SOP
RISK AND OPPORTUNITIES MANAGEMENT

Document number	1.04.006
Version	1.0
Category	Organisation Management
Sub-category	Documentation
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
- **B1. Roles and responsibilities**

C. PROCESS MANAGEMENT ..... PAGE 4
- **C1. Planning**
- **C2. Risk assessment**
- **C3. Documentation**
- **C4. Communication / Opportunities**
- **C5. Quality control**

D. RESOURCE MANAGEMENT (OPTIONAL) ..... PAGE 7
- **D1. Materials and equipment**
- **D2. Potential hazards and precautions to take**
- **D3. Protective wear and safety equipment**

E. REFERENCES ..... PAGE 7
- **E1. Reference to laws, regulations, and guidelines**
- **E2. Reference to other SBP documents**
- **E3. Annexes**
- **E4. Revision history**

SWISS BIOBANKING PLATFORM

A. GENERAL INFORMATION

A1. SCOPE

SBP SOPs are based on Good Biobanking Practices[1] and should serve as reference guidance for biobanks to develop site-specific Work Instructions.

In particular, this SOP provides insights into the biobank risk and opportunities management procedure, including:

- Identification of hazards that may cause harm to people (biosafety) or that may impact biological material or quality objectives, data integrity, IT infrastructure security (data breach, data loss), compliance with governance/ethics/regulatory aspects or any re-lated areas.
- Determination of the likeliness that each hazard will occur and the severity of the possible consequences.
- Decision on actions to be taken to avoid hazards from occurring or to mitigate the risk.
- Preparation of a contingency plan.
- Opportunities arising from the taken actions and continuous improvement.

A risk-based approach is the basis of decision-making in the biobank and is performed at all stages of the biobanking processes. In this document, Failure Mode and Effect Analysis (FMEA) method was adapted to meet the ISO 20387 standard ("Biotechnology – Biobank-ing – General requirements for biobanking") requirements regarding risk management.

A2. OBJECTIVES

- Catalogue and prioritize all the possible hazards to the biobank.
- Analyze the significance and likeliness of the identified risks.
- Identify actions to minimize the risks.
- Use risk analysis to create opportunities and determine the need for risk control related to a specific hazard.
- Raise awareness about hazards (incl. ethics/regulatory aspects) and risks to decision-makers.
- Determine and document the financial added value of risk mitigation in order to better understand the return on investment.

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 abbreviations apply:

SBP = Swiss Biobanking Platform

SOP = Standard Operating Procedure

QR = Quality Representative

FMEA = Failure Mode Effect Analysis

RIAS = Risk Assessment

For this document, the following definitions apply:

Contingency plan = Plan describing the steps to follow if a risk occurs.

Hazard = Anything that cause harm to the biobank and its personnel, including technical, operational and organizational threats.

Risk = The chance that a hazard will cause harm.

Risk assessment = Exploring internal and external hazard and the consequences they have on the biobanking processes.

Risk analysis = Sub-component of the risk assessment, aiming at determining the probability of occurrence and consequences of risks. It is used as a basis to propose actions to decrease the chances of a risk to occur or decrease the impact of the risk if it occurs.

[1] References for Good Biobanking Practices are the professional standards described in the document "Ethical, legal and professional com-pliance list for human research biobanks applicable in Switzerland", available on SBP website (www.swissbiobanking.ch).

