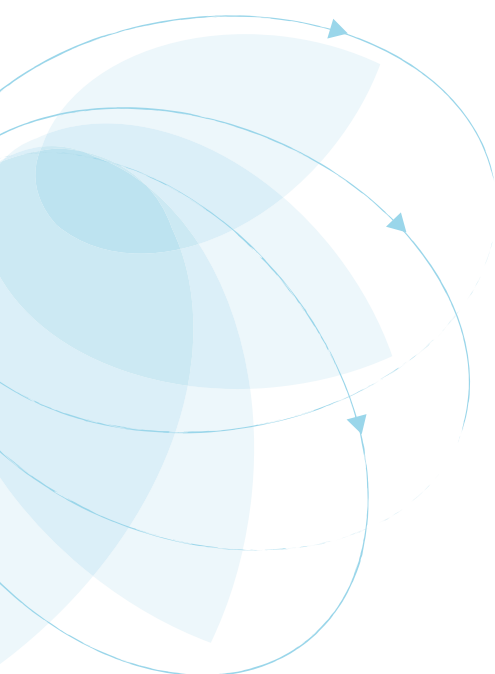


The logo for the Swiss Biobanking Platform features the text "SWISS BIOBANKING PLATFORM" in a red, sans-serif font, arranged in a semi-circle. Below the text is a circular diagram with three white arrows forming a clockwise cycle. A large, dark red, teardrop-shaped graphic is positioned at the bottom left of the circular diagram, partially overlapping the text.

**SWISS BIOBANKING PLATFORM**

The background of the entire page is a light blue color with a faint, repeating pattern of DNA double helix structures.

**BROAD CONSENT  
FOR RESEARCH**  
BEST PRACTICES



## INTRODUCTION

The Swiss Biobanking Platform (SBP), launched in 2015, is a national initiative of the Swiss National Science Foundation (SNSF), which promotes the coordination of biobanks in human and non-human domains. SBP is born from a Swiss wide consortium constituted by the five University Hospitals as well as Sankt-Gallen Hospital. Our goal is to meet the growing demands of research regarding quality control, access to information, transparency and networking of Swiss biobanks. For this purpose, SBP plans to produce a national online catalogue of biobanks, promote harmonization of biobanking processes in accordance with international standards, and provide guidance on legal and ethical issues associated with biobanking activities. These “best practices” provide guidance on proper use of the Broad Consent for Research (BCR), and have been reviewed by Swissethics, Swiss Academy of Medical Science (SAMS), members of the Working Group on Governance (ie. Representatives of the five University hospitals), patients’ organizations, legal and ethical advisers.

## CONTEXT

The Federal Act on Research involving human beings (Human Research Act, HRA), enacted 01.01.2014, allows under certain conditions to establish a BCR, through which a person may give his/her consent for the use of his/her data and biological material for future research projects not yet defined. Currently, in the Institutions which have already implemented a BRC, the use of different templates together with hospitals’ features complicate the conduct of multicenter studies using biobanked samples and data.

In addition, compliance to different cantonal regulations hinders general access to data and samples independently of the center where they are kept. Thus, the variety of templates and the absence of harmonized measures to promote the use of BRC can be confusing for patients and can be an obstacle to biomedical research.

Therefore, to harmonize these processes, a group of experts composed by representatives of SAMS, Swissethics, Swiss Clinical Trial Organisation and SBP has developed a new national template. SBP was involved in the whole development process as a consultant and was mandated to develop guidelines to support the set up and appropriate use of BCR in the Swiss Institutions.

## WHO ARE THESE BEST PRACTICES FOR?

These best practices have been developed to guide local hospital personnel (eg. physicians, nurses, administrative staff, etc), operators of biobanks or researchers as well as members of research ethics committees (REC) and patients’ organizations. They provide them information on how and in which context to use the Swiss BCR model. These best practices have been established in accordance with applicable legal and ethical frameworks.

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# I) CUSTODIANSHIP AND RESPONSIBILITIES

## A. GENERALITIES

These best practices address the need of establishing a custodianship as the caretaking responsibility for a careful application of the legal frameworks, ethical principles, and transparent policies for proper implementation of BCR in each Institution. This is required to ensure respect and privacy of human research participants, confidentiality of associated data, and an appropriate use of biospecimens and data.

