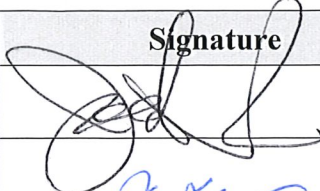
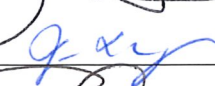

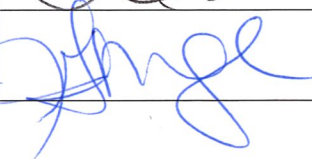


Approvals	Printed Name	Signature	Date
Author	Janet Price-Lutz		13 Nov 2024
Approver	Jenna York		13 Nov 2024
Approver	Robert Orr		25 Nov 2024
Quality Assurance	Jennifer Moush		10 Dec 2024

1.0 PURPOSE

- 1.1 This Standard Operating Procedure (SOP) outlines the process for creating and formatting Policies, SOPs, Work Instructions (WI), Forms and Templates at the Biospecimen Management Core (BMC).

2.0 SCOPE

- 2.1 This SOP applies to all BMC Policies, SOPs, WIs, Forms and templates developed for functions that are performed at BMC in accordance with ISBER “Best Practices” and GxP regulations as required.

3.0 ROLES & RESPONSIBILITIES

Role	Responsibilities
Area Management (AM)	<ul style="list-style-type: none"> Ensures that personnel follow the content and formatting requirements in this SOP for the creation or revision of controlled documentation. Designates appropriate representatives to review changes to documents in a timely manner.
Author	<ul style="list-style-type: none"> Creates Policies, SOPs, WIs and associated Forms and Templates according to the content and formatting requirements outlined in this SOP.
Quality Assurance (QA)	<ul style="list-style-type: none"> Reviews Policies, SOPs, WIs and associated Forms and Templates for compliance to the content and formatting requirements outlined in this SOP.
BMC Personnel	<ul style="list-style-type: none"> Identify all processes that are performed by BMC personnel and need standardization through the creation of Policies, SOPs, WIs, Forms and Templates.

4.0 REFERENCES AND RELATED DOCUMENTS

Document Number	Title
BMC-SOP-06	Controlled Document Management
BMC-TMP-01	Standard Operating Procedure (SOP) Template
BMC-TMP-02	Work Instruction (WI) Template
BMC-TMP-03	Form Template
BMC-TMP-04	Policy Template
N/A	<i>International Society for Biological and Environmental Repositories (ISBER) Best Practices</i> – current edition

5.0 DEFINITION OF TERMS

Term	Definition
Form	Controlled document with fields designed for data/information input.
Policy	A standard written at a high-level describing a corporate philosophy, approach or requirement.
Standard Operating Procedure (SOP)	A written set of instructions that describes how to perform an activity to ensure consistency and reliability.
Template	Controlled document which is modifiable and may have instructions for completion.
Work Instruction (WI)	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 Follow BMC-SOP-06 to obtain a unique identifier for documents.

6.2 Policy, SOP and WI Format (see BMC-TMP-04, Policy Template; BMC-TMP-01, SOP Template; and BMC-TMP-02, WI Template, respectively)

6.2.1 Header: The pre-printed header on every page of each Policy, SOP or WI contains the prearranged format that includes:

- Facility identification/logo
- Document type (Policy, SOP, WI)
- Document title
- Document number
- Revision number

- Supersede date
 - Effective date
 - Page x of y
 - **For WI Only:** Governing SOP Number
- 6.2.2 On the first page of each Policy, SOP or WI, include a signature approver table as exemplified in BMC-TMP-04, BMC-TMP-01 and BMC-TMP-02.
- 6.2.3 Appendix: Include in the body of the appendix:
- Appendix identifier, e.g., Appendix A
 - Title of the Appendix
- Note:** Header continues from the document.
- 6.2.4 Create documents using font “Times New Roman”, 12 point.
- 6.2.5 Information or steps under each section are organized by a sequential numbering system as exemplified in this document.
- 6.2.6 Outline the intended content to develop a logical and sequential flow of ideas and avoid repeating information both within a single document and across multiple documents.
- 6.2.7 State the referenced document type and number when referencing another document within the text of the document. Do not reference the version number of the document.
- 6.2.8 Spell out abbreviations and acronyms the first time they are used in a document unless they are so common as to be universally understood (e.g., GDP).
- Use the full text with abbreviation in parentheses in the first location in the document; the abbreviation may then be used alone thereafter within the document.
- 6.2.9 Place a zero (0) in front of the decimal point for numbers less than one, e.g., 0.25 inches, to reduce the possibility of misreading numbers if the decimal point is poorly printed.
- 6.2.10 Bold the words “Note”, “Caution” and “Warning” and capitalize the first letter of the word. Write notes, cautions or warning statements in the specific section/step of the document where the guidance applies.
- 6.3 Document Content for SOPs, WIs, and Policies
- 6.3.1 Use BMC-TMP-01 to create SOPs, BMC-TMP-02 to create WIs, and BMC-TMP-04 to create Policies.
- 6.3.2 Controlled documents are written with the following sections, in order, except where noted.

- Purpose
- Scope
- Roles and Responsibilities
- References and Related Documents – All documents referenced in the Policy, SOP or WI
- Definition of Terms
- Reagents and Materials (optional) – only SOPs and WIs
- Equipment (optional) – only SOPs and WIs
- Standards (optional) – only SOPs and WIs
- Safety (optional)
- Procedure – This section provides guidance and instructions on how to perform the procedure.
- Appendices – All graphs, tables, examples, etc. (optional)
- Revision History (Prior to the actual Appendices) – Details all of the changes from the previous approved document

6.4 Form Format

6.4.1 Use BMC-TMP-03 to create forms in Word.

6.4.2 If creating forms in other software programs (i.e., Excel®), wherever possible, use the BMC logo. At a minimum, specify that it is a “BMC” Form (in the form title or form header) and have the following elements on the form:

- Form Number and Revision
- Effective Date of the Form
- Page x of y

6.4.3 Divide forms into clearly useable sections and design them to minimize numerous entries of “Not Applicable” (N/A).

6.4.4 Use borderlines to separate sections to ensure accuracy and placement of entries.

6.4.5 If the form needs to include restricted fields that can be completed electronically, use the Restricted Formatting and Editing feature in Microsoft Word to create the necessary form fields.

6.5 Template Format

6.5.1 When creating a new template, refer to section 6.2.

6.5.2 If creating templates in other software programs (i.e., Excel), wherever possible, use the BMC logo. At a minimum, specify that it is a “BMC” document (in the template title or header) and have the following elements in the template footer:

- Template Number and Revision
- Page x of y (may be located in header, as appropriate)

6.5.3 Design templates to be modifiable. Include instructions within the body of the sections of the template or as a cover page to the template to assist users in using the template.

6.5.4 Use different color text for instructions so users of the template know what text is modifiable, removed or left unchanged.

6.6 Document Change Control

6.6.1 BMC-SOP-06 outlines instructions for the tracking and change control management for Policies, SOPs, WIs, Forms and Templates.

7.0 APPENDICES

7.1 Not applicable.

8.0 REVISION HISTORY

Revision No.	Section	Change Description	Date
10.0	All sections	Complete overhaul of SOP to update format, clarify content, move definitions to a central glossary and separate template(s) into separate documents to be managed independently of the SOP. Updated numbering format; formerly SF-1-01.	Current See D-23-08
9.0	See SF-1-01	See SF-1-01	26 Apr 2021