmonisation of legislation of member states relating to removal, grafting and transplantation of human substances and the final text of the 3rd Conference of European Health Ministers (Paris, 16-17 November 1987);

Having regard to the European Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (ETS No. 164) and in particular to Articles 19 and 20 thereof;

Having regard to the Additional Protocol to the Convention on Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine concerning the Transplantation of Organs and Tissues of Human Origin (ETS No. 186);

Considering that:

The principal current use of blood cells collected at the time of birth from the umbilical cord (cord blood) is the collection of haematopoietic progenitor cells (HPC) that can be transplanted into patients with acquired or congenital diseases of the bone marrow. It is likely that such cells will, in the future, constitute a valuable source of cell therapies for the treatment of a wide range of diseases;

Cord blood stored only for autologous use, that is, by the donor or his or her immediate family, is only very rarely used. Furthermore, there is no scientific evidence that umbilical cord blood can be stored for long enough to be of any use to the vast majority of donors. Such storage could limit altruistic donation and thereby limit the possibility of treating those in need;

The unregulated collection of blood at the time of birth could distract the staff caring for mother and child at a critical time;

Even if it is the case that these children do, in the future, develop diseases requiring an HPC transplant, there is evidence to suggest that it is preferable to use allogeneic transplantation to achieve the “graft vs. tumor effect” in hematological diseases. In cases of congenital disease and in some leukaemias with intrauterine cell mutations, autologous HPC transplantation is contraindicated;

The health services of member states should only provide their citizens with proven clinical and cost effective therapies as resources are always limited;

With the aim of ensuring the availability of transplant treatments for an increasing number of people,

Recommends to the member states that,

1. If cord blood banks are established, they should be based on altruistic and voluntary cord blood donation and used for allogeneic transplantation and related research;
2. The promotion of donation for autologous use and the establishment of cord blood banks for autologous use should not be supported by member states or their health services;
3. Accurate information should be provided to the population about the advantages and disadvantages of cord blood banks;
4. Where autologous cord blood banks are being established, the promotional material or information provided to families must be accurate, and fully informed consent to cord blood storage must be obtained;
5. Autologous cord blood banks that are being established must meet the quality and safety standards set out in the Council of Europe's Guide to safety and quality assurance for organs, tissues and cells.

COUNCIL OF EUROPE

COMMITTEE OF MINISTERS

RECOMMENDATION NO. REC(2004)10

of the Committee of Ministers to member States

concerning the protection of the human rights and dignity of persons with mental disorder

*(Adopted by the Committee of Ministers on 22 September 2004
at the 896th meeting of the Ministers' Deputies)¹*

Preamble

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 a greater unity between its members, in particular through harmonising laws on matters of common interest;

Having regard, in particular:

- to the Convention for the Protection of Human Rights and Fundamental Freedoms of 4 November 1950 and to its application by the organs established under that Convention;
- to the 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”) of 4 April 1997;
- to Recommendation No. R (83)2 concerning the legal protection of persons suffering from mental disorder placed as involuntary patients;
- to Recommendation No. R (87)3 on the European Prison Rules;
- to Recommendation No. R (98)7 concerning the ethical and organisational aspects of health care in prison;
- to Recommendation 1235 (1994) of the Parliamentary Assembly of the Council of Europe on psychiatry and human rights;

Having regard to the work of the European Committee for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment;

¹ When adopting this decision, the Permanent Representative of the United Kingdom indicated that, in accordance with Article 10.2c of the Rules of Procedure for the meetings of the Ministers' Deputies, he reserved the right of his Government to comply or not with the Recommendation as a whole.

Having regard to the public consultation on the protection of the human rights and dignity of persons suffering from mental disorder, initiated by the Steering Committee on Bioethics;

Considering that common action at European level will promote better protection of the human rights and dignity of persons with mental disorder, in particular those subject to involuntary placement or involuntary treatment;

Considering that both mental disorder and certain treatments for such disorder may affect the essence of a person's individuality;

Stressing the need for mental health professionals to be aware of such risks, to act within a regulatory framework and to regularly review their practice;

Stressing the need to ensure that persons with mental disorder are never emotionally, physically, financially or sexually exploited;

Conscious of the responsibility of mental health professionals to guarantee, as far as they are able, the implementation of the principles enshrined in these guidelines;

Recommends that the governments of member states should adapt their laws and practice to the guidelines contained in this recommendation;

Recommends that the governments of member states should review their allocation of resources to mental health services so that the provisions of these guidelines can be met.

GUIDELINES

Chapter I – Object and scope

Article 1 – Object

1. This recommendation aims to enhance the protection of the dignity, human rights and fundamental freedoms of persons with mental disorder, in particular those who are subject to involuntary placement or involuntary treatment.
2. The provisions of this recommendation do not limit or otherwise affect the possibility for a member state to grant persons with mental disorder a wider measure of protection than is stipulated in this recommendation.

Article 2 – Scope and definitions

Scope

1. This recommendation applies to persons with mental disorder defined in accordance with internationally accepted medical standards.
2. Lack of adaptation to the moral, social, political or other values of a society, of itself, should not be considered a mental disorder.

Definitions

3. For the purpose of this recommendation, the term:
 - “competent body” means an authority, or a person or body provided for by law which is distinct from the person or body proposing an involuntary measure, and that can make an independent decision;
 - “court” includes reference to a court-like body or tribunal;
 - “facility” encompasses facilities and units;
 - “personal advocate” means a person helping to promote the interests of a person with mental disorder and who can provide moral support to that person in situations in which the person feels vulnerable;
 - “representative” means a person provided for by law to represent the interests of, and take decisions on behalf of, a person who does not have the capacity to consent;
 - “therapeutic purposes” includes prevention, diagnosis, control or cure of the disorder, and rehabilitation;
 - “treatment” means an intervention (physical or psychological) on a person with mental disorder that, taking into account the person’s social dimension, has a therapeutic purpose in relation to that mental disorder. Treatment may include measures to improve the social dimension of a person’s life.

Chapter II – General provisions

Article 3 – Non-discrimination

1. Any form of discrimination on grounds of mental disorder should be prohibited.
2. Member states should take appropriate measures to eliminate discrimination on grounds of mental disorder.

Article 4 – Civil and political rights

1. Persons with mental disorder should be entitled to exercise all their civil and political rights.
2. Any restrictions to the exercise of those rights should be in conformity with the provisions of the Convention for the Protection of Human Rights and Fundamental Freedoms and should not be based on the mere fact that a person has a mental disorder.

Article 5 – Promotion of mental health

Member states should promote mental health by encouraging the development of programmes to improve the awareness of the public about the prevention, recognition and treatment of mental disorders.

Article 6 – Information and assistance on patients' rights

Persons treated or placed in relation to mental disorder should be individually informed of their rights as patients and have access to a competent person or body, independent of the mental health service, that can, if necessary, assist them to understand and exercise such rights.

Article 7 – Protection of vulnerable persons with mental disorders

1. Member states should ensure that there are mechanisms to protect vulnerable persons with mental disorders, in particular those who do not have the capacity to consent or who may not be able to resist infringements of their human rights.
2. The law should provide measures to protect, where appropriate, the economic interests of persons with mental disorder.

Article 8 – Principle of least restriction

Persons with mental disorder should have the right to be cared for in the least restrictive environment available and with the least restrictive or intrusive treatment available, taking into account their health needs and the need to protect the safety of others.

Article 9 – Environment and living conditions

1. Facilities designed for the placement of persons with mental disorder should provide each such person, taking into account his or her state of health and the need to protect the safety of others, with an environment and living conditions as close as possible to those of persons of similar age, gender and culture in the community. Vocational rehabilitation measures to promote the integration of those persons in the community should also be provided.
2. Facilities designed for the involuntary placement of persons with mental disorder should be

registered with an appropriate authority.

Article 10 – Health service provision

Member states should, taking into account available resources, take measures:

- i. to provide a range of services of appropriate quality to meet the mental health needs of persons with mental disorder, taking into account the differing needs of different groups of such persons, and to ensure equitable access to such services;
- ii. to make alternatives to involuntary placement and to involuntary treatment as widely available as possible;
- iii. to ensure sufficient provision of hospital facilities with appropriate levels of security and of community-based services to meet the health needs of persons with mental disorder involved with the criminal justice system;
- iv. to ensure that the physical health care needs of persons with mental disorder are assessed and that they are provided with equitable access to services of appropriate quality to meet such needs.

Article 11 – Professional standards

1. Professional staff involved in mental health services should have appropriate qualifications and training to enable them to perform their role within the services according to professional obligations and standards.
2. In particular, staff should receive appropriate training on:
 - i. protecting the dignity, human rights and fundamental freedoms of persons with mental disorder;
 - ii. understanding, prevention and control of violence;
 - iii. measures to avoid the use of restraint or seclusion;
 - iv. the limited circumstances in which different methods of restraint or seclusion may be justified, taking into account the benefits and risks entailed, and the correct application of such measures.

Article 12 – General principles of treatment for mental disorder

1. Persons with mental disorder should receive treatment and care provided by adequately qualified staff and based on an appropriate individually prescribed treatment plan. Whenever possible the treatment plan should be prepared in consultation with the person concerned and his or her opinion should be taken into account. The plan should be regularly reviewed and, if necessary, revised.
2. Subject to the provisions of chapter III and Articles 28 and 34 below, treatment may only be provided to a person with mental disorder with his or her consent if he or she has the capacity to give such consent, or, when the person does not have the capacity to consent, with the authorisation of a representative, authority, person or body provided for by law.
3. When because of an emergency situation the appropriate consent or authorisation cannot be obtained, any treatment for mental disorder that is medically necessary to avoid serious harm to the health of the individual concerned or to protect the safety of others may be carried out immediately.

Article 13 – Confidentiality and record-keeping

1. All personal data relating to a person with mental disorder should 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. Clear and comprehensive medical and, where appropriate, administrative records should be maintained for all persons with mental disorder placed or treated for such a disorder. The conditions governing access to that information should be clearly specified by law.

Article 14 – Biomedical research

Biomedical research on a person with mental disorder should respect the provisions of this recommendation and the relevant provisions of the Convention on Human Rights and Biomedicine, its additional Protocol on Biomedical Research and the other legal provisions ensuring the protection of persons in research contexts.

Article 15 – Dependants of a person with mental disorder

The needs of family members, in particular children, who are dependent on a person with mental disorder should be given appropriate consideration.

Chapter III – Involuntary placement in psychiatric facilities, and involuntary treatment, for mental disorder

Article 16 – Scope of chapter III

The provisions of this chapter apply to persons with mental disorder:

- i. who have the capacity to consent and are refusing the placement or treatment concerned; or
- ii. who do not have the capacity to consent and are objecting to the placement or treatment concerned.

Article 17 – Criteria for involuntary placement

1. A person may be subject to involuntary placement only if all the following conditions are met:

- i. the person has a mental disorder;
- ii. the person's condition represents a significant risk of serious harm to his or her health or to other persons;
- iii. the placement includes a therapeutic purpose;
- iv. no less restrictive means of providing appropriate care are available;
- v. the opinion of the person concerned has been taken into consideration.

2. The law may provide that exceptionally a person may be subject to involuntary placement, in accordance with the provisions of this chapter, for the minimum period necessary in order to determine whether he or she has a mental disorder that represents a significant risk of serious harm to his or her health or to others if:

- i. his or her behaviour is strongly suggestive of such a disorder;
- ii. his or her condition appears to represent such a risk;
- iii. there is no appropriate, less restrictive means of making this determination; and
- iv. the opinion of the person concerned has been taken into consideration.

Article 18 – Criteria for involuntary treatment

A person may be subject to involuntary treatment only if all the following conditions are met:

- i. the person has a mental disorder;
- ii. the person's condition represents a significant risk of serious harm to his or her health or to other persons;
- iii. no less intrusive means of providing appropriate care are available;
- iv. the opinion of the person concerned has been taken into consideration.

Article 19 – Principles concerning involuntary treatment

1. Involuntary treatment should:
 - i. address specific clinical signs and symptoms;
 - ii. be proportionate to the person's state of health;
 - iii. form part of a written treatment plan;
 - iv. be documented;
 - v. where appropriate, aim to enable the use of treatment acceptable to the person as soon as possible.
2. In addition to the requirements of Article 12.1 above, the treatment plan should:
 - i. whenever possible be prepared in consultation with the person concerned and the person's personal advocate or representative, if any;
 - ii. be reviewed at appropriate intervals and, if necessary, revised, whenever possible in consultation with the person concerned and his or her personal advocate or representative, if any.
3. Member states should ensure that involuntary treatment only takes place in an appropriate environment.

Article 20 – Procedures for taking decisions on involuntary placement and/or involuntary treatment

Decision

1. The decision to subject a person to involuntary placement should be taken by a court or another competent body. The court or other competent body should:
 - i. take into account the opinion of the person concerned;
 - ii. act in accordance with procedures provided by law based on the principle that the person concerned should be seen and consulted.
2. The decision to subject a person to involuntary treatment should be taken by a court or another competent body. The court or other competent body should:
 - i. take into account the opinion of the person concerned;
 - ii. act in accordance with procedures provided by law based on the principle that the person concerned should be seen and consulted.

However, the law may provide that when a person is subject to involuntary placement the decision to subject that person to involuntary treatment may be taken by a doctor having the requisite competence and experience, after examination of the person concerned and taking into account his or her opinion.

3. Decisions to subject a person to involuntary placement or to involuntary treatment should be documented and state the maximum period beyond which, according to law, they should be formally reviewed. This is without prejudice to the person's rights to reviews and appeals, in accordance with the provisions of Article 25.

Procedures prior to the decision

4. Involuntary placement, involuntary treatment, or their extension should only take place on the basis of examination by a doctor having the requisite competence and experience, and in accordance with valid and reliable professional standards.

5. That doctor or the competent body should consult those close to the person concerned, unless the person objects, it is impractical to do so, or it is inappropriate for other reasons.

6. Any representative of the person should be informed and consulted.

Article 21 – Procedures for taking decisions on involuntary placement and/or involuntary treatment in emergency situations

1. Procedures for emergency situations should not be used to avoid applying the procedures set out in Article 20.

2. Under emergency procedures:

- i. involuntary placement or involuntary treatment should only take place for a short period of time on the basis of a medical assessment appropriate to the measure concerned;
- ii. paragraphs 5 and 6 of Article 20 should be complied with as far as possible;
- iii. decisions to subject a person to involuntary placement or to involuntary treatment should be documented and state the maximum period beyond which, according to law, they should be formally reviewed. This is without prejudice to the person's rights to reviews and appeals, in accordance with the provisions of Article 25.

