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Recommendation CM/Rec(2016)6
of the Committee of Ministers to member States
on research on biological materials of human origin

(Adopted by the Committee of Ministers on 11 May 2016
at the 1256th 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) 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;

Acknowledging the fact that personal data must be adequately protected in accordance with data protection principles as laid down in the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (ETS No. 108);

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;

Recognising the value of biomedical research for the advancement of health care and for the improvement of the quality of life and the potential of collections of biological materials of human origin to facilitate the realisation of these benefits;

Stressing that research is often transdisciplinary and international, as reflected in the establishment of international research infrastructures that pool and share samples and data across national borders, and underlining the importance of interoperability in this context;

Taking into account the current and planned development of collections of biological materials of human origin at national level and the existence of collections set up for clinical purposes;

Recalling that biomedical 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 individual;

Stressing that the paramount concern should be the protection of the human being whose biological materials are obtained, stored or used for research;

Emphasising that the interest and welfare of the person 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 persons who may be vulnerable in the context of research, especially to those who are not able to consent;

Considering that new developments in the field of biomedical research, in particular in the field of genetics, increase issues regarding protection of privacy;

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;

Emphasising the importance of earning trust and stressing the role of good and transparent governance of biological materials of human origin stored for research purposes, including the establishment of an appropriate feedback policy;

Recalling that researchers should be allowed fair access to collections developed on the basis of donations of biological materials of human origin made in a spirit of solidarity;

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,

1. recommends to 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 succeeds Recommendation Rec(2006)4;

b. to promote the establishment of codes of good practice to ensure compliance with the guidelines contained in this appendix;

2. entrusts the Secretary General of the Council of Europe with transmitting 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 CM/Rec(2016)6

Guidelines

Chapter I – Object and scope

Article 1 – Object

Member States should protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity, the right to respect for private life and other rights and fundamental freedoms with regard to any research activity governed by this recommendation.

Article 2 – Scope

1. This recommendation applies to the following research activities:
   - 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 biological materials; and
   - the use in a specific research project of biological materials of human origin removed for the sole purpose of that project. This is within the scope of the Additional Protocol concerning Biomedical Research (CETS No. 195).

3. When obtained, stored or used, 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

1. 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 code(s).

In cases where identification is possible through code(s), the user of the biological materials may have direct access to the code(s) or, alternatively, the code(s) may be under the control of a third party.

ii. "non-identifiable biological 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.

2. Non-identifiability should be verified by an appropriate review procedure.

Chapter II – General provisions

Article 4 – Risks and benefits in relation to research activities

1. The physical risks arising from removal of biological materials for storage for future research should be minimised.

2. 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, these risks should not be disproportionate to the potential benefit of the research activities.

3. Possible risks for any individual 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 prevent discrimination against, and to minimise the likelihood of stigmatisation of, any person, family or group.

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

Article 6 – Prohibition of financial gain

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

Article 7 – 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 safeguards should be in place to ensure confidentiality at the time of removal, storage, use and, where appropriate, transfer of biological materials.

Article 8 – 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 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 and storage for future research

Article 10 – Information

1. Prior to consent to or authorisation for the storage of biological materials for future research, the person concerned should be provided with comprehensible information that is as precise as possible with regard to:

- the nature of any envisaged research use and the possible choices that he or she could exercise;
- the conditions applicable to the storage of the materials, including access and possible transfer policies; and
- any relevant conditions governing the use of the materials, including re-contact and feedback.

2. The person concerned should also be informed of the rights and safeguards provided for by law, and specifically of his or her right to refuse consent or authorisation and to withdraw consent or authorisation at any time, in accordance with Article 13. This information should also include any possible limitation on withdrawal of the consent or authorisation.

3. Prior to the removal of biological materials for storage for future research, the person concerned should be provided with additional information specific to the intervention carried out to remove the materials.

4. Persons who, according to law, are not able to consent should be informed in a manner compatible with their understanding.

Article 11 – Biological materials from persons able to consent

1. Biological materials should only be removed for storage for future research with the prior, free, express and documented consent of the person concerned that is:

i. specific to the intervention carried out to remove the materials; and

ii. as precise as possible with regard to the envisaged research use.

2. Biological materials previously removed for another purpose should only be stored for future research with the consent of the person concerned, as provided for by law. Whenever possible, consent should be requested before biological materials are removed.

3. Biological materials previously removed for another purpose and already non-identifiable may be stored for future research subject to authorisation provided for by law.

Article 12 – Biological materials from persons not able to consent

1. Biological materials from a person who, according to law, is not able to consent should only be obtained or stored for future research having the potential to produce, in the absence of direct benefit to the person concerned, benefit to other persons in the same age category or afflicted with the same disease or disorder or having the same condition, and if the aims of the research could not reasonably be achieved using biological materials from persons able to consent.

2. Biological materials should only be removed for storage for future research from a person not able to consent under the following conditions:

a. the removal only entails minimal risk and minimal burden; and

b. written authorisation for such removal has been given by the representative or an authority, person or body provided for by law. The necessary authorisation should be:

i. specific to the intervention carried out to remove the materials; and

ii. as precise as possible with regard to the envisaged research use.

