Instructions for how to get access to tissue samples for research

These instructions are for all **single-centre studies, multicentre studies of existing samples** and for studies where samples shall **not** be released. There are separate instructions for *multicentre studies* of newly collected samples (se definition below) where samples will be released.

Step 1: Always first contact the biobank coordinator of the county council (so called regional coordinator) in question who is a contact link between researchers and biobank custodians.

The regional coordinator can provide information on:

- The specific county council's procedures, where applications should be sent, etc.
- Procedures for research on **existing sample collections.**
- The biobank in which the sample collection should be registered for research on **newly collected samples**.

Contact information of the county council's biobank coordinators is available at www.biobanksverige.se under the tab 'Länkar'/'Ditt landsting'.

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 healthcare 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.
Biobank custodian	Every biobank shall have a biobank custodian appointed by the principal. The biobank custodian is responsible for ensuring 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.
Existing sample collection	Samples collected within healthcare are usually taken for care purposes. The samples belong to the healthcare biobank and comprise a *primary sample collection*. Gaining access to these requires a decision from the biobank custodian, who shall ensure that sufficient material remains for the patient's care and treatment.
Newly collected samples	Samples collected for a specific research project. Note that newly collected samples in the healthcare principal's area of responsibility must be registered in a biobank with the healthcare principal.

Step 2: Apply for access to samples for research

The application procedure differs depending on whether the sample collection will **A) remain** with the healthcare principal or if it will **B) be released** to a recipient biobank. Regardless of which procedure applies, the samples can **C) be sent for analysis.**

A)	**Samples remain**	When the samples **remain** as a primary sample collection at the healthcare principal, the responsibility for the samples remains with this principal and existing procedures in the healthcare principal's biobank are used for storage, withdrawal, security, confidentiality, etc. A researcher's access to the samples and personal data for a specific project is regulated by application (alternative A below).
B)	**Samples to be released**	The responsibility for and the right to use the samples in question can be moved from the healthcare principal to the research principal through a **release**. A sample collection can 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 (alternative B below). 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.
C)	**Sent for analysis**	Regardless if the samples remain or are released, samples may be sent for analysis for certain purposes to another unit 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, a Swedish recipient research principal and Swedish registered recipient biobank who are responsible for the samples are required.

A. Samples will remain as a primary sample collection in the healthcare principal's biobank

1. Complete the application *"1 Access to sample collection and personal data for research",* part I.
2. Also complete the parts that regulate the researcher's access to the sample collection (item 6 in the application).
3. Attach the ethical review application, decision of the ethical review and the patient information.
4. 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).
5. If the sample collection will be sent for analysis, also attach "*2 Certification regarding destruction or return of sample after analysis".*

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.
- Newly collected samples shall be registered in the healthcare principal's biobank to make definite tracing of samples possible.
- Regulating the researcher's access to the sample collection during the project by application.
- If samples are to be sent for analysis domestically or abroad, the following **must** be observed:
    - The healthcare principal's biobank custodian 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 are
        - returned to the healthcare principal's biobank *or* destroyed if the samples have been sent abroad,
        - returned to the healthcare principal's biobank *or* destroyed *or* identification labelling removed (fully anonymized) if the samples were sent domestically.

B. Samples shall be released to a recipient biobank

1. Complete the application *"1 Access to sample collection and personal data for research"*, parts I and II.
2. The agreement shall be established between the biobank custodian for the releasing biobank at the healthcare principal 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 a power of attorney from the research principal).

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.
- Samples shall be registered in the healthcare principal's biobank to make definite tracing of samples possible.

- 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 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,
        - be returned, destroyed *or* have identification labelling removed (fully anonymized) 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.