3. If the measure is to be continued beyond the emergency situation, a court or another competent body should take decisions on the relevant measure, in accordance with Article 20, as soon as possible.

Article 22 – Right to information

1. Persons subject to involuntary placement or involuntary treatment should be promptly informed, verbally and in writing, of their rights and of the remedies open to them.

2. They should be informed regularly and appropriately of the reasons for the decision and the criteria for its potential extension or termination.

3. The person's representative, if any, should also be given the information.

Article 23 – Right to communication and to visits of persons subject to involuntary placement

The right of persons with mental disorder subject to involuntary placement:

- i. to communicate with their lawyers, representatives or any appropriate authority should not be restricted. Their right to communicate with their personal advocates or other persons should not be

unreasonably restricted;

ii. to receive visits should not be unreasonably restricted, taking into account the need to protect vulnerable persons or minors placed in or visiting a psychiatric facility.

Article 24 – Termination of involuntary placement and/or involuntary treatment

1. Involuntary placement or involuntary treatment should be terminated if any of the criteria for the measure are no longer met.

2. The doctor in charge of the person's care should be responsible for assessing whether any of the relevant criteria are no longer met unless a court has reserved the assessment of the risk of serious harm to others to itself or to a specific body.

3. Unless termination of a measure is subject to judicial decision, the doctor, the responsible authority and the competent body should be able to take action on the basis of the above criteria in order to terminate that measure.

4. Member states should aim to minimise, wherever possible, the duration of involuntary placement by the provision of appropriate aftercare services.

Article 25 – Reviews and appeals concerning the lawfulness of involuntary placement and/or involuntary treatment

1. Member states should ensure that persons subject to involuntary placement or involuntary treatment can effectively exercise the right:

i. to appeal against a decision;

ii. to have the lawfulness of the measure, or its continuing application, reviewed by a court at reasonable intervals;

iii. to be heard in person or through a personal advocate or representative at such reviews or appeals.

2. If the person, or that person's personal advocate or representative, if any, does not request such review, the responsible authority should inform the court and ensure that the continuing lawfulness of the measure is reviewed at reasonable and regular intervals.

3. Member states should consider providing the person with a lawyer for all such proceedings before a court. Where the person cannot act for him or herself, the person should have the right to a lawyer and, according to national law, to free legal aid. The lawyer should have access to all the materials, and have the right to challenge the evidence, before the court.

4. If the person has a representative, the representative should have access to all the materials, and have the right to challenge the evidence, before the court.

5. The person concerned should have access to all the materials before the court subject to the protection of the confidentiality and safety of others according to national law. If the person has no representative, he or she should have access to assistance from a personal advocate in all procedures before a court.

6. The court should deliver its decision promptly. If it identifies any violations of the relevant national legislation it should send these to the relevant body.

7. A procedure to appeal the court's decision should be provided.

Chapter IV – Placement of persons not able to consent in the absence of objection

Article 26 – Placement of persons not able to consent in the absence of objection

Member states should ensure that appropriate provisions exist to protect a person with mental disorder who does not have the capacity to consent and who is considered in need of placement and does not object to the placement.

Chapter V – Specific situations

Article 27 – Seclusion and restraint

1. Seclusion or restraint should only be used in appropriate facilities, and in compliance with the principle of least restriction, to prevent imminent harm to the person concerned or others, and in proportion to the risks entailed.

2. Such measures should only be used under medical supervision, and should be appropriately documented.

3. In addition:

- i. the person subject to seclusion or restraint should be regularly monitored;
- ii. the reasons for, and duration of, such measures should be recorded in the person's medical records and in a register.

4. This article does not apply to momentary restraint.

Article 28 – Specific treatments

1. Treatment for mental disorder that is not aimed at producing irreversible physical effects but may be particularly intrusive should be used only if no less intrusive means of providing appropriate care is available. Member states should ensure that the use of such treatment is:

- i. subject to appropriate ethical scrutiny;
- ii. in accordance with appropriate clinical protocols reflecting international standards and safeguards;
- iii. except in emergency situations as referred to in Article 12, with the person's informed, written consent or, in the case of a person who does not have the capacity to consent, the authorisation of a court or competent body;
- iv. fully documented and recorded in a register.

2. Use of a treatment for mental disorder with the aim of producing irreversible physical effects should be exceptional, and should not be used in the context of involuntary placement. Such a treatment should only be carried out if the person concerned has given free, informed and specific consent in writing. The treatment should be fully documented and recorded in a register, and used only:

- i. in accordance with the law;
- ii. subject to appropriate ethical scrutiny;
- iii. in accordance with the principle of least restriction;
- iv. if an independent second medical opinion agrees that it is appropriate; and
- v. in accordance with appropriate clinical protocols reflecting international standards and

safeguards.

Article 29 – Minors

1. The provisions of this recommendation should apply to minors unless a wider measure of protection is provided.
2. In decisions concerning placement and treatment, whether provided involuntarily or not, the opinion of the minor should be taken into consideration as an increasingly determining factor in proportion to his or her age and degree of maturity.
3. A minor subject to involuntary placement should have the right to assistance from a representative from the start of the procedure.
4. A minor should not be placed in a facility in which adults are also placed, unless such a placement would benefit the minor.
5. Minors subject to placement should have the right to a free education and to be reintegrated into the general school system as soon as possible. If possible, the minor should be individually evaluated and receive an individualised educational or training programme.

Article 30 – Procreation

The mere fact that a person has a mental disorder should not constitute a justification for permanent infringement of his or her capacity to procreate.

Article 31 – Termination of pregnancy

The mere fact that a person has a mental disorder should not constitute a justification for termination of her pregnancy.

Chapter VI – Involvement of the criminal justice system

Article 32 – Involvement of the police

1. In the fulfilment of their legal duties, the police should coordinate their interventions with those of medical and social services, if possible with the consent of the person concerned, if the behaviour of that person is strongly suggestive of mental disorder and represents a significant risk of harm to him or herself or to others.
2. Where other appropriate possibilities are not available the police may be required, in carrying out their duties, to assist in conveying or returning persons subject to involuntary placement to the relevant facility.
3. Members of the police should respect the dignity and human rights of persons with mental disorder. The importance of this duty should be emphasised during training.
4. Members of the police should receive appropriate training in the assessment and management of situations involving persons with mental disorder, which draws attention to the vulnerability of such persons in situations involving the police.

Article 33 – Persons who have been arrested

If a person whose behaviour is strongly suggestive of mental disorder is arrested:

- i. the person should have the right to assistance from a representative or an appropriate personal advocate during the procedure;
- ii. an appropriate medical examination should be conducted promptly at a suitable location to establish:
 - a. the person's need for medical care, including psychiatric care;
 - b. the person's capacity to respond to interrogation;
 - c. whether the person can be safely detained in non-health care facilities.

Article 34 – Involvement of the courts

1. Under criminal law, courts may impose placement or treatment for mental disorder whether the person concerned consents to the measure or not. Member states should ensure that the person can effectively exercise the right to have the lawfulness of the measure, or its continuing application, reviewed by a court at reasonable intervals. The other provisions of chapter III should be taken into account in such placements or treatments; any non-application of those provisions should be justifiable.

2. Courts should make sentencing decisions concerning placement or treatment for mental disorder on the basis of valid and reliable standards of medical expertise, taking into consideration the need for persons with mental disorder to be treated in a place appropriate to their health needs. This provision is without prejudice to the possibility, according to law, for a court to impose psychiatric assessment and a psychiatric or psychological care programme as an alternative to imprisonment or to the delivery of a final decision.

Article 35 – Penal institutions

1. Persons with mental disorder should not be subject to discrimination in penal institutions. In particular, the principle of equivalence of care with that outside penal institutions should be respected with regard to their health care. They should be transferred between penal institution and hospital if their health needs so require.

2. Appropriate therapeutic options should be available for persons with mental disorder detained in penal institutions.

3. Involuntary treatment for mental disorder should not take place in penal institutions except in hospital units or medical units suitable for the treatment of mental disorder.

4. An independent system should monitor the treatment and care of persons with mental disorder in penal institutions.

Chapter VII – Quality assurance and monitoring

Article 36 – Monitoring of standards

1. Member states should ensure that compliance with the standards set by this recommendation and by mental health law is subject to appropriate monitoring. That monitoring should cover:

- i. compliance with legal standards;
- ii. compliance with technical and professional standards.

2. The systems for conducting such monitoring should:
 - i. have adequate financial and human resources to perform their functions;
 - ii. be organisationally independent from the authorities or bodies monitored;
 - iii. involve mental health professionals, lay persons, persons with mental disorder and those close to such persons;
 - iv. be coordinated, where appropriate, with other relevant audit and quality assurance systems.

Article 37 – Specific requirements for monitoring

1. Monitoring compliance with standards should include:
 - i. conducting visits and inspections of mental health facilities, if necessary without prior notice, to ensure:
 - a. that persons are only subject to involuntary placement in facilities registered by an appropriate authority, and that such facilities are suitable for that function;
 - b. that suitable alternatives to involuntary placement are provided;
 - ii. monitoring compliance with professional obligations and standards;
 - iii. ensuring powers exist to investigate the death of persons subject to involuntary placement or involuntary treatment, and that any such death is notified to the appropriate authority and is subject to an independent investigation;
 - iv. reviewing situations in which communication has been restricted;
 - v. ensuring that complaints procedures are provided and complaints responded to appropriately.
2. Appropriate follow-up of the results of monitoring should be ensured.
3. In respect of persons subject to provisions of mental health law, the persons conducting monitoring should be entitled:
 - i. to meet privately with such persons, and with their consent or that of their representatives, have access to their medical file at any time;
 - ii. to receive confidential complaints from such persons;
 - iii. to obtain from authorities or staff responsible for the treatment or care of such persons any information that may reasonably be considered necessary for the performance of their functions, including anonymised information from medical records.

Article 38 – Statistics, advice and reporting

1. Systematic and reliable anonymised statistical information on the application of mental health law and on complaints should be collected.
2. Those responsible for the care of persons with mental disorder should:
 - i. receive from those responsible for quality assurance and monitoring:
 - a. regular reports, and where possible publish those reports;
 - b. advice on the conditions and facilities appropriate to the care of persons with mental disorder;
 - ii. respond to questions, advice and reports arising from the quality assurance and monitoring systems.
3. Information on the implementation of mental health law and actions concerning compliance with standards should be made available to the public.

COUNCIL OF EUROPE

COMMITTEE OF MINISTERS

RECOMMENDATION NO. REC(2006)4

of the Committee of Ministers to member States

on research on biological materials of human origin

*(Adopted by the Committee of Ministers on 15 March 2006
at the 958th meeting of the Ministers' Deputies)¹*

Preamble

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 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 one of the aims of the Convention for the Protection of Human Rights and Fundamental Freedoms (ETS No. 5) is the protection of private life;

Considering that the aim of the Convention on Human Rights and Biomedicine (ETS No. 164, hereinafter referred to as "the Convention") and of its Additional Protocol concerning biomedical research (CETS No. 195), as defined in Article 1 of both instruments, 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 and biological sciences, in particular advances obtained through biomedical research, including research using biological materials donated in a spirit of solidarity, contributes to saving lives and improving their quality;

Conscious of the fact that the advancement of biomedical science and practice is dependent on knowledge and discovery which necessitates research on human beings and research involving the use of biological materials of human origin;

Stressing that such research is often transdisciplinary and international;

Taking into account the current and planned development of collections and banks of biological materials at national level;

¹ When adopting this decision, the Permanent Representative of the United Kingdom indicated that, in accordance with Article 10.2c of the Rules of Procedure for the meetings of the Ministers' Deputies, he reserved the right of his Government to comply or not with the Recommendation as a whole.

Taking into account national and international professional standards in the area of biomedical research and the previous work of the Committee of Ministers and the Parliamentary Assembly of the Council of Europe in this field;

Convinced that biomedical research that is contrary to human dignity and human rights should never be carried out;

Stressing that the paramount concern should be the protection of the human being whose biological materials are removed, stored or used for research;

Recalling that research on biological materials should be carried out freely subject to the provisions of this recommendation and the other legal provisions ensuring the protection of the human being;

Emphasising that the interests and welfare of the human being whose biological materials are used in research shall prevail over the sole interest of society or science;

Affirming that particular protection shall be given to human beings who may be vulnerable in the context of research;

Recognising that every person has the right to accept or refuse to contribute to biomedical research and that no one should be forced to contribute to it;

Stressing the importance of appropriate and transparent governance of biological materials stored for research purposes;

Stressing that population biobanks developed on the basis of donations of biological materials made in a spirit of solidarity should not be monopolised by small groups of researchers;

Resolving to take such measures as are necessary to safeguard human dignity and the rights and fundamental freedoms of the individual with regard to biomedical research on biological materials of human origin,

Recommends that the governments of member states adapt their laws and practices to the guidelines contained in appendix to this recommendation and promote the establishment of practice guidelines to ensure compliance with the provisions contained in this appendix;

Entrust the Secretary General of the Council of Europe to transmit this recommendation to the governments of the non-member states of the Council of Europe which have been invited to sign the Convention on Human Rights and Biomedicine, to the European Community and to the international organisations participating in the work of the Council of Europe in the fields of bioethics.

GUIDELINES

CHAPTER I

Object, scope and definitions

Article 1 – Object

Member states should protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity, right to private life and other rights and fundamental freedoms with regard to any research governed by this recommendation.

Article 2 – Scope

1. This recommendation applies to the full range of research activities in the health field involving the removal of biological materials of human origin to be stored for research use.
2. It also applies to the full range of research activities in the health field involving the use of biological materials of human origin that were removed for a purpose other than that mentioned in the previous paragraph; this includes material removed for a previous research project.
3. This recommendation does not apply to embryonic and foetal tissues.
4. The use of biological material of human origin may be accompanied by the use of associated personal data.

Article 3 – Identifiability of biological materials

Biological materials referred to in Article 2 may be identifiable or non-identifiable:

- i. *Identifiable biological materials* are those biological materials which, alone or in combination with associated data, allow the identification of the persons concerned either directly or through the use of a code.

