BIOBANK REGULATION

SBP REGULATION TEMPLATE FOR RESEARCH BIOBANKS

INTRODUCTION

To date, a wide variety of biobanks exists. They can differ in their purpose, size, funding sources, nature of their activities, as well as by the types of biological samples and data collected. Some biobanks are intended for clinical uses and are established to respond to diagnostic or therapeutic needs, whereas others are established for research purposes.

A large number of samples and data should be made accessible to researchers to foster biomedical research progress in the health-care domain. This Swiss Biobanking Platform (SBP) template applies to biobanks whose primary or secondary purpose is research. This template is addressed primarily to SBP partners. SBP encourages others who are involved in managing data or biological material to adopt this Regulation.

As per SBP, a biobank is "*an organized entity responsible for the governance and the management of biological resources*". Likewise, biological resources include *biological material and its associated data*. Associated data stands for *personal data, including health-related data, and preanalytical data*, essential for the evaluation of the biological sample quality.

In compliance with international standards, any biobank managing human samples must have a Biobank Regulation that defines its purpose, operational processes, and organisation.

In Switzerland, this requirement derives from the need of protecting the fundamental rights of participants, in particular, their personal freedom (art. 10 Cst) and privacy (art. 13 Cst), as well as their personality rights (art. 28ss CC). Furthermore, provisions related to research involving human beings (refer notably to art. 118b Cst, art. 43 HRA and art. 5 HRO) and to data protection strongly support the elaboration of such a document.

Beyond the legal requirements and ethical/professional standards, the Regulation promotes transparency concerning its organisation and its activities thereby enhancing public trust.

Note for users: Proposals that may not apply to your biobank are marked with an asterisk ("*"). You can erase the sentence whenever applicable.

For additional information, please contact the SBP:

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BIOBANK REGULATION [NAME OF THE BIOBANK]

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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 standards and to conforming to the governance principles described in this Regulation.

[INSTITUTION LOGO]

swissethics

This document is endorsed by Swissethics

TEMPLATE DEVELOPED BY SWISS BIOBANKING PLATFORM

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1) GENERAL PROVISIONS

1.1 SCOPE

This Regulation defines the purpose, the operational processes, and the organisation of the biobank [Name of the 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 relies on the applicable legal framework; in particular, the legislation on Research involving Human Beings, the cantonal legislation and the one relative to Data Protection. It follows established ethical/professional principles, including the Declaration of Taipei on ethical considerations regarding health-related databases and biobanks (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 [type of biobank; for example, cohort/specific to a particular disease, etc.].

2.* The biobank is multicentric [yes/no] and its principal site is [lead organisation] and of which its secondary ones are: [other secondary Institutions].

2.2 BIOBANK SCOPE

1. This biobank was established for [research/diagnostic/therapeutic/other] purposes. * [Indicate also secondary purposes].

2. * This biobank is intended for [a specific research group/a scientific collaboration] of which the main users are from [the institution/the academic sector/the private sector/sample providers].

2.3 NATURE OF THE BIOLOGICAL RESOURCES

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

2. These biological resources are collected from [outpatients/inpatients/volunteers/vulnerable persons].

2.4 STORAGE DURATION

The biological resources stored in the biobank are kept for a period of [storage duration/an undefined period of time].
Note: If the biobank is established for a fixed duration, it will follow the rules as outlined in section 3.10 "Dissolution of the biobank".

3) GOVERNANCE

3.1 ESTABLISHMENT OF THE BIOBANK

The biobank [Name of the Biobank] was founded on the [Creation date].

3.2 LEGAL STATUS

The biobank is established as a [foundation - name, association - name, company – name, governmental organization - name].
Or
The biobank is an autonomous entity established under the Cantonal law [canton].
Or
The biobank is bound to the [Department/Service/Unit] of [Name of the Institution] and has no independent legal personality.

