



Biobank Regulation

Swiss Center for Musculoskeletal Biobanking | SCMB

Version 2.1 November 2023

Commitment statement:

In agreement with this Regulation, the Swiss Center for Musculoskeletal Biobanking commits itself to protecting the fundamental rights of study 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.

1 GENERAL PROVISIONS

1.1 SCOPE

This Regulation defines the purpose, the operational processes, and the organization of the biobank "Swiss Center for Musculoskeletal Biobanking" (hereafter referred to as "SCMB"). 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 Swiss Biobanking Platform glossary which can be found in Annex I.

1.4 ABBREVIATIONS

DTA	Data Transfer Agreement
GCP	Good Clinical Practice
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

2 DESCRIPTION OF THE BIOBANK

2.1 BIOBANK PURPOSE

The SCMB serves as an open-access reference center for the collection, storage and analysis of tissue and blood samples donated by patients with musculoskeletal conditions.

2.2 BIOBANK SCOPE

The SCMB was established to facilitate research, and in particular musculoskeletal research. It is created to bridge the gap between doctors and scientific researchers to improve the prevention, diagnosis and treatment of specific musculoskeletal diseases (including, but not limiting to, tendon disease, muscle atrophy, rheumatology, sarcoma). Its main users are from the academic as well as the private sector.

2.3 NATURE OF THE BIOLOGICAL RESOURCES

2.3.1 Information related to biological resources stored in the biobank is described in Annex II.

2.3.2 These biological resources are collected from inpatients, outpatients, and volunteers.

2.4 STORAGE DURATION

The biological resources stored in the biobank are kept for a period of 10 years, unless stated differently in the study protocol of a study.

3 GOVERNANCE

3.1 ESTABLISHMENT OF THE BIOBANK

The SCMB was founded on the November 23, 2018.

3.2 LEGAL STATUS

The biobank is bound to the Balgrist Campus AG and has no independent legal personality.

3.3 STRUCTURE

3.3.1 The organizational structure of the biobank is as follows: The biobank consists of a head, responsible for the daily operation of the biobank, a deputy, a biosafety officer and an assistant, responsible for sample logistics and sample processing. The responsible person of the biobank is listed in Annex III.

3.3.2 A separate SCMB Project Review Board decides if a submitted project proposal can be executed, and fulfills the scope of the biobank (cf. organizational chart in Annex III).

3.3.3 A separate SCMB Steward Advisory Board decides on secondary use of samples collected from patients in the Balgrist University Hospital who have given written General Consent on the use of their samples for research purposes.

3.3.4 Within the framework of projects executed in concerto with the Balgrist University Hospital, the SCMB is working in close cooperation with the UCAR Team (see below), as well as with study coordinators belonging to other clinical teams.

3.4 CONSENT

3.4.1 The collection, storage, and use of biological resources is based on both specific consent, specific consent allowing further use of these biological resources and general consent, depending on the project.

3.4.2 Such consent must be freely given, and be preceded by appropriate information. The consent status given by the study participant has to be documented and the consent form has to be archived.

3.4.3 The collection, storage, and use of biological resources are based on the free and informed consent of the patient obtained within the healthcare framework.

3.4.4 Revocation of consent

- Starting from the moment of revocation, all stored samples and data of the study participant in the biobank cannot be utilized for research purposes anymore. Any remaining samples will be destroyed.
- Revocation only applies to future use of the biological resources and data for research purposes. Results obtained prior to revocation and their evaluation are not affected by this decision. The use for diagnostic / therapeutic purpose remains possible.
- In the event of anonymization (also see 3.6.3), revocation is not feasible since intentional measures have been taken to avoid documenting the connection between the personal data of the study participant and the coding of the samples.

