SOP
DOCUMENT MANAGEMENT

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SWISS BIOBANKING PLATFORM

A. GENERAL INFORMATION

A1. SCOPE

The Biobank should develop and maintain a uniform document and record management system that allows bibobank activities to be defined and traced.

A2. OBJECTIVES

- Ensure that biobank activities are documented (description of the steps) and recorded in a well-organised, complete, and accurate Document Management System or BIMS
- Harmonise all documents created or modified by the biobank
- Ensure that all documents created and modified by the biobank comply with the current legislation and regulation
- Provide traceability of documents through a history of modifications
- Facilitate education and training of biobank personnel

A3. ABBREVIATIONS AND DEFINITIONS

The term “document” used here refers to all documents made available for the biobank, including SOPs and templates.
For this document, the following abbreviations apply.
BB = Biobank
BIMS = Biobank Information Management System
QR = Quality Representative
QMS = Quality Management System
SBP = Swiss Biobanking Platform
SOP = Standard Operating Procedure

Add definition of terms if needed/appropriate. It can also be referred to a reference document, e.g. a glossary.
The SBP SOPs are based on Good Biobanking Practices to ensure an optimal setup for 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

The SOP applies to all biobank personnel involved in generating, maintaining, and managing documents and records within the BB.

BB personnel	Responsibility / role
QR	› Analysis of the existing documentation › Assignment of the tracking code to new or modified document › Validation of a new or modified document › Management of documents in the QMS and BIMS › Document distribution and communication › Performs Quality Control
Technical and/or administrative personnel	› Use of the filing system or BIMS › Creation and update request of documents › Consultation of new or updated documents

C. PROCESS MANAGEMENT

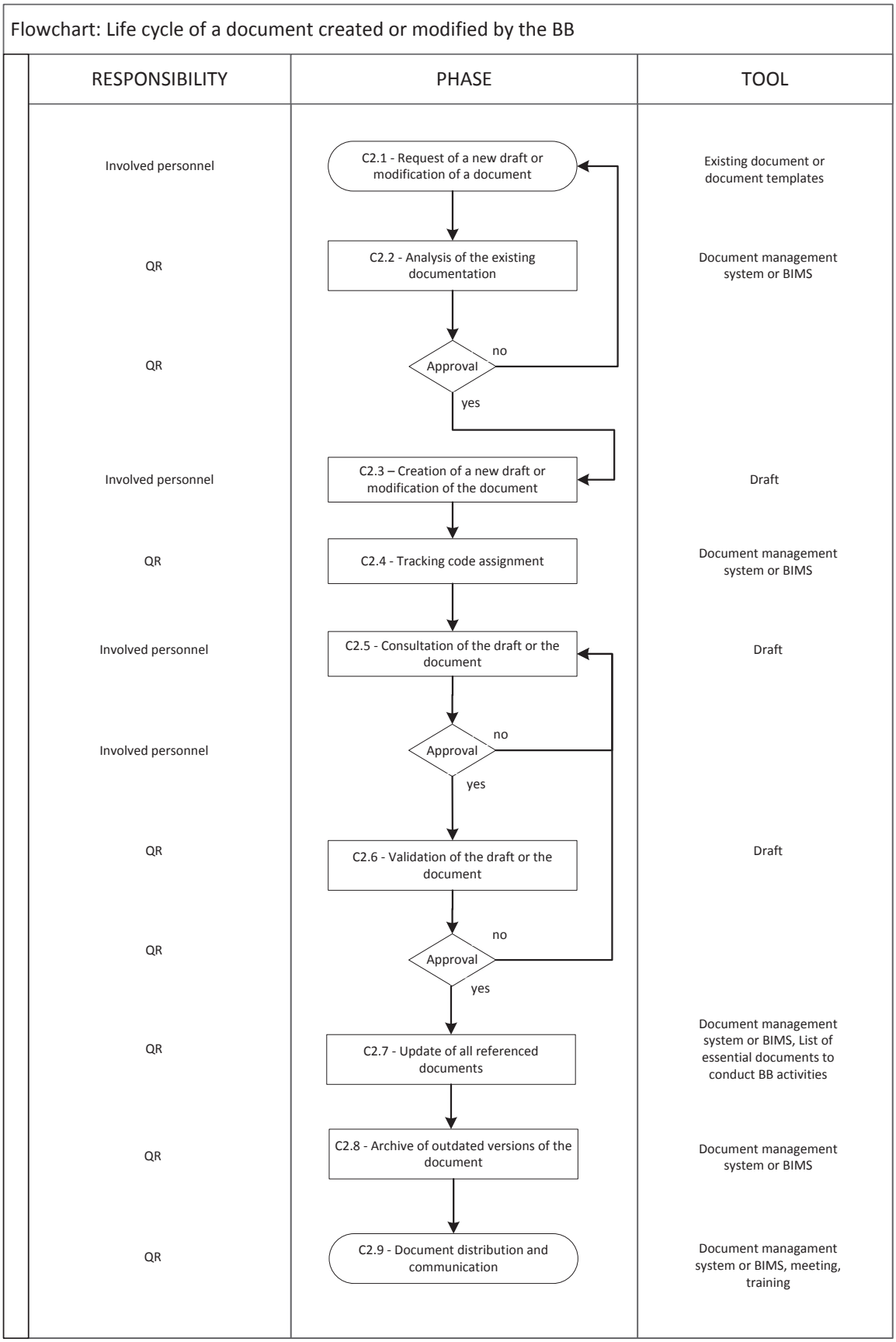
C1. GENERAL PRINCIPLES OF DOCUMENT MANAGEMENT

