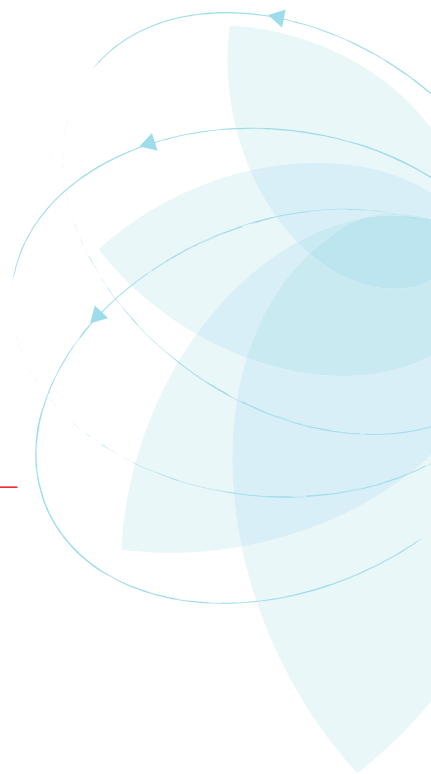


SOP

BIOLOGICAL MATERIAL MANAGEMENT



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Sub-category Handling

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A. GENERAL INFORMATION

A1. SCOPE

This SOP describes how biological material should be collected, received, transported, processed, stored, retrieved, and distributed to ensure the integrity and the quality of the biological material. Additional attention should be addressed on the biological material labelling and tracking procedures to prevent loss of biological materials due to inadequate identifying information and enable the biological-material traceability.

This SOP does not cover biosafety procedures for handling biological material; personnel shall follow institutional safety guidelines and risk-biosafety checklist (Document 2.04.011).

A2. OBJECTIVES

- › Ensure that the biological material handled within the BB fulfils the Sample Acceptance Criteria (Document 2.03.006).
- › Ensure that the preanalytical data associated with each biological material fulfil the appropriate datasets defined by SBP.
- › Ensure that a Sample tracking form (Document 2.03.001) is associated with each biological material handled by the BB. The Sample tracking form documents all relevant information required to identify, track, and locate the biological material throughout all processes.
- › Ensure that biological material is collected and processed following BB Work Instructions by qualified personnel.

A3. ABBREVIATIONS AND DEFINITIONS

For this document, the following abbreviations apply.

BB = Biobank

BIMS = Biobank Information Management System

Mgmt = Management

QR = Quality Representative

SBP = Swiss Biobanking Platform

SOP = Standard Operating Procedure

See SBP Glossary for definitions of biological material, specimen, sample, and other terms.

