**MATERIAL/DATA TRANSFER AGREEMENT**

 between

**Centre Hospitalier Universitaire Vaudois (“CHUV”)**

With an address at Rue du Bugnon 21, 1011 Lausanne, Switzerland

and

**[ ]**

With an address at [ ]

 **(“RECIPIENT**”)

Whereby the parties to this Agreement are also hereinafter collectively referred to as “Parties”.

**Preamble:**

The RECIPIENT [or the Parties] wish[es] to conduct a research project as set forth in Annex A of this Agreement, with the Material and/or Data (as defined below) made available by the PROVIDER. The PROVIDER is willing to provide such Material and/or Data to the RECIPIENT under the terms and conditions as follows hereafter.

**1. Definitions**

* 1. **"Material"** shall mean **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** *[please complete and define the types of material and/or samples]* as further described in Annex A if necessary original and starting material, namely, biological human samples such as blood sample, plasma, serum, biopsies, fluids previously obtained by CHUV from human subjects in the context of a clinical trial sponsored by CHUV (or sponsored by a third party with the consent for the reuse of such samples given by such third party) or in the context of patients‘ care or given on a voluntary basis from donors, including progeny and unmodified derivatives. The Material shall not include Modifications or other substances created by the RECIPIENT through the use of the Material that are not Modifications;
	2. **“Data and or Information relating to Material”** of CHUV shall mean **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** *[please complete the type and form of data and information]* namely the personal health related data and information (either coded, non-coded or anonymised) associated (or not) with the Material including but not limited to clinical data, genotype and genetic data, phenotype, interleukins, medical conclusions, recipes, statistical analysis, datasets;
	3. **"Modifications"** shall mean substances created by the RECIPIENT or at the RECIPIENT that contain or incorporate the Material (original Material, progeny or unmodified derivates) such as tissue engineered products that may contain viable or non-viable cells or tissues of human or animal origin or both and that may also contain additional substances such as biomaterials, scaffolds or matrices, or additional mutations in the DNA or deletions by RECIPIENT by whatever technical means of genes from the DNA of the Material, in addition to the selected mutation which resulting in a modified prototype displays a modified phenotype compared to the Material provided by CHUV under this Agreement;
	4. **“Raw data”** shall mean data generated by machine/lab analysis without interpretation. The following should be return to the PROVIDER: A copy of (1) the raw data files, (2) the Illumina GenomeStudio report and (3) the genotypes in a 'plink' format. The data files to transfer are: Intensity data (\*.idat), Lists the SNP ID and annotation (\*.bpm or \*.opa), Genotyping data from GenomeStudio (report, \*.csv), Genotyping data in plink format (\*.ped, \*.map), and, if available, Illumina cluster file (\*.egt). Genotyping data can be transferred to the SSRC by a password protected media, either CD/DVD or any private data download platform (FTP, own-cloud, HTTP);
	5. **“Research”** shall mean the project entitled **“[ ]”** as further described in Annex A, as approved by RECIPIENT's Ethics Committee and if applicable by CHUV’s Ethic Committee;
	6. “**Information”** shall mean all information other than Data and or Information relating to Material provided to RECIPIENT by CHUV.

**2. Object**

2.1 CHUV will provide RECIPIENT with the Material and/or Data and or Information relating to Material and/or Information (together “Material and Data”) for the Research and under the conditions as set up in this Agreement.

2.2 RECIPIENT and RECIPIENT’s employees or student working under the immediate control and supervision of the RECIPIENT’s principal investigator shall use the Material and Data solely for the Research; Material and Data will be maintained within the sole possession and control of RECIPIENT and his staff. Material and Data and Modifications will be stored in a secure location and will only be used in laboratory animals or *in vitro* experiments, will not be used in therapy involving humans and will not be disclosed, distributed, transferred or sold by RECIPIENT or his staff to any third party for any purposes whatsoever without the prior written agreement of CHUV. Furthermore, RECIPIENT shall not directly use the Material and Data in any manner for a commercial purpose.

