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 exclusively 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 primarily to research biobanks embedded into SBP network as well as to other non-research biobanks, whose secondary purpose will be a requalification as a research biobank.

As per SBP, « a biobank is an organized entity responsible for the management and the custodianship of biological resources ». When at least one of these activities is carried out with biological samples or data, the responsible entity is deemed to be a biobank. Likewise, biological resources *include biological material and its associated data*. Associated data stands for *personal data, including also health-related data, and pre-analytical data*.

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.

For additional information, please contact SBP.
General information: info@swissbiobanking.ch or www.swissbiobanking.ch
Specific questions on the Regulation: sabine.bavamian@swissbiobanking.ch

Swiss Biobanking Platform

SWISS BIOBANKING PLATFORM
Avenue d'Echallens 9, 1004 Lausanne - Switzerland
+41 21 314 46 91 - info@swissbiobanking.ch - www.swissbiobanking.ch

BIOBANK REGULATION [NAME OF THE BIOBANK]

Explanatory Note:
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]

DEVELOPED BY SWISS BIOBANKING PLATFORM

TABLE OF CONTENT

1) GENERAL PROVISIONS

1.1 SCOPE

This Regulation defines the purpose, the operational processes, and the organisation of the biobank [Name of the BB]. It describes the requirements for collecting, storing, and sharing biological material and their associated data (i.e., biological resources) for any ongoing or future research project.

1.2 APPLICABLE LAW

This Regulation relies on the applicable legal framework; in particular, the Federal Act on Research involving Human Beings (HRA) and the Federal Act on Data Protection (FADP). It follows established ethical/professional principles, including the 2016 Taipei Declaration on ethical considerations regarding health-related databases and biobanks as well as the Council of Europe Recommendation CM/Rec(2016)6 on research on biological materials of human origin. The list of laws and recommendations on which this Regulation is based on can be found on the SBP website (www.swissbiobanking.ch).

1.3 DEFINITIONS

The terms used in this Regulation derived from the SBP glossary, which is accessible on the internet at www.swissbiobanking.ch.

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
FADP	Federal Act on Data Protection of 19 June 1992; RS 235.1
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
SBP	Swiss Biobanking Platform

2) GOVERNANCE

2.1 ESTABLISHMENT OF THE BIOBANK

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

2.2 LEGAL STATUS

The biobank is established as a [foundation - name, association - name, company - 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.

2.3 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 I).

2. The responsible person of the biobank is [Position of the person responsible for the biobank].

2.4 CONSENT

1. The collection, storage, and use of biological resources require prior consent: [type of consent]. Such consent must be freely given, actively expressed, and be preceded by appropriate information. The consent status given by the participant has to be documented.

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 associated data of the participant are [anonymised/destroyed]. Note: Revocation is only applicable to future use of the biological resources. Results obtained prior the revocation and their evaluation are not affected by this decision.

2.5 CONFIDENTIALITY MEASURES

1. All samples are stored as [coded/anonymised].

Coding:

2. Coding is performed according to [Specify coding rules] and the key to unlock the code is kept by [Function of the key keeper]. 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.

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.

2.6 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 ».

2.7 PARTICIPANT'S RIGHT TO INFORMATION

2.7.1 Right to consult

At any time, 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 ».

2.7.2 Return of results

1. In compliance with the FADP, the participant can request information at any time from the biobank on the results of research conducted with his/her biological resources.

2. A participant is informed of the return of results policy as described in Appendix III.

2.7.3 Biobank activities

The biobank is committed to publicly communicating relevant information concerning its organisation, operational processes, and activities via [its website /publication of activity reports / Newsletter/scientific publications /Conference presentations…].

2.8 FINANCE

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

2.9 DISSOLUTION OF THE BIOBANK

1. In compliance with the consent of the participant, in the event of the 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 rules on the destruction of biological resources are described in Appendix IV.

3) DESCRIPTION OF THE BIOBANK

3.1 BIOBANK PURPOSE

1. This biobank is [type of biobank; for example, cohort / specific to a particular disease, etc.].

2. The biobank has several sites [yes/no] of which the principal one is [lead organisation] and of which the secondary ones are: [other secondary Institutions].

3.2 BIOBANK SCOPE

1. This biobank was established for [research / diagnostics / therapeutics / other] purposes. [Indicate also secondary purposes if applicable].

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].

3.3 NATURE OF THE BIOLOGICAL RESOURCES

1. The types of biological resources stored in the biobank are described in Appendix II.

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

3.4 STORAGE DURATION

The biological resources stored in the biobank are kept for a period of [storage duration].
Note: If the biobank is established for a fixed duration, it will follow the rules applicable for the destruction of biological resources as outlined in section 2.9 « Dissolution of the biobank ».

4) OPERATIONAL PROCEDURES

4.1 GENERAL PRINCIPLE

The collection, storage, and use of biological resources are carried out according to 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 properly documented 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 Data

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

2. Associated data are [automatically imported via data warehouse / managed by the name of the software / not managed by software / other].

5) GRANTING ACCESS TO BIOLOGICAL RESOURCES

5.1 TERMS OF ACCESS

1. The use of biological resources fulfils the following criteria [criteria].
Or
The use of biological resources is based on [first come, first served] basis.
Or
The use of biological resources is validated by [the biological resources management committee] according to the following criteria: [criteria].

2. The researcher, who has been authorized to use biological resources of the biobank, is committed to protecting the confidentiality of participants and agrees not to attempt to re-identify them, except under the conditions outlined in Article 27, second paragraph, of the HRO1[1], in conformity with the Material Transfer Agreement (MTA) and with the consent of the participant.

3. The biobank will only grant access to its biological resources if the research ethics committee or an equivalent authority has agreed to the request. If the research project is approved, the researcher can have access to the samples and/or data after the MTA has been signed by both parties.

5.2 TRANSFER

1. Any transfer of biological resources must be regulated and documented in a verifiable manner according to the conditions defined in the MTA.

2. The MTA establishes the obligations and responsibilities of both parties concerning the transfer of material of a biobank or a registry, before shipment. The obligations, which have not been expressly attributed to the receiving party by the MTA, remain under the responsibility and the management of the biobank. In all cases, the biobank remains responsible towards participants.

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

5.3 FINANCIAL CONTRIBUTION

No financial contribution has been foreseen for the transfer of biological resources of the biobank.
Or
When a financial contribution is foreseen for the transfer of biological resources, the fees cover [biobank activities, transport, other]. The detail of these costs and the price per sample are listed in Appendix V.

6) QUALITY

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

2. [Name of biobank infrastructure] is in charge of [proposed services].

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

[1] 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.

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 Governance structures
Appendix II Biological resources of the biobank
Appendix III Return of research results to participants
Appendix IV Rules on the destruction of biological resources of the biobank
Appendix V List of costs

APPENDIX 1
GOVERNANCE STRUCTURES

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

For each structure, provide 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 II
BIOLOGICAL RESOURCES OF THE BIOBANK

SAMPLES
- Sample 1: [type], origin: [origin];
- Sample n: [type], origin: [origin].

ASSOCIATED DATA
[Type]

APPENDIX III
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 IV
RULES ON THE DESTRUCTION OF BIOLOGICAL RESOURCES OF THE BIOBANK

Describe the procedure that is used to destroying samples and data issued from the research.

APPENDIX V
LIST OF COSTS

Describe in details the costs of a financial contribution foreseen for the transfer of biological resources (for example, biobank running costs, transport, cost per sample).

Before distribution of any biological resource to third parties, a transfer contract must be agreed upon and signed by both parties.