In the latter case, the user of the biological materials may either:

- a. have access to the code: the materials are hereafter referred to as “coded materials”; or
 - b. not have access to the code, which is under the control of a third party: the material are hereafter referred to as “linked anonymised materials”.
- ii. *Non-identifiable biological materials*, hereafter referred to as “unlinked anonymised materials”, are those biological materials which, alone or in combination with associated data, do not allow, with reasonable efforts, the identification of the persons concerned.

CHAPTER II

General provisions

Article 4 – Codes of good practice

Member states should promote the establishment of codes of good practice to ensure compliance with the provisions of this recommendation.

Article 5 – Risks and benefits

1. The risks for the persons concerned and, where appropriate, for their family, related to research activities, in particular the risks to private life, should be minimised, taking into account the nature of the research activity. Furthermore, those risks should not be disproportionate to the potential benefit of the research activities.
2. Possible risks for the individuals in the same group as the person concerned should also be taken into consideration in this context.

Article 6 – Non-discrimination

Appropriate measures should be taken, in the full range of research activities, to avoid discrimination against, or stigmatisation of, a person, family or group.

Article 7 – Prohibition of financial gain

Biological materials should not, as such, give rise to financial gain.

Article 8 – Justification of identifiability

1. Biological materials and associated data should be anonymised as far as appropriate to the research activities concerned.
2. Any use of biological materials and associated data in an identified, coded, or linked anonymised form should be justified by the researcher.

Article 9 – Wider protection

None of the provisions of this recommendation should be interpreted as limiting or otherwise affecting the possibility for a member state to grant a wider measure of protection than is stipulated in this recommendation.

CHAPTER III

Obtaining biological materials for research

Article 10 – Obtaining biological materials for research

1. Biological materials should be obtained for research in accordance with the provisions of this chapter.
2. Information and consent or authorisation to obtain such materials should be as specific as possible with regard to any foreseen research uses and the choices available in that respect.

Article 11 – Interventions on a person

An intervention should only be carried out to obtain biological materials for storage for research purposes if it complies with the Additional Protocol concerning biomedical research (CETS No. 195, 2005).

Article 12 – Residual biological materials

1. Biological materials removed for purposes other than storage for research should only be made available for research activities with appropriate consent or authorisation, or in accordance with the provisions of Article 22 paragraph 1.ii.
2. Whenever possible, information should be given and consent or authorisation requested before biological materials are removed.

Article 13 – Biological materials removed after death

1. Biological materials should not be removed from the body of a deceased person for research activities without appropriate consent or authorisation.
2. Biological materials should not be removed or supplied for research activities if the deceased person is known to have objected to it.

CHAPTER IV

Collections of biological materials

Article 14 – Principles applicable to all collections of biological materials

1. The person and/or institution responsible for the collection should be designated.
2. The purpose(s) of a collection should be specified. The principles of transparency and accountability should govern its management, including access to and use and transfer of its biological materials and disclosure of information.
3. Each sample of biological material in the collection should be appropriately documented, including information on any relevant consent or authorisation.
4. Clear conditions governing access to, and use of, the samples should be established.
5. Quality assurance measures should be in place, including conditions to ensure security and confidentiality during storage and handling of the biological materials.

Article 15 – Right to change the scope of, or to withdraw, consent or authorisation

1. When a person has provided consent to storage of identifiable biological materials for research purposes, the person should retain the right to withdraw or alter the scope of that consent. The withdrawal or alteration of consent should not lead to any form of discrimination against the person concerned, in particular regarding the right to medical care.

When identifiable biological materials are stored for research purposes only, the person who has withdrawn consent should have the right to have, in the manner foreseen by national law, the materials either destroyed or rendered unlinked anonymised.

2. Where authorisation has been given on behalf of a person not able to consent, the representative, authority, person or body provided for by law should have the rights referred to in paragraph 1 above.
3. Where a person on whose behalf authorisation has been given attains the capacity to give consent, that person should have the rights referred to in paragraph 1 above.

Article 16 – Transborder flows

Biological materials and associated personal data should only be transferred to another state if that state ensures an adequate level of protection.

CHAPTER V

Population biobanks

Article 17 – Scope of chapter V

1. A population biobank is a collection of biological materials that has the following characteristics:
 - i. the collection has a population basis;
 - ii. it is established, or has been converted, to supply biological materials or data derived therefrom for multiple future research projects;
 - iii. it contains biological materials and associated personal data, which may include or be linked to genealogical, medical and lifestyle data and which may be regularly updated;
 - iv. it receives and supplies materials in an organised manner.
2. Population biobanks should meet the requirements set out in this chapter in addition to those of chapter IV.
3. Member states should consider applying the provisions of this chapter to collections that have some, but not all, of the characteristics specified in paragraph 1.

Article 18 – Independent examination

A proposal to establish, or to convert a collection to, a population biobank should be subject to an independent examination of its compliance with the provisions of this recommendation.

Article 19 – Oversight of population biobanks

1. Each population biobank should be subject to independent oversight, in particular to safeguard the interests and rights of the persons concerned in the context of the activities of the biobank.
2. Regular audits should be conducted of the implementation of procedures on access to, and use of, samples.
3. Procedures should be developed for the transfer and for the closure of a population biobank.
4. Population biobanks should publish reports on their past and planned activities at least annually, or more frequently if appropriate.

Article 20 – Access to population biobanks

1. Member states should take appropriate measures to facilitate access by researchers to biological materials and associated data stored in population biobanks.
2. Such access should be subject to the conditions laid down in this recommendation; it may also be subject to other appropriate conditions.

CHAPTER VI

Use of biological materials in research projects

Article 21 – General rule

Research on biological materials should only be undertaken if it is within the scope of the consent given by the person concerned. The person concerned may place restrictions on the use of his or her biological materials.

Article 22 – Identifiable biological materials

1.i. If the proposed use of identifiable biological materials in a research project is not within the scope of prior consent, if any, given by the person concerned, reasonable efforts should be made to contact the person in order to obtain consent to the proposed use.

ii. If contacting the person concerned is not possible with reasonable efforts, these biological materials should only be used in the research project subject to independent evaluation of the fulfilment of the following conditions:

- a. the research addresses an important scientific interest;
- b. the aims of the research could not reasonably be achieved using biological materials for which consent can be obtained; and
- c. there is no evidence that the person concerned has expressly opposed such research use.

2. The person concerned may freely refuse consent for the use in a research project of his or her identifiable biological materials, or withdraw consent, at any time. Refusal to give consent or the withdrawal of consent should not lead to any form of discrimination against the person concerned, in particular regarding the right to medical care.

Article 23 – Unlinked anonymised biological materials

1. Unlinked anonymised biological materials may be used in research provided that such use does not violate any restrictions placed by the person concerned prior to the anonymisation of the materials.

2. Anonymisation should be verified by an appropriate review procedure.

Article 24 – Independent review

1. Research should only be undertaken if the research project has been subject to an independent examination of its scientific merit, including assessment of the importance of the aim of the research, and verification of its ethical acceptability. National law may additionally require approval by a competent body.

2. Member states should apply the provisions concerning ethics committees contained in chapter III of the Additional Protocol concerning biomedical research (CETS No. 195, 2005) to the review of research within the scope of this recommendation.

3. Review procedures may be adapted to the nature of the research and the extent to which the persons concerned could be identified from their biological materials or associated data.

Article 25 – Confidentiality and right to information

The principles of chapter VIII (confidentiality and right to information) of the Additional Protocol concerning biomedical research should be applied to any research project using biological materials and associated personal data.

CHAPTER VII

Re-examination of the recommendation

Article 26 – Re-examination of the recommendation

This recommendation should be re-examined not more than five years after its adoption, notably in the light of the experience acquired in the implementation of its guidelines.

COUNCIL OF EUROPE

COMMITTEE OF MINISTERS

RECOMMENDATION NO. REC(2009)11

of the Committee of Ministers to member States

on principles concerning continuing powers of attorney and advance directives for incapacity

*(Adopted by the Committee of Ministers on 9 December 2009
at the 1073rd 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 a greater unity between its member states, in particular by promoting adoption of common rules in legal matters;

Noting that demographic changes have resulted in an increasing number of elderly people who have become incapable of protecting their interests by reason of an impairment or insufficiency of their personal faculties;

Noting that there continue to be other circumstances in which adults become incapacitated;

Having regard to relevant instruments of the Council of Europe, including the Convention for the Protection of Human Rights and Fundamental Freedoms (ETS No. 5, 1950), the Convention on Human Rights and Biomedicine (Oviedo Convention, ETS No. 164, 1997) and Recommendation Rec(2006)5 of the Committee of Ministers to member states on the Council of Europe Action Plan to promote the rights and full participation of people with disabilities in society: improving the quality of life of people with disabilities in Europe 2006-2015;

Having regard to the Hague Convention on the International Protection of Adults (2000) and the United Nations Convention on the Rights of Persons with Disabilities (2006);

Bearing in mind the relevant case law of the European Court of Human Rights;

Agreeing that Recommendation No. R (99) 4 of the Committee of Ministers to member states on principles concerning the legal protection of incapable adults is a valuable and up-to-date international instrument containing detailed guidance and general advice on legal rules dealing with measures of protection of such adults;

Noting that the above recommendation and the legislation of the member states concerning adults with incapacity strongly promotes self-determination and autonomy;

Considering that self-determination is essential in respecting the human rights and dignity of

each human being;

Noting that in some member states continuing powers of attorney are a preferred alternative to court decisions on representation;

Noting that legislation on continuing powers of attorney and advance directives has recently been passed or proposed in some member states;

Noting that in legal systems where continuing powers of attorney and advance directives are available, adults of all ages increasingly make use of them;

Recognising that there are considerable disparities between the legislation of member states as regards these issues;

Building upon the principles of subsidiarity and necessity contained in Recommendation No. R (99) 4 and supplementing it with principles on self-determination,

Recommends that governments of member states promote self-determination for capable adults by introducing legislation on continuing powers of attorney and advance directives or by amending existing legislation with a view to implementing the principles contained in the appendix to this recommendation.

Appendix to Recommendation CM/Rec(2009)11

Part I – Scope of application

Principle 1 – Promotion of self-determination

1. States should promote self-determination for capable adults in the event of their future incapacity, by means of continuing powers of attorney and advance directives.
2. In accordance with the principles of self-determination and subsidiarity, states should consider giving those methods priority over other measures of protection.

Principle 2 – Definition of terms used in the present recommendation

1. A “continuing power of attorney” is a mandate given by a capable adult with the purpose that it shall remain in force, or enter into force, in the event of the granter’s incapacity.
2. The “granter” is the person giving the continuing power of attorney. The person mandated to act on behalf of the granter is referred to as the “attorney”.
3. “Advance directives” are instructions given or wishes made by a capable adult concerning issues that may arise in the event of his or her incapacity.

Part II – Continuing powers of attorney

Principle 3 – Content

States should consider whether it should be possible for a continuing power of attorney to cover economic and financial matters, as well as health, welfare and other personal matters, and whether some particular matters should be excluded.

Principle 4 – Appointment of attorney

1. The granter may appoint as attorney any person whom he or she considers to be appropriate.
2. The granter may appoint more than one attorney and may appoint them to act jointly, concurrently, separately, or as substitutes.
3. States may consider such restrictions as are deemed necessary for the protection of the granter.

Principle 5 – Form

1. A continuing power of attorney shall be in writing.
2. Except in states where such is the general rule, the document shall explicitly state that it shall enter into force or remain in force in the event of the granter's incapacity.
3. States should consider what other provisions and mechanisms may be required to ensure the validity of the document.

Principle 6 – Revocation

A capable granter shall have the possibility to revoke the continuing power of attorney at any time. Principle 5, paragraph 3, is applicable.

Principle 7 – Entry into force

1. States should regulate the manner of entry into force of the continuing power of attorney in the event of the granter's incapacity.
2. States should consider how incapacity should be determined and what evidence should be required.

Principle 8 – Certification, registration and notification

States should consider introducing systems of certification, registration and/or notification when the continuing power of attorney is granted, revoked, enters into force or terminates.

Principle 9 – Preservation of capacity

The entry into force of a continuing power of attorney shall not as such affect the legal capacity of the granter.

Principle 10 – Role of the attorney

1. The attorney acts in accordance with the continuing power of attorney and in the interests of the granter.
2. The attorney, as far as possible, informs and consults the granter on an ongoing basis. The attorney, as far as possible, ascertains and takes account of the past and present wishes and feelings of the granter and gives them due respect.
3. The granter's economic and financial matters are, as far as possible, kept separate from the attorney's own.
4. The attorney keeps sufficient records in order to demonstrate the proper exercise of his or her mandate.

Principle 11 – Conflict of interest

States should consider regulating conflicts of the granter's and the attorney's interests.

Principle 12 – Supervision

1. The granter may appoint a third party to supervise the attorney.
2. States should consider introducing a system of supervision under which a competent authority is empowered to investigate. When an attorney is not acting in accordance with the continuing power of attorney or in the interests of the granter, the competent authority should have the power to intervene. Such intervention might include terminating the continuing power of attorney in part or in whole. The competent authority should be able to act on request or on its own motion.

Principle 13 – Termination

1. States should consider under which circumstances a continuing power of attorney ceases to have effect.
2. When a continuing power of attorney ceases to have effect in part or in whole, the competent authority should consider which measures of protection might be taken.

Part III – Advance directives

Principle 14 – Content

Advance directives may apply to health, welfare and other personal matters, to economic and financial matters, and to the choice of a guardian, should one be appointed.

Principle 15 – Effect

1. States should decide to what extent advance directives should have binding effect. Advance directives which do not have binding effect should be treated as statements of wishes to be given due respect.
2. States should address the issue of situations that arise in the event of a substantial change in circumstances.

Principle 16 – Form

1. States should consider whether advance directives or certain types of advance directives should be made or recorded in writing if intended to have binding effect.
2. States should consider what other provisions and mechanisms may be required to ensure the validity and effectiveness of those advance directives.

Principle 17 – Revocation

An advance directive shall be revocable at any time and without any formalities.