**3. Compliance with Law, Rules and Regulations**

RECIPIENT agrees to comply with all rules, guidelines and regulations, including but not limited to the ICH-GCP regulations and guidelines, applicable to the Research and the handling, protection and use of the Material and/ Data. RECIPIENT assumes full responsibility for any claims or liabilities which may arise as a result of RECIPIENT’s use or possession of Material and Data. In no case shall the Material be used in humans. RECIPIENT recognizes that Material and Data shall be protected, and must be processed by RECIPIENT, with protection equivalent to the Federal Act on Research involving Human Beings (RS 810.30, HRA), with the Federal Act on Data Protection (RS 235.1, FADP) and with applicable cantonal law on data protection (RSV 172.65, LPrD) (HRA, FADP and LPrD together the “Swiss Data Protection Law”).

**4. Additional requirements for Data and Material Export**

4.1 Neither Party shall assign or subcontract the Research in whole or in part without the prior written consent of the other Party nor export Material and Data without CHUV’s prior written consent. CHUV may agree that RECIPIENT transfer the Material and Data and/or the results of the RECIPIENT’s analyses to a bona fide sub-contractor or affiliate of RECIPIENT provided that:

a) RECIPIENT warrants that the agreements between RECIPIENT and such permitted third parties contain provisions which (i) limit their use to the purpose of conducting the Research, and (ii) contain confidentiality obligations at least equal to those in the Agreement and (iii) comply with any legal requirement and that (iv) Material and Data are duly coded; and

b) RECIPIENT warrants that such export will fully comply with the relevant provisions of the Swiss Data Protection Law reported in Annex B, which constitutes an integral part of the Agreement.

4.2 RECIPIENT therefore undertakes, prior to any use or processing of Material and Data to take any appropriate technical and organizational measures as described in Annex C to protect such Material and Data from any unauthorized use in accordance with the Swiss Data Protection Law and any regulations applicable to the RECIPIENT.

**5. Grant back on derivative Data, Raw Data and Information**

RECIPIENT shall, in accordance with its established practice, keep complete and accurate accounts, notes, data and records of the Research. Upon completion of the Research, RECIPIENT shall disclose to CHUV any and all datasets and results obtained from conducting the Research or relating to the use of the Material and Data (hereinafter "Results") which disclosure shall include, without limitation, copies of relevant summaries and reports. CHUV may decide at its sole discretion to include the derivative datasets and information in CHUV databases and shall treat the Results in confidence to the same extent as for RECIPIENT under clause 7 of this Agreement.

**6. Ownership and Intellectual Property**

6.1 If the Research results in a discovery, an invention or Modifications, whether patentable or not, RECIPIENT shall not license or otherwise make any commercial use of any such discovery, invention or Modifications in the absence of an agreement to be negotiated in good faith by the Parties hereto, providing for, inter alia, the sharing of royalty income.

6.2 Nothing herein shall create or imply a license to RECIPIENT of any intellectual property rights to the Material and Data except for the right to use the Material and Data for the Research only, nor create or imply any obligation of CHUV to enter into any other agreement.

6.3 Neither Party shall use the name and logo of the other, or the name of any of its employees without the prior written approval of the other Party.

**7. Confidentiality Obligations**

7.1 Any Information that is identified as confidential at the time it is disclosed hereunder by CHUV to RECIPIENT (“Confidential Information”) shall be retained in confidence by RECIPIENT, and shall not be disclosed by RECIPIENT to anyone other than its employees working under its immediate control and supervision.

7.2 RECIPIENT'S obligations of non-disclosure and restricted use of Confidential Information shall become effective on the date of disclosure, shall apply to all Confidential Information and shall survive termination of this Agreement, provided that such obligations of non-disclosure and restricted use of Confidential Information shall not extend to Confidential Information disclosed to RECIPIENT by CHUV which:

a) is or becomes part of the public domain, through no action by RECIPIENT;

b) was in the possession of RECIPIENT at the time of disclosure and was not acquired from CHUV under an obligation of confidentiality;

c) was received by RECIPIENT from a third party not under an obligation of confidentiality with respect to such information;

d) is approved for public release by written authorization of CHUV;

e) RECIPIENT can demonstrate was independently developed by or for RECIPIENT without the use of Confidential Information.

f) is required to be disclosed by law or court order.

7.3 CHUV will maintain confidential any discovery, invention or Modifications and Results; in this regard the obligation of non-disclosure as indicated in article 7.2 will also apply to CHUV.

**8. Publications**

8.1 Any publication or other public disclosure, written or oral, concerning, relating to or derived from the Material and Data or their use shall first be provided by RECIPIENT to CHUV for review and comment no later than sixty days (60) prior to submission for publication or other disclosure, to ensure that Confidential Information of CHUV is not disclosed and that Data and or Information relating to Material are duly anonymized. CHUV’s approval may not be unreasonably withheld.

