BIOBANK SVERIGE

Document: *K5. Information on agreements when human biological material is to be sent for an action*
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K5. Information on agreements when human biological material is to be sent for an action

(Material Transfer Agreement, MTA)

Information about what applies when samples (biological material from a living or deceased person or from a foetus) for a specific purpose is to be sent for an action from the principal of the biobank to another legal entity (recipient) outside or within the country.

Action refers to the action to be performed, such as analysis, reformatting, or storage.

Purpose refers to clinical trial, performance study, or other research.

1 Requirements of the Biobank Act (2023:38)

Samples sent for an action from the biobank principal are still considered to be part of the principal's biobank (Chapter 5, Section 7 of the Biobank Act) and the person responsible for the biobank i.e. biobank custodian must (in accordance with what follows from Chapter 5, Section 8 of the Biobank Act) **establish an agreement (MTA or equivalent) with the recipient** on the purpose of making the material available and what is to be done with the samples after the action has been performed. The biobank custodian must also set a condition for making it available that;

a. a sample preserved by the recipient shall, if requested by the biobank custodian, be returned or immediately destroyed or, if it is not possible to destroy it without destroying other samples, be de-identified; and

b. the recipient does not use samples for anything other than the stated purpose.

Furthermore, Chapter 5, Section 10 of the Biobank Act states that a sample may only be sent for research if the sample is to be included in the

- research that has been approved by the Swedish Ethical Review Authority or the Ethical Review Appeals Board in accordance with the Act (2003:460) on the ethical review of research involving humans,
- a clinical trial on medicinal products that has been, or is deemed to have been, authorised in accordance with Regulation (EU) No 536/2014 (CTR),
- a clinical trial that may be initiated or conducted in accordance with provisions in Regulation (EU) 2017/745 or in accordance with the Act (2021:600) with supplementary provisions to the EU regulations on medical devices or regulations issued in connection with that Act (MDR), or
- a performance study that may be initiated or conducted in accordance with provisions of Regulation (EU) 2017/746 (IVDR).

It is not required to establish an agreement per sample, an agreement between the parties may cover many samples, which may have been sent at the same or different times.

2 Agreement templates – MTA

If a region is responsible for samples, there are standardized agreement templates for sending samples for an action (so-called MTA) as below. There is nothing to prevent the templates from also being used by universities, colleges, or other legal entities. However, if changes are made to a template, Biobank Sweden's logo must always be removed. For the latest version of the templates go to biobanksverige.se.

The templates apply to **samples and associated sample data (sample code)**. They do **not** apply to other data relating to the purpose in question. See "3 Frequently Asked Questions Regarding MTA" below.

2.1 Different variants of MTA

There are different variants of MTA. Which template to use depends on who the research principal is or if there is a commercial/non-commercial sponsor (person, company, institution, or organization) responsible for initiating, leading, and arranging the funding of clinical trial/performance study.

Definitions of Biobank, Research Principal, Sponsor, Recipient, Third Party etc. can be found in the relevant MTA template.

- **L2a1. AGREEMENT about making Human Biological Material available to a Research Principal for an Action**
  This template should be used when a region (or a university) is the principal of the biobank and a region (or university) is the research principal and wishes an action to be carried out on a sample.

  The agreement is drawn up between the Biobank by its authorised representative of the principal of the Biobank (usually the Biobank Custodian) and the Research Principal by its authorised representative.

  If the Research Principal is to send samples to a Third Party (for example, an analytical laboratory or other collaboration partner), the Research Principal is responsible for drawing up a written agreement with the Third Party so that the same obligations regarding samples and sample codes as the Research Principal according to the MTA are imposed on the Third Party.

  The following templates can be used if the Research Principal is to send samples to a third party
  These templates can be used when the Research Principal is to send samples to the party referred to as a Third Party in the L2a1 agreement, for analysis or within the framework of a research collaboration.

  The agreement is established between the Research Principal and the Third Party and is made for the purpose of imposing on the Third Party the same obligations regarding samples and sample codes as the Research Principal has according to L2a1.

  There are various examples of agreements between the Research Principal and the Third Party.

  – **L2a1a. Example of wording regarding the transfer of conditions in "L2a1. AGREEMENT about making Human Biological Material available to a Research Principal for an Action" to a Third Party** can be used when the Research Principal is to send samples to a Third Party and impose conditions from L2a1 on the Third Party.

  Universities have also developed more extensive templates.

  – **L2a1b. AGREEMENT for Analysis of Human Biological Material and Data** can be used when the Research Principal is to send samples to a Third Party for analysis.

- **L2a1c. Research Collaboration Agreement** including the appendix **L2a1c1. Appendix 3 – Material Transfer** can be used when the Research Principal has a research collaboration with a Third Party and within the framework of the collaboration is to send samples to the Third Party.

The more extensive agreements include terms and conditions for the analysis assignment or collaboration, such as ownership and use rights of results, publication, personal data processing, etc. Please note that the Appendix 3 (L2a1c1) must be added as an appendix to the *Research Collaboration Agreement (L2a1c)*.

