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COMMITTEE ON BIOETHICS
(DH-BIO)

Working document
on research on biological materials of human origin

This working document is made public under the responsibility of the Committee on Bioethics (DH-BIO). The purpose of this consultation is to elicit comments which will be taken into consideration in finalising the revision process of Recommendation (2006) 4 of the Committee of Ministers of the Council of Europe, on research on biological materials of human origin.

The DH-BIO would be particularly interested in receiving comments on the following issues:

- Storage for future research of residual biological materials (Article 13)
- Removal, storage and use of biological materials from persons not able to consent (Articles 12, 14 and 17, paragraph 4)
- Governance (Articles 20, 21, 22, 23 and 24)

In addition to the priority issues highlighted above, comments are also solicited on the other provisions contained in this document.

Comments should be as precise and concise as possible. They should refer to specific provisions in the document.

Comments should be submitted in English or French, by 15 August 2014 via email to the following address: dgl.consultation@coe.int.

Working document on research on biological materials of human origin

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 of biological materials at national level;

Stressing the importance of the right to privacy in the field of biomedical research, as defined in data protection instruments;

Taking into account the development of new technologies, in particular in the field of genetics, which increase issues regarding privacy and feedback on incidental health-related findings;

Taking into account the establishment of international research infrastructures that pool and share samples and data across national borders;

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;

Stressing that the paramount concern should be the protection of the human being whose biological materials are obtained, 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, especially to those who are not able to consent;

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 good and transparent governance of biological materials stored for research purposes;

Stressing that collections developed on the basis of donations of biological materials made in a spirit of solidarity should not be monopolised by small groups of researchers;

Recognising the value for biomedical research of existing collections set up for clinical purposes;

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 the governments of member states:

a. to adapt their laws and practices to ensure the implementation, including its follow-up, of the guidelines contained in the appendix to this Recommendation, which replaces Rec(2006)4;

b. to promote the establishment of codes of good practice to ensure compliance with the guidelines 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 Union and to other relevant governmental and non-governmental international organisations.

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Appendix to Recommendation Rec( )
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 respect for 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 obtaining of biological materials of human origin for storage for future research purposes;
   - the storage of biological materials of human origin for future research purposes; and
   - the use in a research project of biological materials of human origin that are stored or were previously obtained for another purpose, including a previous research project.

2. This Recommendation does not apply to
   - embryonic and foetal tissues; and
   - the use in a specific research project of biological materials of human origin removed for that purpose. This is within the scope of the Additional Protocol concerning Biomedical Research (CETS No. 195).

3. The collection, storage and use of biological materials of human origin may be accompanied by associated personal data. Where in this Recommendation provisions make reference to biological materials of human origin these extend, where relevant, also to 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 data, allow the identification of the persons from whom the materials have been removed, either directly or through the use of a code.
In the latter case, hereafter referred to as “coded materials”, the user of the biological materials may have direct access to the code or, alternatively the code may be under the control of a third party.

ii. *Non-identifiable biological materials*, hereafter referred to as “anonymised materials”, are those biological materials which, alone or in combination with data, do not allow, with reasonable efforts, the identification of the persons from whom the materials have been removed.

CHAPTER II – General provisions

Article 4 – Risks and benefits

1. The risks for the persons from whom biological materials have been removed 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 from whom biological materials have been removed should also be taken into consideration in this context.

Article 5 – Non-discrimination

1. Appropriate measures should be taken, in the full range of research activities, to avoid discrimination against, or stigmatisation of, a person, family or group.

2. Refusal to give consent or authorisation to the removal, storage or research use of biological materials or the withdrawal or alteration of the scope of the consent or authorisation given should not lead to any form of discrimination against the person from whom biological materials have been removed, in particular regarding the right to medical care.

Article 6 – Prohibition of financial gain

Biological materials should not, as such, give rise to financial gain.

Article 7 – Justification of identifiability

1. Biological materials should be anonymised as far as appropriate to the research activities concerned.

2. Any use of biological materials in an identifiable form should be justified in advance by the researcher.

Article 8 – Confidentiality

1. Any information of a personal nature collected at the time of removal, storage or use of biological materials, or obtained through research should be considered as confidential and treated according to the rules relating to the protection of private life.

2. Appropriate security measures should be in place to ensure confidentiality at the time of removal, storage, use and, where appropriate, transfer of biological materials.

Article 9 – Public information

Member States should take appropriate measures to facilitate access for the public to general information on the nature and objective of research collections and on the conditions relating to the obtaining, storage and use of biological materials for research purposes, including matters relating to consent or authorisation.

Article 10 – 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 – Information and consent

Article 11 – Removal of biological materials for storage for future research

Information

1. Prior to requesting consent to remove biological materials for storage for future research, the person concerned should be provided with comprehensible information:

i. that is specific with regard to the intervention carried out to remove the materials; and

ii. that is as precise as possible with regard to:
- any research use foreseen;
- the conditions applicable to the storage of the materials; and
- other relevant conditions governing the use of the materials.

