

INTRODUCTION

This Material Transfer Agreement (MTA) template governs the transfer and use of human biological material and associated data that is made available by a provider to a non-profit third party that wishes to use this research material and data for its own research purpose. This template is intended to be used by Swiss Biobanking Platform (SBP) partners which work in compliance with the governance principles issued from applicable ethical and legal requirements and which follow professional biobanking standards as stated in their Biobank Regulation. The use of this template is limited to the exchange between academic institutions and is not suitable for the exchange between for-profit organizations.

A MTA must be concluded between legal entities, which are to be bound by the contractual provisions, not between individual scientists involved in the transfer and the related research, since they might not be able to guarantee the implementation of the contractual obligations.

In the majority of instances this template will be suitable without making adaptation. Marked fields have to be completed. In certain settings, modifications will be necessary. In case of need, specific legal advice should be sought.

The template is intended to facilitate the exchange of human biological material and data within Switzerland.

In the event of additional questions please contact SBP. General questions: info@swissbiobanking.ch or www.swissbiobanking.ch Specific questions on MTA: selina.verardi@swissbiobanking.ch

Swiss Biobanking Platform

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FOR THE TRANSFER AND USE OF BIOLOGICAL MATERIAL AND ASSOCIATED DATA

between

[NAME OF PROVIDER ORGANIZATION] ("PROVIDER") [Address of Provider Organization]

and

[NAME OF RECIPIENT ORGANIZATION] ("RECIPIENT") [Address of Recipient Organization]

Provider Authorized Signature(s) (Legally Authorized by Organization) **Recipient Authorized Signature(s)** (Legally Authorized by Organization)

Signature

Name & Title

Date

Provider Authorized Signature(s) (Biobank Responsible Person of Organization) **Recipient Authorized Signature(s)** (Responsible Scientist of Organization)

Signature

Signature

Signature

Name & Title

Date

Name & Title

Name & Title

Date

Date



DEVELOPED BY SWISS BIOBANKING PLATFORM

PROVIDER AND RECIPIENT AGREE AS FOLLOWS:

PREAMBLE

RECIPIENT wishes to conduct RESEARCH with ORIGI-NAL MATERIAL and DATA.

PROVIDER is willing to provide ORIGINAL MATERIAL and DATA to RECIPIENT under the terms and conditions as follows hereafter.

The effective date of this Agreement is the date of the last required signature obtained.

The biological material and data as described in Appendix 1 will be delivered by PROVIDER to RECIPIENT under the terms of this Agreement.

() DEFINITIONS

The following definitions shall apply herein:

DATA

Data provided by PROVIDER to RECIPIENT related to ORIGINAL MATERIAL as described in Appendix 1.

MATERIAL

ORIGINAL MATERIAL, any PROGENY and UNMOD-IFIED DERIVATIVES thereof, the ORIGINAL MATERIAL contained in MODIFICATIONS and DATA related to ORIGINAL MATERIAL.

MODIFICATIONS

Substances created by RECIPIENT which contain/incorporate the MATERIAL in whatever form.

ORIGINAL MATERIAL

Biological material that is to be delivered by PROVIDER to RECIPIENT as described in Appendix 1.

PROGENY

Unmodified descendant from the ORIGINAL MATERIAL, such as virus from virus, cell from cell, or organism from organism.

PROVIDER

Provider organization.

RESEARCH, RESEARCH PROJECT

Research project/purpose and experiments with the MATERIAL to be performed by RECIPIENT, as specified in Appendix 2. Any use will be only for not-for-profit research purpose.

RECIPIENT

Recipient organization.

RESULTS

Data and results obtained from conducting the RESEARCH.

UNMODIFIED DERIVATIVES

Substances created by RECIPIENT which constitute an unmodified functional subunit or product expressed by the ORIGINAL MATERIAL. Some examples include: subclones of unmodified cell lines, purified or fractionated subsets of the ORIGINAL MATERIAL, proteins expressed by DNA/RNA supplied by PROVIDER, or monoclonal antibodies secreted by a hybridoma cell line.

2) SCOPE

- 2.1 PROVIDER will provide RECIPIENT with MATERIAL under the conditions as set forth in this Agreement within [...] days of the effective date.
- 2.2 The MATERIAL is to be used solely by RECIPIENT under the direction of a qualified RECIPIENT's scientist at recipient's organization. The RESEARCH to be conducted by RECIPIENT is restricted to the RESEARCH PROJECT described in Appendix 2.
- 2.3 MATERIAL and MODIFICATIONS will be stored in a secure location and will only be used in laboratory animals or in vitro experiments. MATERIAL and MODIFICATIONS will not be used in human subjects, clinical trials or for diagnostic purpose involving human subjects without PROVIDER's prior written consent. Secure data access, such as passwords and firewalls must be in place to ensure that the DATA is kept secure.
- 2.4 The RECIPIENT will ensure that RECIPIENT's scientist does not transfer the MATERIAL or MODIFICATIONS to anyone who does not work under his or her direct supervision and responsibility at recipient's organization without the prior written consent of PROVIDER.

