BLB
Basel Liver Biobank

BIOBANK REGULATION BASEL LIVER BIOBANK

Version 1: February 2026

In agreement with this Regulation, the biobank commits itself to protecting the fundamental rights of participants, in particular, their dignity, autonomy, privacy, the confidentiality of their data as well as their personality rights. The biobank commits itself to respecting legal requirements and ethical/professional HRA, FDPA, Declaration of Taipei 2016 and to conforming to the governance principles described in this Regulation.

DBM Basel

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TABLE OF CONTENTS

1 GENERAL PROVISIONS 3

1.1 SCOPE 3
1.2 APPLICABLE LAW 3
1.3 DEFINITIONS 3
1.4 ABBREVIATIONS 3

2 DESCRIPTION OF THE BIOBANK 3

2.1 BIOBANK PURPOSE 3
2.2 BIOBANK SCOPE 3
2.3 NATURE OF THE BIOLOGICAL RESOURCES 3
2.4 STORAGE DURATION 3

3 GOVERNANCE 3

3.1 ESTABLISHMENT OF THE BIOBANK 3
3.2 LEGAL STATUS 3
3.3 STRUCTURE 3
3.4 CONSENT 3
3.5 MINORS AND ADULTS INCAPABLE OF JUDGEMENT 3
3.6 CONFIDENTIALITY MEASURES 3
3.7 ACCESS AND TRANSFER 4
3.8 PARTICIPANT'S RIGHT TO INFORMATION 4
3.9 FINANCE 4
3.10 DISSOLUTION OF THE BIOBANK 4

4 OPERATIONAL PROCEDURES 4

4.1 GENERAL PRINCIPLE 4
4.2 SAMPLES AND DATA COLLECTION AND MANAGEMENT 4
4.3 STORAGE OF BIOLOGICAL RESOURCES 4

5 GRANTING ACCESS TO BIOLOGICAL RESOURCES 4

5.1 TERMS OF ACCESS 4
5.2 TRANSFER 4

6 QUALITY 4

7 COMMUNICATION 4

8 APPENDICES 5

1 GENERAL PROVISIONS

1.1 SCOPE

This Regulation defines the purpose, the operational processes, and the organisation of the biobank **Basel Liver Biobank**. It describes the requirements for collecting, storing, and distributing biological material and their associated data (*i.e., biological resources*).

1.2 APPLICABLE LAW

This Regulation has been drawn up in compliance with the applicable legal framework, in particular the Federal Act on Research involving Human Beings (HRA), cantonal legislation, and the Federal Act on Data Protection (FADP). The Regulation follows established ethical and professional principles, in particular the ethical considerations regarding health databases and biobanks set out in the Declaration of Taipei of 2016.

1.3 DEFINITIONS

The terms used in this Regulation are derived from the SBP glossary which can be found in Appendix I.

1.4 ABBREVIATIONS

Cst	Federal Constitution of the Swiss Confederation of 18 April 1999; RS 101
CC	Swiss Civil Code of 10 December 1907; RS 210
DTA	Data Transfer Agreement
HRA	Federal Act on Research involving Human Beings of 30 September 2011; RS 810.30
HRO	Ordinance on Human Research with the Exception of Clinical Trials of 20 September 2013; RS 810.301
MTA	Material Transfer Agreement
SBP	Swiss Biobanking Platform

2 DESCRIPTION OF THE BIOBANK

2.1 BIOBANK PURPOSE

1. This biobank is a disease-specific research biobank for liver diseases (liver biopsy cohort).

2.2 BIOBANK SCOPE

1. This biobank was established for research purposes, in particular to investigate the fundamental mechanisms of liver diseases.

2.3 NATURE OF THE BIOLOGICAL RESOURCES

1. Information related to biological resources stored in the biobank are described in Appendix II.

2. The samples are collected from outpatients and inpatients of the University Hospital Basel.

2.4 STORAGE DURATION

The biological resources are stored in the biobank for an indefinite period of time.

3 GOVERNANCE

3.1 ESTABLISHMENT OF THE BIOBANK

The biobank Basel Liver Biobank was founded on the 5th December 2014.

3.2 LEGAL STATUS

The biobank is affiliated with the Hepatology Research Group at the Department of Biomedicine, University of Basel, and has no independent legal personality.

