Approvals	Printed Name	Signature	Date
Author	Janet Price-Lutz		20Nov2024
Approver	Jenna York		20Nov2024
Approver	Robert Orr		25Nov2024
Quality Assurance	Jennifer Mauck		10Dec2024

1.0 PURPOSE

1.1 This Standard Operating Procedure (SOP) describes the process for the life cycle management of controlled documentation.

2.0 SCOPE

2.1 This SOP applies to the Biospecimen Management Core (BMC) documents and records supporting facility operations involving current GxPs; in addition to quality systems documentation subject to regulatory inspections.

3.0 ROLES AND RESPONSIBILITES

Role	Responsibilities
Approver	• Reviews and approves documentation. When multiple departments approve documentation, approval by a given department indicates agreement with, and the ability to comply with, only those requirements in the documentation applicable to that department and within the scope of that department's assigned responsibilities. • Notifies the Author and Quality Assurance (QA) immediately if any part of the document is unacceptable and requires resolution before approval.
Area Manager	• Reviews and approves/declines obsolescence requests.

Role	Responsibilities
Author	• Creates, evaluates, and revises all the controlled documents required within the scope of their responsibility. • Works with QA to assign appropriate Approvers. • Obtains a document number from QA. • Resolves comments from Reviewers for internal or vendor-controlled documents.
BMC Employees, Contractors and Consultants (as applicable)	• Follow all applicable BMC SOPs, Policies and other applicable controlled documentation when conducting business on behalf of BMC. • Follow this SOP for the writing, revising, approval and/or obsolescence of controlled documents.
Quality Assurance (QA), or designee (where indicated)	• Assigns document numbers, if applicable. • Verifies proper document structure, format, and referencing. • Provides notification of effective documents. • Reviews and approves controlled documentation. • Works with Author to assign Approvers for documents. • Oversees and manages life cycle maintenance of documents within the Quality System. • Ensures training is conducted and recorded on controlled documents, if applicable.
Reviewer	• Reviews document and provides input to the content of the document.

4.0 REFERENCES AND RELATED DOCUMENTS

Document Number	Title
BMC-FRM-01	Document Change Request Form
BMC-TMP-06	Table of Contents Template
BMC-SOP-05	Personnel Training
BMC-SOP-04	Document Distribution and Archiving

Document Number	Title
BMC-SOP-13	Record of Signature, Electronic Signature Agreement and Signature Delegation
N/A	*International Society for Biological and Environmental Repositories (ISBER) Best Practices* – current edition

5.0 DEFINITION OF TERMS

Term	Definition
Administrative Change	Change made to an effective document which does not change the intent/purpose and/or responsibilities and are deemed to be minor in nature, e.g. adding a new SOP/WI category, fixing typographical errors, formatting.
Author/Originator	The person who writes the text of the procedure or who initiates revisions to a document.
Effective status	An approved, controlled document where training has been completed.
Trainee	An employee who, per their job function or as noted on the facility's curriculum, needs to be trained on executing the specified tasks outlined within a document.
GxP	Good practice regulations associated with the development of drug/biological products; e.g., current Good Manufacturing Practice (cGMP), Good Clinical Practice (GCP), and Good Laboratory Practice (GLP).
Standard Operating Procedure (SOP)	An SOP is a written set of instructions that describes how to perform an activity to ensure consistency and reliability.
Work Instruction (WI)	A WI is a more detailed written instruction for a specific activity. Work Instructions provide individuals with step-by-step information to perform a job properly and facilitate consistency in the quality and integrity of a procedure or end result.

6.0 PROCEDURE

6.1 Document Identification

6.1.1 QA assigns document numbers.

6.1.2 Document Prefix: Assign each document a BMC prefix for Biospecimen Management Core.

6.1.3 Department Designation (as needed): For SOPs that are specific to a department within the BMC add one of the department designations listed below.

