START

Access to biobank samples for clinical trials and performance studies*

Step 1:

If the sponsor has not registered a biobank in Sweden, contact a biobank in one of the constituent health care regions with a request for the possibility of taking responsibility for the sample collection: Biobank coordinator: Biobankssamordnare – biobanksverige.se. They can also answer questions and provide support regarding operational service agreements/equivalent are needed.

Questions regarding the process and the forms should be sent to kliniskaprovningar@biobanksverige.se

*** For information on research other than clinical trials and performance studies, see K2.1.**

**** 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. Note that this may apply to the entire tissue preparation as a pathologist may need to assess that sufficient and relevant material remains for the patient's care, diagnosis and treatment. Therefore, always contact the local pathology department when planning the study.

***** 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 archive samples)

The sponsor completes form **T1.1** and, if existing samples are included, form **L1a** and/or **L1b** for each biobank concerned and send it to kliniskaprovningar@biobanksverige.se

Once all parties have signed **T1.1**, samples are established as a sample collection in a health care region's 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)

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*

The sponsor completes form **T7a**, which is signed by the responsible biobank custodian and sent to the biobank coordinator (Biobankssamordnare – biobanksverige.se) in the health care regions where samples are taken to notify that there is a biobank that takes responsibility for samples collected in said region.

Note: In cases where the responsible biobank is a region, this biobank will send T7a

*Existing*** samples that are to be released*

The sponsor completes form **L1a** and/or **L1b** for each concerned biobank and sends it to kliniskaprovningar@biobanksverige.se the same day as the application for clinical trial/performance study is submitted to CTIS

RBC completes form **T1.2** and send it to the biobank custodian where samples are stored.

The biobank custodian at the releasing biobank approves the release

Yes

Is responsible/receiving biobank at a region

No

Establish samples in a biobank according to the routines of the receiver (**T1.1** can be used for this but is not a requirement)

THE END

Overview of forms:

- **T1.1** – Establishment of sample collection
- **T1.2** – Release of samples from one biobank to another
- **L1a** – For existing clinical samples in pathology and cytology biobanks
- **L1b** – For existing samples in biobanks (all other biobanks then clinical samples in pathology and cytology biobanks)
- **T7a** – Form used to inform participating regions about which biobank newly collected samples should be established in

Find the forms here: https://biobanksverige.se/en/documents/

Document: Ti6 Selection of form for clinical trials **Version:** 10.0 **Date:** 2023-09-21

BIOBANK SVERIGE