# STANDARD SOP

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| **Document number** | 2.04.001 |
| **Version** | 1.0 |
| **Category** | Organisation Management |
| **Sub-category** | Documentation |

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| **Authored by** | *Swiss Biobanking Platform* |
|  |
| **Effective date** |  |

## PART A - GENERAL INFORMATION

## A1. SCOPE

## A brief description of the scope of the SOP. It should describe why the SOP is required (e.g., compliance with the law and/or other internal procedures and guidelines).

## A2. OBJECTIVES

## Include a brief bullet-point description of the processes described in the SOP.

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## A3. ABBREVIATIONS AND DEFINITIONS

## When appropriate, a list of definitions and abbreviations should be included for terms used in the SOP.

## For this document, the following definitions and abbreviations apply.BB = Biobank BIMS = Biobank Information Management SystemSBP = Swiss Biobanking PlatformSOP = Standard Operating ProcedureQR = Quality Representative

## Add definition of terms if needed/appropriate. It can also be referred to a reference document, such as a glossary.

## 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.

## PART B – PERSONNEL MANAGEMENT

**B1. ROLES AND RESPONSIBILITIES**

Indicate the Department/Service/Unit covered to whom the SOP will apply and define the responsibilities that the individuals are expected to play.

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| --- | --- |
| BB personnel | Responsibility / role |
| QR | Performs Quality Control |
|  |  |

## PART C – PROCESS MANAGEMENT



**C1. PROCEDURES**

An SOP describes a process. It includes details about the inputs, the outputs, and how the inputs are converted into the outputs, as well as quality control and feedback to ensure consistent and quality results.

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Additionally, the SBP SOPs can serve as a reference for BBs to develop site-specific Work Instructions.

The use of flow charts may be useful, especially in complex procedures. There might be more than one sub-procedure to be de-scribed.

**C1.1. Heading for the first sub-procedure**

* Section(s) required to detail each task of the procedure.

**C1.2. Heading for the second sub-procedure**

* Section(s) required to detail each task of the procedure.

**C2. QUALITY CONTROL**

List the quality control steps to be carried out to guarantee the conformity of all processes and to ensure that the quality requirements have been fully met.

* 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).
* The QR controls that the tasks performed by the personnel are listed in the Personnel file (Document 2.02.001), as established in the Personnel Management SOP (Document 1.02.001)

## PART D – RESOURCE MANAGEMENT (OPTIONAL)

**D1. MATERIALS AND EQUIPMENT**

List the equipment needed to perform the procedure. Equipment description may include but is not limited to the name, model, date of purchase, serial number, inventory tracking number, and manufacturer. All materials needed to perform the procedure should be recorded.

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) |
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**D2. POTENTIAL HAZARDS AND PRECAUTIONS TO TAKE**

List the hazards which are related to the execution of tasks described in this SOP.

List the precautions that must be taken during the executions of tasks described in this SOP.

**D3. PROTECTIVE WEAR AND SAFETY EQUIPMENT**

Specify which the protective wear and/or other safety equipment should be worn by the personnel when executing the tasks de-scribed in this SOP.

Specify whether the protective wear and/or special safety equipment are recommendations only or are mandatory.

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| --- | --- | --- |
| Safety equipment/ protective wear | Recommended | Mandatory |
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## PART E - REFERENCES

**E1. REFERENCE TO LAWS, REGULATIONS, AND GUIDELINES**

Insert relevant references to laws, regulations, and guidelines. When possible, web references should be included.

* 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**

Cross-reference all documents provided by the SBP, which are relevant to this SOP. Insert relevant references as required, suf-ficient for the user to find the source document. Web references should be included where possible.

* 1.04.001 Document Management SOP
* 1.02.001 Personnel Management SOP
* 1.04.002 Non-conformity Management SOP

**E3. APPENDICES**

List any templates cited in the text that has to be attached to this SOP.

* 2.04.009 Quality Control Results.
* 2.02.001 Personnel file

**E4. REVISION HISTORY**

When the SOP is the initial version:

Document number: record the document and version number

Revision date: record effective date of the SOP or “see page 1”

Details of revision: state, “Initial version” or “New SOP”

Author: state name of the author of revision.

When replacing a previous version of the SOP:

Document number: record the document and new version number

Revision date: record effective date of the document reviewed or “see page 1”

Details of revision: record the main changes from the previous SOP

Author: state name of the author of revision

## REVISION HISTORY

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| --- | --- | --- | --- |
| **Document number** | **Effective date** | **Author**  | **Details of revision** |
| 2.04.001 |  | SBP | Initial release |