3. Biological materials previously removed for another purpose from a person not able to consent should only be stored for future research with the authorisation of his or her representative or an authority, person or body provided for by law. Whenever possible, authorisation should be requested before biological materials are removed.

4. If the person not able to consent is an adult, he or she should, as far as possible, take part in the authorisation procedure. If the person not able to consent is a minor, his or her opinion should be taken into 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. Any wishes previously expressed by such a person should be taken into account.

5. Where a person not able to consent, whose biological materials have been stored for future research, attains or regains the capacity to consent, reasonable efforts should be made to seek the consent of that person for continued storage and research use of his or her biological materials.

6. Biological materials previously removed for another purpose from a person not able to consent and which are already non-identifiable may be stored for future research subject to authorisation provided for by law.

Article 13 – Right to withdraw consent or authorisation

1. When a person has provided consent to storage of identifiable biological materials for future research, the person should, without being subject to any form of discrimination, in particular regarding the right to medical care, retain the right to withdraw consent at any time, and, where possible, should also be able to 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 law, the materials and associated data either destroyed or rendered non-identifiable. The person who is considering withdrawing consent should be made aware of any limitations on withdrawal of his or her biological materials.

2. The representative, authority, person or body provided for by law having given authorisation for storage for future research of identifiable biological materials removed from a person who, according to law, is not able to consent, should have the rights referred to in paragraph 1 without any form of discrimination for the person from whom the material has been removed, in particular regarding the right to medical care. Where the person from whom biological materials have been removed attains or regains the capacity to give consent, that person should have the rights referred to in paragraph 1.

Article 14 – 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.

Chapter IV – Governance of collections

Article 15 – General rule

Biological materials intended to be used for future research should only be stored in a structured manner and in accordance with the principles of governance laid down in this chapter.

Article 16 – Governance 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, use and transfer of biological materials, and disclosure of information.

3. Any change of purpose of a collection should be subject to an independent examination of its compliance with the provisions of this recommendation 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 scope of any consent or authorisation.

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

6. Procedures should be established 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 13.

8. Reports on past and planned activities should be made public at least annually, including information about access granted to biological materials and progress on research projects using biological materials. A summary of findings should be made public on completion of each research project.

Article 17 – Individual feedback

1. Clear policies should be in place on feedback concerning findings that are relevant for the health of the persons resulting from the use of their biological materials, including persons who, according to law, are not able to consent.

2. Where provided, feedback should take place within a framework of appropriate health care or counselling.

3. The wishes of individuals not to be informed about findings that are relevant for their health should be observed.

Article 18 – Access

1. Member States should take measures to facilitate appropriate access by researchers to collections of biological materials.

2. Clear conditions governing access to and use of biological materials should be established and documented, including respect for possible restrictions defined by the persons concerned.

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 use of the biological materials to which access was granted.

Article 19 – Transborder flows

1. Biological materials should only be transferred to another State if an appropriate level of protection is either ensured by the law of that State or by legally binding and enforceable instruments adopted and implemented by the parties involved in the transfer for future research activities.

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

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

Article 20 – 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.

3. Oversight mechanisms should cover, at a minimum:

a. 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, at least annually, of reports on past and planned activities, including information about access granted to biological materials and progress on research using biological materials;

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

iv. the provision of 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 13; and

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

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

Chapter V – Use of biological materials in a research project

Article 21 – General rule

1. Biological materials should only be used in a research project if the latter is within the scope of the consentor authorisation given by the person concerned.

2. *a*. 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, reasonable efforts should be made to contact the person concerned. The wish of the person concerned not to be contacted should be observed.

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

i. evidence is provided that reasonable efforts have been made to contact the person concerned;

ii. the research addresses an important scientific interest and is in accordance with the principle of proportionality;

iii. the aims of the research could not reasonably be achieved using biological materials for which consent or authorisationcan be obtained; and

iv. there is no evidence that the person concernedhas expressly opposed such research use.

3. Any use of biological materials in an identifiable form should be justified in advance in the research protocol.

4. Non-identifiable biological materials may be used in a research project provided that such use does not violate any restrictions defined by the person concerned before the materials have been rendered non-identifiable and subject to authorisation provided for by law.

5. Biological materials from persons who, according to law, are not able to consent should only be used for research having the potential to produce, in the absence of direct benefit to the person concerned, benefit to other persons in the same age category or afflicted with the same disease or disorder or having the same condition, and if the aims of the research could not reasonably be achieved using biological materials from persons able to consent.

Article 22 – 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. The 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 23 – Availability of results

1. On completion of the research, a report or summary should be submitted to the ethics committee or the competent body and, if applicable, to the person and/or institution responsible for the collection that granted access to the biological materials.

2. The researcher should take appropriate measures to make public the results of research in reasonable time.

Chapter VI – Re-examination of the recommendation

Article 24 – Re-examination of the recommendation

This recommendation should be regularly re-examined after its adoption, notably in the light of new developments in the field and the experience acquired in the implementation of its guidelines.

Related documents

Meetings

1256th meeting of the Ministers' Deputies (11 May 2016) - Meetings 2016 / 11 May 2016 / *English*