8.2 RECIPIENT agrees to acknowledge CHUV as the source of the Material and Data in all publications containing any Material and Data and Modifications that discloses or relates in any way to RECIPIENT'S use of the Material and Data unless otherwise agreed to by CHUV. It is also requested to cite the CHUV in the acknowledgment section.

8.3 The Parties may also decide that scientific publication are to be submitted jointly after completion of the Research, accommodating all authors of CHUV and RECIPIENT, taking into account individuals who made significant contributions to the Research. The number and scope of publications, co-authorship and order of authors shall be decided jointly based on scientific contributions of all parties concerned by the scientific publication in question, in accordance with academic standards and accepted practices.

**9. Transport**

If applicable, prior to CHUV’s shipment of any Material, RECIPIENT must provide written notice to CHUV that RECIPIENT has obtained an import license, including the import license number, and a copy thereof; or, if no license is required, a written statement that none is required. RECIPIENT is in charge of the transport fees and transport insurance.

**10. Liability and Absence of Warranties**

10.1 The Material provided to RECIPIENT may be experimental in nature, may have biological and/or chemical properties that are unpredictable and unknown at time of transfer, and are to be used in a safe manner and in accordance with all applicable governmental rules and regulations. The Material shall not be used in any project involving human subjects. The Material and Data are provided by CHUV "AS IS." CHUV MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, WITH RESPECT TO THE MATERIAL AND DATA AND EXPRESSLY DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY AND OF FITNESS FOR A PARTICULAR PURPOSE OR USE. CHUV DISCLAIMS ALL WARRANTIES OF NON-INFRINGEMENT WITH RESPECT TO ANY THIRD PARTY RIGHTS AND TITLE, INCLUDING PATENT RIGHTS, IN THE MATERIAL AND DATA.

10.2 RECIPIENT agrees to defend, indemnify and hold CHUV and its directors, trustees, employees and agents harmless from any claims, liabilities, damages and losses that might arise as a result of RECIPIENT'S use of the Material and Data except to the extent of gross negligence or willful misconduct on the part of CHUV.

**11. Termination**

Upon completion of the Research or in case of termination of this Agreement by CHUV, which may be communicated with immediate effect by certified mail to RECIPIENT for breach of this Agreement, RECIPIENT agrees to discontinue use of the Material and Data and will arrange for the return, at its charge, to CHUV or the destruction of the remaining Material and Data, according to the instructions of CHUV.

**12. Revocation**

Parties are aware that, if applicable, should the donor of any Material and Data decide to withdraw totally of partially his/her consent, CHUV shall inform RECIPIENT about such withdrawal and the relevant Material and or Data must immediately be anonymised by RECIPIENT, as instructed by CHUV. In case CHUV instructs RECIPIENT to destroy Material and Data, RECIPIENT shall send a written notification to CHUV that the relevant Material and Data have been destroyed.

**13. Assignment**

RECIPIENT shall not assign or delegate its obligations under this Agreement either in whole or in part without the prior written consent of CHUV.

**14. Modifications and Amendments**

This Agreement constitutes the entire agreement and understanding of the Parties and supersedes any prior agreements or understandings relating to the subject matter hereof. This agreement may not be modified except by a written instrument signed by all Parties.

**15. Governing Law and Jurisdiction**

This Agreement shall be governed by the laws of Switzerland. Any claim or controversy arising out of or related to this Agreement shall be submitted to the competent courts of Canton de Vaud, Switzerland.

This Agreement may be executed in one or more counterparts, each of which when executed and delivered will be deemed to be an original, but all of which taken together will constitute one and the same agreement. This Agreement will become effective when counterparts have been signed by each of the Parties and delivered by facsimile or other means to each other Party. This Agreement may be executed and delivered by facsimile or by .pdf file and upon such delivery the facsimile or .pdf signature will be deemed to have the same effect as if the original signature had been delivered to the other Party.

|  |  |
| --- | --- |
| **CHUV** | **RECIPIENT** |
| Date: | Date: |
| Signature | Signature |
| Name(Title) | Name(Title) |
| Signature | Signature |
| Name(Title) | Name(Title) |

**Annex A: Detailed descriptions**

**Material shall mean:**

[ ]

**Data and Information relating to Material shall mean:**

[ ]

**Research shall mean:**

[ ]

**Annex B**

**Federal Act on Data Protection (RS 235.1, FADP)**

**Art. 6 Cross-border disclosure**

1 Personal data may not be disclosed abroad if the privacy of the data subjects would be seriously endangered thereby, in particular due to the absence of legislation that guarantees adequate protection.

