|  |
| --- |
| Dokument-ID: |

MATERIAL TRANSFER AGREEMENT

L2a1c1. APPENDIX 3 – Material Transfer

## PARTIES

[Name], **”Provider”**

[Department and address], Sweden and

[Party carrying out analyses], **”Recipient”**

Address and country

In the MTA, the said parties are collectively referred to as the **“Parties”** or individually as a **“Party”**.

## Definitions

**“Analyses”** means the analyses to be performed on the Material as described in Attachment 2.

**“Analysis Data”** means all data generated by Recipient’s Analyses of the Material.

**“Biobank”** means the biobank that the Material belongs to and for which a principal is responsible.

**“Code Key”** means information that identifies the connection between a Donor and the Sample Code. Code Key will be held by the Biobank or Provider and will not be made available to Recipient.

**“Data”** means the data listed in Attachment 1, and may include Personal Data. For the avoidance of doubt, Data is regarded as Provider’s Background. A reference to Material in this MTA also is a reference to any provided Data as applicable.

**“Donor”** means the natural person (whether living or deceased) from whom the Material were obtained.

**“L2a1. AGREEMENT”** means an agreement between Provider and the Biobank on the transfer of human biological material to a research principal including its Attachments, attached to this Agreement as Attachments 3.

**“Main Agreement”** means the Research Collaboration Agreement for the project [name of Project].

**“Material”** means the human biological material defined in Attachment 1 together with associated Sample Code and other information related to the Material. Information associated with the human biological material in the Material is considered as Personal Data as long as the Donor is alive and the Code Key still exist.

**“MTA”** means this Material Transfer Appendix including its attachments.

**“Project”** means the research project as described in the Main Agreement.

**“Sample Code”** means the sample ID that replaces directly identifiable information on the samples so that Personal Data can no longer be attributed to a specific Donor without the Code Key.

**“Third Party”** means a party that is not a Party in the MTA including subcontractors.

## BACKGROUND

1. Certain Material and Data will be analysed within the framework of the Project as set out in the Main Agreement in which this MTA is an integrated part.
2. The Biobank is in possession of the Material. In order for the Material to be transferred to Recipient, the Biobank must first approve Provider´s application for access to the Material. If Provider´s application is approved, Provider will enter into an agreement, L2a1. AGREEMENT, with the Biobank, where the conditions for the use of the Material are set out. Recipient acknowledges that Provider in accordance with L2a1. AGREEMENT will be obligated to impose on Recipient, through the terms and conditions of this MTA, certain obligations in respect of the Material as those imposed to Provider by the Biobank in the L2a1. AGREEMENT.

## PERMITTED USE

1. The Parties acknowledge that having received an ethical approval from the Swedish Ethical Review Authority in Sweden is an unconditional condition for Provider to lawfully disclose the Material to Recipient under the conditions of this MTA.
2. Material as defined in Attachment 1 will be transferred to Recipient after mutual signing of the Main Agreement by both Parties.
3. Material will be provided to Recipient in a form ensuring that individual Donors cannot be directly identified, unless required for the performance of the Project and it is consistent with the ethical approval.
4. Recipient undertakes to use the Material solely within the Project and to perform the Analyses as set out in Attachment 2. Any use other than for this purpose is expressly prohibited.
5. Recipient shall ensure:
   1. Compliance with all applicable legislation, regulations, rules, guidelines, policies and ethical requirements, as well as any constraints set forth by institutional review boards and any instructions given at any time by Provider, applicable to the Analyses and applicable to the handling and protection of the Material, regarding the use, storage, and disposal.
   2. Compliance with all applicable legislation, regulations, rules, guidelines, policies and ethical requirements to protect the identity and privacy of Donors from whom the Material were collected and Data may refer to.
6. Recipient shall provide Provider with Analysis Data as instructed by Provider or as otherwise set out in Attachment 2.
7. Recipient shall ensure that only authorised persons within Recipient’s organisation have access to and is allowed to use the Material. Recipient shall ensure that all such authorised persons are informed about and to the extent legally possible agree to abide by all terms and conditions of this MTA including its Attachments before such persons get access to the Material or Analysis Data.
8. The Parties acknowledge and agree that Provider provides the Material for experimental, non-commercial, use only and that neither shall be used for testing on or treatment of humans. Further, Recipient acknowledges that the Material shall be used with all reasonable caution and prudence, since all of their characteristics are not known nor guaranteed Provider.

## DATA PROTECTION AND INFRINGEMENT

1. If a Donor withdraws its consent to use certain Material, Recipient agrees to upon Provider’s or the Biobank’s request, immediately stop any use of the affected Material. Any affected remaining Material shall be returned to the Provider or, if instructed by the Provider, to the Biobank or destroyed, as instructed by Provider in writing.
2. Recipient shall promptly notify Provider, and shall provide all reasonable assistance and information that Provider may need or request if Recipient becomes aware of or believe that:
   1. an unauthorised person or entity has accessed Material or Data;
   2. an unauthorised use or disclosure of the Sample Code has occurred.

## OWNERSHIP

1. The Biobank retains its statutory rights, responsibility and interest in and to the Material in Provider’s, Recipient’s, or any Third Party’s possession. For the avoidance of doubt, this MTA does not transfer any ownership of Material or Background to Recipient.

