SOP
DATA AND SAMPLE TRACEABILITY

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SWISS BIOBANKING PLATFORM

A. GENERAL INFORMATION

A1. SCOPE

This SOP provides guidance on the implementation of quality assurance measures to guarantee the traceability of samples and associated data available at the Biobank.

A2. OBJECTIVES

- Ensure that the Document Management System or BIMS include a full audit trail of changes made to the BB database.
- Ensure the traceability of associated data by performing data verifications periodically.
- Ensure the traceability of samples by performing sample verifications periodically.

A3. ABBREVIATIONS AND DEFINITIONS

For this document, the following abbreviations apply.

BB = Biobank
BIMS = Biobank Information Management System
QR = Quality Representative
SBP = Swiss Biobanking Platform
SOP = Standard Operating Procedure

See SBP Glossary for definitions.

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

B. PERSONNEL MANAGEMENT

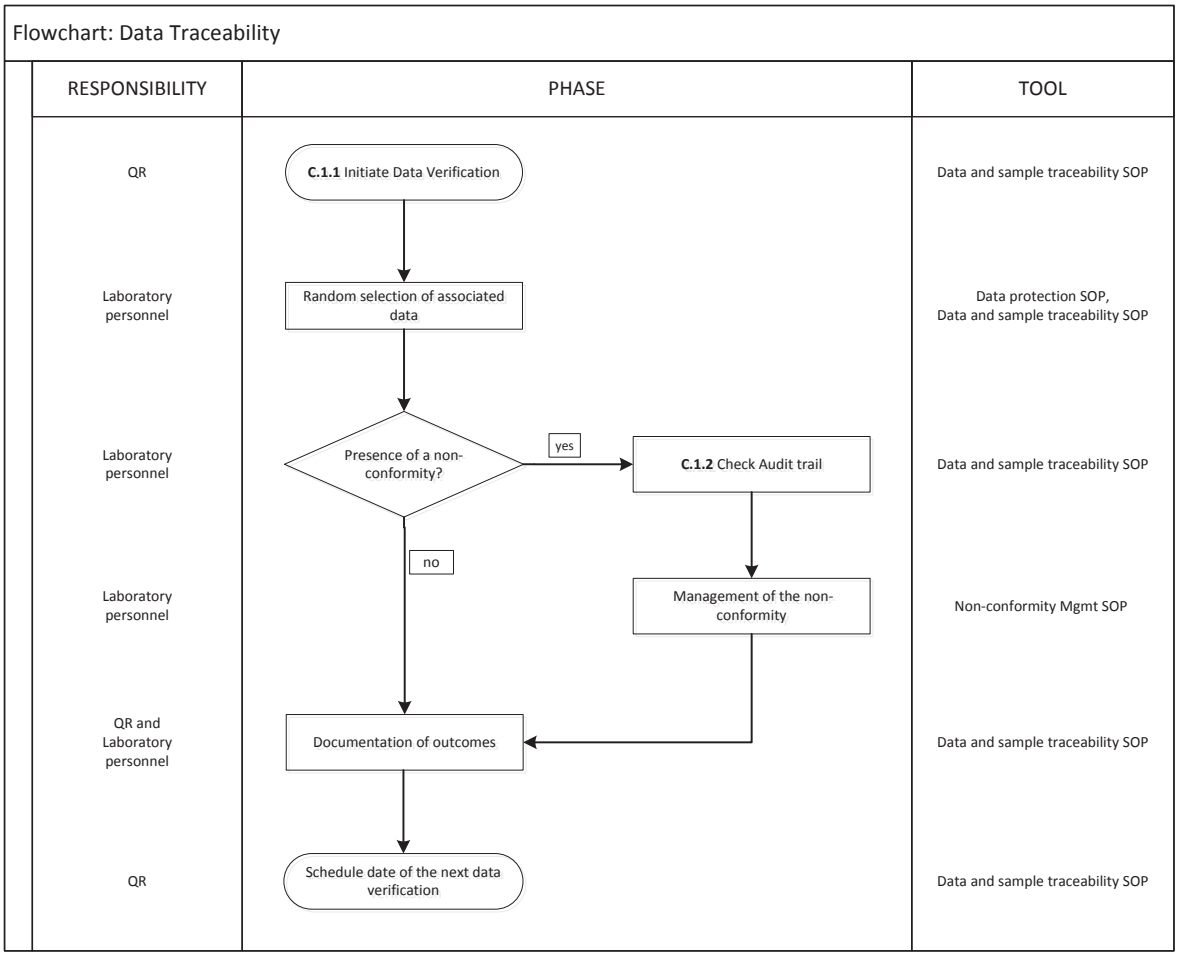
B1. ROLES AND RESPONSIBILITIES

BB personnel	Responsibility / role
Laboratory personnel	› Conduct data and sample verification
QR	› Schedules and initiates the data verification › Schedules and initiates the sample verification › Records data and sample verification outcomes › Performs Quality Control

C. PROCESS MANAGEMENT

