

SOP

PERSONNEL MANAGEMENT

Document number	1.02.001
Version	1.0
Category	Resource Management
Sub-category	Personnel
Authored by	Swiss Biobanking Platform
Effective date	

TABLE OF CONTENT

A.	GENERAL INFORMATION.....	PAGE 2
	A1. SCOPE	
	A2. OBJECTIVES	
	A3. ABBREVIATIONS AND DEFINITIONS	
B.	PERSONNEL MANAGEMENT.....	PAGE 3
	BI. ROLES AND RESPONSIBILITIES	
C.	PROCESS MANAGEMENT.....	PAGE 4
	CI. HUMAN RESOURCES MANAGEMENT	
	C2. TRAINING & EDUCATION	
	C3. QUALITY CONTROL	
D.	RESOURCE MANAGEMENT.....	PAGE 5
	DI. MATERIALS AND EQUIPMENT	
E.	REFERENCE INFORMATION.....	PAGE 5
	E1. REFERENCE TO LAWS, REGULATIONS, AND GUIDELINES	
	E2. REFERENCE TO OTHER SBP DOCUMENTS	
	E3. APPENDICES	
	E4. REVISION HISTORY	

A. GENERAL INFORMATION

A1. SCOPE

This SOP provides guidance on processes concerning Personnel Management, that shall be followed so that the BB personnel have a precise definition of their roles and responsibilities within the BB. Moreover, this SOP covers an outline for training and educating the BB personnel to perform the tasks required by their particular personnel file.

A2. OBJECTIVES

- › Ensure that the role and the responsibility of each BB employee are defined.
- › Ensure that the personnel working conditions and tasks are respected by both parties, i.e., employee and employer.
- › Ensure that job descriptions, descriptions of roles and responsibilities, as well as training records, are recorded in the Document Management System or BIMS.
- › Ensure that personnel is qualified and trained to carry out their assigned tasks.
- › Ensure that existing personnel education and training are up-to-date.

A3. ABBREVIATIONS AND DEFINITIONS

For this document, the following abbreviations apply.

BB = Biobank

BIMS = Biobanking Information Management System

QR = Quality Representative

SBP = Swiss Biobanking Platform

SOP = Standard Operating Procedure

TC = Trainer coordinator

For this document, the following definitions apply.

Trainer = Internal or external employee who regularly carries out the procedure in question, has completed the training program previously, and is skilled in explaining/teaching the elements of the task.

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 can serve as a reference for BBs to develop site-specific Work Instructions.

B. PERSONNEL MANAGEMENT

BI. ROLES AND RESPONSIBILITIES

BB personnel	Responsibility / role
BB Director/Manager	<ul style="list-style-type: none"> › Approves and maintains job descriptions, descriptions of role and responsibility of each employee › Facilitates the training of the personnel › Validates the content of the training courses
Trainer Coordinator	<ul style="list-style-type: none"> › Monitors and maintains appropriate training documentation for all employees › Keeps records of personnel to be trained in each required area, tracks the time of their periodic updates of training › Ensures that the training is complete within the timeframe. › Identifies the needs for supplemental training
Trainer	<ul style="list-style-type: none"> › Prepares the relevant material for the training › Carries out the training activities › Assures that the trainees understand each procedure of the task
Technical personnel	<ul style="list-style-type: none"> › Obtain and maintain the skill sets necessary to perform their assigned tasks
QR	<ul style="list-style-type: none"> › Performs Quality Control

C. PROCESS MANAGEMENT

C1. HUMAN RESOURCES MANAGEMENT

c1.1. Personnel File

- › A personnel file shall be maintained for each employee.
- › It should contain the following information (see Personnel file, Document 2.02.001): job description, roles and responsibilities, and training records of the employee.
- › The personnel file shall be reviewed periodically and updated when required.
- › Personnel files should be readily accessible for audits, as further explained in the Internal audit SOP (Document 1.04.004).

C2. TRAINING & EDUCATION

c2.1 Training records

- › Training documentation shall be created for each employee and updated periodically and every time the employee attends a training module.
- › The training records should include, but may not be limited to the following: bullet-points description of the training program, date of the training, copies of certificates documenting that the employee has received specific training, confirmation on completion of the training module.
- › The training records shall remain available, in compliance with the good biobanking practices, and, when the employee leaves the BB, shall be archived according to the Document Management SOP (Document 1.04.001).
- › Training records should be readily accessible for audits, as further explained in the Internal audit SOP (Document 1.04.004).

C2.2 Training programs for new employees and the already existing personnel

- › Each new employee shall be trained in the particular tasks described in his/her Personnel file. Therefore, the training should be task- and location- specific. These are recommended training sessions that each new employee should attend before start working:
 - › Training on Quality. The BB shall train the personnel to the BB quality management.
 - › Training on the Governance issues.
 - › Training on the use of the Document Management System or BIMS. Each employee must become acquainted with filing the Biological material worksheet (Document 2.03.001) as well as the Document Management System or BIMS.
 - › Site-specific training.
- › Specific training modules for existing personnel shall be implemented.
 - › Supplemental training. The training coordinator shall design additional training modules for existing personnel in case of procedural changes, new operational needs, or as a response to the implementation of preventive/corrective action (see Non-conformity Management SOP, Document 1.04.002).
 - › Updating training. The training coordinator shall schedule updating training for the employee.

C2.3 Assessment of training outcomes

- › At the end of a training session and on an ongoing basis, the Trainer Coordinator should encourage the personnel to review documents relevant to their tasks and discuss any point requiring clarification.
- › A short test should be administered to the personnel at the end of the training. The training completion should be recorded in the training file of each employee.

C3. QUALITY CONTROL

- › Monitor the employee's performance routinely to identify the needs for supplemental training.
- › Control that job descriptions, descriptions of role and responsibility, and trainings, are recorded in the Document Management System or BIMS
- › 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

DI. 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

E. REFERENCE INFORMATION

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
- > 1.04.002 Non-conformity Management SOP
- > 1.03.001 Biological Material 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
1.02.001		SBP	Initial release