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MATERIAL TRANSFER AGREEMENT

L2a3. AGREEMENT about making Human Biological Material available when a Research Principal sends samples for an Action to a Recipient

This Agreement contains conditions for making Material available from the Biobank of the Research Principal to a Recipient who, on behalf of the Research Principal, intend to use the Material for an Action as part of a research project 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, specified in Appendix 2.

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

**“Biobank”:** the biobank at the Research Principal 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 natural person and the Sample Code.

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

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

**“Project”:** the Research Project with approval from the Swedish Ethical Review Authority and whose access to the Material is regulated by a Biobank Agreement.

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

**“Recipient”:** the principal, for example a laboratory, that on behalf of the Research Principal shall perform an Action as part of the Research Project.

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

**“Sample”:** biological material from a living or dead person or from a fetus.

**“Sample Code”:** the sample ID that has replaced directly identifiable information on samples so that they can no longer be directly 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

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| Enter information about the Biobank – Party (in print) |
| Research Principal/Principal of the Biobank (name of Principal):      |
| Name of the Biobank:      | Biobank no. (IVO):      |
| Address of the Biobank:      |
| Postcode:      | City:      |
| Phone:      | E-mail:      |
| Name of the Biobank Custodian:      |
| Enter information about the Recipient – Party (in print) |
| Terms of delivery:      |
| Recipient:      |
| Address:      |
| Postcode:      | City:      |
| Country:      |
| Phone:      | E-mail:      |
| Name of contact person at the Recipient:      |
| 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 or EU-trial no./CIVID:      | Ref. no of approved Biobank Agreement:      |
| Name of responsible researcher for the project (contact person)[[1]](#footnote-1):      |
| Phone:      | E-mail:      |

## BACKGROUND AND PURPOSE

The Biobank contains the Material needed for the Action within the framework of the Project, and access is regulated through a separate Biobank agreement.

The Parties wish to make the Material available to the Recipient to carry out the Action in the Project.

This Agreement regulates the terms under which the Material is received and how the Material shall be handled in connection with the termination of the Agreement.

## SPECIFICATION OF THE MATERIAL

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

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

The parties are aware of that the Material that is sent still is part of the Biobank.

## PERMITTED USE etc.

The Material may only be used for the stated Purpose and Action (specified 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

In the event that a Sample Donor or other person who has given consent to the storage and use of a Sample withdraws its consent to the storage of the Sample in the Biobank or the use of the Sample for certain purposes, the Recipient undertakes to ensure that the use of Samples from the said Sample Donor is immediately discontinued and that any remaining Sample from the Sample Donor is returned to the Biobank or destroyed in accordance with the instructions from the Biobank.

## ACCESS TO THE MATERIAL

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

## SECURITY FOR MATERIAL AND SAMPLE CODE

The Research Principal undertakes to ensure that the Material is never provided to the Recipient with information or data that enables the Recipient to identify the Sample Donor.

The Recipient undertakes to protect the Material, in terms of privacy and security, from unauthorized access and use as well as theft in accordance with applicable data protection and biobank legislation.

The Recipient undertakes not to use the Material under any circumstances to attempt to identify or contact the Sample Donor or its relatives. If the Recipient notices that the Material has been used incorrectly, the Recipient undertakes to contact the Research Principal immediately.

The Recipient understands that the Research Principal will not provide the Recipient with a code key or other information that directly identifies or can be used to identify the Sample Donor.

## THIRD PARTY

In the event that the Recipient sends the Material to a Third Party in accordance with the Purpose, the Recipient shall, through a written agreement with the Third Party, impose on the Third Party the same obligations regarding the Material as are imposed on the Recipient under this Agreement and that the Third Party handles the Material in accordance with the terms of this Agreement.

The Recipient undertakes to document which Third Parties that have accessed the Material and when and for what purposes, to be able to present it to the Research Principal if required.

## LIABILITY etc.

The Recipient undertakes to indemnify the Research Principal 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 of the Material covered by the Agreement, and which is not due to intentional or grossly negligent conduct 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.

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 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 Research Principal has the right to terminate this Agreement with immediate effect if the Recipient 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 Recipient is in breach of the Agreement and if the Recipient has not demonstrated, within one (1) month of the written notification from the Biobank, that this is not the case.

## TREATMENT OF MATERIAL UPON EXPIRATION OR TERMINATION

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

The Recipient 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 the Agreement. The Recipient 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 approval.

The parties acknowledge that this Agreement will prevail over any deviating terms in other agreement relating to the Material.

The parties acknowledge that this Agreement is governed by Swedish law and that any interpretation or dispute arising from the 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.

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| SIGNATURES |
| For the Biobank |
| Signature (authorized representative): |
| Name in print:      | Date:      |
| For the Recipient |
| Signature (authorized representative): |
| Name in print:      | Date:      |

Appendix 1: Samples

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

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| 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 |
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*Add more rows if necessary*

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

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

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| 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:      |

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| 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)