C1. DATA TRACEABILITY

This flowchart describes the procedures to assure the data traceability.



C1.1. Data verification

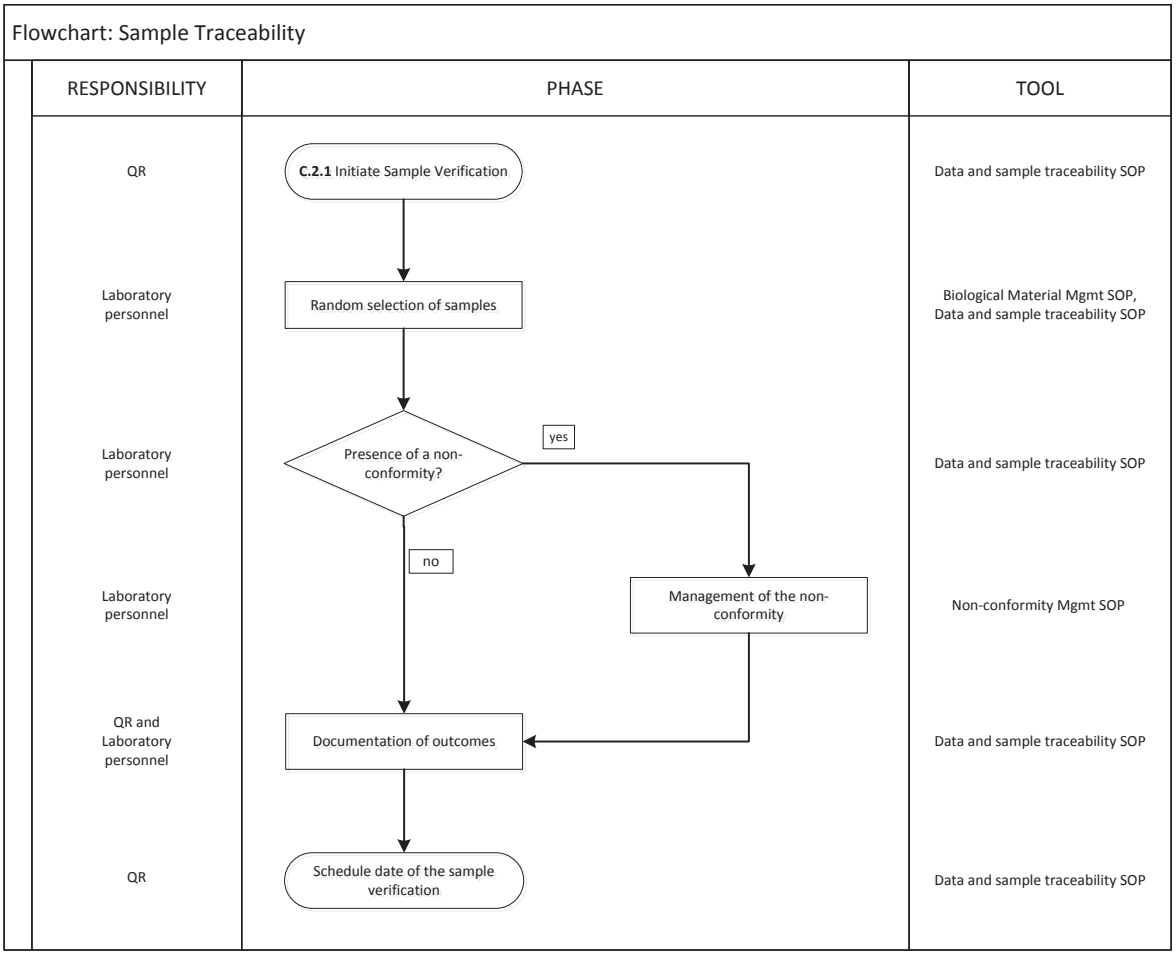
- Data verification is a quality assurance measure that shall be carried out periodically to confirm the integrity of the associated data.
- The QR shall define the frequency of the data verifications.
- The QR shall schedule the date of the data verification and initiate the data verification.
- The laboratory personnel shall carry out data verification by selecting associated data on a random basis. The laboratory personnel shall control if the associated data are complete, correct, and corresponding to the right sample. If the data are corrupted, missing, or incorrect, the laboratory personnel shall immediately modify the information recorded in the BB database or BIMS to reflect the actual situation. The laboratory personnel shall follow the procedures described in the Non-conformity Management SOP (Document 1.04.002).
- The acceptance range for a successful data verification is defined in the BB Work Instructions.
- Data verification outcomes shall be documented and recorded in the Document Management System or BIMS.
- Data verification outcomes shall be made accessible for internal and external audits, as further explained in the Internal audit SOP (Document 1.04.004).