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

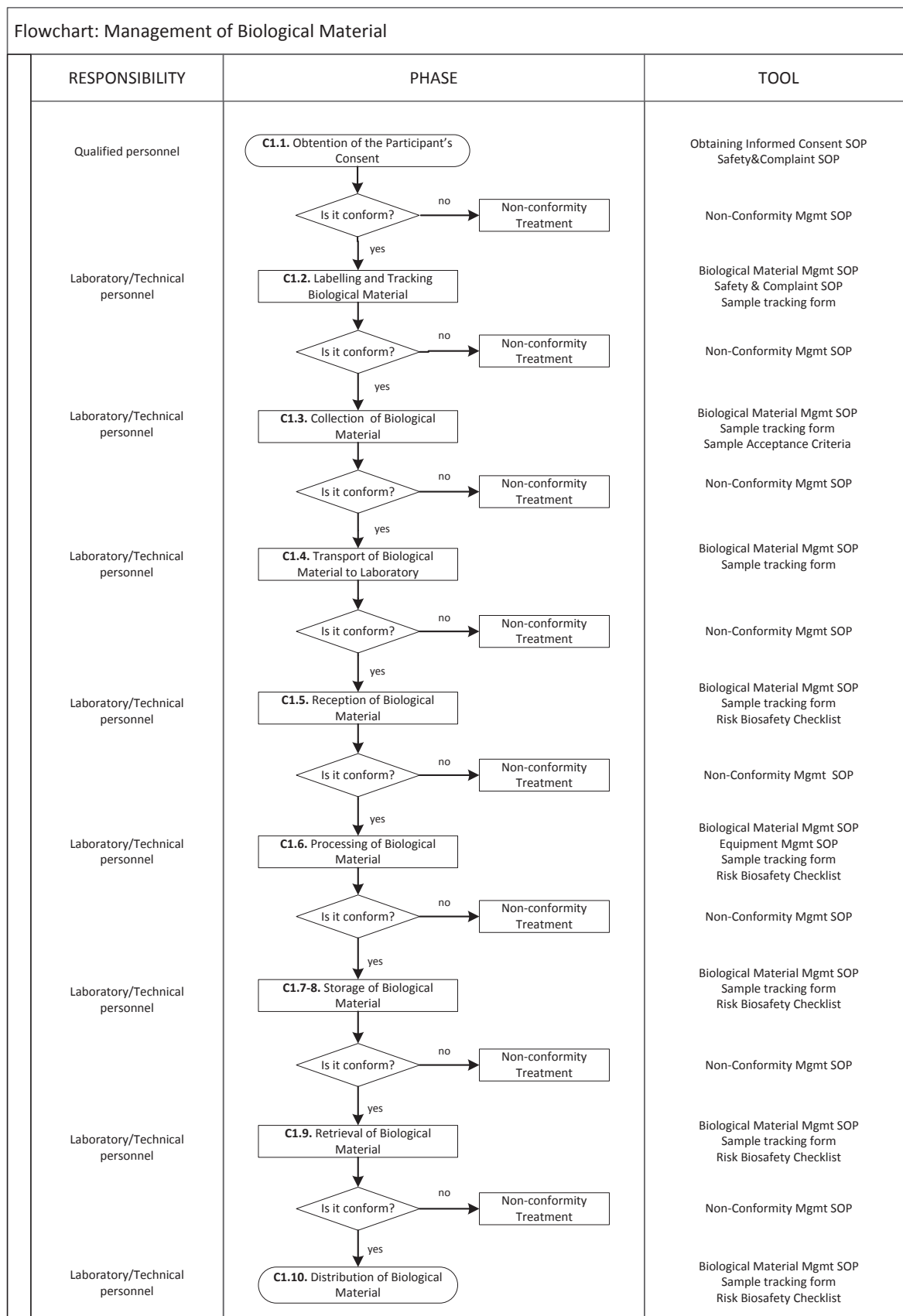
BI. ROLES AND RESPONSIBILITIES

| BB personnel | Responsibility / role |
|-------------------------------------|--|
| Administrative personnel | <ul style="list-style-type: none"> > Prepare and sign Service Level Agreements |
| Qualified personnel | <ul style="list-style-type: none"> > Obtain participant consent > Transport biological material to the laboratory |
| BB Director / Manager | <ul style="list-style-type: none"> > Responds to alarms and oversees that equipment maintenance procedures are carried out > Reviews request, coordinates biological material release and shipment |
| Laboratory / Technical personnel | <ul style="list-style-type: none"> > Collect biological material > Label and track collected or received biological material > Receive biological material > Process biological material > Store biological material > Retrieve biological material > Ship biological material > Respond to alarms and check that equipment maintenance procedures are carried out |
| QR | <ul style="list-style-type: none"> > Performs Quality Control > Allocates unique identifiers for each freezer, refrigerator, or storage facility. > Ensures that the alarms and backup facilities are functional. |

C. PROCESS MANAGEMENT

C1. PROCEDURES

The following flowchart describes the activities to be carried out to manage biological material.



C1.1. Participant's informed consent obtained

- › Qualified personnel shall obtain the Participant's Informed Consent by following the procedures described in the Obtaining Consent SOP (Document 1.01.002).

C1.2 Labelling and Tracking

- › Laboratory/Technical personnel shall introduce the biological material documentation in the BB database or BIMS by assigning a unique tracking code or barcode to each biological material.
- › Laboratory/Technical personnel shall label all containers that will contain biological material.
- › Laboratory/Technical personnel shall ensure that each label adheres perfectly to the surface of the container under all storage conditions.
- › Laboratory/Technical personnel shall ensure that the ink on the labels is resistant to common laboratory solvent and water.
- › Laboratory/Technical personnel shall include information on the label that is compliant with the informed consent.
- › Laboratory/Technical personnel shall ensure that the information on the label corresponds to the one reported in the Sample tracking form (Document 2.03.001).

