BEST PRACTICES

GENERAL CONSENT FOR RESEARCH

WHO ARE THESE BEST PRACTICES FOR ?

These best practices have been developed to guide hospital personnel (e.g. physicians, nurses, administrative staff), 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 national General Consent for Research (GCR) model. These best practices have been established in accordance with applicable legal and ethical requirements.

The Federal Act on Research involving human beings (Human Research Act, HRA), enacted 01.01.2014, allows under certain conditions to establish a GCR, through which a person may give his/her consent for the use of his/her health-related personal data and biological material for known or future not yet defined research projects.

These best practices have been reviewed by swissethics, Swiss Academy of Medical Science (SAMS), members of the Working Group on Governance (i.e. representatives of the five university hospitals), patients' organizations as well as by legal and ethical advisers.

SWISS BIOBANKING PLATFORM
Avenue d'Echallens 9, 1004 Lausanne - Switzerland
+41 21 314 46 91 - info@swissbiobanking.ch - www.swissbiobanking.ch

TABLE OF CONTENT

I)
CUSTODIANSHIP AND RESPONSIBILITIES

A)
GENERALITIES

These best practices address the need of a custodianship being responsible for a careful application of the ethical and legal frameworks as well as transparent policies for proper implementation of GCR in each Institution.

I.A.1 Each hospital is responsible to designate custodianship as trusted caretakers to implement GCR in their respective site. Custodianship will be a structure including a person in charge of defining the strategy at the Institution level supported by an operational expert.

I.A.2 All necessary information regarding informed consent such as research purposes, benefits to participants or questions related to biobanking should be disclosed as should all questions to address patients' concerns be answered. These may include the risks associated with data protection and patients' confidentiality as well as 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 (e.g. custodian(s)) and management with oversight roles).
This governance is required to ensure respect and privacy of research participants, confidentiality and appropriate use of biospecimens and data.

Custodial responsibilities include:
- Participation in the development of overall operational, ethical, and legal policies for implementing GCR in their site.
- Implemention of GCR with the support of these best practices and the aforementioned developed policies.
- Ability to provide all relevant information and documents related to the use of GCR in their Institution.
- Training or education of the hospital personnel in charge of obtaining the consent.
- Protection of participants' rights and well-being with the idea that common good prevails over research interests.

I.B.2 To promote transparency, information on governance, namely management and oversight roles, structures and rules should be made available, for example through the Institution's website.

C)
QUALIFICATIONS, EDUCATION AND TRAINING

I.C.1 Custodians should have qualifications, training and experience requisite to carry out their mandate (e.g. knowledge in biobanking).

I.C.2 Custodians should ensure that the hospital personnel is knowledgeable about the purposes and use of different types of consent (specific versus GCR) by giving a specific training on the subject. The hospital personnel should know to whom they should refer the patients depending on the types of questions, for example to the custodian for practical questions and to the treating physician for medical questions.

II)
TERMS OF PARTICIPATION

A)
RECRUITMENT

II.A.1 GCR allows to use health-related personal data and/or biological material 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[1] or the biobank[2] must handle anonymized or coded data and/or samples. The use of identified data and/or samples is excluded from the scope of GCR 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 GCR is optional. If Institutions decide to include this additional sampling, a 10 ml blood draw is allowed if performed during the clinical management of the patient.

If a patient does not fill in or sign GCR, then he/she should be aware of the putative use and transfer to third parties for research purposes of his/her health-related personal data and/or biological material as follows:

Non-genetic data	›	coded
Genetic data	›	anonymized
Biological material	›	anonymized

Thus, it is important that patient knows about his/her to dissent if he/she disagrees with the use of the aforementionned bioresources.

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, the Declaration of Taipei and the EU CM/Rec (2016)6 on research on biological materials of human origin.

II.A.3 Appropriate measures should be taken when seeking consent from vulnerable persons (e.g. children, persons in emergency situations). 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's questions, each Institution is responsible to provide educational tools/resources and contact information (e.g. custodian).

