SBP MATERIAL TRANSFER AGREEMENT

— VersionSBP 2.0

Introduction

This Material Transfer Agreement (MTA) template governs the transfer and use of human biological material that is made available by a provider to a non-profit third party that wishes to use this research material for its own research purpose. This template has been developed in close collaboration with Swiss Personalized Health Network (SPHN) and is intended to facilitate the exchange of human biological material within Switzerland. It shall 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. In addition, SBP encourages anyone working with biological material to adopt it. The use of this template is limited to the exchange between academic institutions and is not suitable for the transfer to a for-profit organization.

An MTA must be concluded between legal entities, which are to be bound by the contractual provisions, and not only 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 are to be completed. In certain settings, modifications will be necessary. In case of need, specific legal advice should be sought.

Any use of this template is exclusive responsibility of the respective user.

For data transfer, please refer to the Data Transfer and Use Agreement (DTUA) template developed by SPHN.

In the event of additional questions, please contact SBP at info@swissbiobanking.ch

Swiss Biobanking Platform



MATERIAL TRANSFER AGREEMENT

FOR THE TRANSFER AND USE OF BIOLOGICAL MATERIAL

This agreement (hereinafter referred to as the "Agreement") is made and entered into by and between:

The University of Bern Institute of Tissue Medicine and Pathology ("PROVIDER")

CH-3008 Bern (SWITZERLAND)

and

[Name of Recipient Organization] ("RECIPIENT")

[Address of Recipient Organization]

Hereinafter jointly referred to as the "Parties" and individually as a "Party"

PROVIDER Authorized Signature(s)

(Duly Authorized Representative)

RECIPIENT Authorized Signature(s) (Duly Authorized Representative)

Signature	Signature		
Name & Title	Name & Title		
[YYYY/MM/DD]	[YYYY/MM/DD]		
Date	Date		
PROVIDER Authorized Signature(s)	RECIPIENT Authorized Signature(s)		
(Biobank Responsible Person of Organization)	(Responsible Scientist of Organization)		
Signature	Signature		
Name & Title	Name & Title		
[YYYY/MM/DD]	[YYYY/MM/DD]		
Date	Date		



PROVIDER AND RECIPIENT AGREE AS FOLLOWS:

Preamble

RECIPIENT wishes to conduct RESEARCH with ORIGINAL 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 preanalytical data as described in Annex 1 will be delivered by PROVIDER to RECIPIENT under the terms of this Agreement.

1 DEFINITIONS

For the purpose of this 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 Section 4 below.

DATA

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

FOREGROUND INTELLECTUAL PROPERTY (FOREGROUND IP) shall have the meaning set forth in Section 4 below.

INTELLECTUAL PROPERTY RIGHTS

All intellectual property rights throughout the world, whether existing under statute, at common law or equity, registered or unregistered, now or hereafter in force or recognized including trade secrets and know-how.

MATERIAL

ORIGINAL MATERIAL, any PROGENY and UNMODIFIED DERIVATIVES thereof, the ORIGINAL MATERIAL contained in MODIFICATIONS and DATA.

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 Annex 1.

PROGENY

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

RESEARCH, RESEARCH PROJECT

Research project and experiments with the MATERIAL to be performed by RECIPIENT, as specified in Annex 2. Any use will be only for research purpose.

RESULTS

Any output of the RESEARCH, which are not PROGENY or UNMODIFIED DERIVATIVES, such as invention, data, software, algorithms, knowledge, know-how or information that is generated in the RESEARCH, 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

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.
- 2.2 The MATERIAL may not itself be commercialized and is to be used solely by RECIPIENT and defined co-partner of RECIPIENT¹ 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 Annex 2. Restrictions of use of the MATERIAL, if applicable, are stated in Annex 1.
- 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.
- 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 or who is a defined co-partner of RECIPIENT¹ without the prior written consent of PROVIDER.