C1.3 Collection

- › Laboratory/Technical personnel shall ensure that proper equipment for collecting biological material is in service and do not require neither calibration nor maintenance, as defined in the Equipment Management SOP (Document 1.02.002).
- › Qualified personnel shall collect the biological material by following BB Work Instructions. In case of adverse event, the personnel shall follow the procedures described in the Safety & Complaint SOP (Document 1.01.003).
- › Qualified personnel shall fill the Sample tracking form to record all the relevant information of the collection process, electronically or manually. The Sample tracking form should be readily accessible for audits, as further explained in the Internal audit SOP (Document 1.04.004).
- › Since preanalytical variables may affect research and clinical outcomes, the processing of biological material shall be carried out as fast as possible upon collection. Therefore, Laboratory/technical personnel in charge of the Biological Material collection should identify the person responsible for transporting the biological material to the laboratory and arrange for timely transporting and then processing.
- › Upon collection, Laboratory/technical personnel shall check the integrity of the biological material and decide if the biological material can be accepted or has to be rejected based on BB biological-material acceptance criteria. In the presence of any non-conformity, the Laboratory/Technical personnel shall follow procedures described in the Non-conformity Management SOP (Document 1.04.002).

C1.4. Transport to the BB laboratory

- › Qualified personnel shall verify participant's information. In the presence of any non-conformity, the Laboratory/Technical personnel shall follow procedures described in the Non-conformity Management SOP (Document 1.04.002).
- › Qualified personnel shall transport containers to the laboratory or specific area for processing or storage.
- › Qualified personnel shall transport containers by maintaining the temperature constant and preserving the package as defined in the BB Work Instructions.

C1.5. Reception

- › Biological material provided to the BB from an outside source shall be acknowledged upon receipt. A record of the receipt shall be kept in the Sample tracking form (Document 2.03.001).
- › Documents related to this SOP should be readily accessible for audits, as further explained in the Internal audit SOP (Document 1.04.004).
- › Upon reception, Laboratory/technical personnel shall check the integrity of the biological material and decide if the biological material can be accepted or has to be rejected based on BB biological material acceptance criteria. In the presence of any non-conformity, the Laboratory/Technical personnel shall follow procedures described in the Non-conformity Management SOP (Document 1.04.002).
- › Upon reception, Laboratory/technical personnel should verify associated data (in keeping with privacy policies) and ensure that it corresponds with the information on the labels on the collection containers. In the presence of any non-conformity, the Laboratory/technical personnel shall follow procedures described in the Non-conformity Management SOP (Document 1.04.002).

C1.6. Processing

- Before processing, Laboratory/Technical personnel shall verify the integrity of the biological material. Laboratory/Technical personnel shall verify the exactness of the associated data. In the presence of any non-conformity, the Laboratory/Technical personnel shall follow procedures described in the Non-conformity Management SOP (Document 1.04.002).
- Laboratory/Technical personnel shall review the BB protocols to decide which processing method should be performed.
- Laboratory/Technical personnel shall process the biological material by following the BB Work Instructions.
- Laboratory/Technical personnel shall ensure that the equipment employed for the processing is in service and do not require neither calibration nor maintenance, as defined in the Equipment Management SOP (Document 1.02.002).
- The Laboratory/Technical personnel should perform validation of methods before implementing new laboratory methods, or using new equipment to identify potential obstacles that might arise and to undertake preventive/corrective actions to ensure the integrity and the quality of the biological material. The procedures for validating methods are described in the Validation of Methods SOP (Document 1.03.002).
- Upon processing, Laboratory/Technical personnel shall check the integrity of the biological material and decide if the biological material can be accepted or has to be rejected based on BB biological material processing criteria. Laboratory/Technical personnel shall verify the exactness of the documentation associated with the biological material. In the presence of any non-conformity, the Laboratory/Technical personnel shall follow procedures described in the Non-conformity Management SOP (Document 1.04.002).

C1.7. Storage: Facility

- Laboratory/Technical personnel shall store the biological material by following the BB Work Instructions.
- Laboratory/Technical personnel shall document storage location and conditions on the Sample tracking form (Document 2.03.001), in the BIMS or in the database.
- Laboratory/Technical personnel shall ensure that temperature, air flow, humidity, and lightning are appropriate in the storage facility.
- Laboratory/Technical personnel shall ensure backup-power capacity for emergency.
- The BB shall train personnel in emergencies, ensuring rapid and efficient transfer of containers to backup freezers.
- Laboratory/Technical personnel shall ensure that a part of the extra storage capacity remains available at operating conditions at all times.
- Laboratory/Technical personnel shall document biological material transfer to backup freezers in the Sample tracking form (Document 2.03.001), in the BIMS or in the database.

