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MATERIAL TRANSFER AGREEMENT

L2a1b. AGREEMENT for analysis of human biological material and data

## PARTIES

[Name], **”Provider”**

[Department and address], Sweden and

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

Address and country

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

## Definitions

**“Agreement”** means this Material Transfer Agreement.

**“Analyses”** means the analyses to be performed on the Material and/or Data, as described in Appendix 2.

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

**“Background”** means information which is held by the Parties prior to their accession to this Agreement, as well as copyrights or other intellectual property rights pertaining to such information.

**“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 Appendix 1, and may include Personal Data. For the avoidance of doubt, Data is regarded as Provider’s Background.

**“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 appendixes, attached to this Agreement as Appendix 3.

**“Material”** means the human biological material defined in Appendix 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.

**“Personal Data”** means personal data pursuant to Article 4.1 of the EU General Data Protection Regulation 2016/679, “GDPR”.

**“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 this Agreement including subcontractors.

## BACKGROUND

1. The Provider has engaged Recipient to perform certain Analysis on provided Material and, when listed in Appendix 1, Data as a part of Provider´s research project [Name of project]. Material and Data will be transferred from Provider to Recipient and the purpose of the Agreement is to establish contractual arrangements between the Parties relating to the transfer and the Recipients use of the Material and Data.
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 Agreement, 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 is an unconditional condition for Provider to lawfully disclose the Material and Data to Recipient under the conditions of this Agreement.
2. The Material and Data as defined in Appendix 1 will be transferred to Recipient after signing of this Agreement by both Parties.
3. Material and Data will be provided to Recipient in a formensuring that individual Donors cannot be directly identified.
4. Recipient undertakes to use the Material and Data solely to perform the Analyses as set out in Appendix 2.
5. Recipient shall not:
   1. make modifications of the Material without the express written consent of Provider, unless it is not already described in Attachment 2;
   2. use the Material for any profit-making or commercial purposes such as, but not limited to, production, sale, screening or drug design;
   3. use the Material in research projects that grant sublicenses, ownership, or other proprietary rights in the Material to a Third Party;
   4. use the Material for testing in or treatment of humans, in clinical trials, or for diagnostic purposes involving human subjects.
6. Recipient shall provide Provider with Analysis Data as instructed by Provider or as otherwise set out in Appendix 2.
7. 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 instructions given by Provider, applicable to the Analyses and applicable to the handling and protection of the Material and Data, 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 was collected and Data may refer to.
8. Recipient shall ensure that only authorised persons within Recipient’s organisation have access to and are allowed to handle the Material, Data or Analysis Data. 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 Agreement including its Appendices before such persons get access to the Material, Data or Analysis Data.
9. Recipient acknowledges that the Material and Data shall be used with all reasonable caution and prudence, since all of their characteristics are not known for nor guaranteed by Provider.
10. Nothing contained in this Agreement shall be construed as granting of any rights or licenses, or transferring by license or otherwise any rights of the Parties, such as but not limited to know-how, patent rights, copyrights, trade secrets or other intellectual property rights, except as explicitly set forth in this Agreement.

## PERSONAL DATA

1. The Parties agree that all handling of Personal Data under this Agreement shall be in compliance with all applicable personal data rules that apply to each Party. In particular regarding Parties within the EU/EEA-area or otherwise falling within the scope of the GDPR all Personal Data processed under this Agreement shall be processed in accordance with the GDPR.
2. Recipient will process Personal Data on behalf of Provider within the framework of this Agreement and will therefore act as Processor of Personal Data in relation to Provider who is Controller (the terms Controller and Processor being defined in the GDPR). To this end, the Parties have entered a separate Data Processing Agreement, included as Appendix 4.

## DATA PROTECTION AND INFRINGEMENT

1. If a Donor withdraws its consent to use certain Material and Data, Recipient agrees to upon Provider’s request, immediately stop any use of the affected Material and Data. The affected remaining Material and Data 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, Data or Analysis Data;
   2. an unauthorised use or disclosure of the Sample Code key has occurred.
3. Other than the provisions regarding data protection in this Agreement, the Data Processing Agreement may contain additional provisions for the Recipient to comply with. Should any provision in this Agreement be in conflict with a provision in the Data Processing Agreement, the latter shall prevail.

## OWNERSHIP

1. The Biobank retains all rights, title and interest in and to the Material in Provider’s, Recipient’s, or any Third Party’s possession. For the avoidance of doubt, this Agreement does not transfer any ownership of Material, Data or Background to Recipient.
2. Provider is the sole owner of any Analysis Data generated by Recipient’s Analyses of the Material and Data under this Agreement.