COUNCIL OF EUROPE

COMMITTEE OF MINISTERS

RECOMMENDATION NO. REC(2010)6

of the Committee of Ministers to member States

on good governance in health systems

*(Adopted by the Committee of Ministers on 31 March 2010
at the 1081st meeting of the Ministers' Deputies)*

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

Recalling the Warsaw Declaration (2005) wherein it is stated that: “effective democracy and good governance at all levels are essential for preventing conflicts, promoting stability, facilitating economic and social progress”;

Having regard to its Recommendation CM/Rec(2007)7 to member states on good administration, its Recommendation No. R (2000) 10 on codes of conduct for public officials, and its Recommendation No. R (97) 17 on the development and implementation of quality improvement systems (QIS) in health care, wherein member states are encouraged to create, where appropriate, policies and structures that support the development and implementation of such systems;

Building on the achievements of the Council of Europe in fighting corruption, notably by the Group of States against Corruption (GRECO), and promoting good administration;

Bearing in mind the contributions brought to the field of good governance in health systems by, in particular, the European Healthcare Fraud and Corruption Network (EHFCN) and Transparency International;

Noting the relevance of the World Health Organisation’s resolutions and decisions, in particular the Ljubljana Charter on reforming health care (1996), the Health for All Policy Framework (2005) and the Tallinn Charter: Health Systems for Health and Wealth (2008);

Recognising that good governance should be driven by the fundamental values of human rights, the rule of law and democracy;

Recalling Part I of the European Social Charter (revised) (ETS No. 163) which provides that the Parties thereto accept as the aim of their policy, to be pursued by all appropriate means both national and international in character, the attainment of conditions in which the right of everyone to benefit from any measures enabling him to enjoy the highest possible standard of health attainable may be effectively realised;

Recalling the 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 No. 164), in particular:

- Article 1 on the protection of the dignity and identity of all human beings and on guaranteeing everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms;
- Article 2 on the primacy of the interests and welfare of the human being over the sole interest of society;
- Article 3 on the equitable access to health care of appropriate quality;
- Article 4 stating that any intervention in the health field must be carried out in accordance with relevant professional obligations and standards;
- Article 28 stipulating that the fundamental questions raised by the developments of biology and medicine are the subject of appropriate public discussion and that their possible application is made the subject of appropriate consultation; and
- Chapter V on scientific research;

Considering that there are values of good governance which are particularly important in the context of health systems, namely universality, solidarity and equity;

Recognising that the key principles of good governance in public services have a special relevance for health systems, in particular transparency, participation, accountability, effectiveness, efficiency and quality;

Recognising that good governance in health systems cannot be achieved without a long-term strategy and a commitment to achieving political legitimacy, social cohesion and sustainability;

Bearing in mind that decision-making processes should be participatory and transparent to all stakeholders, in particular for citizens;

Recognising the importance of promoting a culture of good governance, as well as developing capacities for policy analysis, advocacy and intersectorial action for health;

Considering that policy making and planning should be informed by the best knowledge available on the issues at hand, including contributions from all relevant disciplines and experiences;

Recognising that a good governance system should contain built-in mechanisms for monitoring and evaluation, as well as performance assessment of the health system based on clear objectives;

Considering that policy making for health systems, like other public governance, should incorporate health impact assessments applied both within health services and in relation to the determinants of health in other policies which can influence health;

Considering that ethical aspects play a particularly important role in achieving good governance in health systems by fostering a culture of integrity and finding appropriate ways of framing codes of conduct, monitoring good governance, managing conflicts of interest and taking measures to prevent and counter fraud and corruption;

Considering that the good governance principles mentioned above apply to the public and private sectors of the health system and to all levels of governance (national, regional and local) following the principle of subsidiarity by focusing on an optimal division of tasks between the relevant levels,

A. Recommends that governments of member states, having due regard to their specific national, regional or local structures and respective responsibilities:

- i. take appropriate steps to ensure good governance of health systems that is based on:
 - fundamental values of human rights, the rule of law and democracy;
 - principles underpinning health systems such as universality, solidarity and equity;
 - good governance principles for public services: transparency, accountability, effectiveness, efficiency, and quality;
 - ensuring that these values and principles should guide practical action taken at all levels and dimensions of the health system including education, training and monitoring;
- ii. respond rapidly and effectively to the changing medical, economic and social environment by ensuring the planning and development of institutional and human good governance capacities;
- iii. develop and adopt a set of ethical principles for health system governance, with special emphasis on the structural determinants, legislative guidelines and codes of conduct in health systems, which aim to prevent and counter corruption, manage conflicts of interest and monitor good governance;
- iv. support an active dissemination of this recommendation and its explanatory report, targeting in particular policy makers, public administration staff and organisations involved in decision making within the health system;
- v. take necessary steps to implement the guidelines contained in the appendix to this recommendation.

B. Entrusts the European Health Committee (CDSF) to monitor and evaluate the implementation of the recommendation in member states.

Appendix to Recommendation CM/Rec(2010)6

GUIDELINES

These guidelines contain:

- **a general framework for codes of conduct in the health sector (attachment I);**
- **a general framework for monitoring governance in the health sector (attachment II); and**
- **an example of a good governance assessment matrix.**

I. Laws and regulations for the good governance of a health system based on fundamental values and principles

1. In all member states, the legislative framework of any given health system should be based on the three fundamental values of the Council of Europe: human rights and human dignity, the rule of law and democracy. To this should be added the right to health protection built on the principles of universality, equity and solidarity.
2. Each member state, taking into account the recommendations of the Council of Europe's High-Level Task Force on Social Cohesion in the 21st century, should develop a value-based good governance framework for its health system, which should:
 - be based on the key principles of accountability, transparency, sustainability and respect for patients' rights;
 - target the prevention of corruption and foster a culture of countering it;
 - concentrate efforts on improving the management of conflicts of interest;
 - appeal to the shared responsibility of all stakeholders in society.
3. Member states are encouraged to put into place a monitoring system to systematically assess the contribution and adequacy of governance mechanisms, such as legislation, policies and regulatory activities aimed at achieving the goals of good governance.

II. Promoting codes of conduct for good governance of a health system

4. Considering the complexity and the professional nature of health services, health legislation in all member states should be complemented by clear and explicit codes of conduct and other self-regulatory tools.
5. Codes of conduct should be developed for different stakeholders in the health sector, such as administrators, managers, policy makers, professionals and their organisations, as well as for all health-related industries, including the media.
6. Codes of conduct should include effective mechanisms for their implementation, monitoring and enforcement.
7. Codes of conduct for health professionals should include specific clauses on conflicts of interest.
8. Governments of member states should promote, subject to national law and the principles of good public policy, the adoption of codes of conduct for good governance in health systems based on the framework presented in attachment I to this appendix.

III. Monitoring good governance of a health systems

9. Explicit values and principles of good governance should become an integral part of a health system, and a shared vision for all stakeholders should be developed in order to enable their implementation and assessment.
10. Member states are encouraged to develop assessment tools to monitor good

governance in health systems. The overall objectives for monitoring good governance should be threefold:

- i. to measure governance in health systems at a national as well as organisational level;
- ii. to monitor the impact of governance from the perspectives of all stakeholders;
- iii. to raise awareness and promote a common understanding of governance in health systems.

11. Assessment frameworks should be based on the premise that improved governance influences all other health system functions, which in turn results in improved performance of the health system and ultimately leads to better health outcomes. Therefore the framework could consist of the following components:

- values: human rights, rule of law and democracy;
- principles: universality, equity and solidarity;
- governance mechanisms: planning, decision making, regulation, control and evaluation;
- outcomes: transparency, accountability, access, participation, effectiveness and efficiency.

An example for a possible general framework for monitoring governance in the health sector is presented in attachment II to this appendix.

IV. Managing conflicts of interest in health systems

12. Member states should proactively attempt to identify areas where conflicts of interest in relation to the health system may arise, and to prevent and counter such conflicts, whether caused by public officials or by non-public agents (private sector), by ensuring that private interests do not interfere with the performance of public or private health-related duties.

13. Special attention should be paid to conflicts of interest of those holding public responsibilities. Appropriate legislation should therefore be developed and a culture in public administration fostered requiring public officials to be accountable and personally responsible. Public officials should:

- be alert to any actual or potential conflict of interest, including nepotism;
- take steps to avoid such conflict;
- disclose any conflict of interests as soon as he or she becomes aware of its existence;
- comply with any final decisions to withdraw from the situation or to divest him/or herself of the advantage causing the conflict;
- declare whether or not he or she has a conflict of interest.

14. All candidates applying for employment in the public service sector should be required to declare any possible conflict of interest, and provision should be made to resolve any such conflict in due time before the appointment is decided.

15. At all levels of the health system there should be adequate regulatory and specific organisational measures making it possible to detect conflicts of interest and to take legal or other actions. This should be managed at individual, institutional and national levels.

16. Any potential conflict of interests related to clinical research activities should be registered and monitored by an independent authority. Information should include all relevant financial and non-financial benefits. Clinical research should be monitored by research ethics committees.

17. Scientific and vocational activities, including continuous medical education intended for health professionals should be organised in such a way as to guarantee their integrity and avoid influence from commercial interests.

18. There should be legal provisions for compulsory financial disclosure of expenditures made by commercial healthcare insurers, healthcare providers or health-related industries for marketing their products and services. Such data should be publicly available with the same level of detail as that requested for research and development.

V. A good governance framework against fraud and corruption

19. Fraud and corruption should be explicitly defined and tackled in all relevant regulatory frameworks at every level of the health system, making it an integral part of all health regulations.

20. Member states should consider establishing an independent anti-corruption body, covering all sectors of activities, at national level. Such a body should be able to take legal and other actions should the need arise.

21. To foster a culture of integrity and thus to prevent corruption, fraud and nepotism, a comprehensive and systemic strategy should be in place. This strategy should include:

- specific guidelines for transparency and enforcing mechanisms at every level of the health system, from national to individual institutional level;
- a high level of political priority and public visibility for the fight against corruption and fraud;
- provisions for professional investigation and public reporting of all cases of detected or alleged health system fraud and corruption;
- arrangements for the possible enforcement of multiple sanctions, such as civil, criminal and/or disciplinary processes, should health system fraud and corruption be proved;
- a system of compensation for the resources lost to fraud and corruption, and the return of the recovered losses;
- a national reporting system with periodic reports on the progress made against fraud and corruption.

VI. Preparing health-related professionals for good governance: the education and training of health professionals, administrators, managers and policy makers in value-

based good governance in health systems

22. Governments of member states should promote the idea of establishing a framework for the education and training of health-related professionals to include the acquisition of adequate competences for good governance and efficient management of health institutions and programmes.

23. Member states should ensure that a competent post-graduate training institution is available at national level, as well as in large regions, with links to both academic and health administrations. Such an institution should contribute to the dissemination of developments in public health and health-service research, as well as serving as a resource for the development, reform and evaluation of health systems.

* * *

ATTACHMENT I TO THE GUIDELINES

General framework for codes of conduct in the health sector (as referred to in paragraph 8 of the Guidelines)

1. Introduction
2. Values and ethical references
3. Legal framework of reference
4. Example of areas to be regulated by a code of conduct in the health sector

NB. Not all areas are applicable to all situations. The order of the items does not reflect priority ranking. The list is non-exhaustive and the items are for illustrative purposes only.

- a. Good professional practice
 - i. Respect for the dignity of people (employees, patients, customers)
 - ii. Honesty and confidentiality
 - iii. Keeping up-to-date professional competence
 - iv. Use of the best scientific evidence
 - v. Compliance with accepted standards
 - vi. Compliance with regulations and legislation
 - vii. Awareness of the needs, demands and expectations of the population, patients and customers
 - viii. Co-operation with colleagues
 - ix. Spirit of moderation, reconciliation, tolerance and appeasement
- b. Use of resources of the service/system
 - i. Cost-effectiveness practice in the use of resources
 - ii. Avoiding using public resources for private gain
 - iii. Prevention of fraud and corruption

- c. Handling of conflict of interests in the best interest of patients and population, whether
 - i. Economic, or
 - ii. Non-economic
- d. Proper access, sharing and use of information
 - i. Research of any information necessary for decision making
 - ii. Duty to disclose all relevant information to the public and authorities
 - iii. Duty to provide information to patients with respect to their needs and preferences
- e. Handling of gifts and benefits
 - i. Existence of an explicit policy concerning gifts
 - ii. Transparency regarding gifts received from interested parties
- f. Research-related topics
 - i. Clinical trials (Helsinki Declaration)
 - ii. Truthful claims of research potential
 - iii. Patient consent with full disclosure of risks
- g. Relationships with other actors in the health sector
 - i. Colleagues and other health professionals
 - ii. Patients and their families
 - iii. Insurers, third-party payers
 - iv. Health-related industries (pharmaceutical, food, advertisement, cosmetic, medical devices, etc.), and other interest groups
 - v. Government officers of health and other sectors (police)
 - vi. Patients and self-help organisations, NGOs, etc.
 - vii. Media
- h. Good corporate governance of health institutions/services/centres
- i. Issues of multiculturalism, tolerance and respect
- 5. Enforcement of the code of conduct
 - a. Recognition of violations
 - b. Composition of the body responsible for dealing with enforcement
 - c. Transparency of procedures and public scrutiny
 - d. Complaints system
- 6. Updating, monitoring and development of the code of conduct
 - a. Process of development of codes of conducts: initiative, ownership, legitimacy

- b. Comprehensiveness
- c. Limitations of codes of conduct
- d. Codes of conduct and legislation

* * *

ATTACHMENT II TO THE GUIDELINES

General framework for monitoring governance in the health sector (as referred to in paragraph 12 of the Guidelines)

1. Introduction: a conceptual framework to define, promote and monitor accountability in the field of health policy as both a means of ensuring good governance and as a preventive measure against corruption and other negative issues.
2. Values and principles underpinning the framework: human dignity, equity, solidarity and professional ethics as articulated in the Ljubljana Charter on Reforming Health Care (World Health Organisation, 1996) and the World Bank governance indicators.
3. Scope of the conceptual framework: organisational, regional, national and international monitoring.
4. Objectives of monitoring:
 - to serve as a reference framework that can become a common instrument for measuring governance in health systems at international, national and organisational level;
 - to observe the impact of governance from the perspectives of all stakeholders;
 - to raise awareness, build public confidence, facilitate learning and promote a common understanding of good governance in health systems.
5. Governance mechanisms: recent work carried out, for example, by the WHO and in Canada (Cirano project), demonstrates that a number of mechanisms can be used in exercising political, economic and administrative authority in the management of health systems. This includes mechanisms for planning, resource management, decision making, providing incentives, control, monitoring and evaluation.
6. Examples of areas to be covered by the assessment matrix (see table below):
 - a. control of corruption – measuring the ability of state institutions and agencies to tackle fraud and prevent corruption;
 - b. transparent and participatory decision making processes – measuring the level and quality of the equal involvement of all stakeholders in decision-making processes;
 - c. accountability – measuring the impact of existing arrangements established to achieve accountability for performance;
 - d. rule of law – measuring the effective compliance with rules and laws;
 - e. open reporting – measuring the openness and willingness of governing bodies to present and share information publicly.

