SOP
SAFETY & COMPLAINT

Document number	1.01.003
Version	1.0
Category	Governance
Sub-category	Regulatory Affairs
Authored by	Swiss Biobanking Platform
Effective date	

TABLE OF CONTENT

A. GENERAL 2
- **A1. Scope**
- **A2. Objectives**
- **A3. Abbreviations and definitions**

B. PERSONNEL MANAGEMENT 3
- **B1. Roles and responsibilities**

C. PROCESS MANAGEMENT 4
- **C1. Safety procedure**
- **C2. Complaint procedure**
- **C3. Quality control**

D. RESOURCE MANAGEMENT 8
- **D1. Materials and equipment**
- **D2. Protective wear and safety equipment**

E. REFERENCES 8
- **E1. Reference to other SBP documents**
- **E2. Reference to laws, regulations, and guidelines**
- **E3. Appendices**
- **E4. Revision history**

APPENDIX 9

SCTO — Swissethics

Template for the notification of serious events (SE) to the ethics committees for research projects not involving clinical trials (HRO)

SWISS BIOBANKING PLATFORM

A. GENERAL

A1. SCOPE

This SOP provides guidance on the procedures to undertake when a serious event (SE) occurs to the participant and when complaints are received formally or informally from the participants in the biobank.

A2. OBJECTIVES

- Ensure that the health of participants is of primary importance.
- Ensure that personnel is trained to perform immediate safety measures to prevent and address the occurrence of serious events (SE) related to sampling.
- Ensure that a SE occurrence is documented and treated in compliance with ethical, legal, and professional requirements.
- Ensure that the complaints are handled in respect of participants' rights.

A3. ABBREVIATIONS AND DEFINITIONS

For this document, the following abbreviations apply.
BB = Biobank
QR = Quality Representative
REC = Research Ethics Committee
SBP = Swiss Biobanking Platform
SE = Serious event
SOP = Standard Operating Procedure

For this document, the following definitions apply.
A SE is defined as any adverse event, which cannot be excluded to be attributable to the sampling of biological material or the collection of health-related personal data, and which (HRO art. 21.2):
a. requires inpatient treatment not envisaged in the protocol or extends a current hospital stay;
b. results in permanent or significant incapacity or disability; or
c. is life-threatening or results in death.

A SE can be defined as related or unrelated to the research project activities.

Unrelated	› The event is in no temporal relationship to the sample collection, and › The event can definitely be explained by underlying disease or other causes
Related	› The event is in a plausible timely relationship to project-specific measures applied, and › The event cannot definitely be explained by underlying disease or other causes

