Information about AGREEMENTS on the transfer of biological material (Material Transfer Agreement, MTA)

Rules for transferring samples

According to **the Swedish Medical Care Biobank Act**, samples taken within the Swedish health care, can be sent for analysis outside of their own Principal for research studies, if the following conditions are met:

- The study must be approved by an ethics committee in Sweden.
- The sample donor must have given his/her consent that the sample can be sent for analysis (unless the ethics review board has given exceptions to this rule).
- The samples must be coded/pseudonymised.
- If the samples are transferred, either within the country or abroad, they shall be returned, destroyed or depersonalised when no longer needed for the purpose for which they were sent.

If the samples are sent abroad for analysis

Different rules apply to whether the samples are sent within or outside of the EU/EEA.

Within the EU/EES: According to the Swedish Personal Data Act (PuL, Personuppgiftslag (1998:204)), coded biobank samples can be sent to all countries in the EU/EEA. The data protection directive of the EU requires all member states to have rules for an equivalent protection of personal data and personal integrity. This also applies to EEA countries. When samples are sent within the EU/EEA, the statement "the sample may be sent abroad for analysis" needs to be stated in the Research participant information (Swe: forskningspersoninformationen).

Outside the EU/EES: Coded samples may be transferred to a Countries outside EU/EEA outside EU/EEA at any of the following situations:

- If there is an adequate level of data protection in the recipient country or if there are specific guarantees that the data and the registered rights will be protected. The European Commission has analysed the data protection rules in other countries and decided that the following countries meet the requirements[1]: Andorra, Argentina, the Bailiwick of Guernsey, the Faroe Islands, the Isle of Man, Israel, Jersey, New Zeeland, Switzerland, Uruguay and Canada (if their legislation for the protection of personal data in the private sector is applicable to the recipient's processing of personal data) and the US (if the recipient has adhered to the Privacy Shield principles).
- If the registered have accepted the transfer of data.

In the Research participant information: It must be apparent in the information that the sample may be sent for analysis to countries outside the EU/EEA, according to Swedish Personal Data Act (PuL).
For more information, please visit the Swedish Data Protection Authority website.

1. Information collected 2016-12-14 from www.datainspektionen.se

Agreement with the recipient when sending samples for analysis

If samples are sent outside the Biobank Principal at the same time as the responsibility for the samples remain, an agreement of the sample handling must be established with the recipient.

If samples and/or personal data can be linked to a person alive, a personal data processing contract concerning the handling of the data is required according to PuL and the biobank requires an agreement on transferring human biological material, MTA (so called Material Transfer Agreement).

If the counties/regions are responsible for the samples, standardized templates as below will be used. The MTA used concerns the samples and data connected to samples, i.e. not any other data connected to the study. Current templates can be found at www.biobankssverige.se.

Within Sweden

If the samples are sent within Sweden a more simplified agreement with the recipient have been developed and can be used: L2b. *"Överenskommelse om prov som skickas för analys inom Sverige"*.

However, nothing prevent using the MTA below.

Outside of Sweden

If samples are sent outside of Sweden, a combined personal data processing contract[2] and MTA will be used: L2a: *"MTA - AGREEMENT on the transfer of human biological materials"*.

Among other things, the MTA regulates how the recipient/analysing laboratory can handle samples as well as how samples will be handled when they no longer are needed for the purpose they were sent.

In a combined MTA it shall be clearly indicated on whose authority the analysis is done i.e. the Principal (controller of personal data), and what type of sample and analysis the project will use. The recipient must ensure that protection of personal data comply with the rules detailed in the Swedish Personal Data Act (PUL).

It should also be stated what will happen to the samples when the agreement is terminated i.e. if the samples should be sent back to the Principal or be destroyed.

2. The Principal can for example delegate the Biobank Custodian to sign personal data processing contracts for personal data linked to the samples. Who the delegate is should be stated in a work and delegation order. A decision on the delegation, as well as the decision on withdrawal of such, must be in writing

Between which parties shall the MTA- agreement be established?

Between the *Biobank custodian* (and at times the data controller if the delegation does not exist, see below) and the *recipient laboratory*.

The principal investigator shall sign the MTA appendix 1 and 2 (in document L2a). The principal investigator is, the researcher with the primary responsibility for the implementation of the research project in Sweden. For example, the primary investigator, national investigator, clinical investigator controller or the sample collection controller.

Who can sign a MTA for the county council/regions biobank?

A combined MTA and personal data processing contract needs to be signed by the *Biobank Custodian* and the Principal's *controller of personal data*

The controller of personal data, i.e. the legal entity for example a county council, are responsible for signing personal data processing contract with the person who processes personal data on behalf of and as instructed by the controller of personal data. The authority to sign personal data processing contracts can be delegated by the Principal.

The Principal can for example delegate the *Biobank Custodian* or the *Biobank coordinator* to sign a combined MTA / personal data processing contract for personal data linked to the sample. Who the delegate is should be stated in a work and delegation order. A decision on the delegation, as well as the decision on withdrawal of such, must be in writing.

Who can sign a MTA for the recipient laboratory?

An authorized representative for the recipient, i.e. laboratory/analyzing unit or companies in or outside of Sweden.

If a single-party agreement exists, for example between a sponsor and a laboratory it is strongly recommended that the sponsor sign the MTA.

Frequently Asked Questions regarding the MTA

Can the template be modified?

Templates published at biobanksverige.se are established by the Swedish National Council of Biobanks (Nationella biobanksrådet). The National Council of Biobanks has audited it's standard agreements and advise against making any changes or alterations to it. County Councils/Regions are recommended by the National Council of Biobanks to use the MTAs that are established by the National Council of Biobanks in its original form.

Comments or questions regarding the templates can be sent to info@biobanksverige.se. The National Council of Biobanks working committee will take received comments into account for any future revisions and after legal review.

Questions concerning Indemnity, section 9 in the agreement:

The Swedish Medical Care Biobank Act (Lag (2002:297) om biobanker i hälso- och sjukvården m.m) state that samples that are sent abroad of Sweden for analysis must belong to a biobank in Sweden.

If the researcher or company does not have a biobank in Sweden, a County Council/Region may under certain conditions take the responsibility of the sample.
To ensure that samples are handled in accordance with the consent and ethical approval, the County Councils / Regions always requires that an MTA is established with the recipient. At the same time, the County Council / Region needs to ensure that the responsibilities and costs that are within the scope of the study do not fall on the County Council / Region and Swedish taxpayers. Costs and liabilities in the study must be clarified between scientists, analytical laboratory and a possible sponsor.

The purpose of section 9 in the MTA-agreement is to keep the Principal (County Council/Region) non-liable if a sample donor would claim compensation due to some improper handling of the sample by someone who received the sample i.e. outside the control of the Principal.

Questions concerning Applicable Law and Disputes, section 13 in the agreement:

The applicable law under this MTA agreement is the one in which the samples are taken. This also applies to any associated information until it is destroyed or depersonalized.

If biobank samples and associated information are collected on patients in Sweden, Swedish legislation applies.

It seems natural that a study is governed by the legislation in the country where the study is conducted. However, if a study lends samples from other countries, the study must be ready to accept the regulations in other countries for how samples can be used and handled.

Consequently, the Principal (County Council/Region) in Sweden responsible for the samples must urge that any disputes that may arise caused by the MTA agreement are settled by Swedish law. For Swedish samples, Swedish legislation should always apply to ensure the rights of Swedish donors and patients.