**MTA 3.0
Project Agreement**

This MTA 3.0 – Project Agreement (referred to as the “**Project Agreement**” or “**PA**”) supplements the MTA 3.0 – Master Legal Instrument available at [INSERT URL] (referred to as the “**Master Legal Instrument**” or “**MLI**”).

This Project Agreement is made and entered into as of the last date signed below (referred to as the “**Effective Date**”)

Between

**[The organization referenced as “Provider” below]**

(referred to as the “Provider”)

and

**[The organization referenced as “Recipient” below]**

(referred to as the “Recipient”)

(Referred to individually as a “Party” or collectively as the “Parties”)

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**PREAMBLE**

The purpose of this Project Agreement is to describe the Research Project for which the Original Biological Resources are transferred, to provide a record of those Original Biological Resources and of the transfer conditions, and to set forth any restrictions of processing and required security measures.

It is completed by the Master Legal Instrument, containing the legal terms that will govern the rights and obligations of the Parties, including the rights to exploit the results generated during the Research Project. The terms of the Master Legal Instrument will apply unless a deviation is specified in this Project Agreement (see Article 7).

The → MLI symbol indicates a reference in the Master Legal Instrument document.

Jointly, the Project Agreement and the Master Legal Instrument form an agreement (referred to as the “Agreement”) binding on the Parties which regulates the transfer and use of specific human biological material and associated data (referred to as the “Original Biological Resources”, as further defined in the MLI) between the Parties.

The Project Agreement may be filled in by the Parties' Project Leaders, but must be signed by representatives of the Parties duly authorized to sign on behalf of the respective Party.

If not otherwise defined in this Project Agreement, capitalized terms contained herein have the meaning given to them in the Master Legal Instrument.

# PARTIES AND PROJECT LEADERS → MLI

|  |  |
| --- | --- |
| Provider Name and Address |  |
| Provider's Project Leader Name and Contact Details |  |
| Recipient’s Name and Address |  |
| Recipient’s Project Leader Name and Contact Details |  |

# RESEARCH PROJECT DESCRIPTION → MLI

|  |  |
| --- | --- |
| Research Project Name |  |
| Research Project Summary |  |
| Recipent's Lab(s) involved with the Research Project |  |
| Recipient’s Auhtorized Subcontractors(who will be authorized to access and use the Biological Resources)  |  |
| Research Project Dates:Starting DateEnd DateTotal Duration |  |
| Methods Planned to be Used |  |
| Ethical Committee Approval:Name of the Ethical CommitteeApproval NumberDate |  |
| The Parties have already executed (or will concomitantly execute) for the Research Project a Data Transfer And Use Agreement (“DTUA”) based on the [template provided by SPHN](https://sphn.ch/services/dtua/). |  [ ]  YESAgreement reference: Important note. If “YES” is ticked, then in particular all aspects pertaining to the processing of Associated Data (which include both Preanalytical Data and Personal Data) will be governed by the DTUA and not this Agreement (see Article 11.2 of the Master Legal Instrument).  |

# ORIGINAL BIOLOGICAL RESOURCES → MLI

Description of Original Biological Resources, including Original Biological Material and Associated Data:

|  |  |
| --- | --- |
| Original Biological Material |  |
| Preanalytical Data (e.g. collection time, transport temperature, centrifuge speed, storing temperature, etc.) |  |
| Personal Data (data relating to individuals, including if transmitted in a coded form) | [ ]  YESDescription: Important note. If no Personal Data is processed or otherwise made available under the Agreement, then Article 4.3 of the Master Legal Instrument and all other provisions therein pertaining to Personal Data shall not apply.  |

# TRANSFER → MLI

## Means of transfer

[Describe how the Orignal Biologicial Resources must be provided to the Recipient]

## Organizational and technical measures implemented to protect the Original Biological Resources during transfer:

[insert description]

## Insurance coverage for the transport of the Biological Materials:

Specify wo shall:

Assume all risks and costs for the transport of the Original Biological Materials?

[ ]  Provider

[ ]  Recipient

 Pay for appropriate insurance coverage for the transport?

 [ ]  Provider

 [ ]  Recipient

# FEES

|  |
| --- |
| Fees for Original Biological Material Preparation and/or Transfer |
| Collection |  |
| Handling |  |
| Storage |  |
| Other (specify) |  |

|  |
| --- |
| **Fees for Distribution** |
| Transport |  |
| Other (specify) |  |

|  |
| --- |
| **Total Fee amount** |
| Total |  |

|  |
| --- |
| **Accounting Data and Payment Terms** |
| Bank |  |
| Account holder |  |
| Account holder address |  |
| Bank location |  |
| IBAN |  |
| Swift/BIC |  |
| Currency |  |
| Payment Terms | Invoice is payable within [30 (thirty)] calendar days upon receipt. For late payment a monthly interest of % will be charged. |

# PROCESSING → MLI

[ ]  [**optional] Further Limitations or Authorization of Processing.**

**Note**: The Master Legal Instrument limits how the Recipient is authorized to process the Original Biological Material (Article 4.2 MLI) and the Modifications (Article 4.3 MLI), in particular by requiring that they are only processed in Switzerland to perform the Research Project. You may specify here additional specifications or restrictions of processing.