7. Assessment process:
 - a. establish an expert group/observatory for governance monitoring;
 - b. data collection, using a variety of sources, including existing databases and information such as the World Bank governance indicators and the European Observatory on Health Systems and Policies, or WHO Regional Office for Europe;
 - c. self-assessment, including performance indicators and surveying key stakeholders using questionnaires;
 - d. reporting and dissemination of findings, through interactive web portals.

8. Enforcement of the framework:
 - composition of a body responsible for dealing with enforcement;
 - transparency of process; and
 - public reporting.

An example of a good governance assessment matrix

Principle	Governance mechanism	Key outcomes	Outcome Indicators	Questions
Transparency	Decision making	Transparent decisions are decisions in which the decision maker clearly presents to others the motivation behind the decisions and explains the reasoning leading to the conclusion (i.e. the actual decision) Privileged access for industry interests undermines public trust	Central register for lobbyists National guidelines for consultation process Complaint and redress mechanism to address concerns	Does a central register for lobbyists exist in this member state? Has the member state produced a national set of guidelines to ensure transparency in consultative processes? Does a complaint and redress mechanism exist? Are inspection reports available to the public?
Participation	Decision making	Participatory decision making implies that each actor has a say in decisions directly proportional to the degree to which the particular decision affects him or her	Patients' representation at board level of state agencies, for example the national institute for health and welfare	Are patients' views represented at board level of the member states' health agencies or institutions?
Accountability	Regulatory interventions – monitoring	Accountability for performance is relevant at all levels, from policy making to clinical practice	Systematic approach to assure quality and safety Code of conduct to govern the behaviour of health administrators and clinical practitioners	Do national standards exist which aim to assure quality and safety in health services? Does the member state have a national code of conduct for administrators and clinical practitioners?
Efficiency	Regulatory interventions – monitoring	Achieving greater efficiency and better value for money is a key governance objective	Member states' activities to detect and counteract fraud and corruption Capacity for independent technology assessment	Have particular institutions or agencies been established to tackle fraud and corruption? Do member states' agencies or institutions participate in the European Healthcare Fraud and Corruption Network (EHFCN)? Do these institutions have a capacity for independent assessment?

COUNCIL OF EUROPE

COMMITTEE OF MINISTERS

RESOLUTION ResAP(2007)2

of the Committee of Ministers to member States

on good practices for distributing medicines via mail order which protect patient safety and the quality of the delivered medicine

*(Adopted by the Committee of Ministers on 5 September 2007
at the 1003rd meeting of the Ministers' Deputies)¹*

The Committee of Ministers, in its composition restricted to the representatives of the states members of the Partial Agreement in the Social and Public Health Field,²

Recalling Resolution (59) 23 of 16 November 1959 on the extension of the activities of the Council of Europe in the social and cultural fields;

Having regard to Resolution (96) 35 of 2 October 1996 revising the Partial Agreement in the Social and Public Health Field, whereby it revised the structures of the Partial Agreement and resolved to continue, on the basis of revised rules replacing those set out in Resolution (59) 23, the activities hitherto carried out and developed by virtue of that resolution, these being aimed in particular at:

- raising the level of health protection of consumers in its widest sense, including a constant contribution to the harmonisation – in the field of products having a direct or indirect impact on the human food chain as well as in the fields of pesticides, pharmaceuticals and cosmetics – of legislation, regulations and practices governing, on the one hand, quality, efficiency and safety controls for products, and, on the other hand, the safe use of toxic or noxious products;
- integrating people with disabilities into the community: definition – and contribution to implement it at European level – of a model coherent policy for people with disabilities, which takes account, simultaneously, of the principles of full citizenship and independent living; contribution to eliminate barriers to integration, whatever their nature: psychological, educational, family-related, cultural, social, professional, financial or architectural;

Having regard to action carried out by the Council of Europe over several years for the purposes of harmonising legislation and practices in the public health field, including those with a view to promoting the safety, quality and effectiveness of medicines and their appropriate use in society;

¹ When adopting this decision, the Permanent Representative of the United Kingdom indicated that, in accordance with Article 10.2c of the Rules of Procedure for the meetings of the Ministers' Deputies, he reserved the right of his Government to comply or not with the Recommendation as a whole.

² Austria, Belgium, Bulgaria, Cyprus, Finland, France, Germany, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Recalling Committee of Ministers' Resolution ResAP(2001)2 concerning the pharmacist's role in the framework of health security, which, in paragraph 9, drew attention to certain practices related to the Internet, as well as illicit importation and illegal distance sales, that may compromise the guarantee of the quality, safety and efficacy of medicines on the market;

Having regard to the aim of the Committee of Experts on Pharmaceutical Questions (P-SP-PH) to develop a simple user-oriented, easily available and accessible information guide to help citizens to select amongst the deluge of information on medicinal products, appropriate modes of prescription and distribution, which resulted in a core message for developing user-oriented guidance¹ offered to Partial Agreement health authorities;

Taking into account that this effort, however, has been and remains insufficient, and considering that:

- Internet trade and mail-order trade in medicines have been growing during recent years;
- criticism of mail-order trade in medicines deals mostly with the dangers of the illegal sale of medicines via the Internet, which may often be counterfeit, whereas the legal trade in medicines via mail order is often overlooked;
- this does not take account of the fact that mail-order trade in medicines is permitted in many countries;
- in December 2003 the European Court of Justice of the European Communities issued a ruling (C-322/01) with implications for the current legislation of European Union member states on mail-order trade in non-prescription medicines;²
- pharmacies will, therefore, increasingly make use of the possibility of selling medicines via mail order;
- as a consequence, consumers and pharmacists wanting to supply medicines to patients by mail order are more than ever confronted with questions of the quality of mail-ordered medicines;
- it is, therefore, necessary to proceed with the development and implementation of good practices for the distribution of medicines by mail order to ensure patient safety and quality of medicines and to fulfil the stipulations of Resolution ResAP(2001)2, paragraph 9.

Having regard to Committee of Ministers' Resolution ResAP(2007)1 on the classification of medicines as regards their supply, superseding Resolution ResAP(2000)1 on the classification of medicines which are obtainable only on medical prescription, which recommends to member states, in the absence of uniform legislation on the supply of medicines, to apply the general provisions on the supply conditions of medicines as set out in ResAP(2007)1, to accept its annually revised appendices, to adopt the general provisions relating to minimum information to be included in prescriptions and to supply information on a regular basis concerning the national legal classification of medicines;³

Having regard to Committee of Ministers' Recommendation Rec(2004)17 on the impact of information technologies on health care – the patient and Internet, which focuses on the use of the Internet for medical purposes;

Considering that the above recommendation does not deal with adequate quality and safety standards with regards to mail-order trade in medicines, which constitute an indispensable aspect of patients' safety;

Noting that illegal mail-order trade in medicines is constantly increasing leading to a considerable hazard for patient safety, namely the distribution of counterfeit medicines;

¹ http://www.coe.int/t/e/social_cohesion/soc-sp/Health_Information_Sources.tif – Medicines and the Internet: user-oriented guidance.

² European Court of Justice ruling of December 11, 2003 in the case C-322/01 Deutscher Apothekerverband e.V. vs. 0800 DocMorris NV and Jacques Waterval.

³ http://www.coe.int/t/e/social_cohesion/soc-sp/Health_Information_Sources.tif – Medicines and the Internet.

Taking into account that mail-order trade in medicines is by and large marketed via the Internet, which is uncontrollable and used as a platform for many illegal offers of medicines, be they for prescription-only medicines or medicines available without prescription, stem from doubtful sources of supply, and be of substandard or uncontrollable quality (for example, counterfeit);

Considering that the only way to protect the public from such illegal offers is to help to differentiate these easily from legal offers which bear a clearly identifiable legal imprint, and that information on a pharmacy website should therefore be understandable, reliable and specific;

Noting that Article 5 of Directive 2000/31/EC on electronic commerce, and the European Commission Communication on quality criteria for health related websites of 29 November 2002 (COM (2002) 667) address the relevant information to be provided for marketing offers on the Internet, but do not deal with quality and safety standards to be used for mail-order trade in medicines;

Having in mind the current practices and legislation regarding mail-order trade in medicines in the European Union, the European Economic Area and Switzerland;

Considering that quality and safety standards to be applied when carrying out mail-order trade in medicines often differ from country to country, or are sometimes not regulated at all;

Taking the view that patients' safety is paramount, and that, if permitted, mail-order trade in medicines therefore requires clear quality and safety standards with a reliable legal basis, and that member states should for this reason enable the implementation of and further adaptation to the state of the art of adequate regulations;

Considering that such regulations should be harmonised at European level because of their increasing cross-border nature;

Recommends that the governments of the member states of the Partial Agreement in the Social and Public Health Field implement the requirements concerning the standards according to which mail-order trade in medicines can take place safely and maintain patient safety and the quality of the supplied medicines, namely standards pertaining to and as set out in the appendix to the present resolution:

- delivery methods and related responsibilities;
- counselling and information for the patient;
- mandatory notification;
- conditions for sale and distribution;
- exclusion of unsuitable medicines from mail-order trade;
- marketing and advertising;
- handling of prescriptions for mail orders of prescription-only medicines;
- establishment of focal points and their role and contribution to international co-operation;
- measures to follow up on offences.

Each government, however, remains free to adopt stricter regulations.

1. Scope of application

This resolution should serve countries which permit, or plan to permit, mail-order trade in medicines as a frame of reference for the criteria and safety standards which should be abided by when such trade is carried out.

2. Definition

“Mail-order trade in medicines” is understood as distance selling of medicines by an authorised person to an individual patient/consumer who ordered them (physical part). Mail-order trade in medicines is by and large marketed via the Internet (virtual part).

3. Pharmacy

As the operation of mail-order pharmacies could greatly benefit, particularly with respect to counselling patients, if it were linked with community pharmacies, mail-order trade in medicines should take place from pharmacies open to the public. Such trade in medicines could also take place from other retailers if they are permitted to sell certain medicines in the member state in question.

4. Person responsible for delivery

Mail-order trade in medicines should be carried out by adequately licensed persons only.

5. Delivery

A quality assurance system for the delivery of the medicines should be established and maintained. This system should ensure:

- a. adequate packaging, transportation and delivery of the medicine ensuring that its quality and effectiveness are preserved;
- b. delivery to the person ordering or an individual nominated by this person;
- c. the possibility to track and trace deliveries.

6. Languages for counselling and information

Patient counselling and information should be, at a minimum, in the language or languages of the country of destination.

7. Counselling and medication surveillance

Counselling of the patient or the recipient of mail-ordered medicines should be provided by e-mail and/or telephone. An adequate level of medication surveillance (for example checking of dosage, interactions and incompatibilities), as required by each national authority, should be maintained.

8. Information for the patient

The patient should be informed about the contact details of the selling pharmacy or another licensed retailer and about the requirement to contact the attending physician if medication-related problems or any adverse effects occur. Medicines delivered should be accompanied by the warning: “Please contact

your pharmacy if package or medicine appears unusual, broken or damaged””

9. Mandatory notification

There should be a system in place for notifying adverse effects, interactions, warnings, recalls and quality defects to the patient and by the patient, as well as for taking in-house measures to guard against such risks.

10. Conditions for sale and distribution

Medicines should only be mailed if authorised for marketing and permitted for sale or distribution via mail-order trade in accordance with the legislation of the country of destination.

11. Exclusion of medicines

Narcotics should, as a rule, be excluded from mail-order trade in medicines. Medicines which could be dangerous – when mail-order traded – for any person or the environment, even when properly packaged, and medicines with an expiry date close to time of delivery are not suitable for mail-order trade.

12. Marketing and advertising

Any marketing of mail-order trade in medicines on web pages on the Internet or otherwise should carry the following information:

- a.* name of the responsible pharmacist or licensed person;
- b.* address and telephone number;
- c.* e-mail address;
- d.* name of licensing authority;
- e.* date of licence and of last inspection;
- f.* clearly indicated prices, specifying whether they are inclusive of tax and delivery costs.

13. Prescription-only medicines

Mail-order trade in prescription-only medicines should only take place under the supervision of a pharmacist against submission of a valid prescription. It may also be submitted electronically if properly authenticated.

14. Liability

The pharmacist or any other licensed person providing for mail-order trade in medicines should be responsible for any shipment and be held liable for proper delivery.

15. Focal point

Countries which permit mail-order trade in medicines should establish a national focal point for easy exchange of information on problems arising in this context and adequate co-operation at international level. Units or agencies rather than individuals should be designated as focal points (for example, single points of contact (SPOCs)). Such focal points should particularly serve those persons with complaints related to mail-order trade in medicines and co-ordinate relevant exchanges of authorities.

16. Offences

Countries should provide for adequate measures to follow up on breaches of the safety standards provided to protect patient safety and the quality of the delivered medicine.

COUNCIL OF EUROPE

COMMITTEE OF MINISTERS

RESOLUTION CM/RES(2008)4

of the Committee of Ministers to member States

on adult-to-adult living donor liver transplantation

*(Adopted by the Committee of Ministers on 12 March 2008
at the 1021st meeting of the Ministers' Deputies)*

The Committee of Ministers, in its composition restricted to the representatives of the States Parties to the Convention on the elaboration of a European Pharmacopoeia,¹

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 public health field;

Having regard to the 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 – ETS No. 164), and in particular Article 19 (General rule) and Article 20 (Protection of persons not able to consent to organ removal) thereof;

Having regard also to the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin (ETS No. 186), and, in particular, Chapter III (Organ and tissue removal from living persons);

Recalling its Resolution (78) 29 on the harmonisation of legislation of member states relating to removal, grafting and transplantation of human substances;

Recalling its Recommendation Rec(2001)5 to member states on the management of organ transplant waiting lists and waiting times;

Recalling its Recommendation Rec(2004)7 to member states on organ trafficking;

Recognising that, in facilitating the transplantation of organs in the interest of patients in

¹ States concerned: Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, “the former Yugoslav Republic of Macedonia”, Turkey and United Kingdom.