**I.A.1** Each hospital is responsible to designate custodianship as the trusted intermediaries and caretakers to implement the BCR in their respective site. Custodianship will be a structure including at least a person in charge of defining the strategy at the Institution level, a legal advisor and an operational expert without any conflict of interest.

**I.A.2** All necessary information regarding informed consent (eg. research purposes, benefits to participants and biobanking) should be disclosed as should all questions to address patients' concerns be answered. Patients should be informed on the risks associated with data protection and patient's confidentiality as well as on the measures that will be taken to safeguard their rights, safety, and well-being.

**I.A.3** The ultimate patient's decision must be documented ideally in the main administrative information system.

## B. GOVERNANCE, MANAGEMENT AND OVERSIGHT

**I.B.1** Institutions are committed to establishing a clear governance structure consisting of responsible authorities (eg. custodian(s)) and management with oversight roles.

Custodial responsibilities include:

- Participation in the development of overall operational, ethical, and legal policies for implementing a BCR in their site.
- Implementation of a BCR with the support of these best practices and the aforementioned developed policies.

- Ability to provide all relevant information and the documents with regard to the use of the consent documents.
- Training or education of the hospital personnel who will be in charge of obtaining the consent.
- Compilation of a research projects' list under the BCR into a publicly available catalogue.

**I.B.2** The governance structure must protect the rights and well-being of participants with the idea that common good prevails over research interests. The consent procedure is carried out in accordance with applicable laws, ethical principles, local regulations and these best practices.

**I.B.3** To promote transparency, information on governance, management and oversight should be made available (eg. through the Institution's website) and include:

- i) the consent documents (ie. form, patient's info letter and brochure)
- ii) these best practices
- iii) the biobank regulation

## C. QUALIFICATIONS, EDUCATION AND TRAINING

**I.C.1** Custodians should have qualifications, training and experience requisite to carry out his/her mandate.

**I.C.2** Custodians should ensure that the hospital personnel is knowledgeable about the purposes and use of different types of consent (specific versus BCR) by giving a specific training on the subject. The hospital personnel is aware of its own knowledge limitations and is subject to audit by an independent organization such as SBP.

**I.C.3** Custodian(s) are responsible for implementing BCR with the support of these best practices as well as any of the local policies, regulations and consent procedures.

# II) TERMS OF PARTICIPATION

## A. RECRUITMENT

**II.A.1** BCR allows to use biological material and/or health-related data in the context of medical research purposes. At the time of collection, future research objectives are possibly not yet defined. The research project, the registry<sup>1</sup> or the biobank<sup>2</sup> must handle coded data and/or samples. The use of identified data and/or samples is excluded from the scope of the BCR and thus requires a specific consent. Besides, patients can be asked to consent for providing an additional biological sample for research projects. This biobanking part of BCR is optional. If institutions are willing to include this additional sampling, it should be performed under the following conditions:

- 1) The sampling is considered to be without additional risk or burden for the patient;
- 2) The sampling is performed during the clinical management of the patient.

If sampling is performed with additional risk or with an inconvenience for the patient, a specific consent should be obtained.

**II.A.2** To obtain and document consent, hospital/ research personnel should comply with the applicable regulatory requirement(s), and to the ethical principles mentioned in the Oviedo Convention, the Declaration of Helsinki and in the newly edicted WMA Declaration of Tapei.

**II.A.3** Appropriate measures should be taken to seek consent from vulnerable persons (eg. children, persons in emergency situations, etc). Those measures should be developed by each Institution to safeguard the rights, safety, and well-being of research participants.

**II.A.4** To be able to address patients' or hospital personnel questions, each institution is responsible to provide contact information. A hotline could be created for this purpose.

## B. ACCESS AND USE OF BIOLOGICAL MATERIAL AND DATA

Biological material and data are intended to be used for research purposes. The terms and conditions of access/ use to the biosamples and data are clearly regulated. Access policies for sharing and distributing specimens must be developed in the biobank regulation.

