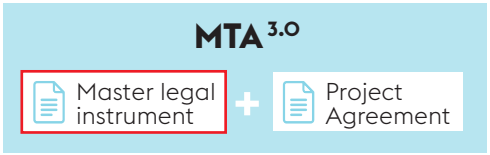

MTA 3.0 MASTER LEGAL INSTRUMENT

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**") referencing this MTA 3.0 – Master Legal Instrument (referred to as the "**Master Legal Instrument**") 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 hereof.

SWISS BIOBANKING PLATFORM
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DEVELOPED BY SWISS BIOBANKING PLATFORM

TABLE OF CONTENT

PREAMBLE

This Master Legal Instrument is only valid if supplemented by a Project Agreement.

When signing the Project Agreement, the Parties shall abide by all terms and conditions of this Master Legal Instrument, except for deviations expressly agreed in the Project Agreement

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

DEFINITIONS

For the purpose of the Agreement, capitalized terms, whether used in singular or plural form, shall have the following meaning:

Associated Data means collectively the Preanalytical Data and, if any (as specified in the Project Agreement) the Personal Data.

Agreement means collectively this Master Legal Instrument and the Project Agreement.

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

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

Biological Resources means collectively the Original Biological Resources and Modifications.

Coded means Personal Data and Original Biological Resources linked to a specific person via a code.

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

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

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

Modifications means any substances created by the Recipient, or the Recipient's Subcontractors, 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, excluding Modifications.

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.

Party means each of the Provider and the Recipient and Parties means both collectively.

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.).

Project Leader means, for each Party, the individual designated by it under the Project Agreement who shall have the role described in the Master Legal Instrument.

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 as specified in the Project Agreement.

Recipient means the organization receiving the Original Biological Resources as specified in the Project Agreement.

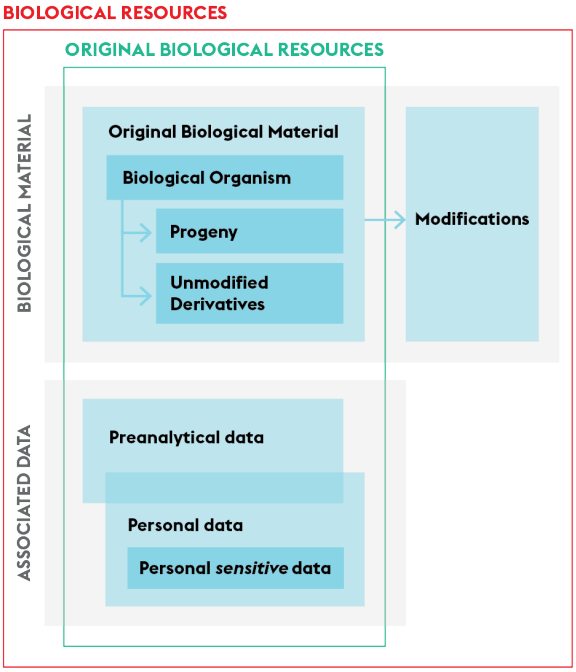
Recipient's Subcontractors means third parties listed in the Project Agreement which are authorized by the Recipient to use and process the Biological Resources.

Research Participant means the natural person whose Biological Resources are processed (often equally referred to as "data subject").

Research Project means the research project sets 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, Modifications and any other 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.** The Provider will provide, and the Recipient shall use, the Original Biological Resources only for conducting the Research Project and under the conditions set forth in the Agreement.

1.2 **Ethics Committee Approval.** The Recipient undertakes to obtain any required approval from the competent ethic committee prior to using the Original Biological Resource as part of the Research Project, 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 by it in compliance with all applicable laws, rules and regulations.

The Provider does not warrant or guarantee that the 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 Biological Resources will not infringe or violate any patent or other proprietary rights of any third party.

ARTICLE 2
PROJECT LEADERS → PA

2.1 **Appointment**. Each Party shall act for all aspects pertaining to the Research Project through its Project Leader designated in the Project Agreement, who shall have the power to represent and bind the Parties, and who shall act as main contact point within their organization.

The Recipient's Research Project shall be the person within the Recipient's organization who takes responsibility for the Research Project, as described in the Ordinance on Human Research with the Exception of Clinical Trials of 20 September 2013.

2.2 **Replacement**. Each Party may replace its Project Leader from time to time by written notice to the other.

ARTICLE 3
TRANSFER → PA

3.1 **Form**. The Provider shall provide the Recipient with Original Biological Resources **in a Coded form**, as described in the Project Agreement. To be considered Coded, the Original Biological Resources shall not be attributed to a specific Research Participant without the use of additional information (key), which shall be kept separately in a secure manner. The Recipient shall not have access to the key.

3.2 **Transport, Insurance and Risks.** Unless otherwise specified in the Project Agreement, the Recipient shall assume all risks and costs for the transport of the Original Biological Materials and shall pay appropriate insurance coverage for their transport.