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

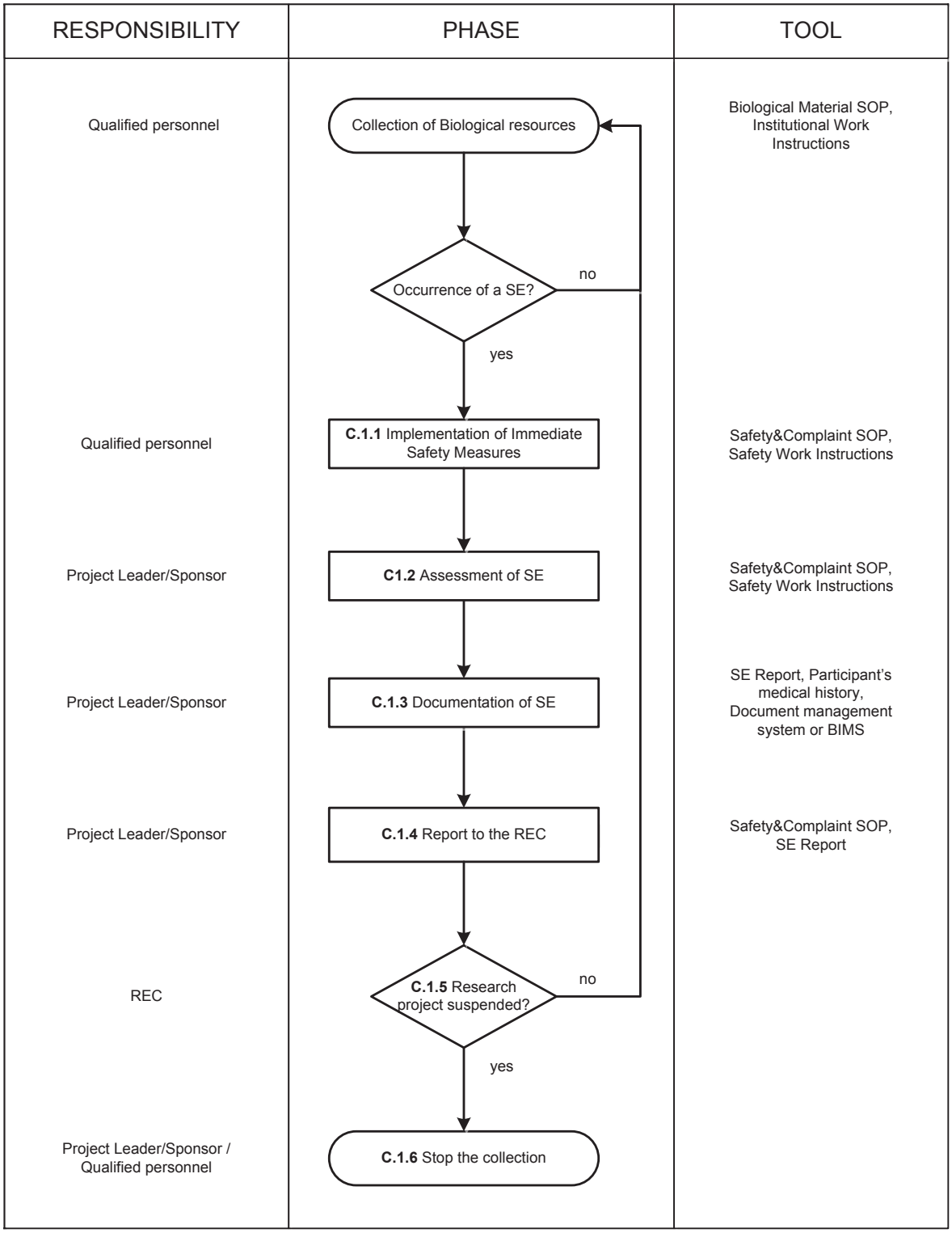
B1. ROLES AND RESPONSIBILITIES

BB personnel	Responsibility / role
Project Leader/Sponsor or BB Manager/Director	› Assesses the causal relationship between an SE and the sample and/or data collection › Notifies the REC of the occurrence of a SE within 7 days › Handles and/or reports to REC formal complaints from the participants › Initiates investigation of complaints › Handles complaints › Regularly implements a complaint review
Research Ethics Committee	› Evaluates if the causes of the SE are related to sampling › Decides if the research project must be interrupted › Reviews formal complaints and investigation of complaints
Qualified personnel	› Collects data and biological material › Undertakes immediate actions to address SE › Handles complaints
QR	› Performs Quality Control

C. PROCESS MANAGEMENT

C1. SAFETY PROCEDURE

This flowchart describes how to handle the occurrence of a SE.



C.1.1. Implementation of Immediate Safety Measures

- Upon the occurrence of a SE, qualified personnel shall carry out Immediate Safety Measures.

C.1.2. Assessment of SE

- Upon occurrence of a SE the Project Leader/Sponsor shall evaluate any causal relationship between the event and the sampling of biological material or the collection of health-related personal data. The causal relationship should be assessed based on the definitions of Related and Unrelated SE.

C1.3. Documentation of SE

- The SE and follow-up information shall be documented in the subject medical history and in the Serious Event Report form provided by Swissethics and attached to this document.
- Documents concerning the occurred SE, including the Serious Event Report, shall be recorded in the Document Management System or BIMS.
- In the event that a participant affected by a SE has filled an informal or formal complaint, the Complaint procedure (Procedure C2, Safety & Complaint SOP) should be followed.

C1.4. Report to the REC

- The Project Leader/Sponsor or BB Manager/Director shall notify the REC of a SE within 7 days.
- The Project Leader/Sponsor or BB Manager/Director shall report to the REC on the imputability of the SE to the collection of health-related personal data or the sampling of biological material.
- In the event that immediate safety and protective measures have to be taken during the conduct of a research project, the Project Leader/Sponsor or BB Manager/Director shall notify the REC of these measures and of the circumstances necessitating them.
- The Project Leader/Sponsor or BB Manager/Director shall submit proposals concerning the next steps to be taken (HRO; Art. 21.4).

