MTA 2.0
MASTER LEGAL INSTRUMENT

FOR THE TRANSFER AND USE OF HUMAN BIOLOGICAL MATERIAL AND ASSOCIATED DATA IN SWITZERLAND

Upon execution of a project agreement (referred to as the "**Project Agreement**") in the form attached that specifies, among others, the research project and the human biological material and associated data to be transferred, the involved organizations agree to be bound by the terms of the MTA 2.0 – Master Legal Instrument (referred to as the "**Master Legal Instrument**").

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PREAMBLE

This Master Legal Instrument is supplemented by a Project Agreement.
Jointly, these two documents regulate the transfer and use of specific human biological material and associated data (referred to as the "**Original Biological Resources**") between organizations.
Any organization planning to sign a Project Agreement regulating the transfer of Original Biological Resources for a particular research project (referred to as the "**Research Project**") must agree to be bound by the terms of the Master Legal Instrument beforehand.
The organization providing the Original Biological Resources is referred to as the "**Provider**", and the organization receiving the Original Biological Resources is referred to as the "**Recipient**". They are also referred to individually as a "**Party**" or collectively as the "**Parties**".
The Project Agreement displays the options the organizations' project leaders (referred to as the "**Provider's / Recipient's Project Leader**") can select to meet the Research Project's particular needs.
When signing the Project Agreement, the Project Leaders, as well as their respective organizations, shall abide by all terms and conditions of this Master Legal Instrument.

The → PA symbol indicates a reference in the Project Agreement document.

DEFINITIONS

For the purpose of this Master Legal Instrument and the Project Agreement, capitalized terms, whether used in singular or plural form, shall have the following meaning:

Background Intellectual Property (Background IP) shall have the meaning set forth in **Article 5** of the Master Legal Instrument.

Coding means the processing of Original Biological Resources in such a manner that they can no longer be attributed to a specific Research Participant without the use of additional information, provided that such additional information is kept separately and is subject to technical and organizational measures to ensure that the Original Biological Resources are not attributed to an identified or identifiable natural person.

Associated Data include Preanalytical Data and Personal Data.

Biobank Regulation is a document that describes the biobank's organization and defines its purpose, governance and operational processes.

Effective Date means the date of last signing of the Project Agreement.

Foreground Intellectual Property (Foreground IP) shall have the meaning set forth in **Article 5** of the Master Legal Instrument.

Intellectual Property Rights means all legal rights granted with the aim to protect the creations of the intellect, registered or unregistered, now or hereafter in force or recognized, including trade secrets and know-how.

Modifications means any substances created by the Recipient, or the Recipient's co-partners, which contain or incorporate the Original Biological Material in whatever form.

Original Biological Material means any material obtained or derived from a biological organism, any Progeny and Unmodified Derivatives thereof, that are to be delivered by the Provider to the Recipient, as described in the Project Agreement.

Original Biological Resources means Original Biological Material and Associated Data that are to be transferred by the Provider to the Recipient, as described in the Project Agreement.

Personal Data means all information relating to an identified or identifiable person, including health-related data.

Preanalytical Data means any data related to the collection, handling, storage and usage of the Original Biological Material (e.g. collection time, transport temperature, centrifuge speed, storing temperature, etc.).

Processing means any operation or set of operations which is performed on Original Biological Resources, whether or not by automated means, such as collection, recording, organization, structuring, storage, adaptation or alteration, retrieval, consultation, use, handling, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction.

Progeny means unmodified descendant from the Original Biological Material, such as virus from virus, cell from cell, or organism from organism.

Provider means the organization providing the Original Biological Resources.

Provider's Project Leader means the Provider's person who takes responsibility for the project as described in the Ordinance on Human Research with the Exception of Clinical Trials of 20 September 2013.

Recipient means the organization receiving the Original Biological Resources.

Recipient's Project Leader means the Recipient's person who takes responsibility for the project as described in the Ordinance on Human Research with the Exception of Clinical Trials of 20 September 2013.

Research Participant means the natural person whose Biological Resources are processed.

Research Project means the project of research as set forth in the Project Agreement, as approved by the Ethics Committee, and for which the Original Biological Resources are transferred and processed.

Results means, without limitation, any output of the Research Project that are not Progeny or Unmodified Derivatives, such as invention, data, software, algorithms, knowledge, know-how or information that is generated in the Research Project, whatever its form or nature, whether or not it can be protected, as well as any rights attached to it, including Intellectual Property Rights.