**II.B.1** Use of biological material and health-related data should be based on a scientifically, legally and ethically appropriate research plan that has been approved by the responsible REC.

**II.B.2** Only few individuals within the institution have access to uncoded personal data. Those individuals should be clearly designated and are bound by medical secrecy. This access is strictly regulated in accordance with rules of good practices and data protection requirements applied within each Institution.

**II.B.3** The biological material and health-related information are only available to researchers in a coded form. In this case, the code should be kept within the Institution by a limited number of designated persons who should be clearly identified and who ideally should have no link with the research project.

**II.B.4** Biological material and data could only be transferred to third parties when the recipient has adequate standards in place regarding privacy and confidentiality. For abroad transfers, it must be guaranteed that at least the same data protection requirements exist at the research site as in Switzerland.

**II.B.5** A transfer agreement<sup>3</sup> (MTA, in the case of biospecimens and DTA, in the case of data) or similar agreement must be signed by interested parties to transfer materials and data among academic, nonprofit, and/or industrial organizations. This document lists or mentions the obligations and responsibilities of parties involved in the transfer of materials from a biobank or a repository prior to shipment.

<sup>1</sup> A registry is a collection of information about individuals, usually focused around a specific diagnosis or condition. Many registries collect information about people who have a specific disease or condition, while others seek participants of varying health status who may be willing to participate in research about a particular disease. Individuals provide information about themselves to these registries on a voluntary basis.

<sup>2</sup> A biobank is an infrastructure for the management of biological materials with associated data which follows high standards of quality and expertise. It collects, stores and distributes biological materials and/or data for scientific and clinical use, and could also provide other services.

<sup>3</sup> A transfer agreement is a contract that governs the transfer of tangible research materials between parties, a provider and a recipient, when the recipient intends to use it for his/her own research purposes. The material transfer agreement (MTA) in the case of biospecimens or the data transfer agreement (DTA) in the case of personal data define the rights of the provider and the recipient with respect to the transferred materials (eg. specimens, reagents, cell lines) and acknowledge responsibilities between parties.

## C. BENEFITS TO PARTICIPANT

Patient has a fundamental right to information. However, research results are analyzed in an aggregated form. Therefore, patient's participation will contribute to medical progress of prevention, diagnosis and treatment of future generation. Patients will thus not be informed on the results of individual research projects where their material or data are used. In very rare cases, nevertheless, the patient could be contacted if a disease or a medical condition was diagnosed in the context of the research project and for which medical actionability does exist or prevention is possible. This includes scientific validity, clinical utility and clinical or prevention significance. Decision to feedback information will be made on a one by one case by an expert committee depending on the disease in question.

### Re-contact and return of results

**II.C.1** To allow re-contact of participants, traceability of the samples and data should be made possible.

**II.C.2** Procedures should be in place to clearly explain how to re-identify research participants.

**II.C.3** Results arising from research conducted using the biobank resources should be made available in easily accessible forms, such as through a newsletter or website.

**II.C.4** To give recognition to resources that have been used in a research project, SBP recommends at publication level to adhere to the Bioresource Research Impact factor (BRIF) initiative which promotes reporting of bioresource use in research articles by following the Citation of BioResources in journal Articles (CoBRA) guideline<sup>4</sup>. Adopting this guideline will improve the quality of bioresource reporting and will allow their traceability in scientific publications, thus increasing the recognition of bioresources' value and relevance to research.

### Disclosure of unsolicited findings

**II.C.5** Consideration should be given to specify the types of results to be disclosed.

**II.C.6** Policies should clearly establish the conditions of re-contact ideally through an identified person (eg. treating physician, counselling service if available) trained in dealing with sensitive issues and impartiality regarding research outcome.

## D. DISCONTINUATION OF RESEARCH PARTICIPANT

Patient's consent is voluntary and valid indefinitely unless his/her revocation which could occur at any time without giving any reason.

**II.D.1** Patient can revoke his/her consent by writing a letter, an e-mail or by phone using the contact information provided in the consent documents. We recommend to acknowledge patient's withdrawal by e-mail or letter. The final patient's decision must be updated.

**II.D.2** The hospital personnel in charge of seeking consent should emphasize that revocation of subject will not affect his/her medical treatment in any way.

