

**SECRETARIAT GENERAL**

DIRECTORATE GENERAL  
HUMAN RIGHTS AND RULE OF LAW

DIRECTORATE OF HUMAN RIGHTS

HUMAN RIGHTS POLICY  
AND DEVELOPMENT DEPARTMENT

*BIOETHICS UNIT*  
Please quote: DG1/BIO/

COUNCIL OF EUROPE



CONSEIL DE L'EUROPE

Strasbourg, 18 March 2014

Dear Madam,  
Dear Sir,

Within the context of the re-examination of Recommendation (2006) 4 of the Committee of Ministers of the Council of Europe, on research on biological materials of human origin, the Committee on Bioethics (DH-BIO) of the Council of Europe has decided to make public for consultation the **working document on research on biological materials of human origin**, carrying the reference DH-BIO/INF (2014) 3.

The document was prepared on the basis of Recommendation (2006) 4, taking into account the outcome of the Symposium on Biobanks and Biomedical Collections, held on 19-20 June 2012 in Strasbourg (France) and the comments made by the delegations of the DH-BIO.

The aim of this work is to address the challenges raised by new developments in the field since 2006. The main issues taken into consideration include:

1. The need to more specifically address the diverse origins and different levels of identification of biological materials stored for future research;
2. The particular situation of the removal, storage and use of materials from persons not able to consent;
3. The increasing importance of the governance of collections in the light of the interests concerned.

The purpose of this consultation is to elicit comments, in particular from the sectors directly concerned (such as researchers, relevant bodies or institutions, patient organisations and biobank managers). These comments will be taken into consideration in finalising the revision process of the Recommendation.

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

**1. Storage for future research of residual biological materials**

Article 13 covers storage for future research of residual biological materials, including materials initially removed within a clinical context or for a specific research project. Article 13 covers both identifiable residual biological materials and already anonymised residual biological materials. In the latter case, as it is not possible to contact the person concerned, storage may require a process of authorisation.

## 2. Removal, storage and use of biological materials from persons not able to consent

Article 12 gives specific consideration to the removal of biological materials from persons not able to consent, for storage for future research. Paragraph 3 sets conditions for such removal, based on the principles set out in Article 17 of the Convention on Human Rights and Biomedicine, available at <http://conventions.coe.int/Treaty/EN/Treaties/Html/164.htm>.

The same considerations apply to Article 14, covering the storage for future research of residual biological materials from persons not able to consent and Article 17, paragraph 4, addressing the use in research projects of biological materials from persons not able to consent.

## 3. Governance

A separate chapter on governance was introduced, including in Article 20 general provisions which are applicable to all collections. More specific provisions have been introduced on individual feedback (Article 21), access (Article 22) and transborder flows (Article 23) which will only be relevant for collections engaging in the activities covered in those articles. The provisions on oversight (Article 24) apply proportionate to the risks involved for the persons whose biological materials are stored in the collection.

In addition to the priority issues highlighted above, you are also invited to comment on the other provisions contained in this document.

The consultation process launched today will close on 15 August 2014. **You are invited to submit comments in English or French, by 15 August 2014 via email to the following address: [dgl.consultation@coe.int](mailto:dgl.consultation@coe.int).**

We thank you in advance for your contribution to this consultation.

Yours sincerely,



Laurence Lwoff  
Secretary of the Committee on Bioethics (DH-BIO)