SOP
DEVELOPING CONSENT FORM

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SWISS BIOBANKING PLATFORM

A. GENERAL INFORMATION

A1. SCOPE

This SOP provides guidance in the development and review of Informed Consent form.
According to this SOP, the participants whose General or Specific Informed Consent is sought shall have the following characteristics:

- Participants and/or their legal representatives understand the information given by the qualified personnel who is seeking the consent;
- Participants and/or their legal representatives have the capacity of judgement to consent.

A2. OBJECTIVES

- Ensure that the rights of the participants are always respected.
- Ensure that the General and Specific Informed Consent forms fulfil the legal and ethical requirements.

A3. ABBREVIATIONS AND DEFINITIONS

For this document, the following abbreviations apply.
BB = Biobank
BIMS = Biobank Information Management System
IC = Institutional Committee
QR = Quality Representative
REC = Research Ethics Committee
SBP = Swiss Biobanking Platform
SOP = Standard Operating Procedure
See SBP Glossary for other definitions.

The SBP SOPs are based on Good Biobanking Practices to ensure an optimal setup for the biobanking activities.
Additionally, the SBP SOPs should serve as a reference for BBs to develop site-specific Work Instructions.

B. PERSONNEL MANAGEMENT

B1. ROLES AND RESPONSIBILITIES

BB personnel	Responsibility / role
BB Manager/Director, Principal Investigator	› Develops/modifies the Informed Consent form
Research Ethics Committee or Institutional Committee	› Reviews the Inform Consent form
QR	› Reviews and approves the Informed Consent form

C. PROCESS MANAGEMENT

C1. GENERAL INFORMATION ON THE INFORMED CONSENT FORMS

The following table provides guidance in choosing the correct Informed Consent under different conditions. The REC decision shall be required for the use of non-coded and coded resources, as defined in the table.

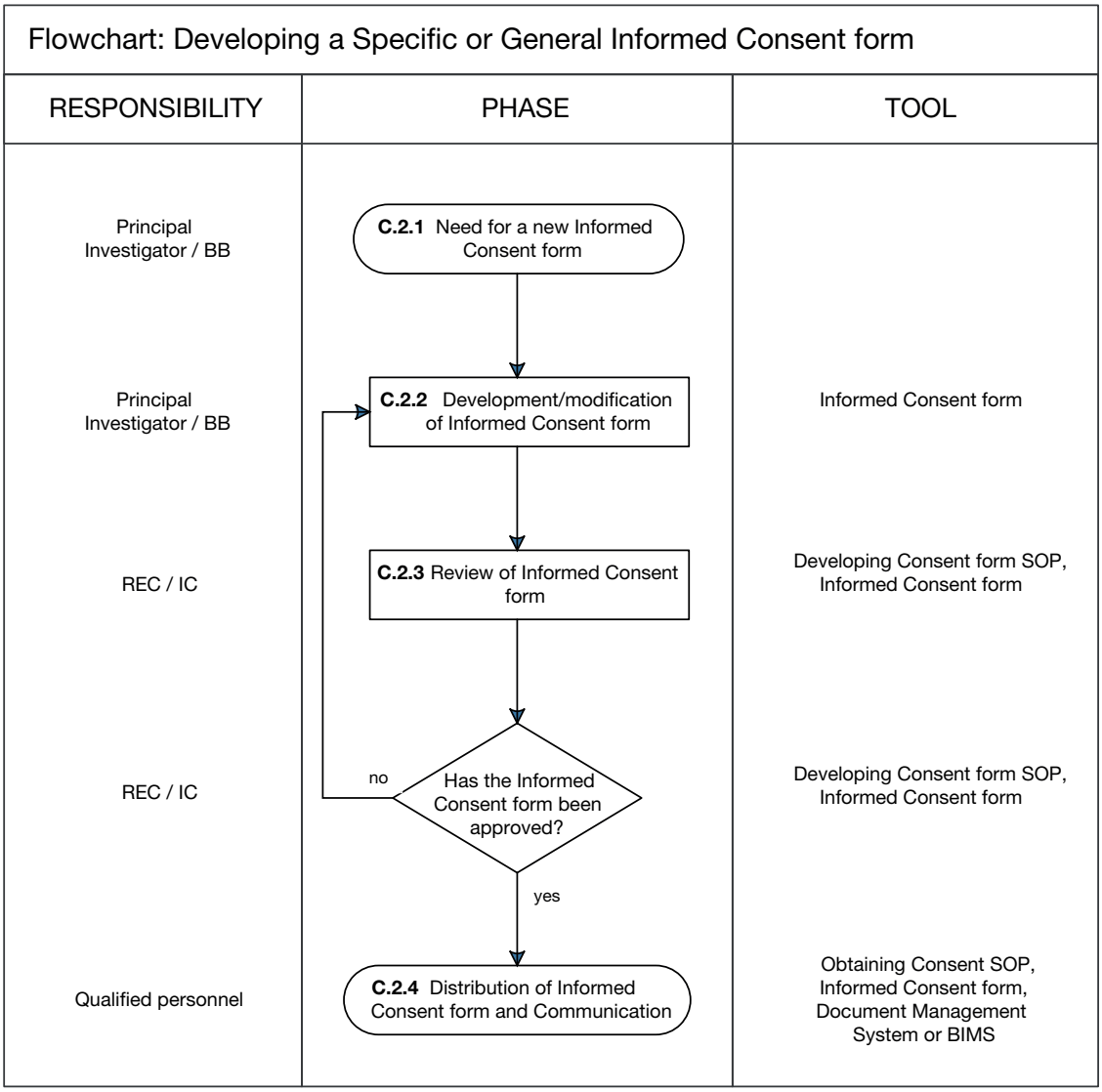
		SPECIFIC CONSENT	GENERAL CONSENT	OPT OUT	NO INFORMED CONSENT REQUIRED	REC DECISION REQUIRED
NON-CODED	Biological Material	X				X
	Genetic Data	X				X
	Non-genetic Data		X			X
CODED	Biological Material		X			X
	Genetic Data		X			X
	Non-genetic Data			X[a]		X
ANONYMISED	Biological Material			X[b]		
	Genetic Data			X[b]		
					X	

