C2c. Checklist for researchers/companies

When applying for sample collection and access to existing samples

Forms and instructions are available at www.biobanksverige.se

A. Release* of samples to your biobank in Sweden

For singlecenter studies or studies with existing samples: A filled out and signed application for access to samples, including appendices, shall be sent to the County Council/Region/biobank in question:

Do not hesitate to contact the County Council/Regions's coordinator if you are unsure of which biobanks to send your application to. Contact information to the biobank coordinators in Sweden are available at www.biobanksverige.se

☐ Access to sample collection "*Access to sample collection and personal data for research*" (document L1), both part I and part II shall be completed. This agreement is signed between releasing biobank (primary/county council/region) through RBC, Principal investigator (same as stated in the ethical application) and the recipient biobank (secondary, e.g. pharmaceutical company).

☐ Enclose copies of the signed ethical application (at least the following sections relevant for biobanking 1:1-1:6, 2:4, 2.5, 2.6, 4.1, 4.2, 8, 9 appendix 1) and the decision from the regional Ethical Review Board.

☐ Enclose copies of the donor information form and consent form. Instructions on what a donor information form should contain can be found at www.cepn.se. An example of a donor information form is available at www.biobanksverige.se under Research

☐ **For existing samples***:* if the application regards "existing samples", enclose appendix L1a and/or L1b, and, if needed, a compilation/list of the samples to be released (e.g. sample ID, personal data).

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* Release of samples means that samples shall be*: 1. transmitted from one Principal to another Principal. 2. transferred or are transferred to a location outside the previous Principal's operation.*

When samples are released for research, the responsibility and rights to use the samples in question are moved from the Healthcare Principal to your biobank.

Released samples may not be released further. Storage with another party is possible under the condition that an agreement exists and that responsibility and rights to use the samples are not transferred.

To make tracing of samples possible, the Healthcare Principal is responsible for saving documentation of samples as well as to who samples were released to.

For multicenter studies with newly collected samples – completed and signed Multicenter study application incl. appendices are sent to decisive Regional Biobank Center (RBC).

Contact information to RBCs in Sweden can be found at www.biobanksverige.se

☐ Multicenter agreement (document N1a). This agreement is signed between releasing biobank (primary/county council/region) through RBC, Principal investigator (same as stated in the ethics application) and the recipient biobank (secondary, e.g. pharmaceutical company).

☐ Enclose copies of the signed ethics application (at least the following sections relevant for biobanking 1:1-1:6, 2:4, 2.5, 2.6, 4.1, 4.2, 8, 9 appendix 1) and the decision from the regional Ethical Review Board.

☐ Enclose copies of the donor information form and consent form. Directions on what a donor information form should contain can be found at www.cepn.se

☐ Complete the information over participating investigators, "*Appendix B*" (document N1b)

B. Send samples for analysis within the country or abroad

Completed and signed application for access to samples incl. appendices are sent to the county council/biobank in your region.

If you do not know which biobank to send the application to, please contact the County Council's/Region's Biobank Coordinator. Contact information to the biobank coordinators in Sweden are available at www.biobanksverige.se

☐ Complete part I in the agreement "*Access to sample collection and personal data for research*" (document L1), between responsible biobank and researcher/company.

☐ Enclose copies of the signed ethical application (at least the following sections relevant for biobanking 1:1-1:6, 2:4, 2.5, 2.6, 4.1, 4.2, 8, 9 appendix 1) together with the approval from the regional Ethical Review Board.

☐ Enclose copies of the donor information form and consent form. Directions on what a donor information form should contain can be found at www.cepn.se

☐ Enclose Material Transfer Agreement (MTA) (document L2a) signed between the Swedish Biobank responsible for the samples in Sweden and the recipient of samples within or outside the country.

See instruction K5 "*Information about AGREEMENTS on the transfer of biological material*"

Please note: Principal researcher and Biobank custodian must regulate how the samples should be handled on expiry of the agreement so the human biological material and personal data no longer can be used for research or any other purpose by the recipient. The samples should be handled according to the ethical application. Biobank Sweden (working committee 1 for regulatory questions), SKL and a few County Councils/Regions have produced an MTA for this purpose.

☐ **For existing samples***:* if the application regards access to "existing samples", enclose appendix L1a and/or L1b, and, if needed, a compilation/list of the samples to be released (e.g. sample ID, personal data).

C. On-sight access

Completed and signed application for access to samples incl. appendices are sent to the county council/biobank in your region. Contact information to the biobank coordinators in Sweden are available at www.biobanksverige.se

☐ Complete part 1 in the agreement "*Access to sample collection and personal data for research*" (document L1), between responsible biobank and researcher/company.

☐ Enclose copies of signed ethical application (at least the following sections relevant for biobanking 1:1-1:6, 2:4, 2.5, 2.6, 4.1, 4.2, 8, 9 appendix 1) and decision from the regional Ethical Review Board.

☐ Enclose copies of the donor information form and consent form. Instructions on what a donor information form should include contain can be found at www.cepn.se

☐ If whole or parts of the sample collection should be sent for analysis, see article B.

☐ **For existing samples***:* if the application regards access to "existing samples" , enclose appendix L1a and/or L1b, and, if needed, a compilation/list of the samples to be released (e.g. sample ID, personal data).

PLEASE NOTE: Samples must be coded/pseudonymisation and returned or destroyed when no longer needed for the purpose they were released.

References;

Biobanks in Medical Care Act (SFS 2002:297)
SOSFS 2002:11 (M) om biobanker i hälso- och sjukvården mm med vid var tid gällande ändringsförfattningar.
County Councils/regions joint Biobank documentations