COUNCIL OF EUROPE
COMMITTEE OF MINISTERS

Recommendation 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)

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;

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.

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Appendix to Recommendation Rec(2006)4

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**.**