Procedure

Biobank - Creation of specific 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).

The document only has updated links in this version.

2. Purpose and scope

The procedure clarifies roles, responsibilities and the approval process in the establishment of specific research biobank where OUS is responsible for research. The procedure also includes routines for closure and destruction of material in a specific research biobank.

When creating a research biobank without connection to a concrete project (general research biobank), see separate procedure.

The procedure does not include the collection and use of material in a research project, the destruction of which is planned material immediately after analysis has been carried out (indicative limit 2 months after collection).

3. Liability

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

4. Procedure

This part of the procedure provides an overview of administrative routines linked to the creation of a research biobank and supplements the research procedure.

4.1 Requirements for approval

Prior approval from REK

Creation of a specific 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 one research biobank.

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

Internal approval process

When creating a specific research biobank, i.e. before collection, storage and use, procedure applies Planning, implementation and completion of medical and healthcare research projects - Must be submitted to REK (The Research Procedure).

If the research biobank also includes biobank material from an existing biobank subject to OUS system responsibility, applies to the procedure for Biobank - Handling and auditing of research biobanks.

When transferring biobank material, the procedure for Access and release of human biological material for research applies.

4.2 Closure of research biobank

When applying for the establishment of a research biobank, an account must be given of when and how the biobank will be closed happen. Before closure, the project manager/responsible person must send a notification to REK and with a copy to the head of department and to research support by e-mail: godkjenning@ous-hf.no

4.3 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 project manager is responsible for organizing inquiries about destruction. In the case of such enquiries, you must ask for identification, possibly ensuring that the person in question is authorized to act on behalf of the sender of the material. Destruction of

biobank material must be documented. The documentation must state who applied, that identification is submitted, and which material has been destroyed/handed over.

5. Definitions

Definitions and terms in medical and healthcare research

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 shall otherwise take place in accordance with the quality document, Undesirable events and risk conditions - registration and analysis of deviations.

7. References

Other eHandbook documents

Definitions and terms in medical and healthcare research

The research instructions - responsibility and authority in research

Research procedure - health research projects

Biobank – Management and auditing of research biobanks

Biobank - Creation and organization of a general research biobank

Biobank - Access and delivery of human biological material for research

Notice of non-conformity - unwanted incidents in research