Consult with the university's legal office before an agreement is drawn up, e.g. based on the fact that the right template is used for the purpose.

- **L2a2. AGREEMENT about making Human Biological Material available for an Action in clinical trials and performance studies**

  This template should be used when a region is the principal of the biobank and when there is a commercial/non-commercial sponsor who has overall responsibility for the implementation of the study.

  The agreement is drawn up between the *Biobank* by its authorised representative (usually the Biobank responsible) and the *Recipient* (Sponsor, or the person authorised by the Sponsor to draw up an agreement on the transfer of the Material and that receives the Material from the Biobank). If the Recipient is to send samples to a Third Party (analysing laboratory or subcontractor), the Recipient shall draw up a written agreement with the Third Party so that the Third Party is subject to the same requirements regarding the sample and sample code as the Recipient under the MTA.

- **L2a3. AGREEMENT about making Human Biological Material available when a Research Principal sends samples for an Action to a Recipient**
  This template should be used when the research principal is the same as the principal of the biobank.

  The agreement is drawn up between the *authorised representative of the Research Principal's Biobank* (usually the Biobank Custodian) and the *Recipient* (the laboratory or collaboration partner that is to carry out an action on behalf of the Research Principal as part of a research project). If the Recipient is to send samples to a Third Party (e.g. an analytical laboratory/collaboration partner), the Recipient is responsible for establishing a written agreement with the Third Party so that it is subject to the same requirements regarding the sample and sample code as the Recipient under the MTA.

  For more information about which parties should sign the various agreements, see Appendix K5a (Swedish only).

3 Frequently asked questions regarding MTA

For more frequently asked questions see biobanksverige.se

3.1 Is MTA or equivalent required if samples are not covered by the Biobank Act?

Even for samples not covered by the Biobank Act, the person responsible for the research is responsible for ensuring that samples are handled in accordance with ethical approval and consent. If the exemption in the Biobank Act regarding samples that are not kept for longer than 9 months and that are destroyed directly after the analysis is applied, the person responsible for the research is responsible for ensuring that the exemption is followed.

For samples that are not covered by the Biobank Act, Biobank Sweden recommends that MTA/equivalent be established if samples are to be sent to another legal entity, but this is not a requirement under the Biobank Act.

Biobank Sweden has not developed any standard templates for samples that are not covered by the Biobank Act. In the first instance, it is recommended that you find out what routines exist regarding this in your own organization. For example, it may be the case that the principal uses its own standard templates for this or uses international standard templates.

3.2 Is a Data Processing Agreement needed?

Simply put, a piece of information (e.g. a sample code) that can be directly or indirectly linked to an individual is personal data (and this even if the recipient does not have a code key and thus cannot or may not make the connection himself).

As a general rule, the sample code in these cases will constitute personal data and thus the principal of the biobank and the recipient have to consider, among other things, provisions of the GDPR and, for example, consider the need for additional regulations / agreements between them in connection with this.

If other personal data is to be processed by the recipient, the provisions of the GDPR need to be taken into account in relation to these as well.

In cases where the recipient is to be regarded as a personal data assistant, a personal data assistant agreement according to GDPR must be established with the recipient. The biobank principal and/or research principal often have their own contract templates for personal data assistant agreements to be used. The Swedish Association of Local Authorities and Regions has also developed a standard template for a Data Processing Agreement.

https://skr.se/download/18.2d09e31b1872c96cd2f5c28c/1689160263548/PUB-avtal-MASTER-%20ENGLISH.docx

A Data Transfer Agreement (DTA) may need to be drawn up in cases where the recipient has an independent personal data responsibility and data is disclosed to the recipient.

Information about personal data responsibility etc can be found on the Swedish Authority for Privacy Protection's website and Biobank Sweden also refers to its own internal organization for support in these issues.

3.3 Are you allowed to make changes to the agreement template?

If changes are made to a template, Biobank Sweden's logo must always be removed. Comments or questions regarding templates are submitted to Biobank Sverige info@biobanksverige.se, which will consider the comments received in future audits.

3.4 What about delivery terms?

L2a1 and L2a2 use the standard Incoterms EXW. Incoterms, International commerce terms, are a series of international trade terms with standardized contract terms on how goods transport costs and responsibilities should be distributed between buyers and sellers. EXW, or Ex Works, is a trade term that defines exactly who bears responsibility for the goods during transport and when the risk passes from "seller to buyer" in international trade.

The terms are used by companies, authorities and organizations worldwide when transporting goods to reduce the risk of unnecessary misunderstandings that can lead to possible legal problems. Incoterms describe who bears the risk during transport, who is to pay the costs and what obligations the "buyer" and "seller" have on delivery and which party is to bear the risk for the goods during transport. By using such internationally known terms with clear references to how

they should be interpreted, contract writing is simplified, and clear terms are created to the advantage of both parties to the agreement.

In the case of biological material from humans, the relationship between seller and buyer does not exist. However, the rules can advantageously be used in the same way to regulate the terms of delivery between the biobank, i.e. the party that sends samples for analysis (instead of the seller in Incoterms EXW) and the recipient/research principal (instead of the buyer in Incoterms EXW). The samples correspond to the goods. The benefits that Incoterms give both buyers/sellers can thus be used by senders/recipients of biological material.

