

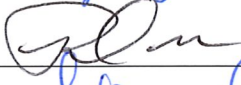

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Approval	Printed Name	Signature	Date
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1.0 PURPOSE


This document describes the procedure for the internal distribution and archiving of the Biospecimen Management Core (BMC) approved documents, and postings. In addition, this procedure provides instructions for the external distribution of BMC documentation.

2.0 SCOPE

This Standard Operating Procedure (SOP) applies to all BMC controlled records that support the BMC processes, operation of BMC archives, and applicable training.

3.0 ROLES AND RESPONSIBILITIES

Role	Responsibilities
BMC Personnel	<ul style="list-style-type: none"> Create documents. Submit documents to QA for distribution and archiving.
Quality Assurance (QA) or designee	<ul style="list-style-type: none"> Distributes and archives documents. Adds security and document settings to each document. Verifies the proper distribution and archival of documents. Verifies accuracy and completeness of documents prior to distribution and archiving. Verifies document destruction criteria is met and approves destruction.

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4.0 REFERENCES AND RELATED DOCUMENTS

BMC-FRM-01	Document Change Request Form
BMC-FRM-05	Interim Archive (Off-Site) Storage Log
BMC-FRM-07	Document Distribution Form
BMC-FRM-08	Permanent Archive Removal Log
BMC-FRM-15	Archive Sign-out Log
BMC-FRM-25	Document Digitizing Verification Form
BMC-SOP-03	Good Documentation Practices
BMC-SOP-06	Controlled Document Management
BMC-TMP-06	Table of Contents Template
Indiana University Research Data Management Policy (current version)	HRPP Policy - Research data management: Human Subjects & IRB: Policies: RESEARCH: Indiana University (iu.edu) - https://research.iu.edu/policies/human-subjects-irb/research-data-management.html
N/A	<i>International Society for Biological and Environmental Repositories (ISBER) Best Practices</i> – current edition

5.0 DEFINITION OF TERMS

Term	Definition
Record	A document stating results achieved or providing evidence of activities performed.

6.0 PROCEDURE

6.1 Issuing Documents


- 6.1.1 Manage controlled documents according to BMC-SOP-06, SOP for Controlled Document Management.

6.2 Distribution and Archiving of BMC Documents

Note: QA, or designee, performs the tasks outlined in Step 6.2. A second individual within QA (or a designee) performs the tasks outlined in Step 6.3.

6.2.1 User Books

- Generate as many copies for the User Books as needed. Ensure the copies are clean representations of the original Principal document.
- Identify each document as a copy with a watermark “Copy”, or stamp.
- Generate an updated version of the Table of Contents (BMC-TMP-02). Ensure the current date is updated and printed on the Table of Contents.


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- Complete Part A1 of BMC-FRM-07, *Document Distribution Form*, listing all the approved documents to be distributed to the User Books and/or obsolete documents to be removed.
- Distribute the documents to the indicated User Books and remove any superseded or obsoleted documents, as needed.
- Attach any superseded or obsoleted documents to BMC-FRM-07.

6.2.2 Network Distribution of PDF Documents

- QA, or designee, creates a PDF copy of the document, if necessary.
- Set document security properties to restrict changes to documents.
 - **Note:** A Password is not required to open the document but is required to edit.
 - Set 'Changes Allowed' permissions to "none" except for any required response sections.
 - When printing documents that are to be used for reference or other purposes where they will not be placed in controlled binders, folders, or User Books, add an "Uncontrolled Copy" watermark and a Print Date to the document. Format the settings so that the watermark and Print Date appear when the document is printed.
 - **Note:** Uncontrolled copies of printed documents are only considered valid for 24hrs after the date printed. Always check to make sure you are using the most current version of a document.
- Word versions of documents
 - Documents available in Word version include Forms and Templates.
 - Do not add watermarks or print date to Forms and Templates as data is entered into these document types.
 - Save Forms with 'Restricted Access' status to prevent inadvertent overwriting of the document.
- Complete BMC-FRM-07, Part A2 listing all the approved documents moved to the appropriate document folders located in the network, the QA Backup (One Drive) and the BMC Website.

Note: Only QA, or designee, has permission to save, delete and modify documents in the approved document folders.
- Move all superseded and obsolete PDF documents to the appropriate archive document folders located on the QA Backup (One Drive).

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Note: Only QA, or designee, has permission to save, delete and modify documents in the archive document folders.

6.2.3 Distribution of Forms and Postings

- Generate as many copies of Forms and/or Postings as needed for the Satellite areas. Ensure the copies are clean representations of the original Principal document.
- Complete Part A3 of BMC-FRM-07 listing all the approved Forms and/or Postings to be distributed to the Satellite areas and/or obsolete Forms and/or Postings to be removed.
- Distribute the Forms and/or Postings to the indicated Satellite areas and remove any superseded or obsoleted Forms and/or Postings, as needed.
- Attach any superseded or obsoleted Forms and/or Postings to BMC-FRM-07.