[a] Under the conditions that the participant has not dissented to the use of non-genetic coded data.
[b] Under the conditions that the participant has not dissented to anonymisation.

Documents and records should be readily accessible for inspection by authorised personnel from regulatory agencies and internal auditors, as defined in the Internal audit SOP (Document 1.04.004).

C2. DEVELOPING AN INFORMED CONSENT FORM

The following flowchart describes the approach to develop an Informed consent form.



C.2.1. Need for biological resources

- A new Informed Consent form should be developed when the BB collects new biological resources, as explained in the Biological Material Management SOP (1.03.001).

C.2.2. Development or modification of Informed Consent form

- Table 1 illustrates the type of Informed Consent is required based on the biological resources needed.
- The research Principal Investigator or BB Manager/Director shall develop or modify an Informed Consent form in compliance with the law and ethical requirements.

C.2.3. Review of the Informed Consent form

- The REC/IC should review the newly developed or modified Informed Consent form. The content of the Informed Consent form should be aligned with legal and ethical requirements. The Informed Consent should be approved by the REC/IC before being distributed.
- In case of a research project, the REC shall review the scientific relevance of the research project as well as its societal impact.

C.2.4. Distribution of the Informed Consent form

- Once the Informed Consent form has been approved, it shall be distributed to participants following the procedure described in the Obtaining Consent SOP (Document 1.01.002).

C3. QUALITY CONTROL

- The QR controls that the consent forms are properly recorded.
- The QR controls that personnel, who are responsible for the development of consent forms, are qualified for the task, as reported in the Personnel file (Document 2.02.001), as established in the Personnel Management SOP (Document 1.02.001).
- Every time the QR performs quality control on the process output, quality control details (date of QC, outcomes) shall be recorded in the Quality Control Results (Document 2.04.009).

D. RESOURCE MANAGEMENT

D1. MATERIALS AND EQUIPMENT

Materials and equipment

E. REFERENCES

E1. REFERENCE TO OTHER SBP DOCUMENTS

- 1.01.002 Obtaining Consent SOP
- 1.04.001 Document management SOP
- 1.02.001 Personnel Management SOP
- SBP Best Practices for General Consent

E2. REFERENCE TO LAWS, REGULATIONS, AND GUIDELINES

- SBP - Ethical, legal and professional compliance list for human research biobanks applicable in Switzerland

E3. APPENDICES

- 2.02.001 Personnel file
- 2.04.009 Quality Control Results

E4. REVISION HISTORY

Document number	Revision date	Author	Details of revision
1.01.001		SBP	Initial release