K1c. Checklist for Researcher who is Sample Collection Controller

When applying for sample collection and access to biobank samples

Forms and instructions are available at www.biobanksverige.se . Guidance to which form to use can be found in document K2 *"Form selector".*

A. Release[1] of samples to your biobank in Sweden

For single-centre studies or studies with existing samples: A filled out and signed application for access to samples, including appendices, shall be sent to the regional biobank in question:

Do not hesitate to contact the region's Biobank Coordinator if you are unsure of which biobank to send your application to. Contact information to the Biobank Coordinators are available at www.biobanksverige.se

☐ Agreement for access "*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 (the Healthcare Principal, i.e. the region where the sample was taken), the Principal Investigator (same as stated in the ethical application) and the recipient biobank (e.g. another region, a university or a pharmaceutical company).

☐ Enclose copies of the signed ethical application[2], and any alteration applications including the approval of them from the Ethical Review Authority[3], for the study in question.

☐ Enclose copies of the research participant information and consent form. Instructions on what research participant information should contain can be found at www.etikprovning.se. An example of a research participant information form (document K3) is available at www.biobanksverige.se under Research (Swedish only)

☐ **For existing samples***:* if the application regards existing biobank samples[4], enclose one of appendix L1a, L1b and/or L1c, and, if needed, a compilation/list of the samples to be released (e.g. sample ID, personal data). If there is need for larger volumes of material, enclose a clarification that states the reason (planned analysis).

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[1] *Release of samples means that samples shall: 1. be consigned from the Principal to another Principal. 2. get transferred or are transferred to a location outside the previous Principal's operation.*
When samples are released for research, the responsibility and the right to use the samples in question are transferred from the Healthcare Principal to your biobank (the Recipient).
Released samples may not be released further. Storage with another party is possible under the conditions that an agreement exists and that the responsibility and right to use the samples are not transferred.
The Healthcare Principal is responsible for documentation referring samples and to whom samples have been released to make tracking possible.

[2] At least the following sections need to be enclosed: *1, 2, 3, 4.1, 4.2, 5, 6.2, 8.2, 9, 11, 14.1, 15.2, 15.3, 15.5, 15.5.1.*
For ethical approval before January 1 2019: 1:1–1:6, 2:4, 2:5, 2:6, 3:3, 4:1–4:2, 8, 9 appendix 1

[3] *Before January 1 2019 by an Ethics Review Board*

[4] *Existing biobank samples include:*
-samples taken within the healthcare system and saved for diagnostics, care and treatment.
-samples taken within the healthcare system and saved for research purposes
-samples that after sampling goes via a pathologist at the Healthcare Principal and get the same treatment as any samples within the healthcare system. This because a pathologist needs to assess which part can be released without affecting the diagnostic.

For multicentre studies with newly collected samples – completed and signed Multicentre study application including appendices are sent to decisive Regional Biobank Centre (RBC).

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

☐ Multicentre agreement (document N1a). This agreement is signed between releasing biobank (primary regions) through RBC, Principal Investigator (same as stated in the ethics application) and the recipient biobank (secondary, e.g. another region, a university or a pharmaceutical company).

☐ Enclose copies of the signed ethical application[2], and any alteration applications including the approval of them from the Ethical Review Authority[3] for the study in question.

☐ Enclose copies of the research participant information and consent form. Instructions on what research participant information should contain can be found at www.etikprovning.se. An example of a donor information form (document K3) is available at www.biobanksverige.se under Research (Swedish only)

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

B. Send samples for analysis within the country or abroad

Refers to existing samples[4] or upcoming sampling that are going to be established at the region's biobank

Completed and signed application for access to samples including appendices are sent to the biobank in your region.

If you do not know which biobank to send the application to, please contact the region's Biobank Coordinator. Contact information to the Biobank Coordinators are available at www.biobanksverige.se

☐ Agreement for access "*Access to sample collection and personal data for research*" (document L1), only complete part 1, between responsible biobank and researcher/company.

☐ Enclose copies of the signed ethical application[2], and any alteration applications including the approval of them from the Ethical Review Authority[3] for the study in question.

☐ Enclose copies of the research participant information and consent form. Instructions on what research participant information should contain can be found at www.etikprovning.se. An example of a research participant information form (document K3) is available at www.biobanksverige.se under Research (Swedish only)

☐ Enclose a Material Transfer Agreement (MTA) (document L2a1, L2a2 or L2a3) established between the Swedish Biobank Custodian, the Researcher and the Sponsor/receiving laboratory within or outside of Sweden regarding how the material are obtained and used as well as how to be handled on expiry of the agreement. .

See instruction K5 "*MTA information*"

Please note: Responsible 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), SKR and a few Regions have produced three different MTAs for this purpose.

☐ **For existing samples***:* if the application regards existing biobank samples[4], enclose one of appendix L1a, L1b and/or L1c, and, if needed, a compilation/list of the samples to be released (e.g. sample ID, personal data). If there is need for larger volumes of material, enclose a clarification that states the reason (planned analysis).

C. On-sight access

Refers to existing samples[4] *or upcoming sampling that are going to be established at the region's biobank*

Completed and signed application for access to samples including appendices are sent to the biobank/region. Contact information to the Biobank Coordinators are available at www.biobanksverige.se

☐ Agreement for access "*Access to sample collection and personal data for research*" (document L1), only complete part 1, between responsible biobank and researcher/company.

☐ Enclose copies of the signed ethical application[2], and any alteration applications including the approval of them from the Ethical Review Authority[3] for the study in question.

☐ Enclose copies of the research participant information and consent form. Instructions on what research participant information should contain can be found at www.etikprovning.se. An example of a research participant information form (document K3) is available at www.biobanksverige.se under Research (Swedish only)

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

☐ **For existing samples***:* if the application regards existing biobank samples[4], enclose one of appendix L1a, L1b and/or L1c, and, if needed, a compilation/list of the samples to be released (e.g. sample ID, personal data). If there is need for larger volumes of material, enclose a clarification that states the reason (planned analysis).

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

References;

Biobankslagen (SFS 2002:297)
SOSFS 2002:11 (M) om biobanker i hälso- och sjukvården mm med vid var tid gällande ändringsförfattningar.
Principer för tillgång till biobanksprov (document K1a)
Guide to Biobanks in Sweden – Access to Samples for Research and Clinical trials (Document K7)
En forskningsstudie om Kronisk Myeloisk Leukemi, KML (document K3)
MTA information (document K5)
AGREEMENT on the transfer of Human Biological Material to a Research Principal (document L2a1)
AGREEMENT on the Transfer of Human Biological Material in case of a Sponsor (document L2a2)
AGREEMENT on the Transfer of Human Biological Material when the Research Principal is the same as the Biobank Principal (document L2a3)