C1.8. Storage: Equipment

- Laboratory/Technical personnel shall perform regular maintenance of all storage equipment as described in the Equipment Maintenance SOP (Document 1.02.002).
- Only one box or rack should be removed at a time.
- The QR shall allocate a unique identifier for each freezer, refrigerator, or storage facility. The QR shall establish number for shelves, racks, and boxes biological materials to be easily identified in case of emergency.
- The QR shall post a 24-hour emergency contact list with multiple personnel that can be reached in case of storage dysfunction.
- The QR shall ensure that freezers have an alarm system in place to detect temperature variations as well as electrical power supply interruption.
- The QR shall ensure that the alarm system is functional.

C1.9. Retrieval

- Biological materials shall be retrieved only for pre-defined purposes, according to the informed consent, or for Quality Control.
- Laboratory/Technical personnel shall locate biological materials to be retrieved on the Document Management System or BIMS and then at the BB storage facility.
- Proper temperature conditions shall be maintained according to the biological material type.
- Upon retrieval, Laboratory/Technical personnel shall check the integrity of the biological material and decide if the biological material can be retrieved based on BB biological material retrieval criteria. Laboratory/Technical personnel shall verify the exactness of the associated data. In the presence of any non-conformity, the Laboratory/Technical personnel shall follow procedures described in the Non-conformity Management SOP

(Document 1.04.002).

- Laboratory/Technical personnel shall place retrieved biological materials in an appropriate container, at an appropriate temperature, and labeled properly as required for shipping.
- Laboratory/Technical personnel shall update the BB database or BIMS as well as in the Sample tracking form (Document 2.03.001).

C1.IO. Distribution

- Laboratory/Technical personnel shall initiate the shipping process after obtaining approval from the BB Director/Manager.
- Laboratory/Technical personnel shall update the BB database or BIMS as well as the Sample tracking form (Document 2.03.001), indicating where the biological material is shipped.
- The personnel shall be trained about the requirements for appropriate packaging and shipping of biological materials.
- Laboratory/Technical personnel shall maintain the Shipping Log (Document 2.03.002) to record reception of biological materials shipped.
- Laboratory/Technical personnel shall select the proper packaging depending on the biological material's characteristics and follow BB Work Instructions.
- Laboratory/Technical personnel shall retrieve biological materials from storage facilities and keep them at the appropriate temperature.
- Laboratory/Technical personnel shall pack the shipment correctly and place appropriate markings and labels onto the outer package.
- Laboratory/Technical personnel shall assemble packaging material, accompanying documentation, and shipping documentation.
- Laboratory/Technical personnel shall track delivery.

C2. QUALITY CONTROL

- The QR ensures that personnel are trained in the use of the Document Management System, BIMS or BB database, and in the management of Biological Material.
- The QR uses the BB database or BIMS and the Sample tracking form (Document 2.03.001) to ensure sample traceability, as defined in the Data and Sample Traceability SOP (Document 1.02.003). In the presence of any non-conformity, the Laboratory/Technical personnel shall follow procedures described in the Non-conformity Management SOP (Document 1.04.002).
- The QR controls that personnel, who are responsible for the management of biological material, 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 ensures that a Service Level Agreement (Document 2.04.010) has been prepared and signed in case of out-sourcing service.
- Quality control outcomes should 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 | Materials and equipment (site-specific) |
|--|--|
| Appropriate equipment for biological material collection | Work Instructions, protocols |
| Appropriate labels for biological material | |
| Freezers, power supplies as well as backup freezers, backup power supplies | |
| Shipping packaging and documentation | |

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 material |

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 SOPS

- › 1.04.001 Document Management SOP
- › 1.02.001 Personnel Management SOP
- › 1.02.002 Equipment Maintenance SOP
- › 1.03.002 Validation of Methods SOP
- › 1.04.002 Non-conformity Management SOP
- › 1.01.002 Obtaining Consent SOP
- › 1.01.003 Safety & Compliant SOP
- › 1.04.004 Internal audit SOP
- › 1.02.003 Data and Sample Traceability SOP
- › 1.02.004 Data protection

E3. APPENDICES

- › 2.03.001 Sample tracking form
- › 2.04.011 Risk-biosafety checklist
- › 2.04.010 Service Level Agreement
- › 2.03.002 Shipping Log
- › 2.04.009 Quality Control Results
- › 2.03.003 Sample Acceptance Criteria
- › SBP Datasets

E4. REVISION HISTORY

| Document number | Revision date | Author | Details of revision |
|-----------------|---------------|--------|---------------------|
| 1.03.001 | | SBP | Initial release |