The regions' joint Biobank documentation

Instructions and procedures

Access to newly collected biobank samples and associated personal data released by e-biobank for multicentre studies

Summary: This document is a guide for clinical investigators, researchers and custodians of e-biobanks and describes the handling of multicentre studies that comprise newly collected samples based on the principles in the document "*Principles for access to biobank samples.*" (document K1a).

About Biobank Sweden
Biobank Sweden (former National Biobank Council and BBMRI.se) is a co-operative for Regions and universities with medical faculties regarding biobank questions. In Biobank Sweden, representatives from trade associations, life science industries and patient organisations are also included. One roll of Biobank Sweden is to further develop a joint, improved and long-term sustainable national biobank infrastructure for healthcare, academy and industry with optimal conditions (prerequisites) for national and international cooperation. Biobank Sweden also aim to facilitate implementation of the Biobanks in Medical Care Act. For more information, see www.biobanksverige.se.

Please note! Always make sure that you have the current version of the document!
Current documents can be found at www.biobanksverige.se

BIOBANK SVERIGE

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Revision

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4.6	2016-11-22	Jessica Seger	Översatt från svenska till engelska
5.0	2017-05-10	Malin Eaker Fält, Sonja Eaker Gunilla Bergström	Uppdatering gällande dokumentnamn, dokument, hänvisningar och ”regioner”.
5.1	2019-01-09	Malin Eaker Fält	Ändringar med anledning inrättande av Etikprövningsmyndigheten 1 januari 2019.
5.2	2019-11-18	Elin Wallin	Strykning av alla ”landsting” samt ändring av begreppet ”komplettering” till ”ansökan om ändring”.

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Introduction

Medical trials constitute about 15 % of all research projects approved by the Swedish Ethical Review Authority (before 1 January 2019 by regional Ethical Review Boards). In these trials, many of which include multicentre studies, approximately 800 000 samples are handled annually. Multicentre studies also occur in other medical research where the client can be a Region or a University. In multicentre studies, it is common that sampling is done at the healthcare provider on behalf of another principal and, where applicable, the sample is sent immediately for analysis, alternatively to a biobank outside the healthcare service. The Biobanks in Medical Care Act's demand for traceability results in an increased administrative handling for multicentre studies since every healthcare principal, every biobank custodian and every clinic collecting samples must be contacted for signing necessary contracts about sampling and release of samples.

On behalf of the Swedish Association of Local Authorities and Regions (SKR), a project group have developed guidelines for multicentre studies when collecting new samples. One aim is to simplify the management of contracts for sampling, decision of release, and use of human material in studies where more than one healthcare principal is concerned. Another aim is to accommodate the Biobank act's demand for traceability by storing the code key, which is created at clinical trials, and other medical research in an e-biobank (or according to agreement between the sample collection controller and the e-biobank principal) to enable future tracking.

Management of contracts and decisions for release is made by *one* Regional Biobank Centre (RBC) where the RBC director have mandate of all concerned regions. By establishing registers in every region, so called e-biobanks, traceability according to the Biobank act can be guaranteed.

This document is aimed at clinical investigators and researchers about to initiate a multicentre study, as well as at biobank custodians for e-biobanks in Sweden.

For further information, see the regions' joint biobank documentation www.biobanksverige.se.

List of RBC directors (www.biobanksverige.se).

List of e-biobanks and biobank coordinators (www.biobanksverige.se).

Principles for handling multicentre studies

- Sweden is divided into six healthcare regions, each with its own Regional Biobank Centre lead by an RBC director. *Decisive* RBC director:

  Studies with ethical approval before 1 January 2019 (approval from a regional Ethical Review Board): *Deciding* RBC director is in the region where the ethical vetting was carried out.

  - Example: If the application for ethical vetting was conducted and approved by the regional Ethical Review Board in Skåne, the biobank application should be sent to RBC in the south healthcare region.

  Studies with ethical approval after 1 January 2019 (approval from the Ethical Review Authority): *Deciding* RBC director is in the region where the research principal/principal investigator/primary investigator is located.

  The research principal can be a region, university, university-college/equivalent or a municipally.

  - Example 1: If the Principal investigator/Primary investigator is situated at Karolinska Institute or Karolinska University Hospital, the application shall be sent to the RBC in Stockholm-Gotland healthcare region.
  - Example 2: If the Principal investigator/Primary investigator is situated at Karlstad university, Örebro university or Uppsala University Hospital (Akademiska sjukhuset), the application shall be sent to the RBC in Uppsala Örebro healthcare region.
- In every county region exists an e-biobank that comprise a register to handle decisions on release of biobank samples and to secure traceability of all samples collected within healthcare for both public and private operations.
- Every custodian of an e-biobank in the country can authorize an RBC director to decide upon establishing a sample collection and release of the same samples and personal data from the regions own e-biobank.
- For handling of multicentre studies with e-biobank, the following applies:
  - Only newly collected samples that shall be released for clinical trials or research projects with approved ethical vetting.
  - Does not comprise existing samples (samples stored in biobanks, as well as samples that are handled by the local pathology laboratory the same way as healthcare samples).
  - Does not comprise samples taken outside regions. The multicentre application can be used in studies that include private healthcare providers if the principal investigator belongs to a region, a municipality, a university or a university-college, and if at least one of the participant healthcare principals is a region. A written authorization between the private healthcare provider and one of the region's e-biobanks is required for a private healthcare provider to be included in a study.
  - Does not comprise samples solely sent for analysis from a primary sample collection with special regulations.

