SSCF Research Biobank

Biobank regulations in connection with research projects involving human beings

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1 Description of the biobank

The Swiss Stem Cell Foundation (SSCF) is an independent and no profit foundation aiming at research and development in the field of mesenchymal stem/stromal cells from adipose tissue, as well as the development of new human cell therapies.

SSCF is operating a biobank (SSCF Research Biobank) for an unlimited period.

The SSCF Research Biobank has been set up to enable research and development of methodologies and technologies for the isolation, characterization, and large-scale production of mesenchymal stem / stromal cells from adipose tissue in a pre-clinical stage. The biobank collects samples and data and stores them for further use in research projects already determined or yet to be defined.

The activities of the biobank are in accordance with the Federal Act of 30 September 2011 on Research involving Human Beings (Human Research Act, HRA), which came into effect on 1 January 2014. The SSCF Research Biobank undertakes to comply with all the relevant legislation and ethical principles.

Samples and data are included in the biobank and stored for use in specified, or as yet unspecified, research projects.

The biobank is financed as follows: private SSCF research funding.

2 Definitions

The following table provides definitions of the terms used in these regulations.

Research	Method-driven search for generalisable knowledge
Donor	Person from whom a sample originates or who is the subject of data
Sample	*Biological material:* bodily substances derived from living persons (e.g. tissue samples, blood, urine and other bodily fluids)
Stromal Vascular Fraction	Population of cells derived from adipose tissue, including mesenchymal stem/stromal cells , immune and hematopoietic cells , endothelial progenitor cells and stromal cells
Mesenchymal stem/stromal cells	Cells isolated from the stromal vascular fraction of various tissues , including bone marrow and adipose tissue. In these tissues they have a regenerative role and show degrees of stemness with the ability to differentiate into adipocytes, osteocytes and chondrocytes. They also possess immunomodulatory and anti-inflammatory properties.
Data	*Health-related personal data:* information concerning the health or disease of a specific or identifiable person, including genetic data (e.g. age, sex, blood test results, health status, conditions, treatments, etc.)
Fetal adnexa	Tissues of foetal origin like cord tissue or amniotic membrane. These tissues possess regenerative properties. They could also have immunomodulatory and anti-inflammatory properties.
Coded	*Coded biological material and coded health-related personal data:* biological material and data linked to a specific person via a code.
Anonymisation	*Anonymised biological material and anonymised health-related data:* biological material and health-related data which cannot (without disproportionate effort) be traced to a specific person.

3 Inclusion of samples/data in the biobank for research purposes

Samples and data are to be included in the biobank for research purposes only when samples and data are anonymised and if the donor has not dissented to anonymisation of the samples concerned.

The surgeon informs the donor on the planned anonymisation of the sample and data. The sample and the data are anonymised by the surgeon before providing the sample and data to SSCF Research Biobank.

In the case of minors or legally incapacitated subjects, consent must be given by the legal representative; in the case of minors capable of judgement, the legal representative's consent must be given in addition to their personal consent.

4 Storage of samples/data in the biobank

Anyone who stores data and/or samples for research must take appropriate operational and organisational measures to protect them, and in particular:

a) restrict the handling of the health-related personal data to those persons who require this data to fulfil their duties.
b) prevent unauthorised or accidental disclosure, alteration, deletion and copying of the health-related personal data.
c) document all processing operations which are essential to ensure traceability.
d) ensure that the technical requirements are met for appropriate storage of the samples.
e) make available the resources required for storage.

5 Quality and safety standards

The biobank complies with the following quality standards: GMP (Swissmedic certification, see Attachments).

The procedures adopted by the biobank to ensure the quality and safety standards are described in the quality management system (QMS) of SSCF and SSCB.

6 Transfer of samples/data for research projects

Samples/data may be used for research projects, provided that the project has been approved by the responsible research Ethics Committee.

Any transfer outside of the SSCF must be governed by a material transfer agreement (MTA) and be appropriately documented.

7 Transfer of samples/data to biobanks

Samples and data stored in the biobank may be transferred to other biobanks only in anonymised form if it is ensured that the legal requirements concerning the storage of data and samples are met.

If samples/data are to be transferred abroad, any requirements which may be applicable for the country concerned are also to be complied with.

Each transfer must be governed by a material transfer agreement (MTA) and be appropriately documented.

8 Re-identification of donors

The anonymization procedure does not allow the re-identification of the donors.

9 Donors' rights

Donors have the rights accorded to data subjects under the applicable legal provisions, and in particular the right to dissent to anonymisation of the samples concerned:

The donors are informed about:

a) The planned anonymization of biological material and personal data.
b) The consequences of the anonymization procedure on experimental results related to donor's health.
c) The possibility of transmitting for research purposes the biological material and data to third parties.

10 Organization of the biobank

The biobank has the following bodies and organisational structure, with the following responsibilities:

a) The General Director takes the strategic, operational and overall responsibility for the operation of the biobank .
b) The Administration is responsible for operating the biobank according to the quality management system (QMS), the biobank regulations, and the provisions of the General Director.
c) The Control Body, composed of the Head of Quality Assurance, manages the quality management system (QMS) and guarantees the standards of quality and safety of the biobank.
d) The laboratory unit manages the activities of the biobank in accordance with the provisions of the Administration

The names of the responsible are indicated in the Organizational Chart of SSCF Research Biobank (see attachments).
The supervisory powers of other bodies, such as the responsible research ethics committee, or of the responsible data protection officer, remain unaffected.

11 Key management

The planned anonymization of the samples and the data does not provide for the creation of a key.

12 Dissolution of the biobank

If the biobank is dissolved, it may be integrated into another biobank, provided that the conditions specified in Section 7 are met.
If integration is not possible and no further use (e.g. diagnosis/treatment) other than research exists, the samples and data are to be destroyed.

13 Any other provisions

- These Regulations shall be made accessible to the public by publication on the website www.sscf.ch/research/research-biobank.
- These Regulations were issued by SSCF.
- These Regulations were approved by Gianni Soldati, SSCF President.
- Valid since (version 2.0): 08.10.2015.
- Revisions (with reasons for revision and date):
  - Version 2.0 (08.10.2015) included date and version number in the footer; added chapter "Any other provisions" and indicated the accessibility to the public of the Regulations.
  - Version 3.0 (05.10.2022) include date and version number in the footer; added definition "Fetal adnexa" in Point 2.

14 Attachment

- GMP certificates
- Organizational chart SSCF Research Biobank
- MTA agreement with EPFL, Lausanne, CH.