C1.2 Audit trail

- The BB database or BIMS shall include a full audit trail of changes made. The audit trail should consist of a detailed history of the data as follows: data creation, changes, deletion, who made the changes, and the date and time of the changes.
- The audit trail shall be automatically updated and documented.
- Audit trails and related documentation shall be made accessible for internal and external audits, as further explained in the Internal audit SOP (Document 1.04.004).

C2. SAMPLE TRACEABILITY

This flowchart describes the procedures to assure the sample traceability.



C2.1 Audit trail

- The sample verification is a quality assurance measure that shall be carried out periodically to confirm that the appropriate biological material is in the correct location as indicated by the BB database or BIMS.
- The QR shall define the frequency of the sample verifications.
- The QR shall schedule the date of the sample verification and initiate the sample verification.
- The laboratory personnel shall conduct the sample verification by selecting samples on a random basis. The laboratory personnel shall control if the label attached to the sample matches the information recorded in the BB database or BIMS. If the sample label is missing or is incomplete or does not match the recorded inventory, the Laboratory personnel shall immediately modify the information recorded in the Document Management System or BIMS to reflect the actual situation. The laboratory personnel shall follow the procedures described in the Non-conformity Management SOP (Document 1.04.002).
- The acceptance range for a successful sample verification is defined in the BB Work Instructions.
- The laboratory personnel should ensure that the temperature of the sample is maintained constant during the sample verification and should minimise the time that the samples are removed from the storage to prevent the sample damage.

- Sample verification outcomes shall be documented and recorded in the Document Management System or BIMS.
- Sample verification records shall be made accessible for internal and external audits, as further explained in the Internal audit SOP (Document 1.04.004).

C3. QUALITY CONTROL

- The QR controls that personnel, who are responsible for the data and sample traceability, 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).
- The QR controls that the sample and data verification activities have been performed at the scheduled date and time.
- Every time the QR performs quality control on the process outputs, 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

The materials and equipment in the following list are recommendations only and may be substituted by alternative/equivalent products more suitable for the specific task or procedure.

Materials and equipment

D2. PROTECTIVE WEAR AND SAFETY EQUIPMENT

Personnel must follow institutional safety requirements and risk-biosafety checklist (Document 2.04.011) at all times.

Safety equipment / protective wear
Safety equipment for handling biological materials

E. REFERENCES

E1. 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]

E2. 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

E3. APPENDICES

- 2.02.001 Personnel file
- 2.04.009 Quality Control Results.

E4. REVISION HISTORY

Document number	**Revision date**	**Author**	**Details of revision**
1.02.003		SBP	Initial release