Recommendation

For the Assessment of Research-related Human Biobanks by Ethics Committees

Recommended by the Permanent Working Party of the German Medical Ethics Committees
Version 2.0 approved by the General Assembly on 10.06.2016

The following recommendation is intended for Ethics Committees who are involved in the approval of research proposals in the context of human biobanks. It specifies the requirements and criteria for the ethical and legal assessment of human biobanks to be set up or that are already being operated. The recommendation covers all kinds of biobanks hosting human biological material, irrespective of size, focus or other particular features. However, some of the proposed requirements are to be adapted to the specific characteristics of the respective biobank.

The recommendation is to be interpreted in connection with the text template "for the use of human biological material and related data in biobanks", Version 2.0 from 10.06.2016. This text template contains fundamental requirements being indispensable part of donor-information and consent forms.

Introduction

Today, biobanks have been recognized as very important resources for medical research. When establishing or operating a biobank, the interests of medical research and the freedom of research have generally to be counter-balanced with the interests and rights of donors, in particular their right to self-determination.

1. Definition and scope of the recommendation

A "biobank" in the sense of this recommendation collects and stores human biological material and related data for medical research purposes. Medical research comprises basic research as well as applied research addressing the detection of diseases (diagnostics), their prediction (prognosis) and their treatment (therapy) and avoidance (prevention).

A "biobank" in the sense of this recommendation equally comprises cooperation or networking between several or multiple collections of human biological material, or collections having common procedural rules and governance.

2. The role of ECs in the set up and operation of biobanks

a. Assessment of the biobank

The establishment of a research-related biobank by public or private organizations/bodies generally needs to be assessed by a public ethics committee from an ethical point of view, irrespective of legal obligations. The same applies in case of relevant changes of the scope or the legal owner of a biobank, or in case of transfer of the collected bio-samples into another organization.

a. Assessment of applying research-projects

Prior to releasing biomaterials and/or related data for a medical research project, the biobank has to require an ethics vote of the ethics committee in charge of the respective project, at least in cases where such a vote has to be provided by law (professional law (physicians) including

the Declaration of Helsinki). The right of the biobank to consult its local ethics committee remains unaffected.

3. Relevant documents needed for the establishment of a biobank

To assess the establishment of a research-related biobank by public or private organizations/bodies the ethics committee requires:

- Information on the scope, governance, procedures, means of documentation and financial plan;
- Information on the kind, collection, storage, QM and QC, use, and security measures regarding biomaterials and related data;
- Information for donors (patients/participants) and corresponding consent-document(s).

4. Assessment criteria for a biobank

a. Donor-Information documents and consent form
The implementation of a research-related biobank by public or private organizations/bodies from an ethical point of view (independent from an obligation by law) needs a vote from a public (research) ethics committee. The same applies in case of relevant changes of the scope or legal

b. Intended use of the biomaterials
The implementation of a research-related biobank by public or private organizations/bodies from an ethical point of view (independent from an obligation by law) needs a vote from a public (research) ethics committee. The same applies in case of relevant changes of the scope or legal

c. Data protection and pseudonymization

c1) Storage of identifying data
The implementation of a research-related biobank by public or private organizations/bodies from an ethical point of view (independent from an obligation by law) needs a vote from a public (research) ethics committee. The same applies in case of relevant changes of the scope or legal
c2) Pseudonymization for storage of biomaterials and related data
The implementation of a research-related biobank by public or private organizations/bodies from an ethical point of view (independent from an obligation by law) needs a vote from a public (research) ethics committee. The same applies in case of relevant changes of the scope or legal
c3) Pseudonymization for release and use of biomaterials and related data
The implementation of a research-related biobank by public or private organizations/bodies from an ethical point of view (independent from an obligation by law) needs a vote from a public (research) ethics committee. The same applies in case of relevant changes of the scope or legal
c4) Reversal of double pseudonymization/conditions of re-identification
The implementation of a research-related biobank by public or private organizations/bodies from an ethical point of view (independent from an obligation by law) needs a vote from a public (research) ethics committee. The same applies in case of relevant changes of the scope or legal

d. Duration of storage and the right of withdrawal
The implementation of a research-related biobank by public or private organizations/bodies from an ethical point of view (independent from an obligation by law) needs a vote from a public (research) ethics committee. The same applies in case of relevant changes of the scope or legal
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e. Use and release of biomaterials and data for research projects

The implementation of a research-related biobank by public or private organizations/bodies from an ethical point of view (independent from an obligation by law) needs a vote from a public (research) ethics committee. The same applies in case of relevant changes of the scope or legal

e1) Application

The implementation of a research-related biobank by public or private organizations/bodies from an ethical point of view (independent from an obligation by law) needs a vote from a public (research) ethics committee. The same applies in case of relevant changes of the scope or legal

c2) Granted rights of use

The implementation of a research-related biobank by public or private organizations/bodies from an ethical point of view (independent from an obligation by law) needs a vote from a public (research) ethics committee. The same applies in case of relevant changes of the scope or legal

f. Conditions for re-contact

The implementation of a research-related biobank by public or private organizations/bodies from an ethical point of view (independent from an obligation by law) needs a vote from a public (research) ethics committee. The same applies in case of relevant changes of the scope or legal

g. Compensation for the biobank (fees-for-service)

The implementation of a research-related biobank by public or private organizations/bodies from an ethical point of view (independent from an obligation by law) needs a vote from a public (research) ethics committee. The same applies in case of relevant changes of the scope or legal

f. Quality management and control and transparency

The implementation of a research-related biobank by public or private organizations/bodies from an ethical point of view (independent from an obligation by law) needs a vote from a public (research) ethics committee. The same applies in case of relevant changes of the scope or legal