2 In the absence of legislation that guarantees adequate protection, personal data may be disclosed abroad only if:

a.

sufficient safeguards, in particular contractual clauses, ensure an adequate level of protection abroad;

b.

the data subject has consented in the specific case;

c.

the processing is directly connected with the conclusion or the performance of a contract and the personal data is that of a contractual party;

d.

disclosure is essential in the specific case in order either to safeguard an overriding public interest or for the establishment, exercise or enforcement of legal claims before the courts;

e.

disclosure is required in the specific case in order to protect the life or the physical integrity of the data subject;

f.

the data subject has made the data generally accessible and has not expressly prohibited its processing;

g.

disclosure is made within the same legal person or company or between legal persons or companies that are under the same management, provided those involved are subject to data protection rules that ensure an adequate level of protection.

3 The Federal Data Protection and Information Commissioner (the Commissioner, Art. 26) must be informed of the safeguards under paragraph 2 letter a and the data protection rules under paragraph 2 letter g. The Federal Council regulates the details of this duty to provide information.

**Federal Act on Research involving Human Beings (RS 810.30, HRA)**

**Art. 42 Export**

1 Biological material or genetic data may be exported for research purposes if informed consent has been given by the person concerned. For consent, Articles 16 and 22–24 and 32 apply *mutatis mutandis.*

2 Non-genetic health-related personal data may be disclosed abroad for research purposes if the requirements specified in Article 6 of the Federal Act of 19 June 1992 on Data Protection are met.

**Cantonal law on data protection (RSV 172.65, LPrD)**

**(non official English version)**

**Art. 17 Cross-border communication of data**

1 The communication to a third country of personal data undergoing processing or intended for processing may only take place if the third country in question ensures an adequate level of protection.

2 The preceding paragraph is not applicable:

if the data subject has given his or her consent, which must in any case be explicit;

if the communication of data is necessary for the performance of a contract between the data subject and the controller or for the performance of pre-contractual measures taken at the request of the data subject;

if the communication is necessary for the conclusion or performance of a contract concluded or to be concluded, in the interest of the data subject, between the controller and a third party;

if the disclosure is, in the present case, essential either to protect a public interest or to establish, exercise or defend a legal claim;

if the communication is, in the present case, necessary to protect the life or physical integrity of the person concerned;

if the communication is made from a public register which, by virtue of legal or regulatory provisions, is intended to inform the public or any person proving a legitimate interest, insofar as the legal conditions for consultation are fulfilled in the particular case;

if sufficient guarantees, in particular contractual guarantees, permit to ensure an adequate level of protection abroad.

**Annex C**

**Minimal Security Requirement**

RECIPIENT shall at least maintain technical and organisational measures that guarantee the confidentiality, integrity, availability and resilience of the systems with regard to processing of data. In particular, the RECIPIENT must:

* deny unauthorized persons access to facilities and data processing systems;
* prevent unauthorised persons from reading, copying, altering or deleting data in/from data processing systems;
* ensure that unauthorized persons are not able to read, copy, modify or remove data upon the electronic transfer of data as well as during the transport of data carriers or saving of data thereon;
* ensure that it is possible to examine and verify if, when and by whom data was entered into the data processing system or if, when and by whom data was modified or removed;
* ensure that data is protected from accidental destruction or loss;
* ensure that data received is not combined with other data unless explicitly authorized by the competent ethics commission for the specific research project;
* restrict the disclosure and handling of data to those persons who require it to conduct the specified research project and to be able to identify each of them;
* ensure adequate organisational measures to protect data, especially by selecting, instructing and supervising the persons involved in the processing of data diligently and appropriately, by implementing and enforcing adequate confidentiality and data protection guidelines, by running regular data protection and privacy trainings, and by documenting all the organisational measures;
* guarantee that the efficacy of technical and organisational measures is regularly reviewed and assessed.
* Implement corrective measures and automatic reporting in case of any suspected data security breach