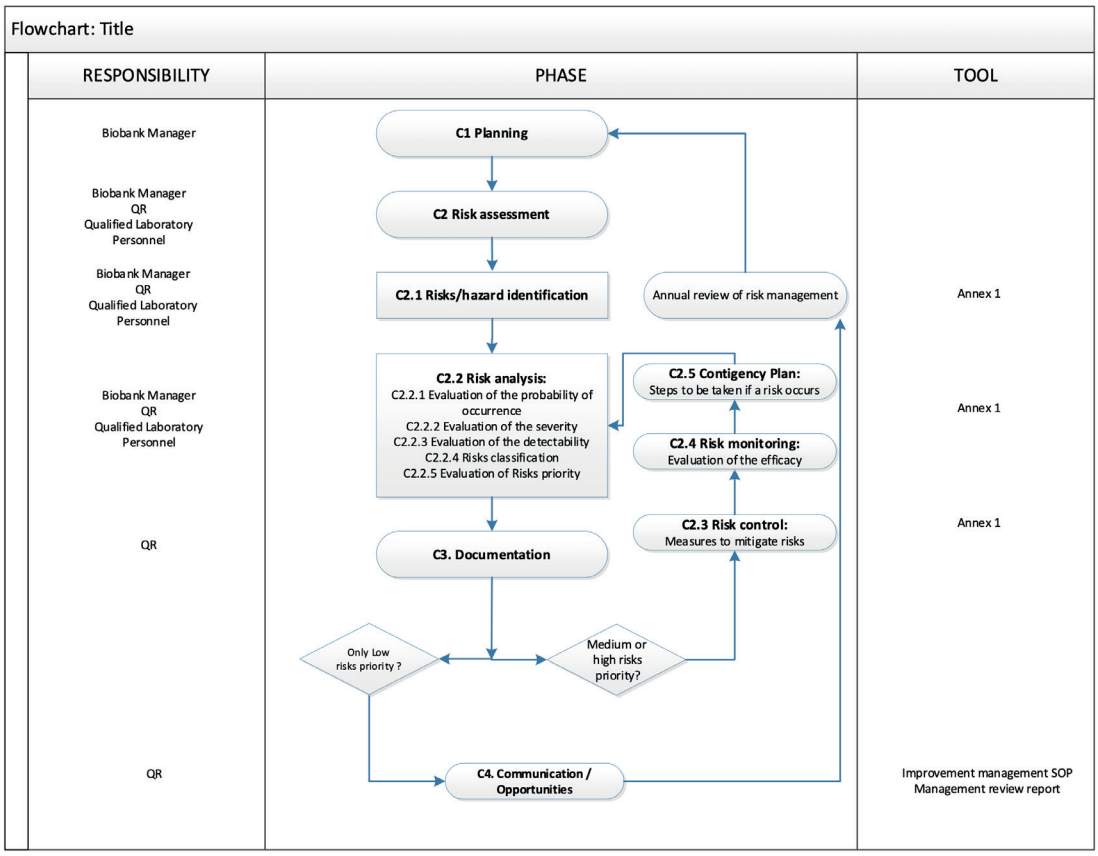
B. PERSONNEL MANAGEMENT

B1. ROLES AND RESPONSIBILITIES

Personnel	Responsibility / role[2]
Biobank Director /Manager	› Plan risk assessment and analysis. › Appoint an adequate expert team to perform risk analysis. › Participate to risk assessment, analysis and risk control processes and approve the risk assessment report. › Approve the contingency plan.
Qualified laboratory Personnel	› Report any new process / activity or modification of a process / activity, or new hazard to the Biobank Director / Manager. › Participate to risk assessment, analysis and risk control processes and approve the risk assessment report and the contingency plan.
Quality Representative	› Coordinate risk assessment, analysis, control and moni-toring processes. › Document risk analysis results in a risk assessment report and prepare a contingency plan. › Coordinate the risk control process by appointing respon-sible persons for the proposed actions and following up the proposed actions at the end of the risk analysis, including risk monitoring. › Integrate risk assessment conclusions in the quality im-provement strategy and in the management review. › Organize annual risk assessment review.

[2] This list is not exhaustive and should be adapted depending on the biobank strategy and available resources.

C. PROCESS MANAGEMENT



C1. PLANNING

Risk assessment and analysis should be performed before introducing new processes or activities, before implementing changes in existing processes or activities, or when the biobank identifies a new hazard.

Changes in existing processes or activities include (the provided list is not exhaustive):

- Collection/processing of samples from new specimens
- New critical instrument (e.g.: freezer, pipetting robot)
- New laboratory method available
- Transport of samples to another storage facility
- New critical reagent available

The biobank manager should plan the risk assessment and analysis by defining:

- The scope of the RIAS (hazards/risks identification, location and who it concerns)
- The resources needed: a competent team of experts should be appointed, who have adequate knowledge of the situation being studied.
- The policies and SOPs impacted, if applicable.
- The risk assessment project timeline.

Annually, the quality representative organizes risk assessment review by contacting the biobank manager and the expert team.

C2. RISK ASSESSMENT

C2.1. Hazards/Risks identification

The expert team, including the biobank manager, organizes a brainstorm meeting to review all the biobanking processes, describes the topics (see annex 1) and identifies the related hazards/risks. Using a fishbone diagram can be helpful to list all the risks to take into consideration.

Hazards include (the provided list is not exhaustive):

- Natural disasters (e.g.: flooding, fire)
- Biological/chemical hazards (e.g.: pandemic diseases)
- Workplace accidents
- Intentional acts (robbery, etc.)
- Technological hazards (data breach, lost database connection, power outage, etc.)
- Interruptions in the supply chain
- A negative public opinion about biobanking
- Decrease of samples requests from research groups
- Decrease of participant rate
- Increasing biobanking and research costs

Corresponding risks should be determined as the chance that these hazards could cause harm.