3.3 STRUCTURE

1. The organisational structures of the biobank are: Overall Direction (Prof. Markus Heim), Operational Direction, Biological Resources Management Committee (cf. organisational chart and list of members of the different structures in Appendix III).

2. The responsible person(s) of the biobank are identified and listed in Appendix III.

3.4 CONSENT

1. The collection, storage, and use of biological resources is based on the free and informed consent of the patient obtained within the healthcare framework. The consent status of the participant is documented and the consent form is archived.
2. Consent may be revoked by the participant at any time and without justification. Such revocation does not entail any disadvantage for the participant with regard to their medical care. The modalities for revocation are set out in the consent form. For further information, participants may contact the biobank as per the details provided in Chapter 7 "Communication" of this Regulation.
3. Upon revocation, the samples and associated data of the participant stored in the biobank for research purposes may no longer be used. In this case, the samples and data will be destroyed.
   Note: Revocation applies only to the future use of biological resources for research purposes. Results obtained prior to the revocation and their evaluation are not affected. Use for diagnostic / therapeutic purposes remains possible.
4. If no consent from the participant is available, the biobank refers the matter to the responsible ethics committee, which may, under the conditions set out in Art. 34 of the HRA, grant an exceptional authorisation for the use of biological resources for research purposes.

3.5 MINORS AND ADULTS INCAPABLE OF JUDGEMENT*

1. In the case of a legal minor who is capable of judgment, written consent is obtained from the minor himself/herself and his/her legal representative.

2. In the case of a legal minor who is incapable of judgment, written consent is obtained from the sole legal representative.

3. In the case of an adult participant who is incapable of judgment or in a state of health that makes him/her incapable of judgment (and in the absence of a document attesting to his/her consent before his/her loss of judgment), consent is obtained from his/her legal representative, a designated trusted person, or the next of kin.

4. In all cases, the status of a legal minor or adult incapable of judgment is documented to facilitate the recollection of his/her consent when acquiring or recovering his/her capacity to consent.

3.6 CONFIDENTIALITY MEASURES

1. Biological resources are stored in coded (pseudonymised) form.
2. Coding is performed according to the following rules: each sample and dataset is assigned a pseudonymous identification number. The key linking this number to patient data is stored in a password-protected, encrypted database on the secure server of the University Hospital Basel.
3. When a researcher who fulfils the access conditions to the biobank's resources (cf. section 5.1 – Terms of Access) is

granted access to biological material and/or associated data, no personal information about the participant is disclosed.

3.7 ACCESS AND TRANSFER

The biobank follows clear rules governing the access and the transfer of biological resources in agreement with the consent of the participant. These rules are described in Chapter 5 « Granting access to biological resources ».

3.8 PARTICIPANT'S RIGHT TO INFORMATION

3.8.1 Right to consult

The participant can consult all information concerning him/her stored in the biobank to correct or delete them as necessary. He/she can also be informed of what has been done with his/her biological resources. The participant can contact the biobank as per the provisions of Chapter 7 « Communication ».

3.8.2 Biobank activities

1. The biobank communicates relevant information concerning its organisation, operational processes, and activities via its website.

3.9 FINANCE

The biobank is funded by third-party funds. Funding covers the entire lifetime of the biological resources stored in the biobank.

3.10 DISSOLUTION OF THE BIOBANK

1. In compliance with the consent of the participant, in the event of the end of its activities and/or dissolution of the biobank, the biological resources stored in the biobank are either transferred and integrated into another biobank with an equivalent level of protection or destroyed.

4 OPERATIONAL PROCEDURES

4.1 GENERAL PRINCIPLE

The collection, storage, and use of biological resources are carried out according to the applicable legislation and ethical/professional HRA, FDPA, Declaration of Taipei 2016 and according to the provisions of the given consent.

4.2 SAMPLES AND DATA COLLECTION AND MANAGEMENT

1. The biobank is responsible for ensuring that any sample and/or data are associated with a valid consent.

2. The collection of biological samples and data will not give rise to any financial compensation or any other material advantage.

4.3 STORAGE OF BIOLOGICAL RESOURCES

4.3.1 Material

Access to the facilities where samples are kept is secured and controlled with the following measures: secured research facilities, restricted access, key and badge control. The temperature of the storage equipment is under surveillance 24/7. Measures in place to ensure the protection of samples are: central alarm system (connected to University Hospital Basel alarm centre), 24/7 temperature monitoring, backup ultra-low temperature freezers and backup liquid nitrogen tanks at the Centre for Teaching and Research, monitoring of CO_2, air conditioner, room temperature monitoring, locked freezers.