2. The persons concerned should also be informed of the rights and safeguards prescribed by law for their protection.

3. The persons concerned should be offered the possibility to exercise choices with regard to the type of research use of their biological materials.

Consent

4. Biological materials may not be removed for storage for future research without the free, express and documented consent of the person concerned:

- that is specific with regard to the intervention carried out to remove the materials; and
- that is as precise as possible with regard to the research use covered, in the light of the information provided in paragraph 1, ii., and includes possible choices made in accordance with paragraph 3.

Article 12 – Removal of biological materials from persons not able to consent for storage for future research

1. Biological materials may only be removed for storage for future research from a person who, according to law, is considered not able to consent with the written authorisation from the representative or an authority, person or body provided for by law. The representative, the authority, the person or the body concerned should beforehand be given the information required by Article 11, paragraph 1, i and ii and paragraphs 2 and 3.

2. Persons not able to consent should be informed in a manner compatible with their understanding. An adult not able to consent should as far as possible take part in the authorisation procedure. The opinion of a minor should be taken in consideration as an increasingly determining factor in proportion to age and degree of maturity. Any objection by the person not able to consent should be respected.

3. Biological materials from persons not able to consent may only be removed for storage for future research having the potential to produce [real and direct benefit to their health or, in the absence thereof,] benefit to persons in the same age category or afflicted with the same disease or disorder or having the same condition. The removal should entail only minimal risk and minimal burden for the person on whom it is carried out.

4. Where a person not able to consent, from whom biological materials have been removed for storage for future research attains the capacity to consent, the consent of that person for continued storage and research use of his or her biological materials should be sought.

Article 13 – Storage for future research of residual biological materials

1. Biological materials removed for purposes other than for storage for future research should only be stored for future research with the consent of the person concerned, provided for by law. This person should beforehand be given appropriate information, as referred to in Article 11, paragraph 1, ii. and paragraphs 2 and 3, including on the right to refuse.

2. Whenever possible, information as referred to in paragraph 1 should be given and consent requested before biological materials are removed.

3. Biological materials removed for purposes other than for storage for future research and already anonymised, may be stored for future research subject to authorisation provided for by law.
Anonymisation should be verified by an appropriate review procedure.

Article 14 – Storage for future research of residual biological materials from persons not able to consent

1. Biological materials removed for purposes other than for storage fur future research from persons not able to consent should only be stored for future research with the authorisation from their representative or an authority, person or body provided for by law. The representative, the authority,

the person or the body concerned should beforehand be given appropriate information, as referred to in Article 11, paragraph 1, ii. and paragraphs 2 and 3, including on the right to refuse.

2. Whenever possible, information as referred to in paragraph 1 should be given and authorisation requested before biological materials are removed.

3. Biological materials removed for purposes other than for storage for future research from persons not able to consent may only be stored for future research having the potential to produce [real and direct benefit to their health or, in the absence thereof,] benefit to persons in the same age category or afflicted with the same disease or disorder or having the same condition.

4. Where a person not able to consent, from whom biological materials have been removed for purposes other than for storage for future research, attains the capacity to consent, the consent of that person for continued storage and research use of his or her biological materials should be sought.

5. Biological materials removed for purposes other than for storage for future research and already anonymised, may be stored for future research subject to authorisation provided for by law.
Anonymisation should be verified by an appropriate review procedure.

Article 15 – Biological materials removed after death

1. Biological materials should only be removed from the body of a deceased person for storage for future research with the consent or authorisation, provided for by law. This consent or authorisation should have been preceded by appropriate information, including on the right to refuse.

2. Biological materials should not be removed for storage for future research if the deceased person is known to have objected to it.

Article 16 – 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 future research, the person should retain the right to withdraw or alter the scope of that consent.
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 anonymised. The person who is considering withdrawing consent should be made aware of any limitations on withdrawal of his or her biological material.

2. The representative, authority, person or body provided for by law having given authorisation for storage for future research of biological materials removed from a person not able to consent, should have the rights referred to in paragraph 1.
Where the person from whom biological materials have been removed attains the capacity to give consent, that person should have the rights referred to in paragraph 1.

CHAPTER IV – Use of biological materials in a research project

Article 17 – General rule

1. Research on biological materials should only be undertaken if it is within the scope of the consent or authorisation given by the person concerned.