3)

COMPLIANCE WITH LAW, RULES AND REGULATIONS

- 3.1 The MATERIAL has been collected and processed by PROVIDER in compliance with all applicable law.
- 3.2 RECIPIENT agrees to comply with all law applicable to the research and the handling of material and data. In particular, RECIPIENT shall refrain from tracing or identifying the identity of any participants who provided the MATERIAL.

3.3¹ RECIPIENT confirms that the RESEARCH PROJECT has been subject to review and approved by the [Name of Ethical Committee (ref number)] as further described in Appendix 2.

4)

RIGHTS AND OBLIGATIONS

- 4.1 PROVIDER and RECIPIENT warrant to each other that they will protect, in their respective areas of responsibility under applicable law and the present agreement, the personality and the fundamental rights of the person providing the MATERIAL, including (i) the right to physical integrity; (ii) the protection of private sphere and (iii) the right to autonomy and informational self-determination.
- 4.2 The MATERIAL shall be used only (i) under the conditions, if any, specified by PROVIDER, including any conditions specified at the time of collection, as set forth in Appendix 1 and (ii) as provided for by law.
- 4.3 A written consent will have been signed by the person providing the MATERIAL.
- 4.4 RECIPIENT agrees to protect MATERIAL against misuse through appropriate organizational and technical measures.
- 4.5 Notwithstanding any provision to the contrary, as between the parties, PROVIDER is and will remain the sole owner of any intellectual property rights over the MATERIAL, including any MATERIAL contained or incorporated in MODIFICATIONS.
- 4.6 Subject to the other terms of this section 4, RECIPIENT will own intellectual property rights only over: (i) MODIFICATIONS (except that PROVIDER retains ownership rights to the MATERIAL included therein) and (ii) those substances created through the use of the MATERIAL or MODIFICATIONS, but which are not PROGENY, UNMODIFIED DERIVATIVES or MODIFICATIONS (i.e. do not contain the ORIGINAL MATERIAL, PROGENY, UNMODIFIED DERIVATIVES).
- 4.7 No compensation:

Subject to the other terms of this 4, RECIPIENT may file patent application(s) claiming inventions made by the RECIPIENT through the use of the MATERIAL. RECIPIENT will notify PROVIDER by signed writing at least 30 days prior to filing any such patent application. PROVIDER will not receive any compensation for such.

4.7 Compensation:

Subject to the other terms of this section 4, RECIPIENT may file patent application(s) claiming inventions made by the RECIPIENT through the use of the MATERIAL. RECIPIENT will notify PROVIDER by signed writing at least 30 days prior to filing any such patent application. In the event that this patent application results in products or services that generate incomes in any form, RECIPIENT will pay PROVIDER compensation as follows: (i) a royalty of [...]%² on the net sales of any such products or services protected by the patent and (ii) in case of sale of RECIPIENT's rights over this patent application or the resulting patent, a one-time royalty of [...]%² on that sale.

4.8 [Optional]

Upon written request by PROVIDER, RECIPIENT will grant PROVIDER a non-exclusive, researchonly, royalty-free, research license over any intellectual property developed by RECIPIENT as a result of RECIPIENT's use of the MATERIAL.

4. [8 or 9]

The Parties will conclude a separate confidential disclosure agreement if they deem it necessary. The parties agree that all data pertaining to any invention, including disclosures under section 4.7, will be treated confidentially by both parties.

5) DISCLAIMERS

Any MATERIAL delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. PROVIDER makes no representations and extends no warranties of any kind, either expressed or implied. There are no express or implied warranties of merchantability or fitness for a particular purpose, or that the use of the MATERIAL or MODIFICA-TIONS will not infringe any patent, copyright, trademark or other proprietary rights of a third party. PROVIDER does not grant RECIPIENT any license over intellectual property owned by PROVIDER.

6) LIABILITY AND INDEMNIFICATION

6.1 In no event shall PROVIDER be liable for any use by RECIPIENT of the MATERIAL and MODIFICATIONS, or any loss, claim, damage or liability, of whatsoever kind or nature, which may arise from or in connection with this Agreement or the use, handling or storage of the MATERIAL and MODIFICATIONS by RECIPIENT.

OR

¹ Section can be deleted for anonymized MATERIAL.

² SBP recommendation: 5-10%

6.2 RECIPIENT assumes all and any liability for damages, which may arise from the use of the MATERIAL and MODIFICATIONS, its storage or disposal. RECIPIENT shall hold harmless PROVIDER and its researchers for any loss, claim or demand, which could be raised by RECIPIENT, or made against RECIPIENT by any other party, due to, or arising from, the use of the MATERIAL and MODIFICATIONS by RECIPIENT, except to the extent caused by the gross negligence or willful misconduct of PROVIDER.

