# C2b. Checklist for biobank custodians

*Biobank custodian decides about access to samples for research. The region's biobank coordinator supports the biobank custodian on questions regarding the Medical Care Act, but also with expertise concerning regulatory systems, routines and outlining biobank agreements. The biobank custodian and the biobank coordinator define how work assignments locally should be allocated for optimal result.*

When access to samples for research is requested, the following points must be fulfilled.

**Ensure:** (general)

- ☐ That an agreement regarding sample handling exists, irrespective of whether samples are to be stored within the biobank, sent for analysis or be released. Please note, in order for samples to be traceable, the healthcare Principal is responsible for saving documentation about where samples are released (recipient Principal/biobank).
- ☐ That the latest version of the application form is used (the form can be found at www.biobanksverige.se). The application must include a signed ethical application[1] (with any supplements), an approval from the Ethical Review Authority and patient information[2]. In cases where supplements to the original ethical application have been made, the decisions and foundation of the supplements should be enclosed.
- ☐ That an agreement is arranged before access is granted and any existing agreements or arrangements for the sample collection is considered in connection with this.
- ☐ That coding/pseudonymisation is relevant and substantial. If someone requesting access to a tissue sample also wants access to an individual donor's personal data, the biobank custodian must consider if the sample can be released with preserved integrity for the individual[3].
- ☐ That handling occurs according to agreed delivery time.
- ☐ That released/dispatched samples are documented in the biobank.

**When release of samples:** (specific)

- ☐ That release of samples are documented in the biobank.
- ☐ That samples do not belong to a secondary sample collection or are stored on behalf of others, and therefore cannot be released.

[1] If the full ethical application is not included, at least the following headings should be enclosed: 1 General information and signatures, 2 Type of research, Purpose and issues to be investigated, 4.1 Explain the methodology incl. procedures, technique or treatment, 4.2 Explain how the methodology differs from a clinical routine procedure or standard treatment, 5 Timetable, 6.2 Explain the statistical basis for the study population/size of the research material, 8.2 How many research participants will be included in the project?, 9 Information and consent, 13.1 Explain any financial agreements with contributors or other financiers (name and amount), 14 Description of biological material. I applicable appendix 4 (if advertising material is used when recruiting research participants) and/or appendix 5 (research participant information).

[2] Sometimes patient information is not necessary. In certain cases, the ethics committee may allow that consent from patient is not needed. This shall appear in the ethics application/-decision.

[3] A code ought to be changed only in exceptional cases, e.g. when tissue samples will be released for a research project and there is no scientific value for the project without access to the sample donor's personal data.

- ☐ That recipient biobank has a registration number from the Swedish Health and Social inspectorate, IVO.
- ☐ That an application of release is sent to IVO (www.ivo.se).

**When sending for analysis:** (specific)

- ☐ That sending of samples are documented in the biobank, including date when samples no longer are needed for the purpose for which they were sent and whether the samples thereafter will be returned or destroyed.
- ☐ That a Material Transfer Agreement[4] (MTA) is established with the recipient, within or outside of the country, regarding sample handling. The agreement shall, among other things, state that samples shall be sent back or be destroyed after the analysis and that the samples are only allowed to be used in the specific research collaboration and within the framework of the ethical approved study (document L2a1, L2a2 or L2a3, for template go to www.biobanksverige.se). For more instructions see document K5 "MTA information".

Please note, if samples have been released, it is the recipient Principal who has responsibility for making sure that an agreement regarding sample handling exists if samples are to be sent further for analysis

- ☐ That signing of MTA follows the order of delegation. Please contact the region's biobank coordinator. See instruction K5 *"MTA information"*.

**For existing samples[5]:** (specific)

- ☐ That the donor has not left a consent form stating that they do not want samples to be used in research. If the donor previously has signed a withdrawal of consent form and stated that samples may not be used in research, the samples may only be used in research if the donor provides consent to the project in question.
- ☐ That the donor's consent has been obtained according to the ethical application.
- ☐ That sufficient sample material is left for the donor's own healthcare and treatment. This assessment can be done, when necessary, in consultation with those responsible for the donor's healthcare.
- ☐ That scientific priority is considered when needed (e.g. several applications for material that is limited).
- ☐ That the sample collection controller is contacted, for example if the sample collection is initiated by research.

**For newly collected samples:** (specific)

- ☐ That consent exists.

**For Region Skåne:** (specific)

- ☐ Biobank application to be sent to the Regional Biobank Centre, the South healthcare region.

[4] If human biological material (samples) shall be sent for analysis/analysis outside of the Biobank Principle, while the responsibility of the sample remains, an agreement that regulates how the sample are to be handled shall be established with the Recipient. The agreement regulates the conditions under which the sample are to be obtained and used, as well as how the sample is to be handled when it is of no use for the purpose in which it was sent.

[5] If the tissue samples shall be used for a new purpose, the samples can only be released if consent or approval exists for the new purpose.

**References;**

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)
Biobanks in Medical Care Act (SFS 2002:297)
MTA information (document K5)
Kvalitetshandbok – Vägledning samt handledning (document J1a)
Principer för tillgång till biobanksprov (document K1a)
Roller och ansvar (document C1)
SOSFS 2002:11 (M) om biobanker i hälso- och sjukvården mm med vid var tid gällande ändringsförfattningar.