|  |
| --- |
| Document-ID:       |

MATERIAL TRANSFER AGREEMENT

L2a1. AGREEMENT about making Human Biological Material available to a Research Principal for an Action

This Agreement contains conditions for making Material available from the Biobank to a Research Principal who intends to use the Material for an Action as part of a research Project that has been approved by the Swedish Ethical Review Authority.

## DEFINITIONS

In this agreement the following definitions are used:

**“Action”:** the action to be performed, such as analyses, reformatting or storing of the Material. Actions are specified in Appendix 2.

**“Agreement”:** means this agreement.

**“Biobank”:** the biobank where the Material is included.

**“Biobank Agreement”:** the form "L1.1 Establishment of sample collection for research”.

**“Code Key”:** the information that identifies the connection between a Sample Donor and Sample Code.

**“Delivery Recipient”:** the legal entity, appointed by the Research Principal, that receives Material for an Action.

**“Material”:** the Samples, defined in Appendix 1, and associated Sample Code.

**“Personal Data”:** means personal data pursuant to Article 4(1) of the General Data Protection Regulation (EU) 2016/679.

**“Project”:** the research Project that is approved by the Swedish Ethical Review Authority and whose access to the Material is regulated through a Biobank agreement.

**“Purpose”:** the research to be performed on the Material. The Purpose is specified in Appendix 2.

**“Research Principal”:** the legal entity in whose activities the research is conducted, usually a university or a region.

**“Sample”:** the biological Material from a living or deceased person or from a fetus.

**“Sample Code”:** the sample ID that has replaced directly identifiable information on Samples so that Personal Data can no longer directly be attributed to a specific individual.

**“Sample Donor”:** the living person from whom a Sample has been taken, or the living person who is carrying or has carried a fetus from which a Sample has been taken.

**“Third Party”:** a natural person or legal entity that is not a party in this Agreement.

## PARTIES AND PROJECT

|  |
| --- |
| Enter information about the Biobank – Party (in print) |
| Principal of the Biobank (legal entity):      |
| Name of the Biobank:      | Biobank no. (IVO):      |
| Address of the Biobank:      |
| Postcode:      | City:      |
| Phone:      | E-mail:      |
| Name of the Biobank Custodian:      |
| Enter information about Research Principal – Party (in print) |
| Research Principal (legal entity):      | Corporate identification no./VAT no.:      |
| Address:      |
| Postcode:      | City:      |
| Phone:      | E-mail:      |
| Enter information about the Project (in print) |
| Project name:      |
| Project working name (if applicable):      | Project-ID (if applicable):      |
| Ref. no. of the ethical approval/s:      | Ref. no. of approved Biobank Agreement:      |
| Responsible researcher for the Project (contact)[[1]](#footnote-1):      |
| Phone:      | E-mail:      |
| Enter information about Delivery Recipient and delivery address[[2]](#footnote-2) (in print) |
| Transport conditions: For transport Incoterms EXW rules applies. |
| Delivery Recipient:      |
| Address:      |
| Postcode:      | City:      |
| Country:      |
| Phone:      | E-mail:      |
| Name of contact person at Delivery Recipient:      |

## BACKGROUND AND PURPOSE

The Research Principal have requested access to Material available in the Biobank to carry out the Project. The Biobank have agreed to make the Material available to the Research Principal for the purpose of the Project, see Appendix 2.

This Agreement regulates the terms under which the Material is received and how the Material shall be handled upon expiration or termination of this Agreement. Access to Material in a Sample Collection is regulated through a separate Biobank Agreement.

## SPECIFICATION OF THE MATERIAL

The Material as specified in Appendix 1 shall be sent to the Delivery Recipient. The Material is provided in coded form so that the person who provides the Sample can only be identified by the Code Key.

The parties are aware that the Sample Code is Personal Data as long as the Code Key exists.

The parties are aware of that the provided Material will still be considered as included in the Biobank.

## PERMITTED USE etc.

The Material may only be used for the specified Purpose and Action (that is described in Appendix 2). The Material shall be used in accordance with in Sweden applicable laws, rules and regulations and the decisions of the Swedish Ethical Review Authority or the Ethical Review Appeals Board.

## WITHDRAWAL OF CONSENT

The Biobank shall inform the Research Principal immediately if the Sample Donor, or another person who has consented to storage and use of a Sample, contacts the Biobank with a withdrawal in accordance with the Biobank Act (2023:38) of their consent to the storage of the Sample in the Biobank or the use of the Sample for certain purposes.

The Research Principal shall immediately inform the custodian of the Biobank if the Sample Donor, or another person who has given consent, contacts the Research Principal with a withdrawal of their consent to the use of a Sample.

In these cases, the Research Principal undertakes, with the necessary support from the Biobank, to ensure that the use of Samples from the Sample Donor in question is immediately discontinued and that any remaining Samples from the Sample Donor are returned to the Biobank or destroyed according to the instructions from the Biobank. The right to use the results of the research that has taken place on the Material is not affected by the withdrawal of consent to the storage or use of a Sample.

## ACCESS TO THE MATERIAL

The Research Principal undertakes to ensure that only authorized persons have access to and use the Material that is provided by the Biobank.

## SECURITY FOR MATERIAL

The Research Principal undertakes to protect the Material, in terms of integrity and security, from unauthorized access and use as well as theft in accordance with applicable data protection and biobank legislation, and under no circumstances use the Material to try to identify or contact the Sample Donor or its relatives. If the Research Principal notices that the Material has been used incorrectly, the Research Principal undertakes to contact the Biobank immediately.