In L2a3, i.e. when the research principal = principal of the biobank, it is up to this legal entity to specify in the MTA what applies to delivery, for example if Incoterms EXW should be used or if there should be other delivery terms. Other terms and conditions also apply in agreements between the Research Principal and Third Party regarding the *AGREEMENT for Analysis of Human Biological Material and Data (L2a1b)* and *the Research Collaboration Agreement (L2a1c)* including *Appendix 3 – Material Transfer (L2a1c1)*.

3.5 What can be stated regarding the delivery address if samples are to be sent to several third parties?

MTA according to Biobank Sweden's templates is always established between two parties. However, there may be cases when samples should be physically sent to multiple locations. For example, when samples are to be sent by the recipient to third parties (two or more).

Example: The principal of the biobank is Region X, the research principal is University Y. The research principal must send samples for analysis to two different third parties, Laboratory A and Laboratory B. The MTA L2a1 is established between Region X and University Y. University Y draws up a written agreement with both Laboratory A and Laboratory B so that they are subject to the same obligations regarding sample and sample code as the research principal according to L2a1 (examples of transfer of conditions can be found in documents L2a1a or *AGREEMENT for Analysis of Human Biological Material and Data (L2a1b)*). Samples should be sent directly from Region X to Laboratory A and Laboratory B.

Under *Delivery address* in L2a1, it shall be indicated that there are several consignees and that details of these are attached in a new appendix to L2a1. A description of the arrangement and the relevant addresses are given in the appendix. Please note that the same information to be filled in, in L1a1, under Delivery recipient and Delivery address must be stated in the appendix incl. the condition that "For delivery, Incoterms EXW apply".

3.6 How should data on materials and number of samples be included in the MTA (Appendix 1)?

Appendix 1 specifies the number of samples actually sent for an action. It can be all samples collected or taken (primary samples) or a subset in the form of, for example, aliquots. The number of samples in the MTA may therefore differ from the number of samples specified in the biobank application.

If the samples have been prepared in such a way that it no longer resembles the original primary sample (e.g. DNA extract from blood, incision from FFPE block), the material sent for action must be specified and not the collected material/primary sample.

3.7 Questions regarding section 10 of the agreement on liability etc.

The Swedish Biobank Act means that samples sent outside Sweden's borders for an action must belong to a biobank in Sweden.

In cases where the research principal or company does not have a biobank in Sweden, the samples can, under certain conditions, be set up in a biobank at a region. If samples are to be sent for an action in a study where the region is not the research principal/sponsor, the region needs to work to ensure that responsibility and costs that lie within the framework of the study do not fall on the region and thus Sweden's taxpayers. Costs and responsibilities within the study must thus be clarified between the research principal, analysing laboratories and a possible sponsor.

The purpose of the section in the MTA is to indemnify the principal of the biobank from any claims from a donor regarding damages due to any incorrect handling of samples by someone who has gained access to samples, i.e. when something that has happened that is beyond the control of the principal of the biobank.

3.8 Questions about legislation in the Agreement

Which law applies to samples and associated sample code?
For the samples and associated sample code sent from Sweden for an action, the Swedish Biobank Act shall apply regardless of where the sample is handled.

The Biobank Act is a national Swedish protection legislation for sample donors. Foreign institutions cannot normally be bound by Swedish legislation but operate under the laws and regulations that apply in the country where the business is conducted. The MTA agreement is a means of ensuring that the recipient complies with the principles set out in the Biobank Act even when samples are sent abroad. An MTA agreement governed by the law of the recipient's country, or the law of another country may result in a risk that all or part of the MTA may not be applicable.

A study is governed by the legislation of the country where the study is conducted, but if the study uses samples from other countries, or if it is a consortium with researchers from several countries, the study or consortium must be prepared to accept other countries' rules for how samples taken in these countries may be used and handled.

This means that the principal in Sweden who is responsible for samples has to demand that Swedish legislation applies to samples taken in Sweden. The condition in the MTA shall ensure the rights of Swedish research subjects/patients under Swedish law.

Which law applies to any possible disputes?
Disputes shall mainly take place in Sweden. In Sweden, it is common for the biobank, which is responsible for samples, not to be actively included in the study. This makes it unreasonable for the biobank to have to litigate any disputes regarding samples in another country if the recipient in any way violates the terms of the MTA. This means that the MTA also includes a condition that any disputes arising from the MTA must be resolved in Swedish courts.

Please note: It is not uncommon in consortia, where researchers/studies from several countries are included, that in a cooperation agreement/consortium agreement there is a dispute resolution that applies under that agreement. This may mean that any disputes in the consortium must be resolved with the legislation of another country, such as Belgium.

The material refers only to the material and the sample code. Any other matters relating to consortia agreements are not regulated by the MTA.

Although other legislation shall apply to any disputes in a collaboration, Swedish legislation shall always apply to samples taken in Sweden.