K5. Information about AGREEMENTS on the Transfer of Human Biological Material (Material Transfer Agreement, MTA) for research and clinical trials

More detailed information coming soon

Agreement for when samples get sent (transferred) for analysis/handling

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.

If a region is the Biobank Principle, standardized agreement templates for the transfer of material (i.e. MTA) are used as described further down. Current templates ca be found at www.biobanksverige.se

The templates apply to the sample and its associated data (sample code). They do not apply to any other data involved in the project. See "FAQ regarding MTA" further down.

If a sample is to be sent within or outside of Sweden

When a region is responsible for the sample (Biobank Principle), the region's standardized templates for MTA shall be used and enclosed with the Biobank Agreement (L1). There are three different forms of MTA

- L2a1. AGREEMENT on the Transfer of Human Biological Material to a Research Principal (version 5.4). This template shall be used when a region is the Biobank Principle and a Swedish university or another region (than the Biobank Principle) is the Research Principle.
- L2a2. AGREEMENT on the Transfer of Human Biological Material in case of a Sponsor (version 5.4). This template shall be used when a region is the Biobank Principle and a Sponsor has the overall responsibility for the implementation of the project (sponsored research).
- L2a3. AGREEMENT on the Transfer of Human Biological Material when the Research Principal is the same as the Biobank Principal (version 5.4). This template shall be used when the Research Principle is the same as the Biobank Principle.

Between whom shall the agreement be established?

- L2a1. Between an authorized representative of the Healthcare Principle's biobank (usually the Biobank Custodian) and an authorized representative of the Research

Principle. If samples shall be sent from the Research Principle to Third Man (e.g. an analysing laboratory or a collaborating institution) the Research Principle is responsible to establish a written agreement with Third Man so that the same obligations, in respect to the samples and the sample codes, are imposed on Third Man as on the Research Principle according to the MTA.

- L2a2. Between an authorized representative of the Healthcare Principle's biobank (usually the Biobank Custodian) and a Recipient (a Sponsor, or the entity that the Sponsor has authorized to establish an agreement for transfer of the Material, that receives the material from the biobank). If samples shall be sent to Third Man (e.g. an analysing laboratory) by the Recipient, the Recipient is responsible to establish a written agreement with Third Man so that the same obligations, in respect to the samples and the sample codes, are imposed on Third Man as on the Recipient according to the MTA.
- L2a3. Between an authorized representative of the Research Principle's biobank (usually the Biobank Custodian) and a Recipient (the laboratory that are commissioned by the Research Principle to perform the analysis as part of the research project). If the samples shall be sent to Third Man (e.g. an analysing laboratory/a subcontractor) by the Recipient, the Recipient is responsible to establish a written agreement with Third Man so that the same obligations, in respect to the samples and the sample codes, are imposed on Third Man as on the Recipient according to the MTA.

FAQ regarding MTA

Is it necessary with a Personal Data Processor Agreement (PDP agreement)?

A sample code that indirectly can be connected to a person through a code key is still personal data even though the Recipient is not allowed or able to make the connection.

According to article 4.8 in the General Data Protection Regulation (GDPR) a Personal Data Processor (the Processor) is "a natural or legal person, public authority, agency or other body which processes personal data on behalf of the Controller". The PDP agreement shall always be established between the Controller and the Processor according to GDPR. However, it is not always easy to determine who the Controller and the Processor are.

Not everyone that gets hired by a Controller for a service, that includes handling personal data, becomes a Processor. The responsibility for the personal data can be held by one entity or jointly my several. If several entities are involved in the same or associated processing of the personal data, it is necessary to clarify who of these entities are the Controller for the processing, so that the entity or entities can ensure GDPR compliance. The Controller has, by definition, authority over the purposes and means of the processing. Laboratories that are hired for an analysis of the sample may often be independent enough to be the Controller for their activity.

This suggests that there is no need for a specific PDP agreement if the only thing that will be sent are the Sample and the associated Data (Sample Code). This, of course, must be decided by the particulars of every individual case.

If other personal data, than the sample code, are to be processed by the Recipient it is required to establish a PDP agreement (according to GDPR) with the Processor (the Recipient). The Swedish Association of Local Authorities and Regions, SKR, has drawn up a standardized

template for a Personal Data Processor Agreement, which can be found (in both Swedish and English) at:

https://skr.se/ekonomijuridikstatistik/juridik/offentlighetsekretessarkiv/dataskyddsforordningengdpr/informationsinsatserkringdataskyddsforordningen/personuppgiftsbitrade.16046.html

In cases where the Recipient is an independent Controller it may be necessary to establish a Data Transfer Agreement (DTA).

Is it allowed to modify the agreement template?

Templates published at www.biobanksverige.se are established by Working Committee 1 (the committee for regulatory questions) on behalf of the National Steering Committee of Biobank Sweden. Biobank Sweden has audited their standard agreements and advise against making any changes or alterations to them. Regions are recommended by Biobank Sweden to use MTAs that are established by Biobank Sweden in its original form.

Comments or questions regarding the templates can be sent to info@biobanksverige.se. Biobank Sweden Working Committee 1 will take received comments into account for any future revisions and after legal review.

Questions concerning section 12 in the agreement:

Which law applies to samples and its associated data?

The applicable law under which the samples are obtained is the same law that applies to the samples and its associated data until it is destroyed. If samples and its associated data are obtained from patients/donors in Sweden, Swedish legislation applies on these samples and its associated data regardless of where the samples are being handled.

A study is governed by the legislation in the country where it is conducted. But if the study acquires samples from other countries, or if it is a consortium with scientists from several countries, the study or the consortium needs to be prepared to accept other countries' rules and laws on how samples obtained in these countries are to be handled.

This means that the Principal in Sweden, that are responsible for samples, must demand Swedish legislation to be applied on samples obtained in Sweden. The terms in the MTA is to ensure Swedish patients'/donors' rights in accordance to Swedish law.

Which law applies in cases of dispute?

It can vary which country's legislation is applicable in cases of dispute. It is not rare when it comes to a consortium, where scientists/studies from several countries are included, that there is a collaboration/consortium agreement of some sort containing how to settle a dispute according to the agreement. This means that cases of dispute in the consortium will be handled with one country's legislation, e.g. Belgium's.

Although one country's legislation governs over cases of dispute in a collaboration, it is always Swedish legislation that governs over samples obtained in Sweden (see above).

It is common that the Swedish biobank, responsible for the samples, is not an active part of the study. Therefore, it is unreasonable to force the biobank to process any dispute concerning samples in another country in case the recipient happens to violate the terms of the MTA. This results in, that the MTA contains a condition that in cases of dispute concerning the MTA it shall be settled in accordance to Swedish law.