Unmodified Derivatives means substances created by the Recipient, which constitute an unmodified functional subunit or product expressed by the Original Biological Material. Some examples include subclones of unmodified cell lines, purified or fractionated subsets of the Original Biological Material, proteins expressed by DNA/RNA supplied by Provider, or monoclonal antibodies secreted by a hybridoma cell line.

ARTICLE 1
RESEARCH PROJECT

1.1 **Scope.** → PA The Parties agree that the research to be conducted by the Recipient, through its Project Leader, with the Original Biological Resources is limited to the Research Project described in the Project Agreement.

The Original Biological Resources may not themselves be commercialized and are to be processed solely by the Recipient and the Recipient's co-partners[1], under the direction of the Recipient's Project Leader.

1.2 **Ethics Committee Approval.** → PA The Recipient and the Recipient's Project Leader acknowledge that the Research Project has to be reviewed and approved by the Ethics Committee in charge, as further described in the Project Agreement.

1.3 **Provider's Warranties.** The Provider warrants that it is entitled to supply the Original Biological Resources, and that such resources have been processed in compliance with all applicable laws, rules and regulations.

It is expressly agreed that the Provider does not warrant or guarantee that the Original Biological Resources will be either safe or accurate, complete, or useful for any particular purpose.

Furthermore, the Provider offers no warranty that the processing of Original Biological Resources and/or Modifications will not infringe or violate any patent or other proprietary rights of any third party.

ARTICLE 2
ORIGINAL BIOLOGICAL RESOURCES → PA

2.1 The Original Biological Resources include the Original Biological Material and Associated Data that are to be transferred for the Research Project.

2.2 The Original Biological Resources are further described in the Project Agreement.

ARTICLE 3
TRANSFER → PA

3.1 **Confidentiality.** The Provider shall provide the Recipient with Original Biological Resources in a coded form, as described in the Project Agreement. The recipient shall not have the key.

3.2 **Insurance.** The Recipient shall be in charge of the transport insurance.

ARTICLE 4
PROCESSING

4.1 **Due Care.** The Recipient and the Recipient's Project Leader are aware that the Original Biological Material and its Progeny are experimental in nature and may have hazardous properties or contain infectious agents, and must therefore be handled with all due care to avoid the propagation of infectious agents.

4.2 **Limitations**. → PA The Original Biological Resources will be processed only (i) under the conditions, if any, specified by the Provider's Project Leader in the Project Agreement, and (ii) as provided for by law.

The Recipient and the Recipient's authorized users shall not (i) provide any Results to third party, except as expressly permitted in this Agreement; or (ii) sell, lease, sublicense, copy or provide the Biological Resources to any third party, except as expressly permitted in this Agreement.

It is expressly understood that the Original Biological Material and Modifications as such may not be used for therapeutic purpose in humans.

Furthermore, the Parties agree that the Original Biological Resources shall not be transferred to or accessed by any third party, for any purposes whatsoever, without the prior written agreement of the Provider and in compliance with the Research Participant's informed consent.

4.3 **Security.** → PA The Recipient shall process the Original Biological Resources and Modifications in a manner that ensures an appropriate level of security, including protection against unauthorized or unlawful access or processing and against accidental loss, destruction or damage, through appropriate organizational and technical measures as described in the Project Agreement and aligned with the Biobank Regulation.

Secure Original Biological Resources and Modifications access shall be guaranteed at all stages of the process.

The Recipient agrees to immediately report (i) any actual or suspected data protection breach, including a breach against applicable data protection regulation or data protection aspects of this Agreement, (ii) any actual or suspected impairment or inadequacy of the Recipient in fulfilling data protection requirements of this Agreement, and (iii) any application to receive, or any actual access to, data by an authority, unless such reporting is not admissible under statutory provisions for important reasons of public interest.

ARTICLE 5
INTELLECTUAL PROPERTY RIGHTS

5.1 **Background IP**. The Parties agree that each Party shall retain all the right, title and interest in and to its respective Intellectual Property Rights, as of the Effective Date (referred to as the "**Background IP**"). Unless otherwise

[1] To be listed in the Project Agreement (if applicable)

agreed, nothing in this Master Legal Instrument or Project Agreement shall be construed as a transfer, license, and/or assignment by a Party to the other Party of ownership of, right, title and interest in and to its respective Background IP.