- The BB shall implement a BIMS or develop a Document Management System that allows for a prompt location, storage, and retrieval of documents.
- The most recent documents, such as SOPs and templates, shall be easily accessible and identifiable by the personnel.
- Documents and records shall be readable and understandable.
- BB Personnel shall be trained in using the Document Management System or BIMS.
- The documents shall be periodically updated and revised . In particular, SOPs should regularly be reviewed, ideally every two years (see List of essential documents to conduct biobanking activities, for suggested review schedule)
- Changes and actions performed on the document shall be recorded. Before applying any significant modifications, deleting or destroying any documents, the BB personnel should refer to QR or someone in a supervisory role.
- Hard copies of records and approved documents shall be stored to protect them from loss or damage.
- The QR shall define a period during which records are retained.
- Paper documents containing confidential data that required to be destroyed shall be passed through a paper shredder before disposal in the general garbage. Electronic documents shall be permanently deleted.
- Training on new/revised documents shall be provided, as established by the Personnel Management SOP (Document 1.02.001).
- All documents shall be made accessible for internal and external audits, as further explained in the Internal audit SOP (Document 1.04.004).

C2. LIFE CYCLE OF A DOCUMENT CREATED OR MODIFIED BY THE BB

The following flowchart represents the life cycle of the document from its creation to its distribution.

Flowchart: Life cycle of a document created or modified by the BB



C2.1 Request of a new draft

- A new draft or a modification of a document shall be a response to a new operational need, change in the legislation/regulation or an incident report.
- Personnel shall propose the creation of a new document or the modification of an already existing one, but only one individual is responsible for the creation/modification of the document.

C2.2 Analysis of the existing documentation

- The QR shall analyse the existing documentation to inquire the legitimacy and the necessity of the draft document.

C2.3 Creation of a new draft

C2.4 The new/modified document should be called “draft” until its final approval. Tracking code assignment

- The QR shall assign a tracking code to the draft or the modified document.

C2.5 Consultation of the draft

- The personnel involved in the tasks related to the draft shall be responsible for consultation process. The draft should circulate to the reviewers for comments and feedback.

C2.6 Validation of the draft

- The QR shall be responsible to incorporate the comments into the draft, review the final draft for accuracy, completeness, and for compliance with legislation, regulations, and best practices. The QR shall revise the draft version date. For significant revisions to previous documents, the major version number should be incremented by 1 (e.g., 1.0 becomes 2.0). For minor revisions to the previous version, the minor version number should be incremented by 1 (e.g., 1.0 becomes 1.1). The first version of the document is always 1.0.
- Once the final draft has been approved, the QR shall add the effective date to the front page of the document. The document is not a draft anymore.

C2.7 Update of referenced documents

- The QR shall revise associated attachments, as applicable. The QR shall update also the ‘List of essential documents to conduct biobanking activities’ document.

C2.8 Archive of outdated versions of the document

- The QR shall archive obsolete documents.

C2.9 New document distribution and communication

- The QR shall be responsible for notifying BB personnel and any other users of the updated document. Ideally, direct users should be notified immediately of new documents. The QR should also ensure that the latest versions of the documents are available at the appropriate place to prevent any accidental use of obsolete documents.

C3. DOCUMENT STANDARDISATION

- All documents shall follow the standardised formats and prescribed templates (see Standard SOP template and Standard document template).. Any deviations from templates should be approved by the QR.
- The document first-page header should contain the following information: title of the document, version of the document, effective date, category and sub-category of the document, approval name.
- A new/modified document should follow the standardised templates.
- Times and dates should be recorded using a consistent format throughout all documentation. Dates should implement a format that is unambiguous such as dd/mm/yyyy, where d stands for day, m stands for month, and y stands for year. Times should implement a format that is unambiguous such as hh:mm, where h stands for hours and m stands for minutes. The twenty-four-hour clock runs as follows: 01:00 through 24:00 with 01:00 representing 1.00 AM and 24:00 represents midnight.
- In the presence of any non-conformities or in case of any adverse event, follow the procedures described in the Non-conformity Management SOP (Document 1.04.002).

C4. QUALITY CONTROL

- Control that the documents meet the standardisation requirements, as defined in Part C3, as a proof of the QMS efficiency.
- Control that the documents have been revised within the timeframe determined for each kind of document.
- Control that only the latest version of documents is available for the personnel.
- 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

E. REFERENCES

E1. REFERENCE TO LAWS, REGULATIONS, AND GUIDELINES

- Canadian Tumor Repository network. Standard Operating Procedures
- NFS 96900-2011
- OECD Best Practices Guidelines for BRCs. – 2007
- ISBER Best Practices for Repositories - 2018

E2. REFERENCE TO OTHER SBP DOCUMENTS

- 1.02.001 Personnel Management SOP
- 1.04.002 Non-conformity Management SOP
- 1.04.004 Internal Audit SOP

E3. APPENDICES

- 2.04.001 Standard SOP Template
- 2.04.002 Standard Document Template
- 2.04.003 List of essential documents to conduct BB activities
- 2.04.009 Quality Control Results.
- 2.02.001 Personnel file

E4. REVISION HISTORY

Document number	Revision date	Author	Details of revision
2.04.002		SBP	Initial release