Instructions

Investigator/Researcher

Proceed from existing templates available at www.biobanksverige.se.

Complete form N1a. *"Access to newly collected biobank samples and associated personal data for multicentre studies"*. Conditions: The sample collection can only be provided/accessible through release.

The application is signed by:

1. Deciding RBC director, or by the person he/she in writing has advocated in his/her place.
2. Biobank custodian for recipient biobank.
3. Investigator/researcher responsible for the project (researcher in charge of implementing the project according to the ethical application).

Research principal can be a region, pharmaceutical company or university. This procedure is only valid if the principal investigator belongs to a region, and if at least one of the participant healthcare principals is a region.

In multicentre studies, the investigator/researcher is responsible for that there are clear sampling instructions/referrals. It should be clearly stated in the information that consent from the sample donor exists, alternatively that consent will be obtained in connection with sampling, where the sample should be sent together with details about the recipient biobank, as well as how data will be registered in the region's e-biobank.

A copy of approval from the Swedish Ethical Review Authority (Etikprövningsmyndighet), signed application for ethical vetting, patient information and potential mandate from private healthcare provider (site) should be sent to decisive RBC director, or the person he/she advocate in his/her place.

Ethical vetting and processing of biobank applications *can* be done simultaneously, but the processing cannot be finalized by the decisive RBC director before an approval from the Swedish Ethical Review Authority exists. Approval from the Ethical Review Authority is a requirement for a decision of access to samples. The approval from the Ethical Review Authority generate a unique RBC number that is used to connect a study with its report on completed sampling.

In relevant cases, when the investigator/researcher is responsible for sampling, the person concerned is also responsible to follow local instructions for registration of the sample in the e-biobank.

If an application during ongoing review needs to be altered in any form the decisive RBC director must be notified. The responsible investigator/researcher needs to complete and sign a form for alteration and send it to the responsible RBC together with relevant appendixes (such as alteration to the Swedish Ethical Review Authority with approval). The decisive RBC must also be notified about changes of principal and extension of sample collection.

Documents:

Document M3: *Instruction for completion of application N1a.*

Document N1a: *Access to newly collected biobank samples and associated personal data in multicentre studies,* including *Appendix A: Sweden's Regions.*

Document N1b: *Appendix B: Principal investigators included in the study.*

Document N2: *Request for alteration of multicentre study application, Appendix A + B.*

Document N4: *Signing of power of attorney* (please note, the principal investigator must belong to a region).

Report on completed sampling:

Document N3a: *Report on completed sampling in multicentre studies.*

Document N3b: *Appendix 1: Report on completed sampling.*

Custodian of the e-biobank:

- Issues authorization for the regional RBC director.
- Responsible for registration of the e-biobank.
- Trace samples in those cases a donor changes his/her consent, for example through Withdrawal of consent.
- Can manage code/pseudonymization keys.

Documents (only available in Swedish):

Document O1: "*Fullmakt för Regional Biobanks Centrum (RBC) chef att i multicenterstudier administrera biobanksprov och tillhörande personuppgifter från lokal e-biobank inom regionen*".

Document P1: *SOP för att spåra prov som utlämnats via e-biobank.*

Document P2: *Överenskommelse e-biobank och provsamlingsansvarig.*

Document P3: *Spårbarhet vid kliniska prövningar.*

(Deciding) RBC Director

- Establish sample collection in the e-biobank in question and decides on release through mandate from custodian of the e-biobank.
- Notify the custodian of the e-biobank about established sample collection.
- Sign contracts on access and release of samples.
- Report release of sample collections to Health and Social Care Inspectorate (Inspektionen för vård och omsorg (IVO).
- Handle alterations during ongoing review (e.g. new sample types, newly admitted e-biobanks).
- Receives rapport of completed sample collection and thereafter report to the custodian of the e-biobank that the study is completed.

Documents (only available in Swedish):

Document M2: handledning till RBC gällande handläggning av multicenterstudier med nyinsamlade prov som ska utlämnas via e-biobank.

Personnel performing sampling in Healthcare

Personnel performing sampling are responsible to follow accompanying instructions, control that information about the donor is correct, and that consent exists. Furthermore, personnel performing sampling should follow local instructions from the biobank custodian and register information about the donor in the local e-biobank if stated in the agreement (see section investigator/researcher above). Sample can be sent according to instructions from the constituent.

Biobank custodian for sample collection in recipient biobank

- Register samples.
- Document the sample handling process at the biobank.

References

Biobanks in Medical Care Act (SFS 2002:297).

Directives and general advice from the National Board of Health and Welfare regarding biobanks in healthcare etc. (SOSFS 2002:11 and current version of respective time-period) Region's joint Biobank documentation (www.biobanksverige.se).