B)
ACCESS AND USE OF BIOLOGICAL MATERIAL AND DATA

Health-related personal data and biological material are intended to be used for research purposes. The terms and conditions of access/use to biospecimens and data are clearly regulated. Access policies for sharing and distributing specimens must be developed by each Institution.

II.B.1 Use of health-related data and biological material 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 Health-related information and biological material are only available to researchers in a coded or anonymized form.

II.B.4 Health-related personal data and biological material can 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.

[1] A **registry** is an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes.

[2] A **biobank** is an organized entity that manages activities such as collect, receive, process, store and retrieve biological resources.

II.B.5 A transfer agreement[3] (MTA, in the case of biospecimens, and DTA, in the case of data) or similar agreement must be signed by interested parties to transfer data and/or material with academic, nonprofit, and/or industrial organizations. This document lists or mentions the obligations and responsibilities of parties involved in the transfer of biological resources from a biobank or a repository prior to shipment.

C)
BENEFITS TO PARTICIPANT

Patient has a fundamental right to information. However, research results are analyzed in an aggregated form. 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. Decision to feedback information will be made on a by case basis. Procedures should be developed by each Institution to clearly explain the process to be followed for such return to participants.

Re-contact and return of results

II.C.1 To allow re-contact of participants, traceability of data and samples must be possible.

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

II.C.3 Results arising from research conducted using biological resources should be made available in easily accessible forms.

Disclosure of unsolicited findings

II.C.4 Consideration should be given to specify the types of results to be disclosed.

II.C.5 Policies should clearly establish the conditions of re-contact ideally through an identified person such as treating physician, counseling service if available, trained in dealing with sensitive issues and impartial regarding research outcome.

D)
DISCONTINUATION OF RESEARCH PARTICIPANT

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

II.D.1 Patient can withdraw 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 in the administrative system.

II.D.2 The hospital personnel in charge of seeking consent should emphasize that withdrawal of consent 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. Patient's biological material after withdrawal and health-related data will no longer be used for research purposes from this point onwards and will be anonymized if patient has not dissented to anonymisation. However, analysis of data, generated from biospecimens 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.

[3] 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 (e.g. specimens, reagents, cell lines) and acknowlegde responsibilities between parties.

III)
PRIVACY AND CONFIDENTIALITY PROTECTIONS

Confidentiality of stored health-related personal data is regulated by the Federal Act on Data Protection. Persons involved in the research must protect confidentiality of such information by using coded or anonymized data and limiting access to the information to third parties. Applying the highest possible ethical standards is necessary in building trust and ensure participation of patients in research activities using biological resources.

III.1 The biobank should put in place a robust infrastructure, including equipment and software, so as to prevent and track unauthorized access to its databases.

III.2 Prior to collection of their health-related data or biological material, participants should receive sufficient information about how their data and materials will be protected.

III.3 Collection, processing, handling, storage, transfer and destruction (if planned) of health-related data or biological material should be conducted in a manner that protects participants' privacy and confidentiality.

III.4 Data protection should involve the separation of information that can readily identify an individual from his/her health-related personal data.

III.5 Biological material stored in biobanks must be coded or anonymized. The coding or anonymization will be performed whenever possible at sample collection and at the latest before storage. Data are coded or anonymized as soon as they are used in a research project. The responsible of the biobank should ensure that only a restricted number of properly authorized staff has access to identifiable information 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 health-related personal data and/or biospecimens and use of non disclosure agreements to prevent inappropriate use of data.

III.7 The level of security should be appropriate to the type of biological resources 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.

IV) REFERENCES

These Best Practices have been written using these following supports:

- Biobanks for research - Opinion no. 24/2015 Bern, NEK/CNE, December 2015
- CIOMS guidelines, version 10, guidelines 9 to 12, September 2015
- 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 – October 2013
- WMA Declaration of Taipei on Ethical Considerations in Health Databases and Biobanks - October 2016
- EU Recommendation CM/Rec (2016)6 on research on biological materials of human origin, May 2016.

Swiss Biobanking Platform
Avenue d'Echallens 9
1004 Lausanne
Switzerland

+41 21 314 46 91
info@swissbiobanking.ch

www.swissbiobanking.ch