3.4.5 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 LEGAL MINORS, CAPABLE AND INCAPABLE OF JUDGEMENT, AND ADULTS INCAPABLE OF JUDGEMENT

- 3.5.1 Definitions of Legal minors (children and adolescents) are described in Annex I.
- 3.5.2 Legal minors capable of judgement
- a) Children: A research project *with an expected direct benefit* may only be carried out in children capable of judgement if the child and their legal representative has given informed consent (in writing for the latter). (HRA, Art. 22).
A research project *with no expected direct benefit* may only be carried out in children who are capable of judgement if, in addition to the above conditions, the research project (1) entails no more than minimal risks and burdens; and (2) can be expected to yield substantial findings which could in the long term be beneficial for persons with the same disease or disorder, or in the same situation (HRA, Art. 22).
 - b) Adolescents: A research project *with or without an expected direct benefit* may only be carried out in adolescents who are capable of judgement if (1) the adolescent has given informed consent in writing; and (2) the legal representative has given informed consent in writing when the research project entails more than minimal risks and burdens (HRA, Art. 23).
- 3.5.3 Legal minors incapable of judgement
- a) Children: A research project *with an expected direct benefit* may only be carried out in children who lack capacity if (1) the legal representative has given informed consent in writing; and (2) the child does not visibly express opposition to the research intervention either verbally or by his or her behavior (HRA, Art. 22).
In addition to the above mentioned conditions, a research project *with no expected direct benefit* may only be carried out in children who lack capacity if (1) it entails no more than minimal risks and burdens; and (2) it can be expected to yield substantial findings which could in the long term be beneficial for persons with the same disease or disorder, or in the same situation (HRA, Art. 22).
 - b) Adolescents: A research project *with an expected direct benefit* may only be carried out in adolescents who lack capacity if (1) the legal representative has given informed consent in writing; and (2) the adolescent does not visibly express opposition to the research intervention either verbally or by his or her behavior (HRA, Art. 23).
A research project *with no expected direct benefit* may only be carried out in adolescents who lack capacity if, in addition to the requirements specified here above, (1) it entails no more than minimal risks and burdens; and (2) it can be expected to yield substantial findings which could in the long term be beneficial for persons with the same disease or disorder, or in the same situation (HRA, Art. 23).
- 3.5.4 Adults incapable of judgement
- Adults: In the case of an adult study 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.

- 3.5.5 In all cases, the status of a legal minor or adult incapable of judgment is explicitly documented to facilitate the recollection of their consent when acquiring their capacity to consent.

3.6 CONFIDENTIALITY MEASURES

- 3.6.1 Biological resources are stored and distributed in accordance with the consent granted by the study participants. In most cases, this means that samples will be pseudonymized (see 3.6.2.) or anonymized (see 3.6.3.). Both pseudonymized and anonymized samples are labeled with an identification code which does not reveal details on the identity of the person who gave permission for its use.
- 3.6.2 Pseudonymization
- a) In accordance with Swiss law (HRO, Art.26), pseudonymized samples stored or distributed by the SCMB will be labeled with a code. The key file, in which the identity of the person(s) giving permission for use of their tissue(s), and the accompanying code, is displayed, is kept separated from the biological material, by a person not involved in the research project.
 - b) 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 study participant is given.
- 3.6.3 Anonymization
- a) Anonymization entails the removal of identifiable personal information and thus prevents any possibility of linking specific samples and/or data to a study participant.
 - b) Anonymized samples stored or distributed by the SCMB will be labeled with a code, but no key file will be created. Consequently, study participants giving permission to anonymization are not able to withdraw consent, to consult, to correct information on their health, or to obtain feedback on relevant results that may concern them.
 - c) The study participant is informed of the consequences of the anonymization, as described above.

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 study 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 study 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 study participant can contact the biobank as per the provisions of Chapter 7 « Communication ».

- 3.8.2 Return of results
- a) A study 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 validity¹, clinical significance², and be actionable³.
 - b) A study participant is informed of the return of results policy which includes the type of results that will be returned to study participants (see Annex V).
 - c) 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.
- 3.8.3 Biobank activities: The biobank communicates relevant information concerning its organisation, operational processes, and activities via its website (www.scmb.balgristcampus.ch), publications of activity reports, scientific publications, and conference presentations.

3.9 FINANCE

The biobank is funded by private as well as public funds, notably from the State Secretariat for Education, Research and Innovation (SERI). Funding through service fees cover the lifetime of the biological resources stored in the biobank.

3.10 DISSOLUTION OF THE BIOBANK

- 3.10.1 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 will be destroyed, the determination of which will be in compliance with the consent of the study participant.
- 3.10.2 The rules on the destruction of biological resources are described in Annex VII.