7) PUBLICATIONS

- 7.1 RECIPIENT shall have the right to publish its RESULTS related to the MATERIAL or MODIFICATIONS and is encouraged to do so. RECIPIENT agrees to acknowledge PROVIDER either as co-authors of the publication or cite as the source of the MATERIAL in all written publications, posters or oral presentations. This applies to any publications on MATERIAL or MODIFICATIONS that discloses or relates in any way to RECIPIENT's use of the MATERIAL, unless otherwise agreed in writing by PROVIDER. The MATERIAL shall be cited at least in the methods and reference sections. [Optional]³ RECIPIENT will acknowledge the name of the biobank and/or individual(s) who have collected the MATERIAL and/or created the biobank in the same fashion.
- 7.2 RECIPIENT agrees to first submit written publications to PROVIDER in confidence for review and comment no later than thirty (30) days prior to submission for publication. RECIPIENT will use a commercially reasonable effort to reflect into the proposed publication any comments made by PROVIDER no later than ten (10) days before the proposed submission.

8) RESEARCH RESULTS

- 8.1 RECIPIENT agrees, in accordance with its established practice, to keep complete and accurate accounts, notes, data and records of the RESEARCH. Upon request, RECIPIENT provides PROVIDER with a summary of any RESULTS obtained.
- 8.2 Upon completion of the RESEARCH, RECIPIENT will disclose to PROVIDER all RESULTS (i) obtained from conducting the RESEARCH or (ii) related to the use of the MATERIAL or MODIFICATIONS, including, without limitation, copies of relevant summaries and reports.

9)

EXPIRATION AND TERMINATION

- 9.1 This Agreement will automatically expire [three] years from the effective date, unless the Agreement is extended in writing by the parties. It is the responsibility of RECIPIENT to seek such an extension.
- 9.2 Either party may terminate this agreement through a 30-day prior written notice to this effect to the other party stating one of the following grounds:
 - i completion of the RECIPIENT's current RESEARCH with the MATERIAL;
 - ii if the recipient's scientist ceases to be employed (or otherwise engaged) by the RECIPIENT organization. In this case, RECIPIENT will inform PROVIDER in writing of such occurrence immediately after this is decided;
 - iii if the RECIPIENT organization ceases, is likely to cease, or threatens to cease carrying on business;
 - iv in case the other party is in material breach of this agreement and has not remedied such breach by the end of the notice period.
- 9.3 On expiration or termination for any reason, the grant of rights to RECIPIENT under the present Agreement will be automatically terminated. RECIPIENT agrees to return or destroy any remaining MATERIAL and return or prevent further access to the data, in accordance with PROVIDER's directions.

9.4 [Optional]

RECIPIENT, at its discretion, will also either destroy the MODIFICATIONS or remain bound by the terms of this Agreement as they apply to MODIFICATIONS.

9.[4 or 5]

The provisions concerning publications, intellectual property, warranty and liability as well as those intended to protect the rights of participants/data subjects shall survive the Agreement's expiration.

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TRANSPORT AND REIMBURSEMENT / FEES

- 10.1 Transmittal fees to be reimbursed to PROVIDER for storage, preparation and shipment costs are specified in Appendix 3.
- 10.2 RECIPIENT is in charge of the transport insurance.

(I) 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 [Name of Canton], Switzerland.

12) APPENDICES

Appendix 1Original MaterialAppendix 2Research Project / PurposeAppendix 3Reimbursement / FeesAll appendices from an integral part of this Agreement.

APPENDIX 1 ORIGINAL MATERIAL

BIOLOGICAL MATERIAL AND ASSOCIATED DATA⁴

The following original material shall be provided from PROVIDER to RECIPIENT: Description of biological material and associated data

[For biological material: number of samples, tissue type, sample types (e.g. paraffin block, EDTA blood, etc.), sample identifiers, preservation and storage details, etc.]

[For data: Number of files, format of files, data fields, number of records, time period covered by data, etc.]

Restrictions of use, if applicable

[...]

Associated data is personal and/or preanalytic data.

Personal data is all information relating to an identifiable person, including health-related data. Health related data is data related to the health or disease of a participant, including genetic data (e.g. clinical, genetic, epidemiological, socio-economic data, etc.). Preanalytic data is data related to the sampling, processing, storage, quality and usage of samples (e.g. sampling time, transport temperature, centrifuge speed, storing temperature, etc.).

APPENDIX 2 RESEARCH PROJECT / PURPOSE

The RESEARCH shall be limited to use of the MATERIAL in connection with the following activities:

| Project Name | |
|--|--|
| Organization Name: Lab(s) and researchers names | |
| Project summary | |
| Project duration | |
| Methods planned to be used | |
| Ethical Committee Approval (name, ref number and date) | |

APPENDIX 3 REIMBURSEMENT / FEES

Invoice is payable within 30 (thirty) calendar days upon receipt. For late payment a monthly interest of [...]% will be charged.

| Fees for MATERIAL | | |
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| Fees for Transport | | |
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| Accounting Data | | |
| Bank | | |
| Account holder | | |
| Bank Details (IBAN,) | | |