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 procurement, exchange and allocation activities;

Considering that organ transplantation is a well-established, life-saving, and effective treatment and may be the only treatment available for some forms of end-stage organ failure;

Aware of the fact that tissue and cell transplantation may be life saving or life enhancing;

Concerned by the universal shortage of organs for transplantation;

Considering that adult-to-adult living donor liver transplantation (Domino liver transplantation, i.e. transplantation into a recipient whose own organ was respected and transplanted into another recipient, is excluded from the scope of this resolution) may be envisaged when suitable organs from deceased donors are not available, provided that all safeguards are implemented in order to guarantee the freedom and safety of the donor and a successful transplant in the recipient;

Convinced also that adult-to-adult living donor liver transplantation is an effective treatment for end-stage liver disease, with the potential benefit of reducing mortality of patients awaiting a transplantation;

Conscious of the risks that living donor liver transplantation may have for the donor and of the need to ensure that all measures are taken to safeguard the donor's health;

Recalling that no organ removal may be carried out on a person who does not have the capacity to consent;

Recommends to member states the following:

1. to instruct the organisation responsible for accrediting transplantation programmes and regulating the allocation of organs to address explicitly the issue of adult-to-adult living donor liver transplantation and establish transplantation programmes accredited to perform this type of transplantation;
2. to ensure that adult-to-adult living donor liver transplantation programmes adhere to the following minimum requirements:
 - a. substantial experience in liver surgery and liver transplantation;
 - b. an active liver-transplantation programme;
 - c. significant mortality in the waiting list;
 - d. a multidisciplinary team experienced in routine and complex liver surgery, covering all operative
 - e. aspects (pre-operative, peri-operative and post-operative);
3. to ensure that the indications for adult-to-adult living donor liver transplantation are recognised indications for deceased donor liver transplantation;

4. to ensure that the organisation responsible for the allocation of organs and accreditation of transplantation programmes establishes clear conditions under which adult-to-adult living donor liver transplantation is ethically acceptable, namely:
 - a. adult-to-adult living donor liver transplantation is only to be performed within authorised/licensed programmes with ongoing feedback;
 - b. the donor and the recipient have a close personal relationship as required and defined by law;
 - c. each single procedure should be approved on a case-by-case basis;
 - d. the motive to donate is solely altruistic. Any financial gain or comparable advantage in connection with the donation is considered illegal;
 - e. the donor has been given appropriate information as to the purpose and nature of the removal as well as on its consequences and risks. The donor has also been informed of the rights and the safeguards prescribed by law for his or her protection, in particular 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 removal or subsequent transplantation procedures. Finally, the donor is provided with comprehensive information on:
 - i. the alternatives to adult-to-adult living donor liver transplantation;
 - ii. the previous experience of the centre where the procedure will be carried out;
 - iii. the risks of morbidity and mortality of the procedure for the donor and the recipient;
 - iv. the likely long-term outcome for the recipient;
 - f. the living donor has given free, informed and specific consent either in written form or before an official body; the donor may freely withdraw consent at any time;
 - g. the donor has been properly screened to identify any physical or psychological contra-indication; the removal may not be carried out if there is a serious risk to the life or health of the donor;
5. to ensure immediate access to the emergency waiting list for organs from deceased donors in case of failure of the remnant liver in the donor or graft failure in the recipient and that specific rules for non-residents apply according to national regulations;
6. to ensure that the necessary conditions and provisions are in place for long-term medical follow up of both donor and recipient, including the monitoring of the short- and long-term effects of transplantation on the health of donors, by the establishment of national registries;
7. to guarantee equitable access to liver transplantation services for all patients in need of a liver transplant, regardless of personal financial means;
8. to ensure that all costs related to the operations and follow-up of donor and recipient are covered, according to the competent organisation's own procedures;
9. to provide for a system of fair compensation for any person who suffered undue damage resulting from transplantation procedures, according to the conditions and procedures prescribed by law.

COUNCIL OF EUROPE

COMMITTEE OF MINISTERS

RESOLUTION CM/RES(2008)5

of the Committee of Ministers to member States

on donor responsibility and on limitation to donation of blood and blood components

*(Adopted by the Committee of Ministers on 12 March 2008
at the 1021st meeting of the Ministers' Deputies)*

The Committee of Ministers, in its composition restricted to the representatives of the States Parties to the Convention on the Elaboration of a European Pharmacopoeia,¹

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

Taking account of the ethical principles set out in the Committee of Ministers' Recommendation No. R (88) 4 on the responsibilities of health authorities in the field of blood transfusion, and in particular Article 1 on voluntary non-remunerated blood donation;

Taking into account the requirements set out in Recommendation No. R (95) 15 on the preparation, use and quality assurance of blood components;

Considering the inherent risks of human blood and therapeutic substances of human origin,

Recommends that the governments of States Parties to the Convention:

1. ensure that blood components are produced solely from blood collected from safe blood donors;
2. foster co-operation and trust between blood establishments and blood donors, in particular by informing the public about the need and criteria for selection of blood donors;
3. guarantee that blood establishments provide prospective donors with clear and appropriate information, including at least the following:

¹ Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, "the former Yugoslav Republic of Macedonia", Turkey and United Kingdom.

- 3.1. the essential nature of blood, blood donation procedure, testing of collected blood, components derived from collected blood;
- 3.2. possible risks to the health of the donor associated with blood donation;
- 3.3. possible risks for the recipient of blood or blood components of a given donor;
- 3.4. the donor's duty to provide the blood establishment with all relevant information to the best of his/her knowledge, in particular on factors and activities which may increase risks for the recipient;
- 3.5. the right to withdraw from donation at any time during the procedure for any reason, including doubts as to his/her suitability as a donor without any need to explain this decision;
- 3.6. the importance for the donor to give the blood establishment post-donation information if the donor has doubts about his/her suitability or in the event of change in health status after donation;
- 3.7. the consequences of failure to provide the information as specified above during the donor assessment procedure;
- 3.8. the confidentiality of all personal information given by donors to the blood establishment, notably those related to health and behaviour;
4. ensure that blood establishments are ultimately responsible for the quality and safety of the blood and blood components collected; in particular, blood establishments should:
 - 4.1. be responsible for the final acceptance or deferral of donors on the grounds of a risk assessment based on regularly updated epidemiological data, and bearing in mind the right of blood recipients to the protection of their health, and the resulting obligation to minimise the risk of transmission of infectious diseases. These rights and obligations override any other considerations, including individuals' willingness to donate blood;
 - 4.2. set up arrangements for fair compensation providing for cases where harm is caused to the recipient and/or the donor of blood and blood components.

COUNCIL OF EUROPE

COMMITTEE OF MINISTERS

RESOLUTION CM/RES(2008)6

of the Committee of Ministers to member States

on transplantation of kidneys from living donors who are not genetically related to the recipient

*(Adopted by the Committee of Ministers on 26 March 2008
at the 1022nd meeting of the Ministers' Deputies)*

The Committee of Ministers, in its composition restricted to the representatives of the States Parties to the Convention on the Elaboration of a European Pharmacopoeia,¹

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 into account its Resolution (78) 29 on the harmonisation of legislation of member states relating to removal, grafting and transplantation of human substances and the final text of the 3rd Conference of European Health Ministers (Paris, 16-17 November 1987);

Having regard to the 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 – ETS No. 164), and in particular to Article 19 (General rule) and Article 20 (Protection of persons not able to consent to organ removal) thereof;

Having regard also to the Additional Protocol to the Convention on Human Rights and Biomedicine concerning the Transplantation of Organs and Tissues of Human Origin (ETS No. 186);

Recalling its Recommendation Rec(2001)5 to the member states on management of organ transplant waiting lists and waiting times;

Recalling its Recommendation Rec(2004)7 to the member states on organ trafficking;

¹ States concerned: Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Republic of Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, “the former Yugoslav Republic of Macedonia”, Turkey and United Kingdom.

Recognising that, in facilitating the transplantation of organs in the interests 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 procurement, exchange and allocation activities;

Recalling the principle that organ removal can be undertaken on a living donor only in the case where a suitable organ from a deceased donor is not available and only when no alternative therapeutic method of comparable effectiveness is available;

Considering that there is a shortage of kidneys for transplantation to patients having reached the end stage of renal failure;

Taking note that the increasing number of transplantations of organs from living donors is one way of reducing the increasing gap between the growing number of patients waiting for kidney transplantation and the limited number of organs procured from deceased donors;

Stressing that transplantation of a kidney from a living donor to a genetically related recipient is a well-established practice in most of the States Parties to the Convention and that in some countries living donor kidney transplantations account for a large proportion of the transplants performed each year;

Knowing that there is very good evidence that living donor kidney transplants, even if the donor is not genetically related to the recipient, lead to similar or better clinical outcomes than with kidneys transplanted from deceased donors;

Stressing that living donor kidney transplants allow for the optimum treatment of receiving a transplant before going on to dialysis (pre-emptive transplant);

Taking into consideration that the removal of a kidney from a carefully selected, healthy individual carries a low risk of complications and has not been shown to have long-term effects on the health of such a donor;

Recalling that no organ removal may be carried out on a person who does not have the capacity to consent,

Recommends to the governments of States Parties to the Convention to take note of the general principles and measures listed in the attached appendix when they draw up the regulations and procedures relating to the donation of a kidney in view of transplantation by a living donor non genetically linked to the receiver:

Appendix to Resolution CM/Res(2008)6

1. States Parties to the Convention may permit the transplantation of kidneys from non-genetically related living donors on condition that:

- the living donor and the recipient have a relationship as required and defined by law; the donor has been given appropriate information as to the purpose and nature of the

removal as well as on its consequences and risks. The donor has also been informed of the rights and the safeguards prescribed by law for his or her protection, in particular 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 removal or subsequent transplantation procedures;

- the living donor has given free, informed and specific consent, either in written form or before an official body; the donor may freely withdraw consent at any time;
- no pressure is exerted on the living donor into donation;
- the organ does not, as such, give rise to financial gain or comparable advantage;
- the living donor has been properly screened to identify any physical or psychological contraindications; the removal may not be carried out if there is a serious risk to the life or health of the donor;
- long-term medical follow-up is provided to living donors. This includes the monitoring of short- and long-term effects of organ removal on the health of the living donor notably by the establishment of officially recognised registries.

2. States Parties to the Convention may require that persons waiting for such transplants be placed on a national waiting list during the period of approval of the potential donor for donation.

3. Any States Parties to the Convention allowing for non-genetically related living kidney donation should establish a register for such transplants which includes a donor register and donor follow-up procedures in line with those existing for transplantations of kidneys removed from genetically related living donors.

4. States Parties to the Convention may permit or prohibit by law non-directed living kidney donations – i.e. “good Samaritan” donors, truly altruist donors or donors involved in a “paired exchange” donation for the purpose of transplantation from a person with no established close personal relationship with the recipient. (This type of donation is in contrast to donation where the donor and the recipient are in close personal relation called “directed donation”). In the States Parties to the Convention authorising donations from non-related living donors, national regulations and appropriate management must be put in place in view of prohibiting and preventing organ trafficking, namely by clearly defined rules for non-residents.

5. States Parties to the Convention should establish an independent mechanism for approving non-genetically related living kidney donor transplants in compliance with Article 10 of the Additional Protocol to the Convention on Human Rights and Biomedicine concerning the Transplantation of Organs and Tissues of Human Origin. It is also recommended that States Parties to the Convention establish such a mechanism for all cases of non-directed donation. Particular attention should be given to cases where the donor is not a resident of the member state concerned. Within the requirements of data protection legislation, registered activities should be reported on a regular basis to the national health authority.

PART B

**CONVENTION ON HUMAN RIGHTS AND
BIOMEDICINE
(ETS NO. 164)**



European Treaty Series - No. 164

**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**

Oviedo, 4.IV.1997

NB: The explanatory report to the Convention is available as a separate document (reference: DIR/JUR (97) 5)

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.



European Treaty Series - No. 168

**Additional Protocol to the Convention on
Human Rights and Biomedicine
on the Prohibition of Cloning Human Beings
(ETS no. 168)**

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.

**Explanatory report to the Additional Protocol
to the Convention on Human Rights and Biomedicine
on the Prohibition of Cloning Human Beings**

1. This Protocol builds on certain provisions of the Convention on Human Rights and Biomedicine, in particular the following: Article 1 provides that 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 13, which provides that 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 18.1, which ensures the protection of the embryo *in vitro* in the framework of research and Article 18.2 which prohibits the creation of embryos for research purposes.

2. Cloning of cells and tissue is considered worldwide to be an ethically acceptable valuable biomedical technique. However, there are different views about the ethical acceptability of cloning undifferentiated cells of embryonic origin. Whatever attitudes towards such cloning techniques exist, the standards set forth in the Convention on Human Rights and Biomedicine as mentioned above form clear barriers against the misuse of human embryos, as their adequate protection is guaranteed and their creation for research purposes is prohibited by Article 18 of the Convention. Therefore, one has to distinguish between three situations: cloning of cells as a technique, use of embryonic cells in cloning techniques, and cloning of human beings, for example by utilising the techniques of embryo splitting or nuclear transfer. Whereas the first situation is fully acceptable ethically, the second should be examined in the protocol on embryo protection. The consequences of the third situation, that is the prohibition of cloning human beings, are within the scope of this Protocol.

3. Deliberately cloning humans is a threat to human identity, as it would give up the indispensable protection against the predetermination of the human genetic constitution by a third party. Further ethical reasoning for a prohibition to clone human beings is based first and foremost on human dignity which is endangered by instrumentalisation through artificial human cloning. Even if in the future, in theory, a situation could be conceived, which might seem to exclude the instrumentalisation of artificially cloned human offspring, this is not considered a sufficient ethical justification for the cloning of human beings. As naturally occurring genetic recombination is likely to create more freedom for the human being than a predetermined genetic make up, it is in the interest of all persons to keep the essentially random nature of the composition of their own genes.

4. This Protocol does not take a specific stand on the admissibility of cloning cells and tissue for research purposes resulting in medical applications. However, it can be said that cloning as a biomedical technique is an important tool for the development of medicine, especially for the development of new therapies. The provisions in this Protocol shall not be understood as prohibiting cloning techniques in cell biology.

5. However, the Protocol does enshrine clear barriers against any attempt artificially to produce genetically identical human beings. The Protocol is not concerned with hormone stimulation to treat infertility in women and which might result in the birth of twins. It explicitly restricts genetic identity to sharing the same nuclear gene set, meaning that any intervention by embryo splitting or nuclear transfer techniques seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited.