Acronym	Department
CTSL	Clinical and Translational Sciences Laboratory
SSF	Specimen Storage Facility

6.1.4 Document Type: Assign each document a document type according to the categories outlined in the table below:

Acronym	Document Type
MAN	Manual
POL	Policy
PST	Posting
SOP	Standard Operating Procedure
WI	Work Instruction
FRM	Form
PRO	Protocol
RPT	Report
TMP	Template

6.1.5 Document Number: Lastly, assign each document a unique two-digit sequential number beginning with 01 for each document type within a department.

6.1.6 Document Revision Number: The Revision Number follows the format N.N. The first revision number (i.e., initial version) is 0.0 for each document.

6.1.7 The resulting document number resembles:

AAA–XXX(X)–YY(Y)-NN

Where:

AAA	Document Prefix - BMC
XXX(X)	Department (as needed)
YY(Y)	Document Type
NN	Increasing sequential number

Example: The fifth work instruction issued in the CTSL is BMC-CTSL-WI-05 Revision 0.0.

6.2 Document Format and Content

6.2.1 Documentation format and content is defined within specific SOPs related to each Document Type.

6.3 Document Change Control

6.3.1 Initiation of a New Document or Revision of an Existing Document

6.3.1.1 Author requests a document number and a Document Change Request (DCR form, BMC-FRM-01) from QA.

6.3.2 Tracking

6.3.2.1 QA tracks document change controls through the use of DCRs and the DCR log (maintained by QA).

6.3.2.2 QA assigns a DCR Number to each document change request and identifies the type of change as follows:

- New
- Revision (Permanent Change)
- Administrative
- Obsolete
- Periodic Review

6.3.2.3 Change request numbers are in the format DCR-XX-NNN where:

XX: Corresponds to the last two digits of the current calendar year

NNN: Is a sequential number beginning with 001

6.3.2.4 Record all change requests in the DCR Log. The DCR Log contains, at a minimum, areas for the following:

- DCR number
- Date of DCR request
- Document number
- Document type
- Prepared by
- Document title
- Effective date of the changed document

6.3.2.5 QA assigns a document identification number to new documents and edits the format of the new document for compliance with this procedure.

Note: The "Supersedes Date" for a new document is "First issue".

Note: The "Supersedes Date" for a revised document is the prior version's Effective Date.

6.3.2.6 QA submits the DCR, a draft copy of the document to be revised or an appropriate template (as available) if the document is new, and any applicable documents to the individual preparing/revising the document.

6.4 New documents

6.4.1 Any individual can initiate a request for a new document.

6.4.2 The Author drafts the document by either using a template provided by QA or by creating a draft using the recommended formatting for the specific document type being created.

6.4.2.1 The Author forwards the draft document to the appropriate stakeholder(s) for review.

6.4.3 Upon completion of the review, the Author forwards the draft document to QA with Parts A and B of the DCR completed to initiate document tracking and change control according to Step 6.3.

6.4.4 QA verifies that the document type and format meet the requirements of document control procedures.

6.4.5 QA also verifies that regulatory or harmonized standards, appropriate to the work, have been consulted and followed.

6.4.6 Once QA completes their review, the document and the DCR are circulated for final signature approval.

Note: QA may void any DCR that has not been approved in a timely fashion without justification. All paperwork (i.e. DCR, training documentation) must be returned to QA for tracking purposes.

6.5 Revised Documents

6.5.1 The Author requests a copy of the current version of the document from QA and initiates a DCR (see 6.3.1).

6.5.2 The Author revises the document using Track Changes and forwards it to the appropriate stakeholders for review.

6.5.3 Upon completion of the revision, the Author forwards the revised document to QA with Parts A and B of the DCR completed to document tracking and change control according to Step 6.3.

6.5.4 QA verifies that the document type and format meet the requirements of corporate document control procedures.

6.5.5 QA also verifies that regulatory or harmonized standards, appropriate to the work, have been consulted and followed.

6.5.6 Once QA completes their review, the document and the DCR are circulated for final signature approval.

6.6 Administrative Changes

6.6.1 Administrative changes are handled in the same fashion as outlined above with the exception that the document's Revision Number goes through a minor increase, instead of a major increase, e.g. 1.0 increases to 1.1 instead of 2.0.