C1.5. Decision of the REC

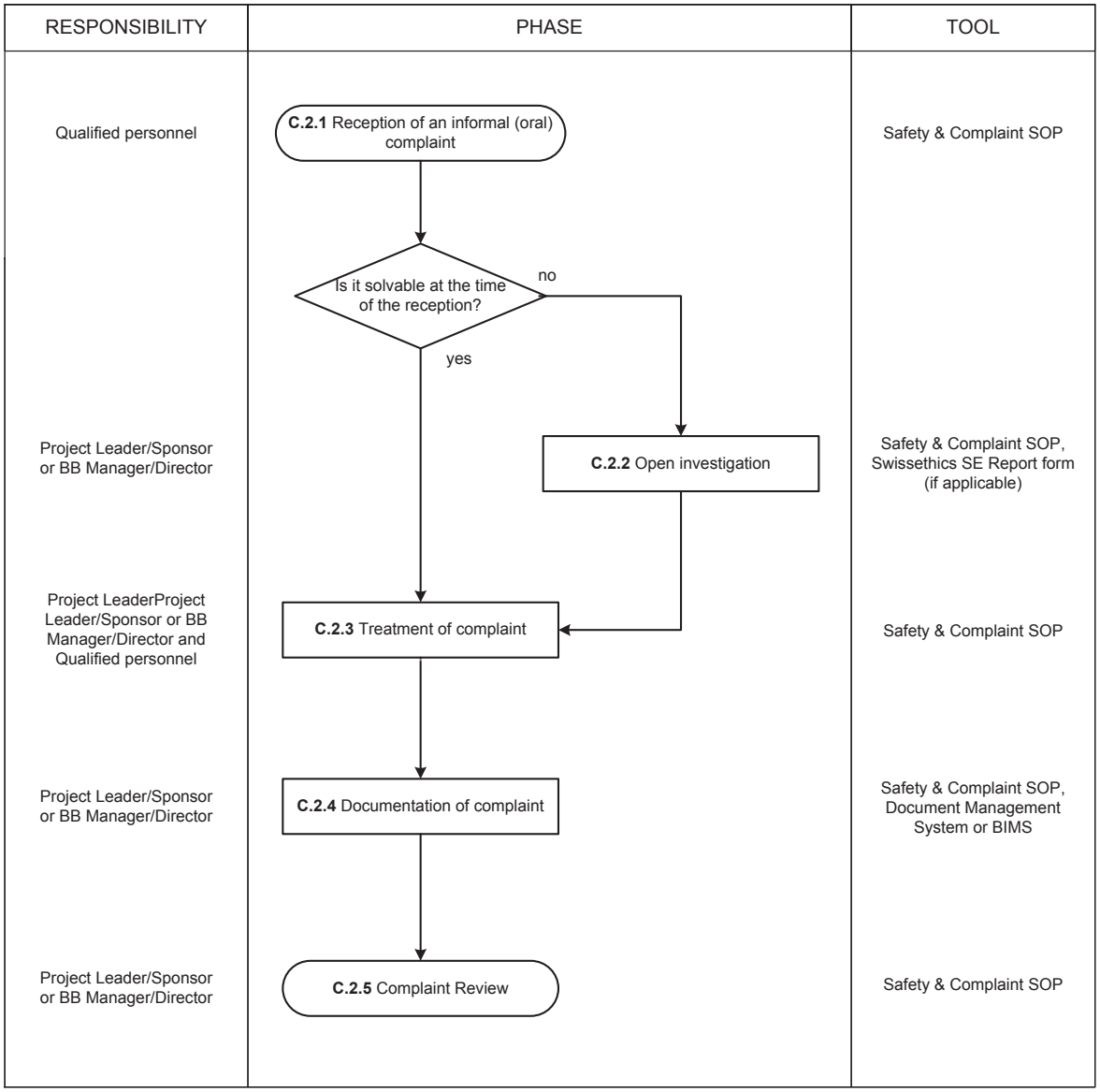
- The REC shall decide on the continuation of the research project within 30 days after receipt of the report (HRO; Art 21.6).

C1.6. Interruption of the collection

- If the REC decides to suspend the project, the data collection and the sampling procedures shall be interrupted. The biological resources shall be handled (i.e., anonymized or destroyed) as described in the Biobank Regulation.
- Upon discontinuation or completion of a research project, the Project Leader/Sponsor shall notify the ethics committee within 90 days (HRO; Art. 22).

C2. COMPLAINT PROCEDURE

This flowchart describes how to handle complaints from participants.



C2.1. Reception of a complaint

- A SE may lead to a participant to submit a complaint. Other events can lead to complaint as well.
- In the event that the BB receives an informal (oral) complaint, the BB personnel shall try to resolve the complaint at the time of reception.
- If the BB personnel cannot resolve the complaint at the time of the reception, the BB personnel shall report the participant's complaint to the BB Manager/Director or the Project Leader/Sponsor in a formal (written) way.

C2.2. Open investigation concerning the event that has caused the complaint

- The Project Leader/Sponsor or the BB Manager/Director shall open an investigation to assess the causes and the circumstances of the event that has led to the complaint.
- The Project Leader/Sponsor or the BB Manager/Director should write a letter to the participant acknowledging the reception of the complaint and explaining the procedure for reviewing it. This letter shall be documented and, then, recorded in the Document Management System or BIMS.