4.3.2 Associated Data

1. Preanalytical data are managed by REDCap and LabKey.
2. Personal data including health-related data are manually entered and managed into REDCap.

5 GRANTING ACCESS TO BIOLOGICAL RESOURCES

5.1 TERMS OF ACCESS

1. Access to biological resources is granted by the Biological Resources Management Committee according to the following criteria: scientific quality, valid ethics approval, compatibility with participant consent, available sample volume.
2. The detailed process from request to receipt of biological resources is described in Appendix IV.
3. A researcher who is authorised to use the biological resources of the biobank commits to refraining from any attempt to re-identify participants, except under the circumstances set out in Art. 27, paragraph 2 of the HRO.
4. Diagnostic and therapeutic uses are given priority in all cases. It is therefore necessary to ensure that a sufficient quantity of material remains available for these purposes. Accordingly, one sample per patient must always be retained exclusively for this purpose.

5.2 TRANSFER

1. Any transfer of biological resources must be regulated and documented in a verifiable manner.

2. The DTA/MTA establishes the obligations and responsibilities of both parties concerning the transfer of material of a biobank before shipment. The DTA is mandatory when personal data are transferred to third parties. The obligations, which have not been expressly attributed to the receiving party by the DTA/MTA, remain under the responsibility and the management of the biobank. In all cases, the biobank remains responsible towards participants within the limits of its accountability.

3. For research projects carried out outside of Switzerland, the recipient must guarantee that the same standards, Declaration of Taipei 2016, which are applicable in Switzerland, concerning the data protection and the rights of participants have been fulfilled.

4. If a financial contribution is foreseen for the transfer of biological resources, the fees cover sample processing, preparation, transport and administrative costs.

6 QUALITY

1. The biobank is operated in accordance with the requirements of the HRA, the FADP, and the ethical principles of the Declaration of Taipei (2016). No formal certification or accreditation is currently in place.
2. The biobank entrusts the following processes to the Hepatology Research Group at the Centre for Teaching and Research, University of Basel and University Hospital Basel: sample processing and long-term storage (ultra-low temperature freezers and liquid nitrogen tanks at the Centre for Teaching and Research, University Hospital Basel).
3. The biobank furthermore collaborates with the central IT department of the University Hospital Basel (data backup and server operations) and the Centre for Teaching and Research (sample storage and alarm system).

7 COMMUNICATION

For any questions or additional information, please contact:

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https://www.dbmr.unibe.ch/research/research_groups/hepatology/index_ger.html

8 APPENDICES

Appendix I: Definitions

Appendix II: Biological resources of the biobank

Appendix III: Governance structures

Appendix IV Detailed process for requesting and obtaining biological resources

REVISION HISTORY

Version	Date of change	Details of revision
1.0	18.2.26	First Release (up–d from Version 1, 5 D cember 2014)

APPENDIX I
Definitions

ASSOCIATED DATA
Personal and/or preanalytical data.

ANONYMIZATION
The irreversible removal of the link between the biological material and/or associated data and the participant, so that no specific participant can be reidentified.

BIOBANK
An organized entity responsible for the governance and the management of biological resources.

BIOBANK INFRASTRUCTURE
An organized facility that offers services to biobanks.

BIOLOGICAL MATERIAL
Any material obtained or derived from a biological organism.

BIOLOGICAL RESOURCES
Biological material and associated data.

CODING
The reversible removal of the link between the biological material and/or associated data and the participant, so that a specific participant can only be reidentified through a key.

DATABASE
An organized collection of data.

DATA TRANSFER AGREEMENT
A legally binding agreement that governs the transfer of data between two parties, when the recipient intends to use them for research purpose. It defines the rights and obligations of the provider and recipient with respect to the use of the data and other related issues, such as confidentiality or intellectual property rights.

GENERAL CONSENT
A form of informed consent given by a participant to allow collection, storage, further use and transfer of his/her biological material and/or associated data collected for future not yet defined research projects.

GOVERNANCE
Biobank Governance includes the structures and the management rules set in accordance with the biobank purpose(s) to ensure its compliance with the applicable legal and ethical requirements.