ARTICLE 4
PROCESSING → PA

4.1 **Due Care.** The Recipient and the Recipient's Project Leader are aware that the Original Biological Materials (including 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**. The Recipient undertakes to use and process the Original Biological Resources under the direction and direct supervision of the Recipient's Project Leader:

- only in and from Switzerland through (i) its own researchers and (ii) any Recipient's Subcontractor(s) designated in the Project Agreement;
- for the sole purpose of, and only as required for, the completion of the Research Project (to the exclusion of any other research, commercial or noncommercial purpose);
- in accordance with all applicable laws; and
- under any additional conditions, if any, specified in the Project Agreement,

In addition, the Recipient and the Recipient's authorized users shall not:

- use the Original Biological Material as such for therapeutic purpose in humans.
- provide any Results to third parties except as expressly permitted in the Agreement; or
- sell, lease, sublicense, copy, transfer, make available or provide the Biological Resources to any third party for any purposes whatsoever, except as expressly permitted in the Agreement.

4.3 **Modifications**. All limitations stated in Article 4.2 above shall also apply to Modifications, unless otherwise specified in the Project Agreement.

4.4 **Personal data**. Each Party shall process Personal Data under this Agreement in compliance with applicable data protection laws. Each Party represents and warrants that any Personal Data of Research Participants required for use in the Research Project that are obtained, handled or used by it will be obtained, handled or used in accordance with all relevant laws and regulations (and where applicable, ethical guidelines) regarding their collection, use, and subsequent disposal and that any ethics committee approvals and, as the case may be, informed consents required for performing the Research Project will be obtained prior to the use in the Research Project. The Personal Data shall not be kept by the Recipient longer than necessary for the purpose of the Research Project, and the Personal Data processing must be limited to the purpose pursued, provided that the Research Participant does not decide otherwise.

4.5 **Security**. The Recipient shall use and process the Biological Resources 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 if the Recipient is a biobank aligned with its Biobank Regulation.

In particular, secure access to the Biological Resources shall be guaranteed at all stages of the process.

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

4.6 **Compliance**. The Recipient shall have in place procedures so that any person it authorizes to use and process the Biological Resources, including the Recipient Project Leader and the Recipient's Subcontractors, comply with the terms of the Agreement and maintain the confidentiality and security of the Biological Resources. The Recipient is responsible for their acts in the performance of this Agreement.

ARTICLE 5
INTELLECTUAL PROPERTY RIGHTS →PA

5.1 **Background IP.** 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 agreed, nothing in this Master Legal Instrument or any 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.** Ownership in, and license to, the Intellectual Property Rights in and to the Results (referred to as the "**Foreground IP**") shall be as set forth in the Project Agreement.

ARTICLE 6
DISCLOSURE OF RESULTS AND PUBLICATIONS →PA[1]

6.1 **Information about Results.** The Recipient's Project Leader agrees to keep complete and accurate accounts, notes, data and records of the Research Project.

Upon completion of the Research Project or on the Provider's Project Leader request, the Recipient's Project Leader will disclose to the Provider's Project Leader all Results obtained from conducting the Research Project, which relate to the processing of the Biological Resources including, without limitation, copies of relevant summaries and reports. The Provider's Project Leader agrees to keep these Results confidential until publication.

6.2 **Publication of Results.** As the main purpose of the Original Biological Resources' use is scientific research, the Recipient shall ensure that its Project Leader make every effort to publish its Results in a timely manner.

6.3 **Provider's Project Leader Review.** The Recipient's Project Leader shall be free to disclose and publish the Results, provided the proposed disclosure is submitted to the Provider's Project Leader for review at least thirty (30) days prior to the scheduled submission for publication or disclosure.

The Provider shall have the right to provide comments on the manuscript no later than 15 days before the proposed submission. The Parties shall discuss in good faith to incorporate any reasonable comments into the publication or disclosure.

Failure to respond within the above-mentioned periods is considered as approval of the publication by the Provider.

6.4 **Acknowledgement**. The Recipient shall acknowledge the Provider's Project Leader as the co-author of the publication, and/or to acknowledge the Provider as the source of the Original Biological Resources in all written publications, posters or oral presentations. This applies to any publication on Biological Resources that discloses or relates in any way to the Recipient's processing of the Biological Resources, unless otherwise agreed in writing by the Parties.

ARTICLE 7
RESEARCH PARTICIPANT'S RIGHTS

7.1 **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 the Agreement, the personality and the fundamental rights of the Research Participants, including (i) the protection of personality rights and (ii) the right to autonomy and informational self-determination.

7.2 **Rights of the Research Participants**. The Provider shall secure the exercise of the Research Participants' rights. The Parties shall respond to requests from the Research Participants within one month after having received the notification.

