START

Access to samples in research*

Step 1:
Contact the biobank(s) (Biobank coordinator) where Samples are planned to be established (responsible biobank) during the study. They can answer questions and provide support regarding which forms to use and how to complete them. They can also inform if operational service agreements/equivalent are needed.

Newly collected samples: Samples collected specifically for the purpose of research. When such samples are taken by a healthcare provider,

They shall not affect or be relevant for regular diagnostics. Note that some tissue samples that are newly collected can be considered to be existing samples. Samples that go through the pathologist and are assessed there in the same way as healthcare samples are considered to be existing samples.

Existing samples: Samples that have been collected and stored in a biobank for a specific purpose (e.g. care of a patient or a specific research project) and where access is desired for another purpose (e.g. research or another specific research project).

Samples are to be established as a new sample collection in a biobank where samples are taken (newly collected) or are stored (existing)

Complete form **L1.1** (*Establishment of sample collection for research*) and send to the biobank custodian where samples are to be established

Samples are established as a sample collection in a biobank.

Samples can be used in the study.

Please note: When necessary and depending on the service desired, there may also be a need for operational service agreements/equivalent that regulate how established samples are to be handled/stored

Are the established samples to be sent for an action within Sweden or abroad?

Yes

Complete applicable MTA form (agreement about making samples available by sending them for an action)

L2a1: Research principal ≠ principal of the biobank.

Research principal is another Swedish region or a Swedish university.

L2a2: A sponsor has the overall responsibility for the implementation.

L2a3: Research principal = principal of the biobank.

In which biobank are samples to be established?

Samples are to be established in a biobank at another principal than where samples are taken (newly collected) or are stored (existing)

newly collected samples

Notify the biobank custodian(s) where samples are to be taken that another biobank is to be the responsible biobank by filling in form **L7** (*Responsible biobank when newly collected samples are to be taken for research*) and send it to the biobank custodian where samples are to be taken.

Note: In cases where the responsible biobank is a region, this biobank will send L7.

Existing samples that are to be released

Complete form **L1.2** (*Agreement on the release of samples and personal data*) and send to the biobank custodian where samples are stored.

Yes

Is responsible/receiving biobank at a region

No

Establish samples in a biobank according to the routines of the receiver.

For all applications, remember to include the following appendices:

- Signed copy of the application of ethical approval
- Decision from the Swedish Ethical Review Authority
- Research participant information with consent forms

If the application regards existing samples, please remember applicable appendices;

- **L1a** (Information about existing clinical samples in pathology and cytology biobank)
- **L1b** (Information about existing biobank sample)
- **L1c** (Information about existing samples in the PKU biobank) (Swedish only)

THE END

BIOBANK SVERIGE

* For information on clinical trials and performance studies, see Ti6.