2. i. If the proposed use of identifiable biological materials in a research project is not within the scope of prior consent or authorisation, if any, given by the person concerned, consent or authorisation to the proposed use should be sought and, to this end, sufficient efforts should be made to contact the person concerned. The wish of the person concerned not to be contacted should be respected.

   ii. Where the attempt to contact the person concerned proved unsuccessful, these biological materials should only be used in the research project subject to independent evaluation of the fulfilment of the following conditions:

a. evidence is provided that sufficient efforts have been made to contact the person concerned;
b. the research addresses an important scientific interest and is in accordance with the principle of proportionality;
c. the aims of the research could not reasonably be achieved using biological materials for which consent or authorisation can be obtained;
d. there is no evidence that the person concerned has expressly opposed such research use.

3. Anonymised biological materials may be used in a research project provided that such use does not violate any restrictions placed by the person concerned prior to the anonymisation of the materials and subject to authorisation provided for by law.
Anonymisation should be verified by an appropriate review procedure.

4. Biological materials from persons not able to consent may only be used for research having the potential to produce [real and direct benefit to their health or, in the absence thereof,] benefit to other persons in the same age category or afflicted with the same disease or disorder or having the same condition.

Article 18 – 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 principles concerning ethics committees contained in chapter III of the Additional Protocol concerning Biomedical Research (CETS No. 195) to the review of the research project 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 from whom biological materials have been removed could be identified from these biological materials.

Article 19 – Availability of results

1. On completion of the research, a report or summary should be submitted to the ethics committee or the competent body.

2. Appropriate measures should be taken to make public the results of research in reasonable time.

CHAPTER V – Governance of collections

Article 20 – General principles

1. The person and/or institution responsible for the collection should be designated and this information should be publicly available.

2. The purpose(s) of the collection should be specified. The principles of transparency and accountability should govern its management, including, where appropriate, access to and use and transfer of its biological materials and disclosure of information.

3. Any change of purpose of a collection should be subject to independent examination and, where necessary, may require that appropriate consent or authorisation of the persons concerned be requested.

4. Each sample of biological material in the collection should be appropriately documented and traceable, including information on the consent or authorisation.

5. Quality assurance measures should be in place, including conditions to ensure appropriate security and confidentiality during establishment, use and, where appropriate, transfer of elements, of the collection.

6. Procedures should be developed for any transfer of the whole or part of the collection as well as for the closure of the collection; these should be in accordance with the original consent or authorisation.

7. Information about the management and use of the collection should be made available to the persons concerned and should be regularly updated, with a view to facilitating, where appropriate, the exercise of the rights laid down in Article 16.

8. The conclusions of the research should be made available to the persons concerned in reasonable time, on request.

9. Reports on past and planned activities, including information about access by third parties, should be published at least annually.

Article 21 – Individual feedback

1. Clear policies should be developed on feedback concerning findings that are significant for the health of the persons arising from the use of their biological materials.

2. Feedback should take place within a framework of health care or counselling.

3. The wishes of individuals not to be informed should be observed.

Article 22 – Access

1. Clear conditions governing access to, and use of, biological materials should be established.

2. Member states should take measures to facilitate appropriate access by researchers to collections of biological materials.

3. Transparent access policies should be developed and published, including arrangements for oversight of access and transfer procedures.

4. Appropriate access mechanisms should be developed to maximise the value of collections. These should include traceability of the uses granted by the collection.

Article 23 – Transborder flows

1. Biological materials should only be transferred to another state if a comparable level of protection is either ensured by the law of that state or by legally binding and enforceable instruments adopted and implemented by the persons involved in the transfer and further processing.

2. The transfer of the biological materials should be done under appropriate safety and confidentiality conditions.

3. A documented agreement between the sender of the biological materials, on the one hand, and the recipient, on the other, should be signed. Appropriate consent or authorisation, including, where appropriate, any relevant restriction established by the person concerned, should be included in the agreement.

Article 24 – Oversight

1. Any proposal to establish a collection of biological materials should be subject to an independent examination of its compliance with the provisions of this Recommendation.

2. Each collection should be subject to independent oversight which is proportionate to the risks involved for the persons whose biological materials are stored in the collection. Such oversight should aim in particular at safeguarding the rights and interests of the persons concerned in the context of the activities of the collection.

Oversight mechanisms should cover, at a minimum:

i. the implementation of security measures and of procedures on access to, and use of, biological materials;

ii. the publication of reports on past and planned activities, including information about access by third parties, at least annually;

iii. the change in the risks to persons whose biological materials are stored in the collection and, where appropriate, revision of policies;

iv. appropriate information to the persons concerned of changes in the management of the collection in order to be able, where appropriate, to exercise the rights laid down in Article 16; and

v. the development and implementation of feedback policies, including regular review.

Oversight mechanisms should be able to adapt to possible evolutions of the collection and of its management.

CHAPTER VI – Re-examination of the Recommendation

Article 25 – Re-examination of the Recommendation

This Recommendation should be regularly re-examined after its adoption, notably in the light of the experience acquired in the implementation of its guidelines.