Swissethics Guide for the preparation of biobank regulations in connection with research projects involving human beings

Valid from 1 January 2014 (entry into force of the Human Research Act and associated Ordinances)

The biobank regulations are of crucial importance for the scientifically and legally sound management of a biobank. The regulations are to be written and reviewed by an expert. The template for biobank regulations is designed to ensure compliance with national legislation and promote the harmonisation of biobanks in Switzerland, in the interests of standardised sample and data quality.

Introduction

The present regulations and explanatory notes were published by the Swiss Ethics Committees on research involving humans (www.swissethics.ch) in 2014. The template is based in turn on the documents published in 2009 by the Swiss Academy of Medical Sciences (SAMS) concerning biobank regulations (and patient information/consent) suitable for use throughout Switzerland. A working group established by swissethics at the end of 2013 integrated the new provisions of the Human Research Act (HRA) into the existing template, to take effect in 2014.

The working group also revised the templates for patient information/consent for the collection of samples/data (see www.swissethics.ch).

The goals pursued by the working group were as follows:

a) implementation of current legal and ethical requirements (in particular, HRA)
b) Swiss-wide harmonisation of regulations, patient information and consent.

The biobank regulations (hereafter "regulations") were coordinated with the above-mentioned patient information/consent for the collection of samples/data.

Below, a few general notes are given concerning the preparation of regulations.
This Guide is intended merely as an aid to the compilation of regulations and does not form part of the template.

Formal aspects:

Each institution/organisation operating a biobank in Switzerland produces locally adapted documents, with a letterhead on the first page.
The entire document is to be paginated (page X of Y), with a revision date (and possibly a version number) included in the footer.
In the template, a box containing additional explanations is included under each heading. These boxes are to be deleted in the regulations.
Text highlighted in grey is to be localised.
If certain points are covered by other documents or regulations, reference is to be made to these (or links provided). This applies in particular to information that changes on a regular basis – e.g. the names of persons responsible.

Target readership, language and publication:

The regulations are intended, firstly, to define the appropriate management of a biobank for biobank operators. Secondly, they should enable researchers to ensure that any samples and data used are of the required quality.
In addition, the regulations are designed to inform the general public about how the samples and data collected are used. The regulations should therefore be accessible to the public. Accordingly, as far as possible, the regulations should be written in such a way that the content is also comprehensible for lay readers, especially the non-technical part.
Technical terms should therefore be avoided, or explained if they are indispensable. Abbreviations and repetition should also be avoided.
The same terms should be used for the same concepts throughout – synonyms are to be avoided.