6.7 Final Document Review and Approval

6.7.1 QA or designee generates a final version of the document for signature approval and routes it for approval.

6.7.2 QA or designee and the Author determine which Departments are responsible for approval based on their responsibility/scope in the document.

6.7.3 If an approver is not available to sign the document, a delegate may sign provided the appropriate signature delegation documentation is in place according to BMC-SOP-13, *Record of Signature, Electronic Signature Agreement and Signature Delegation.*

6.7.4 All references need to be effective for the document to be made effective.

6.8 Training

6.8.1 The effective date should be set allowing a reasonable time for affected trainees to be trained (typically three weeks after document approval).

6.8.2 Conduct training according to BMC-SOP-05, *Personnel Training*.

6.8.3 All individuals authoring and reviewing/approving the document are considered trained. Update training records according to BMC-SOP-05, *Personnel Training* to reflect this.

6.8.4 Not all document types require training; refer to BMC-SOP-05, *Personnel Training* for instructions on how to designate training requirements.

6.8.5 Administrative changes do not require training.

6.9 Obsolete Document

6.9.1 Author contacts QA to initiate a DCR as outlined in Step 6.3.

6.9.2 Author identifies the change as obsolete on the DCR by completing Parts A and B and forwards the DCR to an Area Manager for review and approval.

6.9.3 The Area Manager reviews and either approves, and signs the DCR, or denies the approval of the change by not signing the DCR and forwards the DCR to QA for authorization or rejection and archiving.

6.9.4 QA or designee closes out the DCR by entering the document obsolescence date in the DCR Log, removing the document from use and archiving all paperwork according to BMC-SOP-04, *Document Distribution and Archiving*.

6.10 Periodic Document Review

6.10.1 Perform periodic lifecycle reviews every three years on the following document types: SOPs, Work Instructions, Policies, Forms, Templates and Manuals.

6.10.2 QA initiates the DCR according to Step 6.3 and forwards it with a copy of the document to the appropriate Reviewer(s) given the document content.

6.10.3 Upon completion of the review, the completed DCR and document are returned to QA for final processing.

6.10.4 If there is no change necessary, QA or designee updates the Revision History and routes the document for signatures.

Note: If no changes are made, the Effective Date and the Revision Number remain the same. Document that no changes are required on the DCR, DCR log and the SOP binder Table of Contents (BMC-TMP-06).

6.10.5 QA updates the Periodic Review Date in the DCR Log.

6.10.6 If a change to the document is necessary, revise the document according to Step 6.5.

6.11 Final Document Preparation

6.11.1 QA verifies that the approved document and all required training is complete.

6.11.2 QA adds the effective date to each page of the approved document, as required.

6.11.3 QA enters the current effective date and revision number into the Master Document List.

6.11.4 QA or designee places the hard copy of the effective document bearing the original signatures in a secured location according to BMC-SOP-04, *Document Distribution and Archiving*.

6.11.5 QA closes out the DCR by entering the document effective date in the DCR Log and QA or designee distributes and archives all paperwork according to BMC-SOP-04, *Document Distribution and Archiving*.

6.11.6 Form Preparation

6.11.6.1 QA sets permissions on final electronic versions of Forms to allow for electronic entry of data in fields on the locked Word form. Headers, wording, signature / date fields and overall structure of the document cannot be altered.

6.11.7 QA or designee places the final electronic version of the document in a secure network folder.

6.11.8 QA or designee makes only PDF copies of documents available in a shared network folder, with the exception of forms and templates, (refer to BMC-SOP-04).

7.0 APPENDICES

7.1 Not applicable.

8.0 REVISION HISTORY

Revision No.	Section	Change Description/Justification	Date
9.0	All Sections	Complete overhaul of SOP to update format, clarify content, move definitions to a central glossary and separate Form into separate documents to be managed independently of the SOP. Moved some content related to distribution and archival into separate SOP and applied new numbering format. Formerly SF-1-06.	Current See D-23-08
8.0	See SF-1-06	See SF-1-06	31 Jan 2022