Procedure

Biobank - Creation and organization of a general research biobank

1. Changes since the previous version

The document is based on previous documents and practice at Aker University Hospital HF (AUS), Rikshospitalet HF (RH) and Ullevål University Hospital HF (UUS) and guidelines drawn up by the Biobank and register committee at OUS.

No changes from the previous version, only updated links.

2. Purpose and scope

The purpose of the procedure is to clarify roles, responsibilities and the approval process when establishing and organizing general research biobank where OUS is the institution responsible for research, including clinic-wide general research biobanks. The procedure also includes routines for closure and destruction of material in a general research biobank.

When creating a research biobank in connection with a specific project (specific research biobank), see separate procedure.

All use of material from a general research biobank requires a separate REK approval in line with the routines in the research procedure. See also point 4.1 below.

3. Liability

The research manager, head of department and responsible person for the research biobank are in accordance with the research instructions.

Responsibility for clinic-wide general research biobanks, see point 4.2 below regarding professional advice.

4. Procedure

4.1 Requirements for approval when establishing a general research biobank

Prior approval from REK

Creation of a general research biobank requires prior approval from the Regional Committee for Medical and health research ethics (REK). The same applies to new, changed or extended use of an existing general research biobank.

An application for the creation of a new, changed or extended use of a general research biobank, with attachments, is sent from project manager for REK via the SPREK portal .

It is recommended that advice and guidance be obtained from the Department for Research Administration and the biobank be contacted before the application is sent to REK.

Internal approval process and organization

An application for the creation of a general research biobank must be anchored in the department management before the application is sent to REK. A copy of the application for the establishment of a general research biobank must be sent to: godkjenning@ous-hf.no, while application is sent to REK.

All collection of material to be included in the general biobank shall, unless otherwise stated in the REK approval, be based on broad consent (cf. Health Research Act § 14).

4.2 Organization of clinic-wide general research biobank

Responsible person

Those responsible for clinic-wide research biobanks are jointly appointed between the clinic managers concerned. The person responsible will be responsible for drawing up guidelines for

access to and use of the biobank and that these guidelines are in line with the procedure, Access and release of human biological material for research.

The guidelines must be submitted to the biobank's professional council for opinion and then to the clinic manager(s) for approval.

Professional council

In the case of clinic-wide general research biobanks, the establishment of a professional council as an advisory body is recommended responsible person and affected clinics regarding management and development of the biobank.

Central tasks for the Academic Council should be:

- Give advice to those responsible regarding guidelines for the use of the biobank material in accordance with current routines (see references below), including assisting in the preparation of specific guidelines relevant to the management and use of material in relevant biobanks.
- Continually assess applications for access and use, and give a professional recommendation to the person in charge in line with the biobank's guidelines
- Contribute to ensuring that donors of biobank material and society's interests are safeguarded, through holistic thinking internally, towards the University of Oslo and other organizations
- Interact with other relevant councils/committees/actors internally and externally

Members of the professional council should be appointed by the clinic managers who are affected by the biobank. The faculty should not be too large (5-7 representatives are recommended) and should consist of members with the necessary professional and scientific expertise. Recommended the term of office for committee members is four years.

The hospital's Biobank and register committee must refer to cases where it is unclear or disputed about other people's access and delivery of material from the biobank.

4.3 Closure of general research biobank

Before closure, the project manager must send a message to the head of department and to the head of research administration and biobank.

REK must finally assess the notice of closure (in accordance with section 30 of the Norwegian Health Research Act).

4.4 Destruction of biobank material

Donors of material in a research biobank can demand that the material be destroyed. Exceptions apply where material already exists processed as part of the implementation of the research project. The responsible person for the general research biobank is responsible for organizing inquiries about destruction.

In the event of such enquiries, you must ask for identification, or ensure that the person in question is authorized to act on your behalf as the sender of the material. Destruction of biobank material must be documented. The documentation must state Who applied, that identification was presented, and which material was destroyed/handed over.

4.5 Use of material

Access and use of material from a general research biobank must be based on:

• That the use of material lies within the original broadly defined purpose of the research biobank.

• That the submitter of material and who has given broad consent is regularly given information about the use of the material (cf. § 14 of the Health Research Act).

• That the use is part of a concrete research project with its own prior approval from REK.

See procedure: Access and release of human biological material for research.

5. Definitions

Definitions

6. Deviation or dissent

Deviation reporting must take place in accordance with the hospital's internal deviation system in the business portal, http://intranett.ous-hf.no/ikbViewer/page/achilles/forside, registration and follow-up of unwanted incidents, near misses and dangerous conditions.

Non-conformance processing must otherwise take place in accordance with the quality document Undesirable events and risk conditions - registration and analysis of non-conformities.

7. References

Relevant laws, etc.

ACT of 20 June 2008 No. 44 on medical and healthcare research (Health Research Act)

ACT of 21 February 2003 No. 12 on biobanks (treatment biobanking act)

ACT of 5 December 2003 no. 100 on human medical use of biotechnology etc. (Biotechnology Act)

ACT 2001-05-18 no. 24: Act on health registers and processing of health information (Health Registers Act)

ACT of 14 April 2000 no. 31 on the processing of personal data (the Personal Data Act) with associated regulations

ACT 1999-07-02 no. 64: Act on health personnel etc. (Health Personnel Act)

ACT 1999-07-02 no. 63: Patient Rights Act (Patient and User Rights Act)

Regulation of 24 September 2003 no. 1202 on clinical trials of medicinal products for humans

Regulation of 26 February 2004 no. 511 on the transfer of biobank material abroad

Other eHandbook documents

Biobank - Access and delivery of human biological material for research

Biobank – Management and auditing of research biobanks

The research instructions - responsibility and authority in research

Research procedure - health research projects

Biobank - Creation of specific research biobank