Approvals	Printed Name	Signature	Date
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Quality Assurance	Jennifer Arnold		10 Dec 2024

1.0 PURPOSE

1.1 The purpose of this Standard Operating Procedure (SOP) is to define acceptable practices for completion of records at the Biospecimen Management Core (BMC).

2.0 SCOPE

2.1 This procedure is applicable to BMC personnel, SSF Collaborating Biobank personnel as defined in Steps 2.1.1-2.1.2 This procedure satisfies guidance set forth in ISBER "Best Practices" as related to Good Documentation Practices.

2.1.1 If the SSF Collaborating Biobank has their own Good Documentation Practices procedure a copy of their procedure will be requested by the SSF Director to maintain on file.

2.1.2 Personnel of SSF Collaborating Biobanks which do not have their own Good Documentation Practices will comply with BMC-SOP-03 by training on BMC-SOP-03 Appendix A.

3.0 ROLES AND RESPONSIBILITIES

Role	Responsibilities
BMC personnel	Responsible for following this procedure when completing BMC documentation.
SSF Collaborating Biobank Personnel	Responsible for following this procedure when completing BMC documentation as directed in Section 2.1.
Quality Assurance (QA) and Reviewers	Responsible for reviewing BMC documentation for accuracy, completeness and compliance to this procedure.

4.0 REFERENCES AND RELATED DOCUMENTS

Document Number	Title
BMC-SOP-04	Document Distribution and Archiving
BMC-SOP-13	Record of Signature, Electronic Signature Agreement and Signature Delegation
BMC-FRM-09	Record of Signature/Electronic Signature Agreement
N/A	*International Society for Biological and Environmental Repositories (ISBER) Best Practices* – current edition

5.0 DEFINITION OF TERMS

Term	Definition
ALCOA	Attributable, Legible, Contemporaneous, Original and Accurate
Appendices	Supplementary material attached at the end of the original document.
Backdating	The practice of attributing an earlier completion date to information which had been entered previously but not adequately initialed and dated at the time of entry, so it appears as if documentation occurred at the time work was originally completed.
GDP	Good documentation practices
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).
Laboratory Notebook	Hard-covered book with a sewn/sturdy binding and sequentially numbered pages.
Memoranda	A communication that contains directive, advisory, or informative matter.
N/A	Not applicable
Performed By	Individual that executed the defined task.
Recorded By	Individual that recorded data on BMC documents.

Term	Definition
Reviewed By	• Person who ensures the record is correctly completed and in accordance with the Good Documentation Practices • Person who assesses recorded data to verify correctness against pre-defined requirements
Signature, Electronic	An individual's electronic authenticated credentials which have the same meaning as the individual's handwritten signature.
Signature, Handwritten	A handwritten mark of an individual in a manner consistent with the employee's signature record per BMC-SOP-13.
Verified By	Identifies the person who is responsible for proving that specified requirements have been fulfilled, through confirmation of information/data by examination, and supported by objective evidence.

6.0 PROCEDURE

6.1 Requirements for written data entry on BMC documents

6.1.1 Follow ALCOA principles when making entries. Ensure entries are:

- Attributable - Able to be ascribed to a particular individual.
- Legible
- Contemporaneous - Recorded at the time of the event.
- Original - Record actions on any unofficial document at the time of event occurrence.
- Accurate

6.1.2 Use indelible (smear and water-resistant) black or blue ink.

- Felt-tip markers, pencils, gel or erasable pens are not permissible.

6.1.3 Make entries on BMC document (e.g., visitor log, form) in the space provided or within an appropriate location.

6.1.4 Recording data on Post-it notes, paper scraps, gloves, or legal pads is not acceptable.

6.1.5 When entering or correcting data, do not use arrows, ditto marks, and/or symbols in lieu of the actual data value. All information must be recorded to sufficiently describe the information which is being recorded.

6.1.6 Record the associated units of measure, unless already defined in the data field. Common abbreviations can be used to document units (e.g., "° "for degree, "C" for Celsius).

6.1.7 Report data to be clear and traceable so that review by multiple reviewers result in consistent interpretation.

6.1.8 Where the original data is not included, report data identifying the approved and archived raw data source.

6.1.9 Recorded data must be complete and include all required information.

6.1.10 Include complete data from all work performed.

6.1.11 When data is obtained from an instrument, record the instrument identification (ID).

6.1.12 When a review or verification of recorded data is required, someone other than the person(s) who recorded the data conducts the review or verification.

6.2 Late Entry

6.2.1 Use the current date when preparing documents and entering information – Do not back-date or date documents in advance.

Note: Backdating is fraudulent. Provide an explanation for the delay to substantiate the delayed entry.