¹ To be listed in Annex 2 (if applicable)

3 COMPLIANCE WITH LAW, RULES AND REGULATIONS

- 3.1 The MATERIAL has been collected and processed by PROVIDER in compliance with all applicable laws.
- 3.2 In case of full or partial withdrawal of consent, the PROVIDER must inform the RECIPIENT of this revocation without delay. If applicable, the RECIPIENT ought to anonymize the MATERIAL according to the Human Research Ordinance *as per* the PROVIDER's request, unless one of the exceptions listed in Article 10 of the Human Research Ordinance applies. A written notification shall be sent to the PROVIDER upon receipt and after completion of the request.
- 3.3 RECIPIENT agrees to comply with all laws applicable to the research and the handling of biological material. In particular, RECIPIENT shall refrain from tracing or identifying the identity of any participants who provided the MATERIAL.
- 3.4 RECIPIENT confirms that the RESEARCH PROJECT has been subject to review and approved by the [Name of Ethical Committee (approval number)] as further described in Annex 2.
- 3.5 RECIPIENT is aware that the ORIGINAL MATERIAL and its PROGENY may contain infectious agents and that it should be handled accordingly. RECIPIENT confirms to perform the activity in accordance with local law before processing the ORIGINAL MATERIAL or its PROGENY in a way that infectious agents may be propagated.
- 3.6 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 protection of privacy and (ii) the right to autonomy and informational self-determination.
- 3.7 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 Annex 1 and (ii) as provided for by law.
- 3.8 PROVIDER confirms that a written consent covering the intended use has been signed by the relevant person providing the MATERIAL or by his legal representative. In case such consent is lacking and cannot be obtained, RECIPIENT shall request lawful authorization from the competent Ethical Committee for the use of MATERIAL.
- 3.9 RECIPIENT agrees to protect MATERIAL against misuse through appropriate organizational and technical measures as described in Annex 3. Secure MATERIAL access and security shall be guaranteed at all stages of the process.

4 INTELLECTUAL PROPERTY RIGHTS

- 4.1 **BACKGROUND IP**. The Parties agree that each Party shall retain all title, right and interest in and to its respective INTELLECTUAL PROPERTY RIGHTS, as of the date of entry into force of this Agreement (the "BACKGROUND IP"). Unless otherwise agreed herein, nothing in this Agreement shall be construed as a transfer, license, and/or assignment by a Party to the other Party of ownership of, title, right or interest in and to its respective BACKGROUND IP.
- 4.2 The RECIPIENT is the owner of the RESULTS. FOREGROUND IP. All right, INTELLECTUAL PROPERTY RIGHTS, title and interest in and to the RESULTS (the "FOREGROUND IP"), shall be owned and vest in the RECIPIENT.

5 DISCLAIMERS

5.1 Any ORIGINAL MATERIAL delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties or contain infectious agents. 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 MODIFICATIONS will not infringe any patent, copyright, trademark or other proprietary rights of a third party.

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.
- 6.2 RECIPIENT assumes all and any liability for damages, which may arise from his 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 third 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.
- 6.3 **FOREGROUND IP**. The Parties 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.

7 PUBLICATIONS

- 7.1 The most important purpose of biological resources' use is scientific research and RECIPIENT shall make every effort to publish its RESULTS related to the MATERIAL MODIFICATIONS. RECIPIENT agrees to or 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 publication 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/ acknowledgement² sections. RECIPIENT will acknowledge the name of the biobank and/or individual(s) who have collected the MATERIAL and/or created the biobank.
- 7.2 RECIPIENT shall communicate to PROVIDER any kind of publication of the RESULTS, no later than 30 days from the date of acceptance."
- 7.3 All publications of the RESULTS must be compliant with the Authorship Guidelines of the Swiss Academies of Arts and Sciences, as updated from time to time³.