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

- 4.2.1 The biobank is responsible for ensuring that any sample and/or data are associated with a valid consent.
- 4.2.2 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: The room in which the tissues are stored has restricted access to SCMB staff only. The temperature of the storage equipment is under surveillance 24/7. Measures in place to ensure the protection of samples are: a central alarm with 24/7 on-duty service, continuous monitoring of temperatures of both the storage room and the storage tanks and freezers, availability of a pre-cooled backup freezer, backup liquid nitrogen, room temperature monitoring. Freezers inside the storage room are locked and can only be accessed by SCMB staff.
- 4.3.2 Associated Data
- a) Preanalytical data are managed by the commercial LIMS software programme SLIMS (Agilent).
 - b) Postanalytical data is managed by the Principal Investigator of the study.

5 GRANTING ACCESS TO BIOLOGICAL RESOURCES

5.1 TERMS OF ACCESS

- 5.1.1 The access of biological resources is granted to the Principal Investigator of the study. The detailed process for requesting and obtaining biological resources is described in Annex VII.
- 5.1.2 The researcher, who has been authorized to use biological resources of the SCMB, agrees not to attempt to re-identify the study participants, except under the conditions outlined in Art. 27, second paragraph, of the HRO⁴.
- 5.1.3 The biobank will only grant access to its biological resources for projects that have been approved by the responsible ethics committee or equivalent authority.

5.2 TRANSFER

- 5.2.1 Any transfer of biological resources must be regulated and documented in a verifiable manner.
- 5.2.2 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,

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 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.

remain under the responsibility and the management of the biobank. In all cases, the biobank remains responsible towards study participants within the limits of its accountability.

- 5.2.3 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 study participants have been fulfilled.
- 5.2.4 If a financial contribution is foreseen for the transfer of biological resources, the fees cover transport and shipment costs.

6 QUALITY

- 6.1.1 Health-related data, in pseudonymized form, are stored in the database RedCap.
- 6.1.2 The biobank uses the Abacus ERP Business Software suite for the management of its financial activities.

7 COMMUNICATION

For any questions or additional information, please contact:
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8 APPENDICES

- Annex I: Definitions
- Annex II: Biological resources of the biobank
- Annex III: Governance structure
- Annex IV: Consent Template
- Annex V: Return of research results to study participants
- Annex VI: Rules on the destruction of biological resources of the biobank
- Annex VII: Process for requesting and obtaining biological resources

ANNEX 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 (DTA)

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 that connects the personal data of a study participant to their study encryption code.

LEGAL MINORS

In line with Swiss law, legal minors include children, i.e. individuals under 14 years of age, and adolescents, i.e. individuals over 14 years of age but still under 18 years old.

MATERIAL TRANSFER AGREEMENT (MTA)

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

STUDY PARTICIPANT

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

SPECIMEN/SAMPLE

Specimen: A specific quantity of biological material such as tissue, blood or urine taken from a single subject or participant at a specific time. Sample: A single unit containing material (e.g. plasma, serum, DNA, RNA, cells, etc.) derived from one specimen.

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.

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 within the consent form and should be disclosed with the concerned study participant during the consent process.

ANNEX II: BIOLOGICAL RESOURCES OF THE BIOBANK

Biological material:

Following tissue types are stored in the SCMB:

- Wound fluid; origin: patients with non-healing wounds
- Blood, serum; origin: patients with rheumatic disorders
- Blood, plasma; origin: patients with rheumatic disorders
- Skin tissue; origin: patients with rheumatic disorders
- Abscess, origin: patients with non-healing wounds
- Tumor tissue; origin: sarcoma patients
- Nerve tissue; origin: Morton Neuroma patients
- Muscle tissue; origin: patients with lower back pain.
- Tendon tissue; origin: left-over material from tendon reconstructions
- Cerebrospinal fluid; origin: patients with spinal cord injury
- Stool samples; origin: patients with spinal cord injury
- Bladder tissue; origin: patients with spinal cord injury

This list does not exclude other tissue types from entering the SCMB, including those from non-musculoskeletal origin.

These biological resources are collected from inpatients, outpatients, and volunteers.

