SOP
OBTAINING CONSENT

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SWISS BIOBANKING PLATFORM

A. GENERAL INFORMATION

A1. SCOPE

This SOP provides guidance in the process of obtaining the voluntary consent of participants who have been appropriately informed.

A2. OBJECTIVES

- Ensure that the rights of the participants are always respected.
- Ensure that the only qualified personnel approach participants with the purpose of obtaining an Informed Consent.
- Ensure that the decisions taken by the participants are documented. Informed Consent forms, Informed Consent status as well as withdrawals are recorded.

A3. ABBREVIATIONS AND DEFINITIONS

For this document, the following abbreviations apply.
BB = Biobank
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

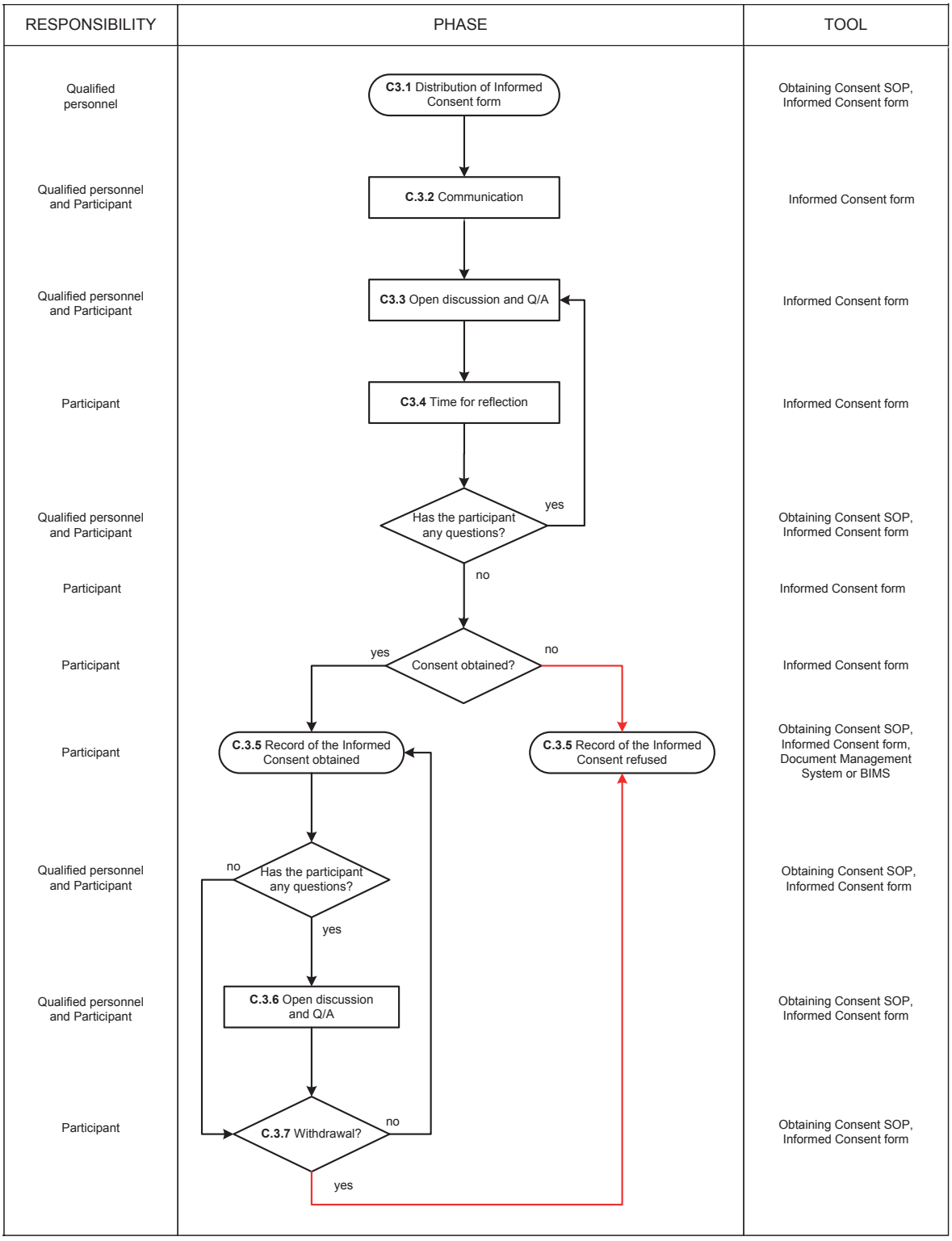
This SOP provides guidance in the process of obtaining the voluntary consent of participants who have been appropriately informed.

BB personnel	Responsibility / role
Qualified personnel	› Inform participants › Obtain the Informed Consent › Record Informed Consent forms, Informed Consent status and withdrawals of the participants
Research Ethics Committee	› Reviews and approves the Informed Consent form
QR	› Performs Quality Control

C. PROCESS MANAGEMENT

C1. OBTAINING PARTICIPANT'S CONSENT

The following flowchart describes the approach to obtain a participant's consent.



C.1.1. Distribution of the Informed Consent form

- Qualified personnel shall distribute the Informed Consent form to the participants.
- The distributed Informed Consent form should be approved by the Research Ethics Committee.

C.1.2. Communication with the participants

- The consent is informed when it is collected as a result of complete and appropriate information that allows the individual to make an informed decision. The information shall be given in an understandable form: it shall be adapted to each individual, in a language commonly spoken by the latter, taking into account the participant's level of knowledge in the research field.

C.1.3. Open discussion and Q/A

- The qualified personnel seeking for the consent shall encourage an open discussion with the participant and answer participant's questions. The Informed Consent shall be given on a voluntary basis, and the participant shall not be coerced to sign the Informed Consent form.
- The qualified personnel seeking for the consent shall ensure that the participant has fully understood the information contained in the Informed Consent form.

C.1.4. Time for reflection for the participant.

- Participants shall be given time to read the form, understand the information, and consider possible participation.

C.1.5. Record of the Informed Consent status

- If the voluntary Informed Consent has been obtained, qualified personnel can proceed to the collection of the biological resources from the participants, as described in the Biological Material Management SOP (Document 1.03.001).
- Informed Consent forms and Informed Consent status (Yes, No, No answer, date) shall be recorded.
- Documentation related to the Consent status shall be made accessible for internal and external audits, as further explained in the Internal audit SOP (Document 1.04.004).

C.1.6. Open discussion and Q/A

- After the Informed Consent form has been signed, qualified personnel shall be available to answer further participant's questions.

C.1.7. Withdrawal of consent

- The participant has the right to revoke the previously given consent at any moment and without giving any explanation.
- If the consent has been revoked, the participant's biological resources will either be anonymised or destroyed (as per the Institutional Biosafety directives). The withdrawal only applies to the future use of the collected biological samples and data; in other words, the results obtained before the withdrawal and their evaluation are not affected.
- The documents reporting the withdrawal of consent shall be made accessible for internal and external audits, as further explained in the Internal audit SOP (Document 1.04.004).

C2. QUALITY CONTROL

- The QR controls that the decisions taken by the participants are documented, and that Informed Consent forms, Informed Consent status, and withdrawals are recorded.
- The QR controls that personnel, who are responsible for the obtention of the consent, 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

- 1.04.001 Document management SOP
- 1.03.001 Biological Material Management SOP
- 1.04.002 Non-conformity Management SOP
- 1.02.001 Personnel Management SOP
- 1.04.004 Internal Audit
- 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 [Status as of 1 March 2018]

E3. APPENDICES

- 2.04.009 Quality Control Results
- 2.02.001 Personnel file

E4. REVISION HISTORY

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