C2b. Checklist for biobank custodians

Biobank custodian decides about access to samples for research. The County Council's/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 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 the latest version of the application form is used (the form can be found at www.biobanksverige.se). The application must include signed ethical application, an approval from the Review Ethics Board and patient information[1]. If the full ethical application is not included, at least the following headings should be enclosed; 1:11:6, 2:4, 2:5, 2:6, 4:1-4:2,8, 9 appendix 1. 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 should consider if the sample can be released with preserved integrity for the individual[2].
- ☐ That handling occurs according to agreed delivery time.
- ☐ That released/dispatched samples are documented in the biobank.

When release of samples: (specific)

- ☐ That samples do not belong to a secondary sample collection or are stored on behalf of others, and therefore cannot be released.
- ☐ That agreement on sample handling exist[3]. Healthcare Principal is responsible for storing documentation on where samples are released (recipient Principal /Biobank). The recipient

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[1] 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.

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

[3] To send tissue samples from a Biobank for research purpose to a recipient in another country requires a Swedish Research Institute to submit an application for release. **The applicant (the Swedish Research Institute/ recipient biobank in Sweden) shall ensure that samples sent for analysis are only used according to ethics approval and are returned or destroyed when no longer needed for the purpose for which they were released**, e.g. by signing a contract with the analysing laboratory (so called Material Transfer Agreement, MTA).

principal is responsible for making sure that an agreement for sample handling exists if samples are dispatched further for analysis[3].

☐ 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 agreement regarding sample handling exist[4].

☐ That an agreement for sample handling exists at recipient laboratory ensuring that samples are handled in accordance with the decision from the Swedish Ethics Review Board, and that samples are returned or destroyed when no longer needed for the purpose for which they were released. Templates for MTA (document L2a *"AGREEMET on the transfer of human biological materials"* and document L2b *"Överenskommelse avseende destruktion eller återlämnande av prov efter analys"*). See instruction K5 *"Information about AGREEMENTS on the transfer of biological materials"*.

☐ That signing of MTA follows the order of delegation. See instruction K5 *"Information about AGREEMENTS on the transfer of biological materials"*.

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.

☐ 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)

For newly collected samples: (specific)

☐ That consent exists.

For Region Skåne: (specific)

☐ Biobank application to be sent to the Regional Biobank Centre, Södra sjukvårdsregionen.

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

[4] To send tissue samples from a Biobank for research purpose to a recipient in another country requires a Swedish Research Institute to submit an application for release. If the application is approved and samples are sent directly from a primary biobank, a Material Transfer Agreement shall be set up between responsible biobank in Sweden, responsible researcher and the analysing laboratory ensuring **that samples only are used according to ethics approval and are returned or destroyed when no longer needed for the purpose for which they were released**.

[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.