C2.2. Risk Analysis

C2.2.1. Evaluation of the probability of occurrence

The probability of occurrence is assessed and assigned in one of the following three categories:

- Low: The probability, that the risk occurs, is improbable.
- Medium: The probability, that the risk occurs, is partially probable.
- High: The probability, that the risk occurs, is probable.

C2.2.2. Evaluation of the severity

The severity is assessed and assigned in one of the following three categories:

- Low: The impact of the risk has no influence or only a limited influence. Long term damage cannot occur.
- Medium: The impact of the risk has a moderate influence. Short to medium term damage can occur.
- High: The impact of the risk has a significant and negative influence. Serious short- and long-term consequential damage can occur.

C2.2.3. Evaluation of the detectability

The risk detection is assessed and assigned in one of the following three categories:

- High: The probability, that the risk is detected, is always possible.
- Medium: The probability, that the risk is detected, is partially possible.
- Low: The probability, that the risk is detected, is improbable.

C2.2.4. Risk classification

After evaluating the risk probability and severity, the risk classification is assessed, for example according to following matrix:

		Risk probability		
		Low	Medium	High
Risk severity	High	Risk class 2	Risk class 1	Risk class 1
	Medium	Risk class 3	Risk class 2	Risk class 1
	Low	Risk class 3	Risk class 3	Risk class 2

C2.2.5. Evaluation of the risk priority

The risk priority is determined by a combination of the risk class and risk detection, for example according to the following matrix:

		Risk detectability		
		High	Medium	Low
Risk class	1	Medium risk priority	High Risk priority	High Risk priority
	2	Low risk priority	Medium risk priority	High Risk priority
	3	Low risk priority	Low risk priority	Medium risk priority

C2.3. Risk control

The expert team propose actions to prevent identified hazards from occurring or to mitigate the risks (see Annex 1). In particular, risks priority is used to decide when actions are specifically required:

- Actions to mitigate Risks with high priority are mandatory
- Actions to mitigate Risks with medium priority are recommended
- Risks with low priority do not require specific actions

The Quality representative appoint a responsible person to put in place each mandatory and recommended actions following the risk analysis, with a target date.

C2.4. Risk monitoring

At the end of the risk control process, proposed measures are reviewed and their efficacy is evaluated. For this purpose, a new risk analysis is performed according to ch. 2.2 and a new classification is calculated (see annex 1). New actions are proposed if needed.

C2.5. Contingency plan

Following the risk analysis, a contingency plan is prepared, describing the steps to follow if a risk really occurs, in order to reduce its impact by rapid action. The contingency plan details who will be involved, what must be done and when, where will the plan take place, and how it will be executed.

C3. DOCUMENTATION

Risk assessment is documented according to annex 1. QR is responsible to summarize the results obtained (risks scoring and proposed measures) in a risk assessment report for the expert team.

C4. COMMUNICATION / OPPORTUNITIES

QR integrates results described in the Risk assessment report to the annual management review, as a basis for improvement management. Arising opportunities are evaluated in the frame of the management review.

Annually, the risk assessment and analysis are updated if needed. Novel as of yet unidentified risks are included.

C5. QUALITY CONTROL

NA

D. RESOURCE MANAGEMENT (OPTIONAL)

D1. MATERIALS AND EQUIPMENT

NA

D2. POTENTIAL HAZARDS AND PRECAUTIONS TO TAKE

NA

D3. PROTECTIVE WEAR AND SAFETY EQUIPMENT

NA

E. REFERENCES

E1. REFERENCE TO LAWS, REGULATIONS, AND GUIDELINES

- Laboratory biosafety guidance related to coronavirus disease 2019 (COVID-19), annex 2, World Health Organization
- Swiss Ordinance on handling organisms in contained systems (ContainO)
- Ordonnance suisse sur la protection des travailleurs contre les risques liés aux microorganismes (OPTM)

E2. REFERENCE TO OTHER SBP DOCUMENTS

Please find refer to the following documents that are relevant to this WI [3].

- 1.04.002 Non-Conformity Management SOP
- 1.04.003 Improvement Management SOP
- 2.04.007 Non-Conformity Report Form
- 2.04.005 “Management review report”

E3. ANNEXES

- Annex 1: Risk Assessement template.
  https://swissbiobanking.ch/sops-forms/

E4. REVISION HISTORY

Version	Revision date	Author	Details of revision
V1.0		SBP	Initial release

[3] All the aforementioned documents are available on: https://swissbiobanking.ch/sops-forms/.