C2.3. Treatment of the complaint

- The resolution of the complaint shall be carried out by qualified personnel.
- The Project Leader/Sponsor or the BB Manager/Director should write a letter to the participant summarizing the outcomes of the complaint review and indicating the resolution of the complaint. This letter shall be documented and, then, recorded in the Document Management System or BIMS.
- The complaint shall be treated and solved.

C2.4. Record of the documentation related to the complaint

- Documents, including the letters and reports written by the Project Leader/Sponsor, shall be recorded in the Document Management System or BIMS and made accessible for internal and external audits, as further explained in the Internal audit SOP (Document 1.04.004).

C2.5. Complaint review

- The Project Leader/Sponsor or the BB Manager/Director should performed a complaint review regularly. The outcomes of the complaint review shall be documented and recorded in the Document Management system or BIMS and made accessible for internal and external audits, as further explained in the Internal audit SOP (Document 1.04.004).

C3. QUALITY CONTROL

- Control that the personnel is trained to handle immediate safety measures, as written in the Personnel File (Document 2.02.001).
- Control that the SE documentation is recorded in the Document Management System or BIMS.
- Control that every step or actions undertaken to handle a complaint has been documented and recorded in the Document Management System or BIMS.
- Every time the QR performs quality control, quality control details (date of QC, outcomes) should be recorded in the Quality Control Results (Document 2.04.009).

D. RESOURCE MANAGEMENT

D1. MATERIALS AND EQUIPMENT

Materials and equipment

D2. PROTECTIVE WEAR AND SAFETY EQUIPMENT

Personnel shall follow institutional safety requirements and the Risk-biosafety checklist (document 2.04.011) at all times.

Safety equipment/ protective wear
Safety equipment for handling samples and undertaking Safety measures.

E. REFERENCES

E1. REFERENCE TO OTHER SBP DOCUMENTS

- 1.04.001 Document Management SOP
- 1.02.001 Personnel Management SOP
- 1.04.002 Non-conformity Management SOP
- 1.04.004 Internal Audit SOP

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
- Serious Event Report by Swissethics

E4. REVISION HISTORY

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

swiss clinical trial organisation

swissethics

Schweizerische Ethikkommissionen für die Forschung am Menschen
Commissions d'éthique suisses relative à la recherche sur l'être humain
Commissioni etiche svizzere per la ricerca sull'essere umano
Swiss Ethics Committees on research involving humans

HRO research project: Serious Event Report[1]

Please complete the form by replacing all text modules in square brackets. Use "x" for check boxes.

The project leader must report a serious event (SE), where causality cannot be excluded, to the ethics committee within 7 days. In the event that a sponsor[2] takes responsibility for the research project, reporting procedures are adapted accordingly.

Serious Event (SE) information

Participant ID	Year of birth	Sex	SE onset date	SE stop date	Report type
[code]	[year]	[ ] F / [ ] M	[day/month/year]	[day/month/year or cont.]	[ ] initial [ ] follow up [ ] final
Contact details of the site of SE occurrence [name and full address]					Check SE [ ] life-threatening or results in death [ ] results in permanent or significant incapacity or disability [ ] requires inpatient treatment not envisaged in the protocol or extends a current hospital stay
Describe the SE and the connection to project procedures (including relevant test/lab data) [free text]					

Evaluation of the event

Project start [day/month/year]	Date of project interruption [day/month/year]
The research project encompasses the [ ] sampling of biological material [ ] collection of health-related personal data	It cannot be excluded that the event is attributable to the [ ] sampling of biological material [ ] collection of health-related personal data
Was this an unexpected serious event? [ ] yes [ ] no	Did the SE occur in connection with an investigation involving a radiation source (according to HRO Art. 19)? [ ] yes → FOPH must be informed within 7 days from the SE onset date [ ] no
Did the situation improve upon discontinuing the project? [ ] yes [ ] no [ ] n/a	

Concomitant intervention(s) and history

Concomitant intervention(s) and dates of conduct (exclude those used to treat event) [free text]
Other relevant history (e.g. diagnostics, allergies, etc.) [free text]

Proposal how to proceed

[ ] continuation, no adjustments required	[ ] definitive termination of research project
[ ] change protocol/safety section	[ ] other: [free text]

General and reporter information

Sponsor name and address (if different from project leader) [name and address]	Contact details of the site of SE occurrence [name and full address, contact telephone, email address]		
Title of research project (short title) [short title]	BASEC research project number [year-xxxxx]	EC name (concerned EC) [EC name]	EC name (lead EC, if applicable) [EC name]
Name and contact information of project leader [name, contact telephone, email address]	Place, date and signature of project leader		

[1] Refer to HRO Art. 21
[2] Responsibilities of project leader and sponsor according to HRO Art. 3