HEALTH-RELATED DATA
Data related to the health or disease of a participant, including genetic data (e.g. clinical, epidemiological, socio-economic data, etc.).

INFORMED CONSENT
Voluntary and informed expression of the free will of a participant or his/her legal representative to allow the collection, storage, use and transfer of his/her biological material and/or associated data for research purposes.

KEY
The information which allows the coding to be undone, so that the biological material and/or associated data can be linked back to a specific participant.

MATERIAL TRANSFER AGREEMENT
A legally binding agreement that governs the transfer of biological material and data between two parties, when the recipient intends to use them for research purpose. It defines the rights and obligations of the provider and recipient with respect to the use of the material and data and other related issues, such as confidentiality or intellectual property right

NON-OPPOSITION
A consent mechanism where consent is implied unless an active choice is made to refuse a process after having been informed.

PARTICIPANT
Living or deceased person who provides his/her biological material and/or associated data to the biobank.

SPECIMEN
A specific quantity of biological material such as tissue, blood or urine taken from a single subject or participant at a specific time.

PREANALYTICAL DATA
Data related to the sampling, processing, storage and usage of biological material (e.g. sampling time, transport temperature, centrifuge speed, storing temperature, etc.).

PERSONAL DATA
All information relating to an identified or identifiable person, including health-related data.

SAMPLE
A single unit containing material (e.g. plasma, serum, DNA, RNA, cells, etc.) derived from one specimen.

SPECIFIC CONSENT
A form of informed consent given by a participant concerning the collection and storage of his/her biological material and/or associated data as well as their use and transfer for a defined/specific research project.

WITHDRAWAL
Withdrawal of previously given consent.

(Consequences of withdrawal are defined in consent form and should be disclosed with the concerned participant during the consent process.)

APPENDIX II
Biological Resources of the biobank

Biological material

1. Liver biopsies: a. snap frozen, stored in liquid nitrogen; b. OCT embedded, stored at -20°C; c. Formalin fixed paraffin embedded (FFPE)
2. Blood
3. Serum
4. Plasma
5. Stool samples

Inclusion criteria: Patients with liver diseases treated at the Division of Gastroenterology and Hepatology, University Hospital Basel, who have provided written informed consent.

Health-related personal data Liver disease, disease course, date of death.

The key for the coded biological resources stored in the biobank is held by Prof. Markus Heim, Head of the Hepatology Research Group, Department of Biomedicine, University of Basel.

APPENDIX III
Governance structures

The biobank is organised as follows:

Overall Direction:
Prof. Dr. med. Markus Heim, Head of the Hepatology Research Group, Department of Biomedicine, University of Basel.

Operational Direction:
Hepatology Research Group, Department of Biomedicine, University of Basel.

The operational direction of the biobank is assured by: Prof. Dr. med. Markus Heim, Head of the Hepatology Research Group, Department of Biomedicine, University of Basel +41 61 265 25 25 markus.heim@unibas.ch

Members of the Hepatology Research Group responsible for sample processing and storage:
Dr. Sandro Nuciforo
Dr. Lukas Kübler
Sylvia Ketterer
Xueya Wang

Members of the Hepatology Research Group responsible for patient recruitment, biopsy and blood collection:
Prof. Markus Heim
Prof. Christine Bernsmeier
PD Dr. Fahim Ebrahimi
Kelly da Sylva

Biological Resources Management Committee:
Prof. Markus Heim (Chair)
Dr. Tuyana Boldanova
Dr. Sandro Nuciforo
Dr. Lukas Kübler

The Biological Resources Management Committee under the direction of Prof. Markus Heim grants access to the biological resources of the biobank.

Basel, 26 March 2026

APPENDIX IV
Detailed process for requesting and obtaining biological resources

1. Submission of a written request to the biobank management (markus.heim@unibas.ch) with a description of the research project and the required resources.
2. Review of the request by the Biological Resources Management Committee based on the following criteria: scientific quality, ethics approval, compatibility with participant consent, available sample volume.
3. Communication to the applicants regarding available material and estimated costs for the provision of the material.
4. Upon approval: signature of an MTA (for material) and/or DTA (for data).
5. Provision of resources by the operational direction of the biobank.
6. Invoicing of incurred costs to the applicants by the operational direction of the biobank.