**II.D.3** The consequences of withdrawal should be disclosed with the participants during the consent process. This information includes the handling of patient's biological material after withdrawal and health-related data which will no longer be used for research purposes from this point onwards. However, analysis of data, generated from biosamples distributed to researchers prior to the discontinuation of participation may occur, provided that such analysis falls within the scope of the analysis described in the REC-approved protocol.

**II.D.4** To allow appropriate handling of patient's biological material and health-related data after withdrawal, samples and data traceability is mandatory.

<sup>4</sup>Bravo E, Calzolari A, De Castro P, et al. Developing a guideline to standardize the citation of bioresources in journal articles (CoBRA). BMC Medicine 2015;13:33 (doi: 10.1186/s12916-015-0266-y)

# III)

## PRIVACY AND CONFIDENTIALITY PROTECTIONS

An important aspect of storing health-related data is the absolute confidentiality regulated by the Federal Act on Data Protection. Collection and storage of information could, if disclosed to third parties, cause harm, stigma or distress. Persons involved in the research must protect confidentiality of such information by, for example, using coded data and limiting access to the information to third parties. Applying the highest possible ethical standards is necessary to ensure support and participation of participants, physicians, researchers, and others in research activities using biological material and data.

- III.1** The biobank should be managed and operated in such a way as to prevent inappropriate use or unauthorised access to participants' biological materials and health-related data. In this regard, the biobank should put in place a robust infrastructure, including equipment and software, so as to prevent and track unauthorised access to its databases.
- III.2** Prior to collection of their biological materials or data, participants should receive sufficient information about how their materials and data will be protected.
- III.3** Collection, processing, handling, storage, transfer and destruction of biological materials and data should be conducted in a manner that protects participants' privacy and confidentiality of their specimens and data.
- III.4** Data protection should involve the separation of information that can readily identify an individual from his/her health-related data, including genotypic data.
- III.5** Biological material stored in biobanks must be coded. The coding whenever possible will be performed at sample collection and at the latest before storage. Data are coded as soon as they are used in a research project. Thus, researchers can only use coded material and data. The responsible of the biobank should ensure that only a restricted number of properly authorised staff have access to these identifying informations as part of their assigned duties. Such access must be documented to ensure compliance and only be exercised when necessary. The key to the code remains within the institution and is kept by one or several designated persons with ideally no link to the research project.
- III.6** Clear policies for protecting confidentiality of identifiable information should be established. Such procedures may include coding, establishing limited access or varying levels of access to biospecimens and/or data, use of nondisclosure agreements or firewalls to prevent inappropriate use of data.
- III.7** The level of security should be appropriate to the type of biospecimen resource and the sensitivity of the data it houses. Genetic data, in particular, may involve additional risks such as discrimination and/or stigmatization, and these concerns may have an impact on research participants' families or broader population groups. De-identification of research data cannot completely guarantee privacy given the growth in publically available and electronically shared databases, as well as evolving technologies for linking different types and sources of data. Respect for research participants requires transparency about the trade offs between limiting access to individual medical data and facilitating the greatest utility of such data in research.

# IV)

## REFERENCES

These Best Practices have been written using these following supports:

- Biobanks for Research - Opinion no. 24/2015 Bern, December 2015 - NEK/CNE
- CIOMS guidelines (version 10 september 2015) - guidelines 9 to 12
- Federal Act on Data Protection (LPD) 235.1 - 19 June 1992
- Guidelines for human biobanks, genetic research databases - Department of Health Western Australia (February 2010)
- ICH Harmonised tripartite guideline/guideline for good clinical practice E6(R1) - Part 4.8 Informed Consent of Trial Subjects
- ISBER Best Practices for Repositories - 2012
- NCI Best Practices for Biospecimen Resources - March 2016
- The Oviedo Convention: protecting human rights in the biomedical field - April 1997
- OECD Guidelines on Human Biobanks and Genetic Research Databases - 2009
- WMA Declaration of Helsinki on ethical Principles for Medical Research Involving Human Subjects - June 1964
- WMA Declaration of Tapei on ethical considerations in Health Databases and Biobanks, Taiwan - October 2016