## CONFIDENTIALITY

1. Within the framework of this Agreement, the Parties may disclose information of a confidential nature to one another.

‘Confidential Information’ refers to any kind of information that a Party (‘Disclosing Party’) discloses to another Party (‘Receiving Party’) within the framework of this Agreement, provided that:

* + in the case of written information, the information at the time of disclosure was clearly marked with the designation "Confidential" or
  + in the case of non-written information, the Receiving Party is clearly informed at the time of disclosure that the information is to be regarded as confidential and that the Disclosing Party confirms this in writing within ten (10) working days of the point of disclosure.
  + Confidential Information does not include information which
  + is or becomes public knowledge other than through a breach of this Agreement,
  + the Party can demonstrate was in its possession prior to the time of such Party’s execution of the Agreement,
  + has legally come to the knowledge of a Party independently of the other Parties, or
  + the disclosing Party later notifies as no longer confidential;
  + after the signing of the Agreement was demonstrably generated by a Party on its own, independently of any information provided to it under this Agreement.

1. The Receiving Party undertakes to treat the received Confidential Information in a strictly confidential manner, not to disclose any part of it to third parties, not to use the Confidential Information for purposes other than the implementation of the Agreement and not to disseminate Confidential Information within its own organisation to a degree beyond that which is necessary for implementing the Agreement.

The aforementioned confidentiality provisions apply for three (3) years after the Agreement expires in accordance with Section 12, but never longer than ten (10) years from the point at which the information was received.

1. The confidentiality obligations in this Agreement does not apply to disclosure of information that a Receiving Party discloses in accordance with applicable laws, regulations or equivalent mandatory provisions including rules of a stock exchange, court judgments or administrative decision by a competent authority.
2. The Parties acknowledge and agree that if a Party is a Swedish public authority, this Clause 8 is subject to the provisions of the Freedom of the Press Act (tryckfrihetsförordningens (1949:105)) and the Public Access to Information and Secrecy Act (offentlighets- och sekretesslagen (2009:400)).

## THIRD PARTIES

1. If a Third Party has been designated in Appendix 2 to carry out Analyses; or if Provider has approved in writing the provision or transfer of Material and/or Data to a Third Party, Recipient undertakes to ensure that the terms of this Agreement are extended mutatis mutandis to any Third Party before the Third Party receives any access to the Material and/or Data. Recipient will remain strictly responsible for such Third Party’s compliance with the provisions of this Agreement.
2. Before any Personal Data is transferred by Recipient to a Third Party in a country outside the EU/EEA that does not offer an adequate level of data protection, Recipient and the Third Party must agree to adhere to appropriate Standard Contractual Clauses approved by the European Commission.

## WARRANTIES AND LIABILITY

1. Material and Data is provided without any warranties or representations that Material and Data can be used without risk. Provider has no obligation to compensate Recipient for damage caused to the Recipient when using the Material and Data.
2. 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 Agreement or from its use of Material, Data, Background and Analysis Data whether owned by that Party or obtained by it from another party according to this Agreement.
3. A Party is not liable to compensate loss of production, loss of profit or other indirect, incidental, consequential, special or punitive damages arising from this Agreement unless such Party has breached its obligations under this Agreement intentionally.
4. The terms of this Agreement shall not be construed to amend or limit any applicable statutory liability of the Parties.

## FORCE MAJEURE

1. If a Party's fulfilment of its obligations under this Agreement is significantly hindered or prevented due to obstacles beyond that Party's control, or obstacles which the Party could not reasonably be expected to have anticipated at the time of Agreement and whose consequences the Party could not reasonably have avoided or overcome (force majeure), that Party shall not be held liable for any delay and shall be except from paying any damages and other penalties that are caused by such force majeure circumstances. A Party that fails to fulfil any obligations under this Agreement due to force majeure shall notify the other Parties of this failure and the reasons therefore without undue delay. If an obstacle persists for more than two (2) months, the other Parties have the right to terminate the Agreement with immediate effect.