7.3 **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. In such case, in accordance with Art. 10 HRO[2], the Recipient shall – after data evaluation has been completed – immediately stop using the Biological Resources and either (at the option of the Provider) anonymize or destroy them at its own costs, and shall notify the Provider in writing upon anonymization or destruction.

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1 Note : this Article will not apply in case the Parties have executed a DTUA (See Article 11.2 below)

2 Human Research Ordinance (RS 810.301)

7.4 **No Re-Identification**. The Recipient shall refrain from tracing or identifying any Research Participant whose Biological Resources relate to.

ARTICLE 8
FEES AND COSTS → PA

Unless otherwise specified in the Project Agreement: (i) no fee shall be due by a Party to the other under this Agreement; and (ii) each Party shall bear its own costs associated with this Agreement.

ARTICLE 9
LIABILITY AND INDEMNIFICATION

9.1 **In General**. Subject to Articles 9.2 and 9.3 below, the Parties assume no liability for any damages, including but not limited to any indirect or consequential loss or similar damage (e.g. loss of profit, loss of revenue or loss of contracts) suffered in connection with the Agreement, provided such damage was not caused by a willful intent or act of gross negligence.

9.2 **Use of Biological Resources.** Except to the extent prohibited by law, the Recipient assumes all liability for damages that may arise from its use, storage or disposal of the Biological Resources. The Provider will not be liable to the Recipient for any loss, claim or demand made by the Recipient, or made against the Recipient by any other party, due to or arising from the use of the Biological Resources by the Recipient, except when caused by the gross negligence or willful misconduct of the Provider or breach of its warranties in Article 1.3 of this Master Legal Instrument.

9.3 **Use of Foreground IP or Results**. The Parties shall use the Foreground IP and Results at their own risk. A Party using any of the Foreground IP or Results shall, to the fullest extent permitted by 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 or Results.

ARTICLE 10
EXPIRATION AND TERMINATION → PA

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

10.2 **Termination**. Either Party may terminate the Project Agreement:

- without cause at any time with a 3-month prior written notice to the other Party; or
- for cause in case the other Party is in material breach of the Agreement, and such breach is either incapable of remedy or has not been remedied within a 30-day notice period.

10.3 **Consequences**. On expiration or termination of the Project Agreement for any reason:

- **Original Biological Resources:** the right for the Recipient to process and use the Original Biological Resources shall be automatically terminated. In accordance with the Provider's directions, the Recipient shall immediately, and at its own cost, return or destroy the Original Biological Resources and shall notify the Provider in writing upon destruction.
- **Modifications:** unless otherwise specified in the Project Agreement, the right for the Recipient to process and use the Modifications shall also be automatically terminated and the Recipient shall immediately, and at its own cost, destroy the Modifications and shall notify the Provider in writing upon destruction.

10.4 **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 expiration or termination of the Agreement.

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ARTICLE 11
MISCELLANEOUS → PA

11.1 **Entire Agreement and Hierarchy**. Subject to Article 11.2, the Agreement, including this Master Legal Instrument and the Project Agreement (together with any document referenced therein or schedule attached thereto) constitute the entire agreement and understanding of the Parties and supersede any prior agreements or understandings relating to the subject matter hereof. In case of conflict or discrepancy, the Project Agreement shall prevail over the Master Legal Agreement.

11.2 **Ad hoc DTUA.** If the Parties have executed for the same Research Project a *Data Transfer And Use Agreement* ("**DTUA**") based on the template provided by SPHN, the Parties agree that:

- the definition of (Original) Biological Resources in this Master Legal Instrument shall be deemed to refer only to (Original) Biological Material, excluding any Associated Data;
- all aspects pertaining to the processing of Associated Data (which include both Preanalytical Data and Personal Data) shall be governed by the DTUA and the provision of the Agreement shall not apply to the Associated Data; and
- Article 6 (Disclosure of Results and Publications) of this Master Legal Instrument shall not apply and be replaced entirely by the provisions of the DTUA, which for clarity shall be deemed to cover Modifications and any other output of the Research Project that are not Progeny or Unmodified Derivatives.

11.3 **Amendments.** The Agreement may not be modified, except by a written instrument signed by all Parties.

11.4 **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.

11.5 **Electronic Form.** An original signature or a copy thereof, including a "portable document format" or PDF copy, or a signature generated by industry standard electronic signature software (e.g. Docusign), which is transmitted by email shall constitute an original signature for purposes of the Agreement and shall have the same legal force and effect as the exchange of original signatures; while the term "in writing" shall include communications by email or other electronic forms.

11.6 **Governing Law and Dispute Resolution.** Unless otherwise specified in the Project Agreement, the Agreement shall be governed by Swiss laws, excluding it conflict of laws provisions and any dispute arising out of or related to the Agreement shall be submitted to the competent courts at the registered office of the Provider.