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. If the RESEARCH PROJECT does not lead to any publication before the expiration of this contract, RECIPIENT provides PROVIDER, upon request, with a summary of any RESULTS obtained.
- 8.2 Upon completion of the RESEARCH or on PROVIDER's request, RECIPIENT will disclose to PROVIDER all RESULTS obtained from conducting the RESEARCH, which relate to the use of the MATERIAL or MODIFICATIONS, including, without limitation, copies of relevant summaries and reports. PROVIDER agrees to keep these RESULTS confidential until they are published.

9 EXPIRATION AND TERMINATION

9.1 This Agreement will automatically expire the earliest of the following dates: (i) on completion of the RECIPIENT's current RESEARCH with the MATERIAL, or (ii) 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 30day prior written notice to this effect to the other Party stating one of the following grounds:
- 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 discontinue use of MATERIAL. Recipient shall, in accordance with PROVIDER's directions, return or destroy any unused ORIGINAL MATERIAL.
- i. if the RECIPIENT organization ceases, is likely to cease, or threatens to cease carrying on business;
- ii. 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.
- 9.4 RECIPIENT, at its discretion, will also either destroy the MODIFICATIONS or remain bound by the terms of this Agreement as they apply to MODIFICATIONS.
- 9.5 The provisions concerning publications, intellectual property, warranty and liability as well as those intended to protect the rights of participants shall survive the Agreement's expiration.

10 MODIFICATIONS AND AMENDMENTS

- 10.1 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.
- 10.2 If any portion of this Agreement is in violation of any applicable regulation, or is unenforceable or void for any reason whatsoever, it should be put in writing and discussed by the Parties. Such portion will be inoperative and the remainder of this Agreement will be binding upon the Parties.

11 FEES AND TRANSPORT

- 11.1 Transmittal fees to be reimbursed to PROVIDER for sample production, preparation and shipment costs are specified in Annex 4.
- 11.2 RECIPIENT is in charge of the transport insurance.

³ <u>http://www.akademien-schweiz.ch/en/dms/E/Publications/Guidelines-and-Recommendations/integrity/Academies_Authorship.pdf</u>

² Select appropriate citation: e.g. acknowledgement section for the case where no marker paper with a DOI is available.

12 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.

13 ANNEXES

Annex 1. Original Material and Data

- Annex 2. Research Project/Purpose
- Annex 3. Material Transfer Specification
- Annex 4. Fees and Transport
- All Annexes are integral part of this Agreement.



ORIGINAL MATERIAL and DATA

The following original material shall be provided from PROVIDER to RECIPIENT:

Description of biological material and 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.]

Restrictions of use, if applicable

[...]



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)	
Co-partner(s) (if applicable, e.g. collaboration with other labs for analysis)	



MATERIAL TRANSFER SPECIFICATION

List here all organizational and technical measures implemented to protect MATERIAL against misuse (i.e. unauthorized access, accidental loss, destruction or damage) and during transfer.



FEES AND TRANSPORT

Requested Services/Support per tissue sample, prices in CHF	Number*	^{*1} Tarif	Admin. Lab- total
Collection			
Grossing (histologic sampling) of resection, per case		9	
Snap frozen biobank sample (tumor and normal), per case		20	
Paraffin control block (normal), per block		30	
Paraffin control block (tumor/diseased), per block		30	
Reception TBB, per case		48	
DMSO preserved sample (5 years <-130°C)		50	
Distribution			
Request handling incl. query for samples/MTA/consent management (per project)		150	
Sample handling, per case		30	
Exit control, frozen sectioning and H&E, per case		42	
Frozen sectioning, per slide		20	
Paraffin cuts, incl. H&E (control paraffin block), per slide		15	
Pathologist Quality Control Report, per case		16	
Sending material (Box, Dry ice, Transport, Documents for shipping)		to be discussed	
Extended ELSI support		to be discussed	
Clinical/Pathological data		to be discussed	

Biobank administration (inventory Management per sample) for non SNF founded projects	35	
TOTAL		

*1Different tariffs are available for non-medical faculty Prices are reviewed annually and adjusted if necessary