6. In conformity with the approach followed in the preparation of the Convention on Human Rights and Biomedicine, it was decided to leave it to domestic law to define the scope of the expression "human being" for the purposes of the application of the present Protocol.

7. The term "nuclear" means that only genes of the nucleus – not the mitochondrial genes – are looked at with respect to identity, which is why the prohibition of cloning human beings also covers all nuclear transfer methods seeking to create identical human beings. The term "the same nuclear gene set" takes into account the fact that during development some genes may undergo somatic mutation. Thus monozygotic twins developed from a single fertilised egg will share the same nuclear gene set, but may not be 100% identical with respect to all their genes. It is important to note that the Protocol does not intend to discriminate in any fashion against natural monozygotic twins.

8. This Protocol is an important step in drawing up clear ethical and legal provisions in the area of reproductive medicine. Together with the provisions in Articles 1, 13, 14 and 18 of the Convention, it enshrines important ethical principles which should form the basis for further developments of biology and medicine in this field not only today but also in the future.



European Treaty Series - No. 186

**Additional Protocol
to the Convention
on Human Rights and Biomedicine
concerning Transplantation
of Organs and Tissues
of Human Origin
(ETS no. 186)**

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;

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.



CETS No. 195

**Additional Protocol
to the Convention
on Human Rights and Biomedicine
concerning Biomedical Research
(CETS No. 195)**

Strasbourg, 25.01.2005

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 “the Convention”),

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, 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 and biological sciences, in particular advances obtained through biomedical research, contributes to saving lives and improving quality of life;

Conscious of the fact that the advancement of biomedical science and practice is dependent on knowledge and discovery which necessitates research on human beings;

Stressing that such research is often transdisciplinary and international;

Taking into account national and international professional standards in the field of biomedical research and the previous work of the Committee of Ministers and the Parliamentary Assembly of the Council of Europe in this field;

Convinced that biomedical research that is contrary to human dignity and human rights should never be carried out;

Stressing the paramount concern to be the protection of the human being participating in research;

Affirming that particular protection shall be given to human beings who may be vulnerable in the context of research;

Recognising that every person has a right to accept or refuse to undergo biomedical research and that no one should be forced to undergo such research;

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

Have agreed as follows:

CHAPTER I

Object and scope

Article 1 – Object and purpose

Parties to this Protocol 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 any research involving interventions on human beings in the field of biomedicine.

Article 2 – Scope

1. This Protocol covers the full range of research activities in the health field involving interventions on human beings.
2. This Protocol does not apply to research on embryos *in vitro*. It does apply to research on fetuses and embryos *in vivo*.
3. For the purposes of this Protocol, the term “intervention” includes:
 - i. a physical intervention, and
 - ii. any other intervention in so far as it involves a risk to the psychological health of the person concerned.

CHAPTER II

General provisions

Article 3 – Primacy of the human being

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

Article 4 – General rule

Research shall be carried out freely, subject to the provisions of this Protocol and the other legal provisions ensuring the protection of the human being.

Article 5 – Absence of alternatives

Research on human beings may only be undertaken if there is no alternative of comparable effectiveness.

Article 6 – Risks and benefits

1. Research shall not involve risks and burdens to the human being disproportionate to its potential benefits.
2. In addition, where the research does not have the potential to produce results of direct benefit to the health of the research participant, such research may only be undertaken if the research entails no more than acceptable risk and acceptable burden for the research participant. This shall be without prejudice to the provision contained in Article 15 paragraph 2, sub-paragraph ii for the protection of persons not able to consent to research.

Article 7 – Approval

Research may only be undertaken if 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 research, and multidisciplinary review of its ethical acceptability.

Article 8 – Scientific quality

Any research must be scientifically justified, meet generally accepted criteria of scientific quality and be carried out in accordance with relevant professional obligations and standards under the supervision of an appropriately qualified researcher.

CHAPTER III Ethics committee

Article 9 – Independent examination by an ethics committee

1. Every research project shall be submitted for independent examination of its ethical acceptability to an ethics committee. Such projects shall be submitted to independent examination in each State in which any research activity is to take place.
2. The purpose of the multidisciplinary examination of the ethical acceptability of the research project shall be to protect the dignity, rights, safety and well-being of research participants. The assessment of the ethical acceptability shall draw on an appropriate range of expertise and experience adequately reflecting professional and lay views.
3. The ethics committee shall produce an opinion containing reasons for its conclusion.

Article 10 – Independence of the ethics committee

1. Parties to this Protocol shall take measures to assure the independence of the ethics committee. That body shall not be subject to undue external influences.
2. Members of the ethics committee shall declare all circumstances that might lead to a conflict of interest. Should such conflicts arise, those involved shall not participate in that review.

Article 11 – Information for the ethics committee

1. All information which is necessary for the ethical assessment of the research project shall be given in written form to the ethics committee.
2. In particular, information on items contained in the appendix to this Protocol shall be provided, in so far as it is relevant for the research project. The appendix may be amended by the Committee set up by Article 32 of the Convention by a two-thirds majority of the votes cast.

Article 12 – Undue influence

The ethics committee must be satisfied that no undue influence, including that of a financial nature, will be exerted on persons to participate in research. In this respect, particular attention must be given to vulnerable or dependent persons.

CHAPTER IV

Information and consent

Article 13 – Information for research participants

1. The persons being asked to participate in a research project shall be given adequate information in a comprehensible form. This information shall be documented.
2. The information shall cover the purpose, the overall plan and the possible risks and benefits of the research project, and include the opinion of the ethics committee. Before being asked to consent to participate in a research project, the persons concerned shall be specifically informed, according to the nature and purpose of the research:
 - i. of the nature, extent and duration of the procedures involved, in particular, details of any burden imposed by the research project;
 - ii. of available preventive, diagnostic and therapeutic procedures;
 - iii. of the arrangements for responding to adverse events or the concerns of research participants;
 - iv. of arrangements to ensure respect for private life and ensure the confidentiality of personal data;
 - v. of arrangements for access to information relevant to the participant arising from the research and to its overall results;
 - vi. of the arrangements for fair compensation in the case of damage;
 - vii. of any foreseen potential further uses, including commercial uses, of the research results, data or biological materials;
 - viii. of the source of funding of the research project.
3. In addition, the persons being asked to participate in a research project shall be informed of the rights and safeguards prescribed by law for their protection, and specifically of their right to refuse consent or to withdraw consent at any time without being subject to any form of discrimination, in particular regarding the right to medical care.

Article 14 – Consent

1. No research on a person may be carried out, subject to the provisions of both Chapter V and Article 19, without the informed, free, express, specific and documented consent of the person. Such consent may be freely withdrawn by the person at any phase of the research.
2. Refusal to give consent or the withdrawal of consent to participation in research shall not lead to any form of discrimination against the person concerned, in particular regarding the right to medical care.
3. Where the capacity of the person to give informed consent is in doubt, arrangements shall be in place to verify whether or not the person has such capacity.

CHAPTER V
Protection of persons not able to consent to research

Article 15 – Protection of persons not able to consent to research

1. Research on a person without the capacity to consent to research may be undertaken only if all the following specific conditions are met:

- i. the results of the research have the potential to produce real and direct benefit to his or her health;
- ii. research of comparable effectiveness cannot be carried out on individuals capable of giving consent;
- iii. the person undergoing research has been informed of his or her rights and the safeguards prescribed by law for his or her protection, unless this person is not in a state to receive the information;
- iv. the necessary authorisation has been given specifically and in writing by the legal representative or an authority, person or body provided for by law, and after having received the information required by Article 16, taking into account the person's previously expressed wishes or objections. An adult not able to consent shall as far as possible take part in the authorisation procedure. The opinion of a minor shall be taken into consideration as an increasingly determining factor in proportion to age and degree of maturity;
- 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 ii, 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; and any consideration of additional potential benefits of the research shall not be used to justify an increased level of risk or burden.

3. Objection to participation, refusal to give authorisation or the withdrawal of authorisation to participate in research shall not lead to any form of discrimination against the person concerned, in particular regarding the right to medical care.

Article 16 – Information prior to authorisation

1. Those being asked to authorise participation of a person in a research project shall be given adequate information in a comprehensible form. This information shall be documented.

2. The information shall cover the purpose, the overall plan and the possible risks and benefits of the research project, and include the opinion of the ethics committee. They shall further be informed of the rights and safeguards prescribed by law for the protection of those not able to consent to research and specifically of the right to refuse or to withdraw authorisation at any time, without the person concerned being subject to any form of discrimination, in particular regarding the right to

medical care. They shall be specifically informed according to the nature and purpose of the research of the items of information listed in Article 13.

3. The information shall also be provided to the individual concerned, unless this person is not in a state to receive the information.

Article 17 – Research with minimal risk and minimal burden

1. For the purposes of this Protocol it is deemed that the research bears a minimal risk if, having regard to the nature and scale of the intervention, it is to be expected that it will result, at the most, in a very slight and temporary negative impact on the health of the person concerned.

2. It is deemed that it bears a minimal burden if it is to be expected that the discomfort will be, at the most, temporary and very slight for the person concerned. In assessing the burden for an individual, a person enjoying the special confidence of the person concerned shall assess the burden where appropriate.

CHAPTER VI Specific situations

Article 18 - Research during pregnancy or breastfeeding

1. Research on a pregnant woman which does not have the potential to produce results of direct benefit to her health, or to that of her embryo, foetus or child after birth, may only be undertaken if the following additional conditions are met:

- i. the research has the aim of contributing to the ultimate attainment of results capable of conferring benefit to other women in relation to reproduction or to other embryos, fetuses or children;
- ii. research of comparable effectiveness cannot be carried out on women who are not pregnant;
- iii. the research entails only minimal risk and minimal burden.

2. Where research is undertaken on a breastfeeding woman, particular care shall be taken to avoid any adverse impact on the health of the child.

Article 19 – Research on persons in emergency clinical situations

1. The law shall determine whether, and under which protective additional conditions, research in emergency situations may take place when:

- i. a person is not in a state to give consent, and
- ii. because of the urgency of the situation, it is impossible to obtain in a sufficiently timely manner, authorisation from his or her representative or an authority or a person or body which would in the absence of an emergency situation be called upon to give authorisation.

2. The law shall include the following specific conditions:

- i. research of comparable effectiveness cannot be carried out on persons in non-emergency situations;
- ii. the research project may only be undertaken if it has been approved specifically for

emergency situations by the competent body;

- iii. any relevant previously expressed objections of the person known to the researcher shall be respected;
 - iv. where the research has not the potential to produce results of direct benefit to the health of the person concerned, it 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 category or afflicted with the same disease or disorder or having the same condition, and entails only minimal risk and minimal burden.
3. Persons participating in the emergency research project or, if applicable, their representatives shall be provided with all the relevant information concerning their participation in the research project as soon as possible. Consent or authorisation for continued participation shall be requested as soon as reasonably possible.

Article 20 – Research on persons deprived of liberty

Where the law allows research on persons deprived of liberty, such persons may participate in a research project in which the results do not have the potential to produce direct benefit to their health only if the following additional conditions are met:

- i. research of comparable effectiveness cannot be carried out without the participation of persons deprived of liberty;
- ii. the research has the aim of contributing to the ultimate attainment of results capable of conferring benefit to persons deprived of liberty;
- iii. the research entails only minimal risk and minimal burden.

CHAPTER VII Safety and supervision

Article 21 – Minimisation of risk and burden

1. All reasonable measures shall be taken to ensure safety and to minimise risk and burden for the research participants.
2. Research may only be carried out under the supervision of a clinical professional who possesses the necessary qualifications and experience.

Article 22 – Assessment of health status

1. The researcher shall take all necessary steps to assess the state of health of human beings prior to their inclusion in research, to ensure that those at increased risk in relation to participation in a specific project be excluded.
2. Where research is undertaken on persons in the reproductive stage of their lives, particular consideration shall be given to the possible adverse impact on a current or future pregnancy and the health of an embryo, foetus or child.

Article 23 – Non-interference with necessary clinical interventions

1. Research shall not delay nor deprive participants of medically necessary preventive, diagnostic or therapeutic procedures.
2. In research associated with prevention, diagnosis or treatment, participants assigned to control groups shall be assured of proven methods of prevention, diagnosis or treatment.
3. The use of placebo is permissible where there are no methods of proven effectiveness, or where withdrawal or withholding of such methods does not present an unacceptable risk or burden.

Article 24 – New developments

1. Parties to this Protocol shall take measures to ensure that the research project is re-examined if this is justified in the light of scientific developments or events arising in the course of the research.
2. The purpose of the re-examination is to establish whether:
 - i. the research needs to be discontinued or if changes to the research project are necessary for the research to continue;
 - ii. research participants, or if applicable their representatives, need to be informed of the developments or events;
 - iii. additional consent or authorisation for participation is required.
3. Any new information relevant to their participation shall be conveyed to the research participants, or, if applicable, to their representatives, in a timely manner.
4. The competent body shall be informed of the reasons for any premature termination of a research project.

CHAPTER VIII

Confidentiality and right to information

Article 25 – Confidentiality

1. Any information of a personal nature collected during biomedical research shall be considered as confidential and treated according to the rules relating to the protection of private life.
2. The law shall protect against inappropriate disclosure of any other information related to a research project that has been submitted to an ethics committee in compliance with this Protocol.

Article 26 – Right to information

1. Research participants shall be entitled to know any information collected on their health in conformity with the provisions of Article 10 of the Convention.
2. Other personal information collected for a research project will be accessible to them in conformity with the law on the protection of individuals with regard to processing of personal data.

Article 27 – Duty of care

If research gives rise to information of relevance to the current or future health or quality of life of research participants, this information must be offered to them. That shall be done within a framework of health care or counselling. In communication of such information, due care must be

taken in order to protect confidentiality and to respect any wish of a participant not to receive such information.

Article 28 – Availability of results

1. On completion of the research, a report or summary shall be submitted to the ethics committee or the competent body.
2. The conclusions of the research shall be made available to participants in reasonable time, on request.
3. The researcher shall take appropriate measures to make public the results of research in reasonable time.

CHAPTER IX

Research in States not parties to this Protocol

Article 29 – Research in States not parties to this Protocol

Sponsors or researchers within the jurisdiction of a Party to this Protocol that plan to undertake or direct a research project in a State not party to this Protocol shall ensure that, without prejudice to the provisions applicable in that State, the research project complies with the principles on which the provisions of this Protocol are based. Where necessary, the Party shall take appropriate measures to that end.