## THIRD PARTIES

1. If a Third Party has been designated in Attachment 2 to carry out Analyses; or if Provider has approved in writing the provision or transfer of Material to a Third Party for this purpose, Recipient undertakes to ensure that the terms of this MTA are extended *mutatis mutandis* to any such Third Party before the Third Party receives access to the Material. Recipient will remain strictly responsible for such Third Party’s compliance with the provisions of this MTA.

## WARRANTIES AND LIABILITY

1. The Material is provided as a service to the research community. Except as expressly set out in this MTA, the Material is supplied to the Recipient with no warranties either expressed or implied, including any warranty of quality, of performance, of merchantability or fitness, or that the Material can be used without risk. Provider makes no representations that the use of the Material will not infringe any patent or proprietary rights of Third Parties.
2. In no event shall Provider be liable for any use by Recipient of the Material or any loss, claim, damage or liability which may arise from or in connection with this MTA or the use, handling, storage or transportation of the Material unless Provider has breached its obligations under this MTA intentionally or through gross negligence.
3. Each Party shall be solely liable for any loss, damage or injury to Third Parties resulting from the performance of the said Party’s obligations by it or on its behalf under this MTA or from its use of any Material and Analysis Data whether owned by that Party or obtained by it from another Party.
4. The terms of this MTA shall not be construed to amend or limit any applicable statutory liability of the Parties.

## TERM AND TERMINATION

1. If the Biobank for any reasons does not grant an approval as set out in 3.2 above this MTA will be terminated immediately upon notice of Provider. If the L2a1. AGREEMENT is terminated, regardless of the cause this MTA is terminated with immediate effect upon notice of Provider.
2. If the Swedish Ethical Review Authority does not give ethical approval or withdraws the same for the project relating to the Material, Provider has the right to terminate this MTA with immediate effect upon notice of Provider.
3. Any obligations arising from this MTA which by their nature should continue to apply even after the MTA’s expiry or termination, shall continue to apply.

## TREATMENT OF MATERIAL AND DATA UPON EXPIRATION OR TERMINATION

1. Recipient agrees, on the expiration or termination of this MTA, to immediately stop the use of the Material and Data. Recipient agrees, as instructed in Attachment 1 or otherwise instructed in writing by Provider, to return to Provider or destroy any residual Material and Data. Recipient shall also delete any copies of the Material and Data in such a way that it cannot be recreated, thereby ensuring that no Material or Data is retained by Recipient. Recipient shall however have the right to retain copies of any Data that are required in order for recipient to comply with any applicable laws, rules and regulations.

## ATTCHMENTS

1. The Appendixes forming an integral part of this MTA are:

Attachment 1: Description of Material and/or Data to be transferred

Attachment 2: Description of analyses

Attachment 3: L2a1. AGREEMENT

|  |  |
| --- | --- |
| SIGNATURES | |
| This Agreement has been drawn up in two (2) original copies, of which each Party has received one copy. | |
| Recipient | |
| Signature: | |
| Name and title in print: | Date: |
| Provider | |
| Signature: | |
| Name and title in print: | Date: |

Appendix 1: Detailed description of Material and/or Data to be transferred to Recipient

|  |  |  |
| --- | --- | --- |
| Describe the Material to be transferred | | |
| 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*

|  |
| --- |
| State the expected end date for using the Material according to this Agreement |
| State when the analysis is planned to be finished (year, month): year-month  Samples will be:  Completely used up during the analysis.  Destroyed after analysis. Enter expected date for destruction of samples (year, month): year-month  Returned after analysis. Enter expected date for return of samples (year, month): year-month  Other: |

|  |
| --- |
| Describe the Data to be transferred  and end for using Data  The sample code is included in the definition of Material and should not be entered under Data. The data to be entered here can refer to, for example, survey data about the samples.  If no data other than the sample code will be sent, apply "No Data will be transferred". |
| Data:  No Data will be transferred  Recipient shall on the expiration or termination of this Agreement  Destroy all remaining Data as well as copies of Data. Recipient shall within thirty (30) calendar days of the expiration or termination of this Agreement provide Provider with a certificate of destruction. |

|  |  |  |  |
| --- | --- | --- | --- |
| Delivery  Information about delivery Recipient and delivery address | | | |
| **Conditions for transports**: For transport, Incoterms 2020 DAP Recipient rules apply. | | | |
| Delivery Recipient: | | | |
| Address: | | | |
| Postcode: | City: | | Country: |
| E-mail: | | Phone: | |
| Name of contact person at Delivery Recipient: | | | |

Appendix 2: Description of analyses

|  |
| --- |
| The Analysis |
| Recipient will carry out the following analyses:  [Insert detailed specification of the analyses for which the human biological Material is transferred. Specify so that only such use that are included in the ethical review authority decision may be conducted and so that there is no room left for other use/analyses]. |

|  |
| --- |
| Reporting and timelines |
| Recipient will provide Provider with progress reports when required and a final report not more than [weeks/months] after completion or termination of the work.  [Insert detailed specification of what the reports should contain.] |

|  |
| --- |
| Transfer of Analysis Data |
| [Insert detailed specification on when and how the Analysis Data shall be transferred to Provider in a secure way] |

|  |  |
| --- | --- |
| Contact information | |
| For Provider | |
| Name: | Department: |
| E-mail: | Phone: |
| For Recipient | |
| Name: | Department: |
| E-mail: | Phone: |

Appendix 3: L2a1 AGREEMENT between Provider and the Biobank

L2a1. AGREEMENT on the transfer of Human Biological Material to a Research Principal, including its Appendices.