5.2 **Foreground IP**. → PA All the right, Intellectual Property Rights, title and interest in and to the Results (referred to as the "**Foreground IP**") are set forth in the Project Agreement.

ARTICLE 6
RESEARCH PARTICIPANT'S RIGHTS

6.1 **Fundamental Rights**. The Provider and the Recipient warrant to each other that they will protect, in their respective areas of responsibility under applicable law and both the Master Legal Instrument and the Project Agreement, the personality and the fundamental rights of the Research Participants, including (i) the protection of privacy and (ii) the right to autonomy and informational self-determination.

6.2 **Withdrawal of Consent**. In case of Research Participant's full or partial withdrawal of consent, the Provider shall inform the Recipient of such a withdrawal in writing, without delay. Upon notification, the Recipient shall stop using the Research Participant's Original Biological Resources.

Furthermore, according to the Research Participant's choice as reported by the Provider, the Recipient shall immediately either anonymize or destroy at its own cost all the Original Biological Material and Data for which consent was withdrawn, and shall notify the Provider in writing upon anonymization or destruction.

6.3 **No Re-Identification**. The Recipient shall refrain from tracing or identifying any Research Participant who provided the Original Biological Resources.

ARTICLE 7
LIABILITY AND INDEMNIFICATION

7.1 Each Party shall be liable to, and indemnify, the other Party for actual costs, charges, damages, expenses or losses suffered by the other Party resulting from any of the first Party's violation of this Master Legal Instrument and/or of the Project Agreement.

7.2 The Recipient shall assume all and any liability, and shall hold harmless the Provider for any loss, claim, damage of whatsoever kind or nature, which could be raised by the Recipient, or made against the Recipient by any third party, due to, or in connection with, the Recipient's processing of the Original Biological Resources and Modifications, except to the extent caused by the Provider's gross negligence or willful misconduct.

7.3 The Parties shall use the Foreground IP at their own risk. A Party using any of the Foreground IP shall, to the fullest extent permitted by the applicable law, defend, indemnify and hold the other Party harmless against third party claims (including but not limited to claims based on mandatory product liability law), which are based on the Party's use of the Foreground IP.

ARTICLE 8
EXPIRATION AND TERMINATION

8.1 **Expiration**. The Project Agreement will automatically expire: (i) on completion of the Research Project it describes; or (ii) three (3) years from the Effective Date, unless the Project Agreement is extended in writing. It is the responsibility of the Recipient's Project Leader to seek such an extension.

8.2 **Termination**. Either Party may terminate the Project Agreement at any time giving a thirty (30) -day prior written notice to the other Party, stating one of the following grounds:

- if the Recipient ceases, is likely to cease, or threatens to cease carrying on business;
- in case the other Party is in material breach of this Master Legal Instrument and/or the Project Agreement, and has not remedied such a breach by the end of the notice period.

8.3 **Consequences**. On expiration or termination of the Project Agreement for any reason, the grant of rights to the Recipient, the Recipient's Project Leader, and the Recipient's co-partners under the Master Legal Instrument and the Project Agreement will be automatically terminated.

In such cases, the Recipient and the Recipient's Project Leader agree to discontinue any processing of the Original Biological Resources. In accordance with the Provider's directions, the Recipient and the Recipient's Project Leader shall immediately, and at their own cost, return or destroy the Original Biological Resources, including any remaining Original Biological Material, and shall notify the Provider in writing upon destruction.

The Recipient and the Recipient's Project Leader ensure that their co-partners abide by the above rules.

8.4 **Survival Clauses**. The provisions concerning publications, Intellectual Property Rights, due care, warranties, liability, and indemnification as well as those intended to protect the Research Participants' rights, shall survive the Project Agreement expiration or termination.

ARTICLE 9
AMENDMENTS AND SEVERABILITY CLAUSE

9.1 **Amendments**. This Master Legal Instrument and the Project Agreement constitute the entire agreement and understanding of the Parties and supersede any prior agreements or understandings relating to the subject matter hereof. They may not be modified, except by a written instrument signed by all Parties.

9.2 **Severability**. In the event any provision of this Master Legal Instrument and/or of the Project Agreement is deemed invalid or unenforceable, in whole or in part, that part shall be severed from the remainder of the Master Legal Instrument and/or the Project Agreement and all other provisions should continue in full force and effect as valid and enforceable. In such event, a valid provision that comes closest to the intended purpose of the unenforceable or invalid provision shall be agreed to replace it.