6.2.2 If missing or late data is discovered during a review of the quality record, the data can be entered provided:

- The missing data can be corroborated.
- The person who performed the task or their manager provides the data.
- Include an explanation as to why the data is missing.

6.3 Original Data

6.3.1 Do not obliterate, erase, write over or discard data and/or information.

6.3.2 If original data are recorded anywhere other than the prescribed document, retain the information by attaching it to the original document. When unable to attach data because of amount see section 6.4. Adhere to all requirements regarding attachments.

- All data, including support data, if applicable, must be permanently affixed to or referenced on the appropriate document.

6.3.3 In the event where the original source document becomes illegible, attach it to a new copy of the same form with the data transcribed.

6.3.3.1 Reference the original form on the new form, noting that the data has been transcribed from the original with a reason (e.g., original form illegible).

6.3.3.2 Add a footnote to the original form indicating that the data has been transcribed to the new form with the same reason (e.g., data illegible, transcribed to new form, attached).

6.3.4 In the event that a copy of an original document is required, clearly label the photocopy, "COPY".

- This is not required in the event of a photocopy of an existing document previously stamped or documented as a COPY.

6.3.5 Identify documents used as examples for training with "For Training Purposes Only".

6.4 Criteria for Attachments to Documents

6.4.1 Affix attachment(s) in a secure manner (staple, tape, sleeve protector, etc.) to the appropriate governing document without obscuring any information. Minimize folding of attachments where possible.

6.4.1.1 Identify and link all documentation, including any attached references to the primary record by ensuring sufficient pertinent information is recorded on documents to trace references to their source.

6.4.1.2 Sequentially number each attachment.

6.4.1.3 Label each page of each attachment(s) with page X of Y. Pagination of Attachments do not need to be included in the pagination of the parent record.

6.4.1.4 When affixing labels, post-it notes, etc. to an attachment, initial and date the addition. Ensure that a portion of the initial and date overlap onto both the affixed item and the attachment page.

6.4.2 When it is not possible to affix certain types of materials (data packages, notebooks, etc.), ensure that the governing document refers to the location of the separate material, and the separate material references the document with which it is associated.

6.5 Use of Signature and/or Initials on BMC Documents

6.5.1 Document your signature and/or initials in a manner consistent with your employee signature record per BMC-SOP-13.

6.5.2 Staff are not permitted to sign for another member of staff unless delegated per BMC-SOP-13.

6.5.3 Document only the work that you perform.

Note: Recording data for another employee is considered falsification of records. When you sign or initial a document, you are accepting responsibility for the task as referenced in the document.

6.5.4 A valid signature may be handwritten or electronic.

- Signatures must be traceable to an individual employee per the employee's Record of Signature and Electronic Signature Agreement form BMC-FRM-09.
- If the person's first and last name in the signature is not legible, the person's first and last name must also be printed in the record and clearly associated with that signature.

6.5.5 Whenever a signature is recorded, a date is also required.

6.5.6 Where a full signature is required, initials alone are not permitted unless specifically allowed by the document/procedure and a full signature appears in the same document.

6.5.7 Individuals "performing", "recording", "verifying" or "reviewing" activities related to Quality Records comply with the requirements outlined under the definition for each role.

6.5.8 The signatory may not use dittos, and/or symbols in lieu of an actual signature.

6.5.9 Recorded data must be signed (by the person who recorded the data) and dated on the day that the data is recorded.

6.5.10 Do not attempt to alter or correct another individual's work. Only the personnel making the original entry can correct that entry.

- In the case where personnel are not available to make a correction, a notation can be made by the personnel's supervisor or management indicating the reason the person is unavailable to make the required correction.

6.5.11 Do not use signature pads, scanned signatures, or duplicated original signatures to replace a handwritten signature.

6.6 Abbreviations, Acronyms, and Symbols

6.6.1 Ensure any abbreviations, acronyms and symbols used in documentation are clear and standardized throughout the document for consistent interpretation. For each abbreviation, acronym, and symbol used, ensure:

- It is spelled out or defined the first time it is used, or;
- Use a glossary or table to explain it.

6.7 Recording Date and Time on BMC Documents

6.7.1 Record the date in the format day-month-year, DDMMMYYYY. For example, 16MAR2019

6.7.2 Always record the date using:

- Day - 2 numerals (DD)
- Month – three-letter abbreviation, first 3 letters of month (MMM)
- Year - 4 numerals (YYYY)
- Example: 09OCT2014

6.7.3 When creating documents that require using numerals for the date, specify the format used (i.e. MM/DD/YYYY).

6.7.4 Record time using 12 Hour Clock (Meridian Time) or 24-Hour Clock (military format) as follows:

12 Hour Clock	24 Hour Clock
11:59am or 11:59pm	11:59 or 23:59
12:00am or 12:00pm	00:00 or 12:00

6.8 Completing Blank Spaces, Error Corrections, Annotations and Footnotes

6.8.1 All fields on forms must be completed. Do not leave blank spaces on a document. Draw a single line through any space or section when there is no appropriate entry. Enter N/A, and initial and date.