3.3 STRUCTURE

1. The organisational structures of the biobank are: [strategic direction, operational direction, administrative 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 a [specific consent/specific consent allowing further use of these biological resources/general consent].
Such consent must be freely given, and be preceded by appropriate information. The consent status given by the participant has to be documented and the consent form has to be archived. The consent template is provided in Appendix IV.
Or
The collection, storage, and use of biological resources is based on the free and informed consent of the patient obtained within the healthcare framework.

2.* Consent can be revoked at any time and without justification by the participant. Such a revocation does not entail any prejudice especially regarding the medical care of the participant. Revocation modalities have been described in the consent form. Should the participants require any further information, they may contact the biobank as per the provisions of Chapter 7 « Communication ».

3.* Upon revocation, all samples and data of the participant stored in the biobank for research purposes could not be used from this point onwards. In this case, these samples and data will be [anonymised/destroyed].
Note: Revocation is only applicable to future use of the biological resources for research purposes. Results obtained prior the revocation and their evaluation are not affected by this decision. The use for diagnostic/therapeutic purpose remains possible.

4. If the requirements for informed consent are not met, the biobank refers to the responsible ethics committee, which may in exceptional circumstances authorize the use of biological resources for research purposes under the conditions provided in article 34 HRA.

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 as [coded/anonymised/identified].

* *Coding:*

2. Coding is performed according to [Specify coding rules]. The key keeper is not involved in any research project using the biological resources of the biobank.

3. When biological material and/or associated data are transferred to a researcher, who fulfils the access conditions to the biobank resources (cf. section 5.1 – Terms of access), no identifying information from the participant is given.

Or

* *Anonymisation:*

2. Anonymisation entails the removal of identifiable personal information and thus prevents any possibility of linking specific samples and data to a participant. Consequently, the participant is no longer able to withdraw his/her consent, to consult, to correct information on his/her health, or to obtain feedback on relevant results that may concern him/her.

3. The participant is informed of the consequences of the anonymisation, as described at point 2.

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 Return of results *

1. A participant has the right to be informed about research results pertaining to his/her health in accordance with his/her consent and the applicable ethical standards. If returned, these results should meet at least the following criteria: analytical validity[1], clinical significance[2], and be actionable[3].

2. A participant is informed of the return of results policy which includes the type of results that will be returned to participants (see Appendix V).

3. The decision to return individual research results has to be taken by an expert committee on a case-by-case basis. In all cases, the right of not to know shall be preserved.

4.* Additional criteria can be applied when returning results to legal minors and adults incapable of judgment.

3.8.3 Biobank activities

1. The biobank communicates relevant information concerning its organization, operational processes, and activities via [its website/publication of activity reports/Newsletter/scientific publications/Conference presentations/other].

2.* A follow-up table of research projects carried out with the biological resources of the biobank is available in Appendix VI.

3.9 FINANCE

The biobank is funded by [public/private/public and private] funds from [Mention the funding sources] for a duration of [funding duration]. Funding covers the 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.

2.* The destruction rules of biological resources are described in Appendix VII.

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1 They accurately and reliably identify a particular clinical characteristic.

2 They identify a significant risk of a potentially serious health problem.

3 There is a therapeutic or preventive intervention or other possible actions that have the potential to change the course of this disease or condition.

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 standards 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 [yes/no] with the following measures: [locked equipment, restricted access, signature at the entrance, etc.] and the temperature of the storage equipment is under surveillance 24/7 [yes/no]. 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].

4.3.2 Associated Data

1. Preanalytical data are managed by [Name of the system].

2. Personal data including health-related data are [automatically imported via data warehouse/manually imported/other] into [Name of the software].

5) GRANTING ACCESS TO BIOLOGICAL RESOURCES

5.1 TERMS OF ACCESS

1. The access of biological resources fulfils the following criteria [criteria].
Or
The access of biological resources is based on [first come, first served] principle.
Or
The access of biological resources is validated by [the biological resources management committee] according to the following criteria: [criteria].
The detailed process for requesting and obtaining biological resources is described in Appendix VIII.