## TERM AND TERMINATION

1. This Agreement will enter into force upon both Parties signature and will remain in full force and effect until the Analyses are finalized and Provider has received all Analysis Data from Recipient, and the Parties has completely fulfilled their obligations under this Agreement. The Agreement may be terminated earlier by either Party in accordance with the following articles.
2. Each Party shall have the right to terminate this Agreement with immediate effect upon the occurrence of any of the following events:
3. the other Party becomes bankrupt or insolvent or a receiver is appointed to take possession of the other Party’s business or property, or the other Party has assigned its interest to creditors;
4. the other Party is more than thirty (30) calendar days delayed in payments that are due under this Agreement; or
5. if it is deemed impossible for Recipient to comply with new instructions from Provider regarding security and data protection, including instructions under the Data Processing Agreement.
6. Each Party may terminate this Agreement by giving the other Party thirty (30) calendar days’ notice if the other Party commits a material breach of this Agreement, which it fails to remedy within fourteen (14) calendar days after receipt of written notice from the non-defaulting Party specifying the breach and requesting remedy.
7. If the Biobank for any reasons does not grant an approval as set out in article 3.2 above or if the Donor withdraws its consent for use of the Material this Agreement will be terminated immediately upon notice of Provider. If the L2a1. AGREEMENT is terminated, regardless of the cause this Agreement is terminated with immediate effect upon notice of Provider.
8. 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 Agreement with immediate effect upon notice of Provider.
9. Any obligations arising from this Agreement which by their nature should continue to apply even after the Agreement’s expiry or termination, shall continue to apply.

## TREATMENT OF MATERIAL, DATA AND ANALYSIS DATA UPON EXPITATION OR TERMINATION

1. Recipient agrees, on the expiration or termination of this Agreement, to immediately stop the use of the Material and Data. Recipient agrees, as instructed in Appendix 1 or otherwise instructed in writing by Provider, to return to Provider or destroy any residual Material and any 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 and/or Data is retained by Recipient.
2. Upon expiration or termination of this Agreement and after Recipient has provided Provider with all Analysis Data as set out in this Agreement, and Provider has confirmed its receipt thereof, Recipient shall delete all Analysis Data in such a way that it cannot be recreated, thereby ensuring that no Analysis Data is retained by Recipient, unless otherwise explicitly agreed between the Parties.
3. For the avoidance of doubt, the terms concerning Data and Analysis Data in this article 13 includes all data, regardless of the medium through which the data has been fixed. Recipient shall provide Provider with a confirmation of destruction and other measures within thirty (30) calendar days of the expiration or termination of this Agreement or otherwise instructed by Provider. Recipient shall have the right to retain such copies of Data and Analysis Data that are required in order for Recipient to comply with any applicable laws, rules and regulations.

## MISCELLANEOUS

1. Amendments and modifications

Any amendments or modifications to this Agreement must be made in writing, and signed on behalf of the Parties by their respective duly authorized representative(s), in order to be binding and effective. Changes to Appendix 1 may however be made in writing upon clear mutual agreement between the Parties, without the need of a signed formal amendment.

1. No partnership or agency

Nothing in this Agreement shall be deemed to constitute a joint venture, agency, partnership, or any other kind of formal business grouping or entity between the Parties, and shall in no way constitute a contract of employment.

1. Notices

All reports and notices or other communication required or desired to be given under this Agreement will be given in writing and delivered by person, or by registered mail addressed to the Party at its address first set above in this Agreement or such other address as the Party otherwise advice in writing.

1. No Waiver

No provision of this Agreement will be deemed waived or any breach excused unless such waiver or consent excusing the breach is in writing signed by the Party giving the waiver or consent. A waiver of a provision of this Agreement will not be construed to be a waiver of a subsequent breach of the same provision.

1. Assignment

The Parties shall not assign, transfer or sublicense its rights or obligations under this Agreement to any Third Party, in whole or part, without the prior written consent of the other Party.

1. Severability

If any provision in this Agreement becomes invalid, illegal or unenforceable, it shall not affect the validity of the remaining provisions of this Agreement. In such a case, the Parties shall be entitled to request that a valid and practicable provision be negotiated which fulfils the purpose of the original provision.

1. Governing law and dispute settlement

This Agreement shall be governed by the laws of Sweden. Any dispute, controversy or claim arising out of or in connection with this Agreement, or the breach, termination or invalidity thereof, shall be settled amicably through negotiations. If the Parties are unable to settle a dispute through negotiations, the dispute shall be referred to a public court in Sweden. If both Parties are governmental agencies of the Swedish state, the dispute shall instead be settled by a superior governmental body for final decision.

1. Appendices

The Appendixes forming an integral part of this Agreement are:

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

Appendix 2: Description of analyses, reporting and finance

Appendix 3: L2a1. AGREEMENT

Appendix 4: Personal Data Processing Agreement

The terms of Appendix 4 takes precedence over the terms of this Agreement and all of its appendices in case of conflict.

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| 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

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| 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 |
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*Add more rows if necessary*

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| 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: |

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| 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. |

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| 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, reporting and finance

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| 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.] |

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| 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.] |

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

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| Financial |
| The maximum amount fee for services will be [SEK/EUR] |
| Invoices and related documents are to be billed to:  [University]  [ref. no.]  [address]  Sweden |

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| 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, including its Appendixes.

Appendix 4: Personal Data Processing Agreement