- If a field continues across a page break due to formatting (e.g. in Word, Excel, etc.), cross-off, N/A and initial and date both sections.

Note: Electronic databases may not allow N/A to be entered into a field due to field requirements (numeric data only) or the database may record the user information before a user electronically signs a record. In such cases, the database field requirements take precedence.

- If blank lines are crossed out in error, enter data/information in another copy of the document and attach the two documents together as described in 6.3.3, or enter data/information in another page of the notebook and make reference to the new page. Alternatively, add a footnote and explain the error in the comments section, as applicable.

- Do not write in the area that was crossed out and include an appropriate comment and initial and date.
- If a field is left blank and discovered at a later time, the individual originally completing the record lines out the field with their initials, current date and a brief explanation. A team member who is responsible for reviewing documents or the individual's supervisor may also cross-off the field.
- When permitted to be left blank, clearly identify the spaces or empty fields as "intentionally left blank". Electronic databases may not allow this verbiage to be added. In such cases, system parameters take precedence.

6.8.2 To correct an error:

- Draw a single, straight line through the length of the error
- Make corrected entry near the original error
- Record error code, as directed in Step 6.8.4
- Record your initials and the current date

Error Correction Example with Error Correction Directives:

#~~01 May 2016~~# *01 May 2018* ***NOT*** *01 May 2~~016~~ 2018*

##WD## **JLC 01 May 2018**

Single, straight line through length of error

* Corrected entry near the original error

##Error Code, as directed in Step 6.8.4

**Initials and current date

Error Correction Example without Error Correction Directives:

~~01 May 2016~~ 01 May 2018 WD JLC 01 May 2018

6.8.3 Do not obscure the original entry in any way (no white-out, over-writing, or multiple cross-outs).

6.8.4 If the reason for the correction is not obvious, include a note to explain why the correction was made. For more obvious corrections, such as calculation errors, below are examples of acceptable abbreviations that may be used:

Error Code	Definition
CE	Calculation Error
EE	Entry Error
LE	Late Entry① ①*Document an explanation to substantiate the entry and the reason for the delay in recording.*
SE	Spelling Error
WD	Wrong Date
TE	Transcription Error

6.8.5 If a correction is complex or needs further explanation requiring additional space, use a footnote near the original entry employing an alphanumeric format as shown below:

- Starting with the number "1" or letter "a", place the alphanumeric with a circle around it next to the error. (e.g. ① or ⓐ)
- Where there is space on the page, document the correction using referenced footnote, initial and date.

Note: Do Not use asterisks (*) for correction footnotes.

- If multiple corrections are made on one page, use the next number as a footnote within the same page.
- If the same correction is required to be made by the same person within the same page, use one footnote reference.

6.9 Memoranda and Appendices

6.9.1 When provided as supportive evidence to a quality record, the Author signs and dates memoranda and appendices and attaches them to the quality record.

6.9.2 Where memoranda or appendices are provided to a project or investigation, cross-reference to the corresponding activity file number (e.g. Investigation, Corrective and Preventative Action (CAPA) or Non-Conformance Report (NCR)).

- Include enough information to clearly indicate the scope, timeframe, and/or other applicable bounding information in the Memoranda.

6.9.3 An email cannot be used as a "stand alone" quality record.

- When an email is used as a supplement to a quality record, limit the content of the email to the immediate subject, with no additional subjects, attachments, or editorial content.
- Include the associated reference number (e.g. CAPA) on the email and the Sender's or Receiver's signature and date (the signature may be either electronic in a validated system or on a hard copy with indelible ink).

