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| Document-ID:       |

MATERIAL TRANSFER AGREEMENT

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

This Agreement contains conditions for making Material available from the Biobank to a Recipient who intend to use the Material for an Action as part of a clinical trial or a performance study with approval from the Swedish Ethical Review Authority or approval according to applicable EU Regulation 2014/536 (CTR), 2017/745 (MDR) or 2017/746 (IVDR).

## 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 to this agreement.

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

**“Biobank Agreement”:** the form *T1. Establishment of sample collection for clinical trials and performance studies*

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

**“Delivery Recipient”:** the legal entity, appointed by the Sponsor, 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 clinical trial or performance study with approval from the Swedish Ethical Review Authority or the Medical Products Agency in accordance with the applicable EU regulation on clinical trials or performance studies (EU Regulation No 2014/536 on clinical trials on medicinal products for human use, EU Regulation No 2017/745 on medical devices, or EU Regulation No 2017/746 on medical devices for in vitro diagnostics), and whose access to the Material is regulated by a Biobank Agreement.

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

**“Recipient”:** the Sponsor, or whoever Sponsor has authorized to establish Agreements concerning making the Material available.

**“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 they can no longer be directly attributed directly 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.

**“Sponsor”:** the person, company, institution, or organisation responsible for initiating, managing, and arranging the financing of a clinical trial or a performance study.

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

## PARTIES AND PROJECT

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| 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 the Recipient – Party (in print) |
| [ ]  The Recipient is the Sponsor | [ ]  The Recipient is the person to whom the Sponsor has authorized to establish the MTA |
| Name of Sponsor:      | Corporate identification no./VAT no.:      |
| Name of Recipient (if other than Sponsor):      | Corporate identification no./VAT no:      |
| Address of Recipient:      |
| Postcode:      | City:      |
| Country:      |
| 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 or EU-trial no./CIVID:      | Ref. no of approved Biobank Agreement:      |
| Name of contact point for Biobank related questions in clinical trials or performance studies:      |
| Phone:      | E-mail:      |
| Enter information about Delivery Recipient and delivery address[[1]](#footnote-1) |
| 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 Biobank holds 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 and the Biobank agrees to make the Material available to the Recipient 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 in connection with the termination of the 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 submitted 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 decisions of the Swedish Ethical Review Authority or the Board of Appeal for Ethical Review or the Medical Products Agency in accordance with applicable EU Regulation 2014/536 (medicinal products for human use - CTR), 2017/745 (medical device -MDR) or 2017/746 (medical device for in-vitro diagnostics - IVDR), and whose access to the Material is regulated via a Biobank agreement.

## WITHDRAWAL OF CONSENT

In the event that the Sample Donor, or another person who has given consent for the 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 Recipient must be informed of this immediately.

In the event that the Sample Donor, or another person who has given consent, contacts the Recipient with a withdrawal of their consent to the use of a Sample, the Recipient shall immediately inform the custodian of the Biobank of this.

In these cases, the Recipient 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 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 Biobank 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 Biobank immediately.

The Recipient understands that the Biobank 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 Biobank if required.

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

## LIABILITY etc.

The Recipient undertakes to indemnify 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 of the Material covered by the 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.

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 Biobank 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 this 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 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.

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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. Responsible for the completion of the information is the one specified as Sponsor according to the applicable approval for clinical trial or performance stud

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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

Responsible for the completion of the information is the one specified as Sponsor according to the applicable approval for clinical trial or performance study.

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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 only such use included in the approval for clinical trial or performance study. No room should be 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. If there are several Delivery Recipients, details of these shall be appended in an additional appendix to L2a2. A description of the arrangement and the relevant addresses must be stated in the appendix. Note that the Delivery Recipient is a Third Party if the Sponsor is not the Delivery Recipient itself. [↑](#footnote-ref-1)