6.2.4 Update the Master Document List and place the hard copy of the effective document bearing the original signatures in a secured, fireproof filing cabinet.

6.2.5 Forward the executed copy of BMC-FRM-07 to a second individual in QA (or a designee) for verification.

6.3 Document Distribution/Archiving Verification (BMC-FRM-07, Parts B1-B3)

6.3.1 QA, or designee, verifies that the indicated documents have been distributed or archived to the proper User Books and network folders as listed on Parts A1-A3 of BMC-FRM-07. Document the verification in BMC-FRM-07, Parts B1-B3.


6.3.2 QA, or designee, verifies the accuracy of the document security settings.

6.3.3 QA, or designee, verifies placement of the original effective document in a secured, fireproof filing cabinet.

6.3.4 If the distribution is complete and accurate, QA, or designee, completes Parts B1-B3 of BMC-FRM-07, destroys superseded and obsoleted copies of documents, and archives the completed form in QA.

6.3.5 If the distribution is incomplete or inaccurate, QA, or designee, completes Part C of BMC-FRM-07 and returns it to the individual who performed the distribution for corrections, then, once corrections have been made, repeats Steps 6.3.1 – 6.3.4.

- Document acceptance of the corrected distribution/archiving in Part D of BMC-FRM-07.

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6.4 Hardcopy Record Maintenance and Archival

6.4.1 Attach the Document Change Request Form (DCR), BMC-FRM-01, to the Master or original document and store hardcopies in restricted access fireproof filing cabinets.

6.4.2 As documents are superseded, stamp or write “Superseded” across the first page of the superseded document and file behind the new Master.

6.4.3 Document Obsolescence

- Stamp or write across the first page “Obsolete”.
- Attach the fully executed DCR to the obsoleted document.
- File the package in restricted access fireproof filing cabinets.

6.5 Document Retention

6.5.1 All documents are archived in the BMC archive for the minimum retention periods defined in Appendix A.

6.6 Digital Document Retention

6.6.1 Documents required to be digitized prior to relocation to off-site storage or destruction are defined in Appendix A.

6.6.2 Record documents scanned or confirmed digitized on BMC-FRM-25, *Document Digitizing Verification Form*.

6.6.3 Verification

6.6.3.1 Prior to off-site storage relocation (completed per Section 6.7) or document destruction (completed per Section 6.8), BMC personnel verify digitized documents as directed on BMC-FRM-25.

6.6.3.2 Document the verification on BMC-FRM-25.


Note: Verification that all content on the source document is included in the scanned document includes confirming that any comments near the edges of documents are captured in the scanned document.

6.7 Interim Off-Site Archive

6.7.1 If storage space in the fireproof cabinets is needed, documents may be moved off site for intermediate storage prior to destruction.

6.7.2 On-site retention for all documents is defined in Section 6.5 and Appendix A.


6.7.3 Manage off-site storage using an IU-approved vendor.

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- 6.7.4 Store archive documents off-site according to the Indiana University Research Data Management Policy (current version), and per the following requirements:
- Use standard letter-paper width banker's boxes.
 - Complete BMC-FRM-05, *Interim Archive (Off-Site) Storage Log*, with a detailed list of documents for off-site relocation.
 - Barcode each box with Barcode labels and record the barcode number on BMC-FRM-05.
 - Label each box with a brief description of contents as described in BMC-FRM-05.
 - For ease of reference and organization, number each box sequentially as recorded on BMC-FRM-05.
- 6.7.5 Electronically store a completed copy of BMC-FRM-05 in a limited access shared folder within the CTSIProcessingLabs folder.
- 6.7.6 Store the hardcopy version of the completed form in the Document Control Binder within the BMC Operations Management Office.
- 6.7.7 Prior to off-site storage relocation, BMC personnel conduct a 100% verification of the Off-Site Storage Log for data entry accuracy.
- Document the verification on BMC-FRM-05.
- 6.7.8 A second BMC individual completes a 10% check of each line item in BMC-FRM-05 and documents the review on BMC-FRM-05.
- 6.7.9 Document removal to offsite storage on BMC-FRM-15, *Archive Sign-out Log*.
- 6.7.10 Upon verifying accuracy, request pickup from the IU-approved vendor.
- 6.7.11 Requesting delivery of boxes to the vendor and return of boxes previously stored at the vendor requires the BMC vendor account number and barcode of each box.
- Re-approval/re-verification is not required for the return of these boxes.