6.10 GxP Document Retention

6.10.1 Retain GxP documentation with signatures according to BMC-SOP-04.

7.0 APPENDICES

7.1 Appendix A: Good Documentation Practices for SSF Collaborating Biobank Personnel

8.0 REVISION HISTORY

Revision No.	Section	Change Description/Justification	Date
0.0	N/A	New document outlining the process for good documentation practices.	Current

Appendix A: Good Documentation Practices for SSF Collaborating Biobank Personnel

1. PURPOSE
    a. Appendix A defines acceptable Good Documentation Practices for SSF Collaborating Biobank Personnel (CBP) completing records at the Biospecimen Management Core (BMC) whose Collaborating Biobank does not have their own Good Documentation Practices.
    b. Training in Good Documentation Practices (GDP) consists of a review of the generally recognized practices, which are followed to preserve the integrity of data and records.
2. PROCEDURE
    a. Data entry on BMC SSF documents
        i. Follow ALCOA principles when making entries. Ensure entries are:
            - **A**ttributable - Able to be ascribed to a particular individual
            - **L**egible
            - **C**ontemporaneous - Recorded at the time of the event
            - **O**riginal - Record actions on any unofficial document at the time of event occurrence.
            - **A**ccurate
        ii. Use indelible (smear and water-resistant) black or blue ink.
            - Felt-tip markers, pencils, gel or erasable pens are not permissible
        iii. Make entries in spaces provided on SSF documents (e.g., visitor log, training forms).
        iv. Recorded data must be complete and include all required information
        v. Blank Spaces
            1. All fields on forms MUST be completed
                - Do not leave blank spaces on a document
    b. GDP DONTs
        i. When entering data, do not use arrows, ditto marks, and/or symbols in lieu of the actual data value.
        ii. Do not obscure the original entry in any way
            - No obliterations
            - No over-writing
            - No multiple cross-outs

- No white-out

iii. Backdating - attributing an earlier completion date to information which had been entered previously but not adequately initialed and dated at the time of entry, so it appears as if documentation occurred at the time work was originally completed. Refer to Section 2e.

c. Original Data

i. Document only the work that you perform.

- **Note:** Recording data for another employee is considered falsification of records. When you sign or initial a document, you are accepting responsibility for the task as referenced in the document

ii. Do not obliterate, erase, write over or discard data and/or information.

iii. Do not attempt to alter or correct another individual's work. Only the personnel making the original entry can correct that entry.

- In the case where personnel are not available to make a correction, a notation can be made by the personnel's supervisor or management indicating the reason the person is unavailable to make the required correction.

d. Recording Dates on BMC Documents

i. Record the date in the format day-month-year, DDMMMYYYY. For example, 16MAR2019

ii. Always record the date using:

- Day - 2 numerals (DD)
- Month - three-letter abbreviation, first 3 letters of month (MMM)
- Year - 4 numerals (YYYY)
- Example: 09OCT2014

e. Late Entry

i. Use the current date when entering information

- Do Not back-date
- Do Not date documents in advance
- **Backdating** is fraudulent. Provide an explanation for the delay to substantiate the delayed entry.

f. Use of Signature / Initials on BMC Documents

i. Document your signature and/or initials in a manner consistent with your employee Record of Signature and Electronic Signature Agreement form BMC-FRM-09.

ii. Staff are not permitted to sign for another member of staff unless delegated per Record of Signature, Electronic Signature Agreement and Signature Delegation form BMC-SOP-13.

iii. The signatory may not use dittos, and/or symbols in lieu of an actual signature or initials.

iv. Document only the work that you perform per Original Data section 2c.

v. Do not attempt to alter or correct another individual's work per Original Data section 2c.

g. Error Corrections

i. To correct an error:

- Draw a single, straight line through the length of the error
- Make corrected entry near the original error
- Record error code, as applicable
- Record your initials and the current date

Error Correction Example:

#~~01 May 2016~~# *01 May 2018* ***NOT*** *01 May ~~2016~~ 2018*

##WD## **JLC 01 May 2018**

Single, straight line through length of error

* Corrected entry near the original error

##Error Code, as directed in Section 2.g.iii

**Initials and current date

ii. When correcting errors, do not use arrows, ditto marks, and/or symbols in lieu of the actual data value.

iii. Error Codes

- If the reason for the correction is not obvious, include a note to explain why the correction was made. Examples of acceptable abbreviations that may be used:

Error Code	Definition
EE	Entry Error

Error Code	Definition
LE	Late Entry[①] [①]*Document an explanation to substantiate the entry and the reason for the delay in recording.*
SE	Spelling Error
WD	Wrong Date

iv. If a correction is complex or needs further explanation requiring additional space, use a footnote as directed in Section 2h.

h. Footnotes

i. Starting with the number "1" or letter "a", place the alphanumeric with a circle around it next to the error. (e.g. ① or ⓐ)

- **Note:** Do Not use asterisks (*) as footnotes

ii. If multiple footnotes are on one page, use the next number as a footnote within the same page.

iii. Where there is space on the page, define footnote using referenced footnote number/letter, initials and date.

iv. Initial and date footnotes

i. Comments and explanations are provided via numbered footnotes, which are initialed and dated as directed in Section 2h.