2.* The researcher, who has been authorized to use biological resources of the biobank agrees not to attempt to re-identify the participants, except under the conditions outlined in Article 27, second paragraph, of the HRO[4].

3. The biobank will only grant access to its biological resources for projects that have been approved by the responsible ethics committee or equivalent authority.

4.* In all cases, priority is given to diagnosis and therapy. It is therefore necessary to ensure that enough material remains available, a sample per patient shall be thus always kept for this purpose.

[4] a) breaking the code is necessary to avert an immediate risk to the health of the person concerned; b) a legal basis exists for breaking the code; or c) breaking the code is necessary to guarantee the rights of the person concerned, and in particular the right to revoke consent.

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, 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 [list which biobank activities, transport, other].

6) QUALITY

1. The biobank has a Quality Management System [yes/no] and has been [certified/accredited] on [date] based on the following criteria: [standards].

2.* [Name of biobank infrastructure] is in charge of [outsourced processes].

3. The biobank collaborates with [list support services] for the management of its activities.

Note: Copy of relevant quality documents is provided in Appendices x, y, z. [Specify documents added in the Appendices section by completing the list in Chapter 8 "Appendices"].

7) COMMUNICATION

For any questions or additional information, please contact:
[Name of contact person]
[Telephone]
[E-mail]

[Address of the biobank]
[Zip code]
[City]

[Website]

8)
APPENDICES

Appendix I Definitions
Appendix II Biological resources of the biobank
Appendix III Governance structures
Appendix IV* Consent Template(s)
Appendix V* Return of research results to participants
Appendix VI* Follow-up table of research projects carried out with the biological resources
Appendix VII* Rules on the destruction of biological resources of the biobank
Appendix VIII Detailed process for requesting and obtaining biological resources
Appendix x, y, z

REVISION HISTORY

VERSION	EFFECTIVE DATE	DETAILS OF REVISION
1.0		Initial release

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 management and the custodianship 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 rights.

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
- Specimen 1: [type]; origin: [origin]
- Specimen n: [type]; origin: [origin]

- Sample 1: [type]; temperature of storage [Temp]; for solid samples: [type of fixation/stabilization]
- Sample n: [type]; temperature of storage [Temp]; for solid samples: [type of fixation/stabilization]

Inclusion criteria: [specify]

HEALTH-RELATED DATA
[Type]

These biological resources are collected from [outpatients/inpatients/volunteers/vulnerable persons].
* For biological resources stored in the biobank in a coded form, the key is held by [Key keeper Name and Function].

APPENDIX III
GOVERNANCE STRUCTURES

The organisation of the biobank is composed of the following governance structures: [list of structures].

[For each structure, provide here the organisational chart of the biobank with the list of the members, including their roles and responsibilities.]

The operational direction of the biobank is assured by:

› [Name of the responsible person]
[Telephone]
[E-mail]

› [Name of the operational manager]
[Telephone]
[E-mail]

*A biological resources management committee grants the access to the biological resources of the biobank.

APPENDIX IV*
CONSENT TEMPLATE(S)

[Insert here a copy of the consent form(s)]

APPENDIX V*

RETURN OF RESEARCH RESULTS TO PARTICIPANTS

The biobank informs the participants of the following results: [type of results: general outcome of the research project, individual research results, incidental findings] according to the following conditions and procedures: [describe conditions and procedures].

APPENDIX VI*

FOLLOW-UP TABLE OF RESEARCH PROJECTS CARRIED OUT WITH THE BIOLOGICAL RESOURCES

Approval Date	BASEC ID	Project Title	Multi/ monocentric	Involved Sites	Principal Investigator	Type of used resources	Risk Cat.	Project Status

APPENDIX VII*
RULES ON THE DESTRUCTION OF BIOLOGICAL RESOURCES OF THE BIOBANK

[Describe the procedure that is used to destroying samples stored for research purpose.]

APPENDIX VIII
DETAILED PROCESS FOR REQUESTING AND OBTAINING BIOLOGICAL RESOURCES

[Describe in details the request process including the criteria to obtain biological resources.]