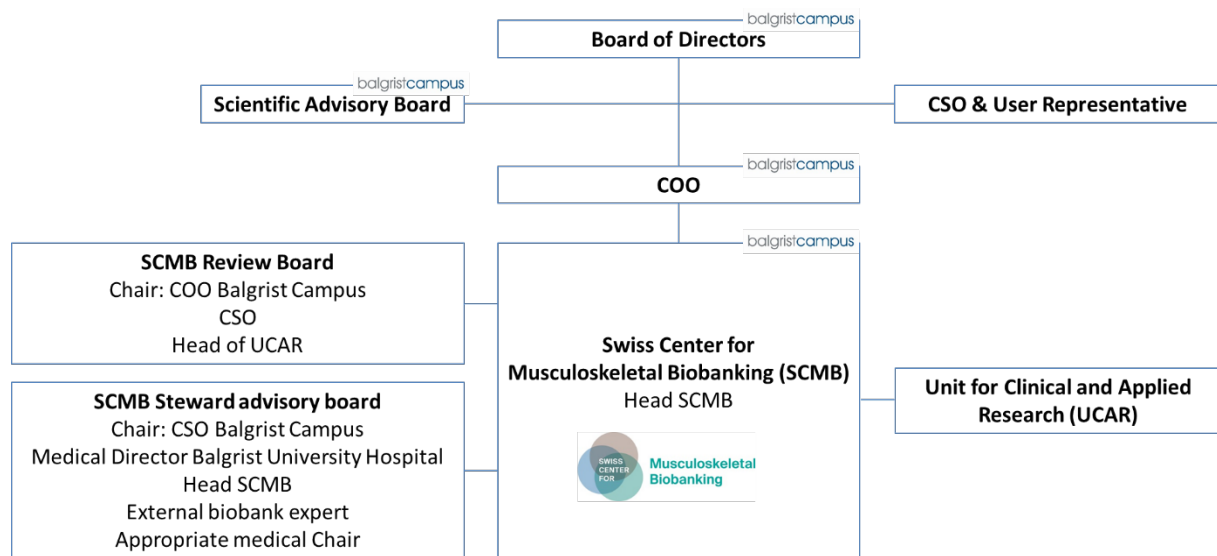
Samples are stored at either 4°C, -20°C, -80°C or -150°C (liquid nitrogen vapor). Solid samples are stored in either RNALater, 4% paraformaldehyde or Optimal Cutting Temperature (OCT) embedding material. Liquid samples are usually stored in separate aliquots (e.g. 1 mL aliquots) to allow segmented thawing.

Health-related data:

Health-related data is stored in pseudonymized form in the database RedCap.

ANNEX III: GOVERNANCE STRUCTURE

The organization of the biobank is composed of the following governance structure:



The biobank is headed by:

Sander Botter, PhD

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sander.botter@balgristcampus.ch

ANNEX IV: CONSENT TEMPLATE

As service provider, the SCMB relies on the Principal Investigator (PI) of a study to supply consent forms. As such, the PI bears full responsibility for correct application and administration of the consent forms. The SCMB requests a confirmation that valid consent forms are indeed available for distributed samples.

As sample collector, the SCMB uses the general consent template of the Balgrist University Hospital, which is available upon request.

ANNEX V: RETURN OF RESEARCH RESULTS TO STUDY PARTICIPANTS

At request, the biobank can inform participants of a study about the general outcome of the research project. Individual research results cannot be transferred due to the pseudonymization procedure, except under the conditions outlined in Article 27, second paragraph, of the HRO. The SCMB operates a website (www.scmb.balgristcampus.ch) which also includes an overview of the scientific publications resulting from studies in which study participants (through the SCMB) have played a role.

ANNEX VI: RULES ON THE DESTRUCTION OF BIOLOGICAL MATERIAL OF THE BIOBANK

All tissues designated for destruction are disposed in a special container for medical hazardous waste. These containers are collected by an external company certified for handling medical hazardous waste. The container is then destroyed through burning.

ANNEX VII: PROCESS FOR REQUESTING AND OBTAINING BIOLOGICAL RESOURCES

A request for sample transfer must be sent via e-mail to scmb@balgristcampus.ch at least 24h prior to transfer to the researcher. SCMB staff will retrieve the samples and update the sample database accordingly. For samples collected by the SCMB with general consent from the Balgrist University Hospital, the SCMB Steward Advisory Board decides on secondary use of the biological material prior to release.