CHAPTER X

Infringement of the provisions of the Protocol

Article 30 – 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 or principles set forth in this Protocol at short notice.

Article 31 – Compensation for damage

The person who has suffered damage as a result of participation in research shall be entitled to fair compensation according to the conditions and procedures prescribed by law.

Article 32 – Sanctions

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

CHAPTER XI

Relation between this Protocol and other provisions and re-examination of the Protocol

Article 33 – Relation between this Protocol and the Convention

As between the Parties, the provisions of Articles 1 to 32 of this Protocol shall be regarded as additional articles to the Convention, and all the provisions of the Convention shall apply accordingly.

Article 34 – Wider protection

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

Article 35 – 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 no later than five years from the entry into force of this Protocol and thereafter at such intervals as the Committee may determine.

CHAPTER XII Final clauses

Article 36 – 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 37 – 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 36.

2. In respect of any State 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 38 – 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 39 – 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 40 – Notifications

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 Protocol 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 37 and 38;
- 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 (France), this 25 January 2005, 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.

Appendix to the Additional Protocol on Biomedical Research

Information to be given to the ethics committee

Information on the following items shall be provided to the ethics committee, in so far as it is relevant for the research project:

Description of the project

- i. the name of the principal researcher, qualifications and experience of researchers and, where appropriate, the clinically responsible person, and funding arrangements;
- ii. the aim and justification for the research based on the latest state of scientific knowledge;
- iii. methods and procedures envisaged, including statistical and other analytical techniques;
- iv. a comprehensive summary of the research project in lay language;
- v. a statement of previous and concurrent submissions of the research project for assessment or approval and the outcome of those submissions;

Participants, consent and information

- vi. justification for involving human beings in the research project;
- vii. the criteria for inclusion or exclusion of the categories of persons for participation in the research project and how those persons are to be selected and recruited;
- viii. reasons for the use or the absence of control groups;
- ix. a description of the nature and degree of foreseeable risks that may be incurred through participating in research;
- x. the nature, extent and duration of the interventions to be carried out on the research participants, and details of any burden imposed by the research project;
- xi. arrangements to monitor, evaluate and react to contingencies that may have consequences for the present or future health of research participants;
- xii. the timing and details of information for those persons who would participate in the research project and the means proposed for provision of this information;
- xiii. documentation intended to be used to seek consent or, in the case of persons not able to consent, authorisation for participation in the research project;
- xiv. arrangements to ensure respect for the private life of those persons who would participate in research and ensure the confidentiality of personal data;
- xv. arrangements foreseen for information which may be generated and be relevant to the present or future health of those persons who would participate in research and their family members;

Other information

- xvi. details of all payments and rewards to be made in the context of the research project;
- xvii. details of all circumstances that might lead to conflicts of interest that may affect the independent judgement of the researchers;
- xviii. details of any foreseen potential further uses, including commercial uses, of the research results, data or biological materials;
- xix. details of all other ethical issues, as perceived by the researcher;
- xx. details of any insurance or indemnity to cover damage arising in the context of the research project.

The ethics committee may request additional information necessary for evaluation of the research project.



COUNCIL CONSEIL
OF EUROPE DE L'EUROPE

CETS No. 203

**Additional Protocol
to the Convention on Human Rights
and Biomedicine
concerning Genetic Testing
for Health Purposes
(CETS No. 203)**

Strasbourg, 27.11.2008

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 “the Convention on Human Rights and Biomedicine”, ETS No. 164),

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;

Bearing in mind the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (ETS No. 108) of 28 January 1981;

Bearing in mind the work carried out by other intergovernmental organisations, in particular the Universal Declaration on the Human Genome and Human Rights, endorsed by the General Assembly of the United Nations on 9 December 1998;

Recalling that the human genome is shared by all human beings, thereby forming a mutual bond between them while slight variations contribute to the individuality of each human being;

Stressing the particular bond that exists between members of the same family;

Considering that progress in medical science can contribute to saving lives and improving their quality;

Acknowledging the benefit of genetics, in particular genetic testing, in the field of health;

Considering that genetic services in the field of health form an integral part of the health services offered to the population and recalling the importance of taking appropriate measures, taking into account health needs and available resources, with a view to providing equitable access to genetic services of appropriate quality;

Aware also of the concerns that exist regarding possible improper use of genetic testing, in particular of the information generated thereby;

Reaffirming the fundamental principle of respect for human dignity and the prohibition of all forms of discrimination, in particular those based on genetic characteristics;

Taking into account national and international professional standards in the field of genetic services and the 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 fundamental rights and freedoms of the individual with regard to genetic testing for health purposes,

Have agreed as follows:

Chapter I – Object and scope

Article 1 – Object and purpose

Parties to this Protocol 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 tests to which this Protocol applies in accordance with Article 2.

Article 2 – Scope

- 1 This Protocol applies to tests, which are carried out for health purposes, involving analysis of biological samples of human origin and aiming specifically to identify the genetic characteristics of a person which are inherited or acquired during early prenatal development (hereinafter referred to as “genetic tests”).
- 2 This Protocol does not apply:
 - a to genetic tests carried out on the human embryo or foetus;
 - b to genetic tests carried out for research purposes.
- 3 For the purposes of paragraph 1:
 - a “analysis” refers to:
 - i chromosomal analysis,
 - ii DNA or RNA analysis,
 - iii analysis of any other element enabling information to be obtained which is equivalent to that obtained with the methods referred to in sub-paragraphs a.i. and a.ii.;
 - b “biological samples” refers to:
 - i biological materials removed for the purpose of the test concerned,
 - ii biological materials previously removed for another purpose.

Chapter II – General provisions

Article 3 – Primacy of the human being

The interests and welfare of the human being concerned by genetic tests covered by this Protocol shall prevail over the sole interest of society or science.

Article 4 – Non-discrimination and non-stigmatisation

- 1 Any form of discrimination against a person, either as an individual or as a member of a group on grounds of his or her genetic heritage is prohibited.
- 2 Appropriate measures shall be taken in order to prevent stigmatisation of persons or groups in relation to genetic characteristics.

Chapter III – Genetic services

Article 5 – Quality of genetic services

Parties shall take the necessary measures to ensure that genetic services are of appropriate quality. In particular, they shall see to it that:

- a genetic tests meet generally accepted criteria of scientific validity and clinical validity;
- b a quality assurance programme is implemented in each laboratory and that laboratories are subject to regular monitoring;
- c persons providing genetic services have appropriate qualifications to enable them to perform their role in accordance with professional obligations and standards.

Article 6 – Clinical utility

Clinical utility of a genetic test shall be an essential criterion for deciding to offer this test to a person or a group of persons.

Article 7 – Individualised supervision

- 1 A genetic test for health purposes may only be performed under individualised medical supervision.
- 2 Exceptions to the general rule referred to in paragraph 1 may be allowed by a Party, subject to appropriate measures being provided, taking into account the way the test will be carried out, to give effect to the other provisions of this Protocol.

However, such an exception may not be made with regard to genetic tests with important implications for the health of the persons concerned or members of their family or with important implications concerning procreation choices.

Chapter IV – Information, genetic counselling and consent

Article 8 – Information and genetic counselling

- 1 When a genetic test is envisaged, the person concerned shall be provided with prior appropriate information in particular on the purpose and the nature of the test, as well as the implications of its results.
- 2 For predictive genetic tests as referred to in Article 12 of the Convention on Human Rights and Biomedicine, appropriate genetic counselling shall also be available for the person concerned.

The tests concerned are:

- tests predictive of a monogenic disease,
- tests serving to detect a genetic predisposition or genetic susceptibility to a disease,
- tests serving to identify the subject as a healthy carrier of a gene responsible for a disease.

The form and extent of this genetic counselling shall be defined according to the implications of the results of the test and their significance for the person or the members of his or her family, including possible implications concerning procreation choices.

Genetic counselling shall be given in a non-directive manner.

Article 9 – Consent

- 1 A genetic test may only be carried out after the person concerned has given free and informed consent to it.

Consent to tests referred to in Article 8, paragraph 2, shall be documented.

- 2 The person concerned may freely withdraw consent at any time.

Chapter V – Persons not able to consent

Article 10 – Protection of persons not able to consent

Subject to Article 13 of this Protocol, a genetic test on a person who does not have the capacity to consent may only be carried out for his or her direct benefit.

Where, according to law, a minor does not have the capacity to consent, a genetic test on this person shall be deferred until attainment of such capacity unless that delay would be detrimental to his or her health or well-being.

Article 11 – Information prior to authorisation, genetic counselling and support

- 1 When a genetic test is envisaged in respect of a person not able to consent, the person, authority or body whose authorisation is required shall be provided with prior appropriate information in particular with regard to the purpose and the nature of the test, as well as the implications of its results.

Appropriate prior information shall also be provided to the person not able to consent in respect of whom the test is envisaged, to the extent of his or her capacity to understand.

A qualified person shall be available to answer possible questions by the person, authority or body whose authorisation is required, and, if appropriate, the person in respect of whom the test is envisaged.

- 2 The provisions of Article 8, paragraph 2, shall apply in the case of persons not able to consent to the extent of their capacity to understand.

Where relevant, appropriate support shall be available for the person whose authorisation is required.

Article 12 – Authorisation

- 1 Where, according to law, a minor does not have the capacity to consent to a genetic test, that test 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.

- 2 Where, according to law, an adult does not have the capacity to consent to a genetic test because of a mental disability, a disease or for similar reasons, that test 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.

Wishes relating to a genetic test expressed previously by an adult at a time where he or she

had capacity to consent shall be taken into account.

The individual concerned shall, to the extent of his or her capacity to understand, take part in the authorisation procedure.

- 3 Authorisation to tests referred to in Article 8, paragraph 2, shall be documented.
- 4 The authorisation referred to in paragraphs 1 and 2 above may be withdrawn at any time in the best interests of the person concerned.

Chapter VI – Tests for the benefit of family members

Article 13 – Tests on persons not able to consent

Exceptionally, and by derogation from the provisions of Article 6, paragraph 1, of the Convention on Human Rights and Biomedicine and of Article 10 of this Protocol, the law may allow a genetic test to be carried out, for the benefit of family members, on a person who does not have the capacity to consent, if the following conditions are met:

- a the purpose of the test is to allow the family member(s) concerned to obtain a preventive, diagnostic or therapeutic benefit that has been independently evaluated as important for their health, or to allow them to make an informed choice with respect to procreation;
- b the benefit envisaged cannot be obtained without carrying out this test;
- c the risk and burden of the intervention are minimal for the person who is undergoing the test;
- d the expected benefit has been independently evaluated as substantially outweighing the risk for private life that may arise from the collection, processing or communication of the results of the test;
- e the authorisation of the representative of the person not able to consent, or an authority or a person or body provided for by law has been given;
- f the person not able to consent shall, in proportion to his or her capacity to understand and degree of maturity, take part in the authorisation procedure. The test shall not be carried out if this person objects to it.

Article 14 – Tests on biological materials when it is not possible to contact the person concerned

When it is not possible, with reasonable efforts, to contact a person for a genetic test for the benefit of his or her family member(s) on his or her biological material previously removed for another purpose, the law may allow the test to be carried out in accordance with the principle of proportionality, where the expected benefit cannot be otherwise obtained and where the test cannot be deferred.

Provisions shall be made, in accordance with Article 22 of the Convention on Human Rights and Biomedicine, for the case where the person concerned has expressly opposed such test.

Article 15 – Tests on deceased persons

A genetic test for the benefit of other family members may be carried out on biological

samples:

- removed from the body of a deceased person, or
- removed, when he or she was alive, from a person now deceased,

only if the consent or authorisation required by law has been obtained.

Chapter VII – Private life and right to information

Article 16 – Respect for private life and right to information

- 1 Everyone has the right to respect for his or her private life, in particular to protection of his or her personal data derived from a genetic test.
- 2 Everyone undergoing a genetic test is entitled to know any information collected about his or her health derived from this test.

The conclusions drawn from the test shall be accessible to the person concerned in a comprehensible form.

- 3 The wish of a person not to be informed shall be respected.
- 4 In exceptional cases, restrictions may be placed by law on the exercise of the rights contained in paragraphs 2 and 3 above in the interests of the person concerned.

Article 17 – Biological samples

Biological samples referred to in Article 2 shall only be used and stored in such conditions as to ensure their security and the confidentiality of the information which can be obtained there from.

Article 18 – Information relevant to family members

Where the results of a genetic test undertaken on a person can be relevant to the health of other family members, the person tested shall be informed.

Chapter VIII – Genetic screening programmes for health purposes

Article 19 – Genetic screening programmes for health purposes

A health screening programme involving the use of genetic tests may only be implemented if it has been approved by the competent body. This approval may only be given after independent evaluation of its ethical acceptability and fulfilment of the following specific conditions:

- a the programme is recognised for its health relevance for the whole population or section of population concerned;
- b the scientific validity and effectiveness of the programme have been established;
- c appropriate preventive or treatment measures in respect of the disease or disorder which is the subject of the screening, are available to the persons concerned;
- d appropriate measures are provided to ensure equitable access to the programme;

- e the programme provides measures to adequately inform the population or section of population concerned of the existence, purposes and means of accessing the screening programme as well as the voluntary nature of participation in it.

Chapter IX – Public information

Article 20 – Public information

Parties shall take appropriate measures to facilitate access for the public to objective general information on genetic tests, including their nature and the potential implications of their results.

Chapter X – Relation between this Protocol and other provisions and re-examination of the Protocol

Article 21 – Relation between this Protocol and the Convention

As between the Parties, the provisions of Articles 1 to 20 of this Protocol shall be regarded as additional articles to the Convention on Human Rights and Biomedicine, and all the provisions of the Convention shall apply accordingly.

Article 22 – Wider protection

None of the provisions of this Protocol shall be interpreted as limiting or otherwise affecting the possibility for a Party to grant persons concerned by genetic testing for health purposes a wider measure of protection than is stipulated in this Protocol.

Article 23 – 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 24 – Signature and ratification

This Protocol shall be open for signature by Signatories to the Convention on Human Rights and Biomedicine. 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 25 – 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 24.
- 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 26 – Accession

- 1 After the entry into force of this Protocol, any state which has acceded to the Convention on Human Rights and Biomedicine 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 27 – 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 28 – 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 on Human Rights and Biomedicine 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 25 and 26;
- 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 27th day of November 2008, 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 on Human Rights and Biomedicine and to the European Community.