The County Council's/region's joint Biobank documentation

Instructions and procedures

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

Summary: This document is a guide for clinical investigators, researchers and custodians of e-biobanks and describes the handling of multicenter studies that comprise newly collected samples based on the principles in the document "*Principles for access to biobank samples and personal data for research*." (document K1).

About Biobank Sweden
Biobank Sweden (former National Biobank Council and BBMRI.se) is a co-operative for County Councils/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

Revision

Versions-nummer	Datum	Ansvarig	Ändringar mot tidigare version
0.2	20060528	Gunilla Bergström	Var i princip bara ett register
0.41	20060531	Göran Elinder	Från skelett till lite mer bindväv
0.5	20060602	Gunilla Bergström	Mest redaktionella
0.6	20060607	Gunilla Bergström	Begreppet ”Beslutande RBC-chef” infört
0.61	20060705	Göran Elinder	Revidering efter möte 20060612
0.65	20060906	Göran Elinder Gunilla Bergström	Revidering efter kommentarer från ref grupp
0.70	20060925	Göran Elinder Östen Karlsson Gunilla Bergström	Revidering efter telefonmötet 20060908
0.80	20061009	Gunilla Bergström	Revidering vid telefonmötet 2006-10-09
0.86	20061109	Göran Elinder	Revidering efter samverkan med SKL
0.87	20061113	Göran Elinder	Revision efter telefonmöte
0.88	20061117	Göran Elinder	Efter NBR-AU-möte Lund 20061115
0.90	20061127	Göran Elinder	Efter NBR-biobankssamordarmöte 20061121
0.91	20061129	Göran Elinder	Efter kommentarer från Gunilla B. 20061128
0.92	20061229	Göran Elinder	Inkomna kommentarer från gruppen och diskussioner med Tommy Söderström/Gunnel Tybring.
0.93	20070108	Göran Elinder	Sammanslagna resultat av flera diskussioner
0.94	20070112	Göran Elinder	Kraftig omarbetning efter ny mall efter idéer från Gunnel tybring/Jan Forslid/Tommy Söderström
0.98	20070209	Göran Elinder	Efter AU-möte i Göteborg
0.99	20070302	Göran Elinder	Remissversion
1.0 test	20070326	”Multicentergruppen”	Konsensus efter remissvar till godkänd testversion
4.0	20070327	Göran Elinder	Fastställd av arbetsutskottet till Nationellt biobanksråd
4.6	20131119	Sonja Eaker, Katarina Petlz	Uppdaterad med anledning av nya myndigheten Inspektionen för vård och omsorg. Byte av versionsnummer för anpassning av uppdaterade mallar.
4.6	20161122	Jessica Seger	Översatt från svenska till engelska
5.0	20170510	Malin Eaker Fält, Sonja Eaker Gunilla Bergström	Uppdatering gällande dokumentnamn, dokument, hänvisningar och ”regioner”.

Table of content

Introduction

Medical trials constitute about 15% of all research projects approved in regional ethical review boards. In these trials, many of which include multicenter studies, approximately 800 000 samples are handled annually. Multicenter studies also occur in other medical research where the client can be a County Council/Region or a University. In multicenter 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 health care service. The Biobanks in Medical Care act's demand for traceability results in an increased administrative handling for multicenter 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 Swedish Association of Local Authorities and Regions (SKL), a project group have developed guidelines for multicenter 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.

The Principle is based on management of contracts and decisions for release is made by *one* Regional Biobank Center (RBC) where the RBC director have mandate of all concerned County councils/Regions. By establishing registers in every county council/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 multicenter study, as well as at biobank custodians for e-biobanks in Sweden.

For further information, see County councils/Regions' joint Biobank documentation www.biobanksverige.se.

List of RBC directors (www.biobanksverige.se)

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

Principles for handling multicenter studies

- Sweden is divided into six regions, each with its own Regional Biobank Center lead by a RBC director. *Decisive* RBC director is the one within whose region the ethic review is processed.
- In every county council/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 through a personal mandate commission a RBC director to decide upon establishing a sample collection in the own e-biobank and release of the same samples and personal data from the county councils/regions own e-biobank.
- For handling of multicenter studies with e-biobank, the following applies:
    - Only newly collected samples that shall be released for clinical trials or research projects with approved ethical review.
    - Does not comprise already existing biobank samples (samples stored in biobanks, as well as samples that are handled by the pathology the same way as healthcare samples).
    - Does not comprise samples taken outside County councils/Regions. The multicenter application can be used in studies that include private healthcare providers if the Principal Investigator belongs to a County council/Region, and if at least one of the participant Healthcare Principals is a County council/Region. A written authorization between the private healthcare provider and one of the County council's/Region's e-biobanks is required for a private healthcare provider to be included in the 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 under the heading "Research".

Complete form N1a. *"Access to newly collected biobank samples and related personal data for multi-center 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 ethics application).

Research Principal can be a county council/region, pharmaceutical company or university. This procedure is only valid if the Principal Investigator belongs to County council/Region, and if at least one of the participant Healthcare Principals is a County council/Region.

In multicenter 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 recipient biobank, as well as how data will be registered in the concerned county council's/region's e-biobank.

A copy of approval from an Swedish Ethical Review Board (Etikprövningsnämnd (EPN)), 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 review and processing of biobank applications *can* be done simultaneously, but the processing cannot be finalized by the decisive RBC director before an approval by the Swedish Ethical Review Board exists. Approval from the ethical review board is a requirement for a decision of access to samples. The approval from the Ethical Review Board generate a unique RBC number that is used to connect a study to 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 supplemented with new information the decisive RBC director must be notified. The responsible investigator/researcher needs to complete and sign a form for complementation and send it to responsible RBC together with relevant appendixes (such as supplementation to Swedish Ethical Review Board and its approval). The decisive RBC must also be notified about change of principals 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 multicenter studies,* including *Appendix A: Sweden's County Councils/Regions*

Document N1b: *Principal investigators included in the study*

Document N2: *Supplementation to multucentre study application, Appendix A + B*

Document N4: *Signing of power of attorney* (please note, the Principal investigator must belong to County Council/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/pseudonymisation keys

(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 e-biobank custodian 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 e-biobank custodian that the study is completed.

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)

SOSFS (2002:11)

SOSFS (2004:2)

SOSFS (2006:19)

SOSFS (2007:22)

SOSFS (2008:25)

SOSFS (2009:33)

County Council's/Region's joint Biobank documentation
www.biobanksverige.se