
Biobank regulations in connection with research projects involving human beings

[Name of the biobank]

NOTE:

This is a template for the preparation of biobank regulations which are in accordance with the Federal Act on Research involving Human Beings (Human Research Act, HRA) and with the associated Ordinances.

The template is accompanied by a Guide including additional explanations. Text elements which need to be adapted are highlighted in grey – e.g. [name of the biobank].

The most recent versions of the template and explanatory notes are available for download at:

<http://swissethics.ch/templates.html>

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1 Description of the biobank

Here, a general description of the biobank and the broader context is to be given. Suggested wordings are provided below:

[Name of the biobank operator] is operating a biobank, [name of the biobank], [for an unlimited period/ for a period of ... years].

The [name of the biobank] was established to facilitate research, and in particular biomedical research. The aim is to improve prevention, diagnosis and treatment in human medicine. In addition, the samples and data collected can also be used for research to improve our understanding of fundamental disease mechanisms.

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 [name of the 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: [main source of funding]

2 Definitions

Other terms and definitions may be added as appropriate.

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	<i>Biological material</i> : bodily substances derived from living persons (e.g. tissue samples, blood, urine and other bodily fluids)
Data	<i>Health-related personal data</i> : 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.)
Coded	<i>Coded biological material and coded health-related personal data</i> : biological material and data linked to a specific person via a code.
Key	The information which allows the coding to be undone, so that samples/data can once again be linked to the donor/data subject.
Anonymisation	<i>Anonymised biological material and anonymised health-related data</i> : 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

Here, the general conditions are to be described under which samples can be included in the biobank, as well as the conditions under which the samples may no longer be used for research purposes.

Samples and data are to be included in the biobank for research purposes if one of the following conditions is met:

- a) In the event of coding: the donor has signed a consent form for the use of samples and data for research purposes.
- b) In the event of anonymisation: the donor has not dissented to anonymisation of the samples concerned.

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.

Declarations and any revocations of consent are to be managed in such a way that consent can be verified, with the biobank also being required:

- a) to know whether the donor wishes to be informed of results relating to his health, wishes to forgo such information, or has designated a person who is to make this decision on his behalf;
- b) to ensure that, in the event of consent being revoked, the samples and data are anonymised or no longer used for research purposes.

4 Storage of samples/data in the biobank

Please also specify any conditions for the storage of samples in your biobank which differ from the general conditions already mentioned.

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

This section must explain how the biobank assures the quality and safety of samples. For example: electronic monitoring of refrigerators and freezers, measures to be taken in the event of incidents,

documentation of temperature deviations.
If appropriate, reference may also be made to a separate document or regulations.

The biobank complies with the following quality standards: [ISO, Tubafrost, etc.]

6 Transfer of samples/data for research projects

Other requirements for the transfer of samples applicable to your biobank should be indicated.

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 [name of institution] must be governed by a material transfer agreement (MTA) and be appropriately documented.

7 Transfer of samples/data to biobanks

Additional local requirements should be indicated here (e.g. link to the MTA mentioned below).

Samples and data stored in the biobank may be transferred to other biobanks in coded 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

If appropriate, reference may also be made to a separate document or regulations.

In the case of samples coded for research purposes and coded data, the code may only be broken if:

- 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;
- c) breaking the code is necessary to guarantee the rights of the person concerned, and in particular the right to revoke consent.

9 Donors' rights

The suggested wording should be retained as the bare minimum, but it may also be expanded.

Donors have the rights accorded to data subjects under the applicable legal provisions, specifically the applicable Data Protection Act, and in particular:

- a) the right to request information as to whether data concerning them is being processed and to access such data;
- b) the right to have incorrect personal data corrected;
- c) the right to revoke their consent at any time, without stating their reasons, with the result that the samples and data stored in the biobank are anonymised or are no longer used for research purposes.

10 Organisation of the biobank

Here, it should be apparent how your biobank is actually organised and who the people responsible are (names), or where this information can be found. If responsibilities are divided among various bodies/individuals, it should be clear who is responsible for what, or where this information can be obtained (job description/regulations, etc.)

The biobank has the following bodies and organisational structure (reference to current organisation chart or list of responsibilities)

- a) The Board exercises strategic/operational management functions and has overall responsibility for the running of the biobank.
- b) Management is responsible for operations and enforcement of the regulations, and implements the directives of the Board.

Other bodies, if appropriate:

- c) The supervisory body.
- d) The key trustee, in accordance with the Operating Procedure specified in Section 11, manages the key which links the person to the samples and data concerned.
- e) Auditor [description of the biobank's auditing function].

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

If the key for your biobank is also managed by your institution, this should be explained here. Otherwise, it should be explained that this key is managed externally (or possibly how/by whom) and that the institution itself has no access to the key.

[Description of who creates the coding keys for the biobank]

The body managing the key which links samples and data to the person concerned, has the following duties:

- a) It stores the key securely.
- b) It ensures that samples or data can be linked to the donor/data subject in cases where one of the conditions specified in Section 8 is met.

The key management body fulfils its duties independently and acts in accordance with a binding Operating Procedure which is open to public inspection.

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 were issued by ...

These regulations were approved by ...

Date of entry into force:

Revised versions – indicating reasons for revision and date

14 Annexes

Please list any documents referred to in the regulations (if possible, including links to the current version of each document).
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