 Deviation to Art. 4.2 MLI (Processing of Original Biological Material)

 [include here Description]

Deviation to Art. 4.3 MLI (Processing of Modifications)

[include here Description]

## Security

The Recipient shall implement the following organizational and technical measures to ensure the security of Original Biological Resources and Modifications:

→ If any measure listed below is not implemented, the Recipient should provide a justification in the right-hand column.

### Biological Material

|  |  |
| --- | --- |
| **Access to the facilities where samples are kept is secured and controlled with the following measures:** | **Justification for deviation** |
|[ ]  locked equipment |  |
|[ ]  restricted access |  |
|[ ]  signature at the entrance  |  |
|[ ]  others [specify] |  |
|[ ]  The temperature of the storage equipment is under surveillance 24/7. |  |
| **Measures in place to ensure the protection of samples are:** |
|[ ]  central alarm  |  |
|[ ]  monitoring temperature  |  |
|[ ]  backup freezer |  |
|[ ]  backup CO2 air conditioner |  |
|[ ]  room temperature monitoring  |  |
|[ ]  locked freezers |  |

### Associated Data

Note: This section should not be filed if a DTUA is executed for the same Project Agreement (box “yes” ticked in Article 2 above).

The Recipient shall at least maintain technical and organizational measures that guarantee the confidentiality, integrity, availability and resilience of the systems with regard to processing of Associated Data.

|  |  |
| --- | --- |
| **In particular, the Recipient must:** | **Justification for deviation** |
|[ ]  deny unauthorized persons access to facilities and data processing systems; |  |
|[ ]  prevent unauthorized persons from reading, copying, altering or deleting data in/from data processing |  |
|[ ]  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 and 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 Committee 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 organizational 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 organizational measures; |  |
|[ ]  guarantee that the efficacy of technical and organizational measures is regularly reviewed and assessed. |  |
|[ ]  implement corrective measures and automatic reporting in case of any suspected data security breach. |  |

# LEGAL ASPECTS

## REQUIRED: Ownership and License of Foreground IP [Select only one of five options]

Note: In this Agreement “Foreground IP” refers to all the Intellectual Property Rights in and to the Results (such as Modifications and any other output of the Research Project that are not Progeny or Unmodified Derivatives).

|  |  |
| --- | --- |
| [ ]  Option 1 | **The Parties have executed a DTUA and want to apply the mechanism specified in the DTUA.**Any Foreground IP generated in the context of this Agreement (including Modifications) will be governed by the rules specified in the DTUA, applicable mutatis mutandis. |
| [ ]  Option 2 | **The Recipient owns all Foreground IP, no license is granted to the Provider** |
| [ ]  Option 3 | **The Recipient owns all Foreground IP, but a license is granted to the Provider**The Recipient hereby grants to the Provider a royalty-free, worldwide, non-transferrable, non-exclusive, irrevocable license to access and use Foreground IP for purpose of internal scientific research only. |
| [ ]  Option 4 | **The Recipient and the Provider Jointly Own all Foreground IP**The Recipient and the Provider will set forth, by separate mutual agreement, their respective rights, duties and responsibility relating to the Joint Foreground IP. Such an agreement shall not cause a delay that contravenes Article 6 of the Master Legal Instrument. |
| [ ]  Option 5 | **The Parties opt for another legal regime:** [include here legal terms] |

## OPTIONAL: Royalties [Select only one of three options]

|  |  |
| --- | --- |
| [ ]  Option 1 | The Parties have executed a DTUA and want to apply the mechanism specified in the DTUA. |
| [ ]  Option 2 | The Recipient will pay to the Provider [a fair share of or [...]% on] any net revenues received by the Recipient for the commercialization of the Foreground IP. |
| [ ]  Option 3 | No fees or royalties shall be due by the Recipient to the Provider in connection with the use and commercialization of the Foreground IP. |

## OPTIONAL: Governing Law and Dispute Resolution [Select only if you want to deviate from Article 11.6 of the MLI]

|  |  |
| --- | --- |
| [ ]  Governing Law | The Agreement shall be governed by the laws of [country] |
| [ ]  Dispute Resolutions | Any dispute arising out of or related to the Agreement shall be exclusively resolved as follows:[insert description] |

## OPTIONAL: Other deviations from the Master Legal Instrument [this must only be filled in if you want to agree on deviations from the terms of the MLI]

|  |  |
| --- | --- |
| **Clause** | **Deviation**  |
| [Insert ref to clause to be deviated from] | [include here legal terms] |
| [Insert ref to clause to be deviated from] | [include here legal terms] |

## OPTIONAL: Additional Terms [this must only be filled in if you want to agree on additional terms]

|  |
| --- |
| [include here legal terms] |
| [include here legal terms] |

**SIGNATURES**

By signing this Project Agreement, the Parties enter into a binding legal Agreement governed by this Project Agreement, any schedule referenced herein and the Master Legal Instrument.

|  |  |
| --- | --- |
| **PROVIDER***Duly Authorized Representative* | **PROVIDER***Duly Authorized Representative* |
|  |  |
| Signature | Signature |
|  |  |
| Name & Title | Name & Title |
|  |  |
| Date | Date |

|  |  |
| --- | --- |
| **RECIPIENT***Duly Authorized Representative* | **RECIPIENT***Duly Authorized Representative* |
|  |  |
| Signature | Signature |
|  |  |
| Name & Title | Name & Title |
|  |  |
| Date | Date |