The Research Principal acknowledge that the Biobank will not provide the Research Principal with a code key or other information that directly identifies or can be used to identify the person who submitted the Sample.

## THIRD PARTY

If the Recipient uses a Third Party for the Purpose and the Action covered by Appendix 2, the Recipient is responsible for ensuring that the Third Party is, through a written agreement, subject to the same obligations, limitations, and conditions for handling the samples as set out in this Agreement.

In cases where the Recipient has stated a Third Party as the Delivery Recipient, the Recipient must enter into an agreement with the Third Party before samples may be sent from the Biobank.

The Research Principal undertakes to document the Third Parties who have accessed the Material and when access has occurred and for what purposes access has been granted, to be able to present it to the Biobank if necessary.

The Research Principal undertakes to ensure that Material is never provided to Third Parties with information or data that enables Third Parties to identify the person who has provided the Sample.

## LIABILITY etc.

The Research Principal undertakes to indemnify the Principal of the Biobank and/or its employees from any claim by a Third Party, including reasonable legal costs, caused by or arising from improper use, loss or damage as a result of the use, handling, storage, transport or other activities concerning the Material covered by this Agreement, and which is not due to gross negligence or wilful act of the Biobank.

In the event of compensation for damages and penalties due to incorrect processing of Personal Data, Articles 82 and 83 of the General Data Protection Regulation apply.

Administrative fines pursuant to Article 83 of the General Data Protection Regulation or Chapter 6. Section 2 of the Act (2018:218) with supplementary provisions to the EU General Data Protection Regulation shall be borne by the Party to whom such a fee has been imposed.

## TERM AND TERMINATION OF THIS AGREEMENT

This Agreement shall come into force on [insert date] and shall remain in force until the Purpose is completed, but no later than [insert date] unless the agreement has been previously extended.

The Biobank has the right to terminate this Agreement with immediate effect if the Research Principal is in material breach of its obligations under this Agreement or becomes bankrupt, liquidated, or otherwise becomes insolvent.

The Biobank also has the right to terminate the Agreement if the Biobank suspects that the Research Principal is in breach of the Agreement, if the Biobank sends a written notification to the Research Principal concerning the suspected breach, and the Research Principal within one (1) month from the notification have not demonstrated that it is not in breach of this Agreement.

## TREATMENT OF MATERIAL UPON EXPIRATION OR TERMINATION

The Research Principal undertakes to immediately discontinue the use of the Material upon expiration or termination of this Agreement.

The Research Principal undertakes, in accordance with the instructions from the Biobank, to return or destroy any remaining Material as soon as possible, but no later than thirty (30) calendar days after the expiration or termination of this Agreement, whichever occurs first. The Research Principal has the right to retain such copies as are required for compliance with applicable Swedish statutes and regulations.

## MISCELLANEOUS

The parties acknowledge that terms in the Agreement may not be changed or modified without the parties' prior written agreement.

The parties acknowledge that, this Agreement will prevail over any deviating terms in other agreements relating to the Materials.

The parties acknowledge that this Agreement is governed by Swedish law and any interpretation or dispute arising from this Agreement, which the parties cannot resolve on their own, shall be decided by a Swedish general court.

The Agreement has been drawn up in two (2) originals, of which the parties have taken one (1) copy each.

|  |
| --- |
| SIGNATURES |
| For the Biobank |
| Signature (authorized representative): |
| Name in print:      | Date:      |
| For the Research Principal |
| Signature (authorized representative): |
| Name in print:      | Date:      |

Appendix 1: Samples

The following Samples shall be sent. The person responsible for completing the information below is the Principal Investigator according to the application of ethical approval.

|  |
| --- |
| Describe the Samples to be sent |
| Describe the content and extent, for example type of tissue, cells/cell lines, blood or blood plasma, prepared DNA, urine, etc. | No. of individuals | No. of samples |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |

*Add more rows if necessary*

Appendix 2: Purpose and Action, the research to be conducted on the Material

The person responsible for completing the information below is the Principal Investigator according to the application of ethical approval.

|  |
| --- |
| Describe the Purpose for which the Material shall be used. |
| Specify *the Purpose* for which the material shall be used. Specify so that only such use that are included in the approval from the Ethical Review Authority or the Ethical Review Appeals Board may be conducted and so that there is no room left for other use. |
| Description of the Project and any storage of Material upon completion of the Project:      |

|  |
| --- |
| Describe the Action that shall be performed on the Material and specify how the Samples will be handled after the completion of the Purpose. |
| Action (describe clearly)[ ]  Analysis, describe:      [ ]  Reformatting, describe:      [ ]  Storage, describe:      [ ]  Other, describe:       |
| Specify how Samples shall be handled after the completion of the Purpose[ ]  Samples are completely used up during the Action[ ]  Samples shall be destroyed after the Action, specify expected date of destruction of samples (year, month):      [ ]  Samples shall be returned, specify expected date of return of samples (year, month):      **The last possible end date for use of the Materials, is stated in Section 11.** |

1. The principal investigator, named in the ethical approval. [↑](#footnote-ref-1)
2. If there are several Delivery Recipients, details of these shall be appended in a new appendix to L2a1. A description of the arrangement and the relevant addresses are to be stated in the appendix. Note that the Delivery Recipient is a Third Party if the Research Principal itself is not the Delivery Recipient. [↑](#footnote-ref-2)