Instructions for access to samples for research under the multicentre principle

Specific terms for the multicentre principle – the samples shall be **newly collected** (i.e. recently collected for the specific research project) and shall be **released** to a recipient biobank.

The application for multicentre studies is processed by a Regional Biobank Centre (RBC). The application shall be sent to the RBC in the region in which the ethical review was conducted.

Healthcare principal

Here, county councils/regions. Sweden is divided into 19 county councils and two regions with the responsibilities of county councils. All samples collected within a county council (e.g. samples collected at local healthcare clinics, hospitals or by care staff) are initially the county council's responsibility. The principal bears utmost responsibility pursuant to the Biobanks in Medical Care Act and the Personal Data Act.

Registration of samples in biobank

All samples collected within the healthcare principal's area of responsibility must be registered in one of the healthcare principal's biobanks. This is to know which samples have been taken and to make tracing possible.

E-biobank

An electronic biobank at the healthcare principal in which samples are registered as a primary sample collection to guarantee traceability. **The multicentre principle** can be used in the county councils that have established e-biobanks. A list of which county councils/regions have an e-biobank can be found at www.biobanksverige.se.

Biobank custodian

Every biobank shall have a biobank custodian appointed by the principal. The biobank custodian is responsible for compliance to the Biobanks in Medical Care Act in accordance with the principal's written directives. The **healthcare principal's biobank custodian** is also charged with reviewing applications and deciding on access to samples for research from his/her respective biobank.

Multicentre Principle

The handling of agreements and decisions regarding release are made by one RBC, where the RBC Director has authorisation from the e-biobanks. In other words, the e-biobank custodians have written authorisations for all RBC directors to make decisions regarding the registry and release of sample collections into and from their respective e-biobanks.

Release

Responsibility for and right of use to the samples in question is transferred from the healthcare principal to the research principal by a **release.** Recipients of released samples are either biobanks belonging to a research principal or to another designated biobank with whom the research principal has an agreement. Samples can only be released to a biobank registered in Sweden. The samples are then moved to a location outside the healthcare principal's operations and form a *secondary sample collection* at the research principal. A secondary sample collection may not be released further. The healthcare principal's biobank custodian continues to be responsible for saving documentation regarding samples and to whom samples are released to make tracing possible.

Sent for analysis

Samples from a secondary sample collection may be sent for analysis to another unit for certain purposes for research or within the pharmaceutical company or to another contracted company *domestically* or *abroad* **without** it being considered a matter of a release. The samples shall **not** be placed at the disposal of the recipient operation, but rather sent for a specific measure.

Terms

1) Samples and personal data may not disclose the sample donor's identity.
2) The sample donor shall have provided consent to the samples potentially being sent to another unit domestically or abroad.
3) When samples are no longer needed for the given research project, they shall be returned or destroyed.
4) If samples are sent abroad for analysis, a Swedish recipient research principal and Swedish registered recipient biobank who are responsible for the samples are required.

Step by step

1. Go into www.biobanksverige.se. For English, choose "Summary in English".
2. Complete the application *"Access to newly collected biobank samples and associated personal data in multicentre studies"* and *"Appendix B"*.
3. Attach the ethical review application, decision of the ethical review and the patient information.
4. Send the application to the Regional Biobank Centre (RBC) sited in the region in which the ethical review was submitted.
5. The application shall be signed by the chief researcher, i.e. the researcher who is primarily responsible for the conduct of the project (as under heading 1:3 in the application to the ethical review board) and an authorised representative of the recipient biobank (often the biobank custodian) at the research principal (or by the biobank custodian of another principal on the power of attorney of the research principal).
6. After a decision by the RBC Director, a copy of the agreement is sent to the biobank custodian of the recipient biobank and the chief researcher. The original is stored at the deciding RBC, which also reports the release of the sample collection to the National Board of Health and Welfare.
7. After an approved application, the principal investigators at each site or other suitable person shall immediately contact the e-biobank custodian at the respective county council to agree on how the transfer of personal data to the e-biobank will take place.
8. When the sample collection is concluded: The chief responsible researcher shall inform the deciding RBC of the point in time of the concluded sample collection and the sample collection's final scope divided by county council. Forms are available at www.biobanksverige.se "*Templates for concluded studies"* and appendix for the template for conclusion: *Appendix 1*

Fee

The fee for the processing of multicentre studies is SEK 6,250, including 25% VAT (2011). Cases that are re-opened for e.g. additions of new sites, are charged a fee per hour commenced (SEK 500/hr incl. 25% VAT).

Important to keep in mind

- An approved ethical review with applicable appendices must exist.
- In some genetic studies, advanced review by the Swedish Data Inspection Board shall exist.
- Permit from the Swedish Medical Products Agency shall exist for clinical trials for medical products.
- Consent by the patient for the current project must exist, unless the ethical review board has granted an exemption.
- The samples must be pseudonymised/coded.
- Personal data may **not** be sent in the same parcel as the samples.
- If the samples shall be **sent for analysis** from the secondary sample collection, the following **must** be observed:
    - The research principal's biobank custodian (at the research principal's biobank or at another biobank with which the research principal has an agreement) must have continued responsibility for the samples.
    - The samples must be pseudonymised/coded.

- Personal data may **not** be sent in the same parcel as the samples.
- Consent must exist.
- The samples shall be returned *or*
  - destroyed if the samples have been sent abroad
  - destroyed *or* identification labelling removed if the samples were sent domestically.
- If samples shall be sent **abroad** for analysis, it is *also* required that a Swedish research institution submits the application to the RBC and that the samples first are released to a biobank registered in Sweden. With regard to permitted storage times of samples in another country – the length of permitted storage times abroad while awaiting analysis can differ between different projects and between different health care principals.