6.8 Document Destruction

- 6.8.1 When the archive retention period outlined in Appendix A has been met, documents may be destroyed.
- 6.8.2 Following the retention period, notify PIs of specimen-related document destruction, and if requested, provide the documentation to them.
- 6.8.3 Complete BMC-FRM-08, *Permanent Archive Removal Log*, with a detailed list of documents for destruction.

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- 6.8.4 Prior to moving documents to destruction, BMC personnel conduct a 100% verification of BMC-FRM-08 and each document to verify retention period and data entry accuracy. Document the verification on BMC-FRM-08.
- 6.8.5 A second BMC individual completes a 10% check of each line item in BMC-FRM-08 and documents the review on BMC-FRM-08.
- 6.8.6 The Archivist documents destruction on BMC-FRM-15, *Archive Sign-out Log*.
- Retain this form indefinitely in the Document Destruction Binder.
 - Use a printed copy of the manifest to detail each document removed. Attach to BMC-FRM-15.
- 6.8.7 QA approval required prior to document destruction. Refer to BMC-FRM-08.
- 6.8.8 Upon receipt of QA approval, BMC Management requests destruction of boxes already stored at the vendor. The BMC vendor account number and barcode of each box is required.
- 6.9 Requesting Archived Documents
- 6.9.1 Request archived documents from QA, or designee.
- 6.9.2 QA, or designee, records removal of archived materials on BMC-FRM-15, *Archive Sign-out Log*. Record date, requestor, Material Checked out, and issuer initials, and forwards the materials to the Requestor.
- 6.9.3 Upon return of materials, QA, or designee, records return date in the BMC-FRM-15 and returns materials to the archives.

7.0 APPENDICES

- 7.1 Appendix A: Minimum Record Retention Requirements

8.0 REVISION HISTORY

Revision No.	Section	Change Description	Date
0.0	N/A	New document outlining the process for the distribution and archiving of controlled documentation. SSF Controlled Document Management SOP SF-1-6 will be retired once BMC-SOP-04 and BMC-SOP-06 are effected.	Current See D-23-08

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Appendix A: Minimum Record Retention Requirements

Document Description		Overall Retention (Years)	Onsite Retention (Years)	Digital Retention Required
*Only if scanned and retained per BMC-SOP-04		#If Overall Retention and/or Onsite Retention requirements are not met		
1	Obsolete SOPs	0*	0*	yes
2	Obsolete Form Versions	0*	0*	yes
3	Obsolete Templates	0*	0*	yes
4	Non-Freezer Equipment Monitoring & Maintenance Records	3 or 0*	1*	yes [#]
Freezer-Related and Specimen-Related Records				
5	Freezer Equipment Monitoring & Maintenance Records	7 or 3 years after study closure, whichever is longer	1	yes [#]
6	Freezer Intake Records - Duration of unit retention in SSF + additional years indicated in next column	7 or 3 years after study closure, whichever is longer	1	yes [#]
7	Freezer (LN ₂ and MRU) Alarm Testing Worksheets	7 or 3 years after study closure, whichever is longer	1	yes [#]
8	Specimen-Specific Records (Intake, Release, Processing) - Duration of Sample Retention + additional years indicated in next column	7 or 3 years after study closure, whichever is longer	1	yes [#]
9	Storage agreements - Closed SSF Freezer Accounts <i>with freezer removed from the SSF</i>	7 or 3 years after study closure, whichever is longer	1	yes [#]
10	Storage agreements - Closed SSF Freezer Accounts <i>with freezer remaining housed in the SSF</i>	1	1	yes
Alarm System Management and Response				
11	Alarm System Management and Response (with the following exceptions)	∞	n/a	n/a
12	Alarm Printouts (Hard copies)	5	1	yes [#]
13	Alarm Logs (electronic)	∞	n/a	n/a
14	On-Call Personnel Log (Template)	0*	0*	yes
15	SSF Siemens Alarm Response Guide	0*	0*	yes
16	Alarm System Administrators (Template)	0*	0*	yes

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Document Description		Overall Retention (Years)	Onsite Retention (Years)	Digital Retention Required
*Only if scanned and retained per BMC-SOP-04		#If Overall Retention and/or Onsite Retention requirements are not met		
17	Alarm System Daily Maintenance Log	1	1	yes
18	APOGEE Insight Services Startup Parameters Daily Verification	0*	0*	yes
Facility-Related Documents				
19	Facility-Related Documents (with the following exceptions)	∞	n/a	n/a
20	Facility Commissioning and Validation Plans	∞	10	yes
21	MRU Room Maintenance Log	1	1	yes [#]
22	LN ₂ System Daily Usage Log	1	1	yes
23	LN ₂ System Maintenance Log – Quarterly and Annual Assessments	1	1	yes
24	LN ₂ Expected Use Calculation – Hard Copies	0*	0*	yes
25	LN ₂ Expected Use Calculation – Digital Versions	∞	n/a	n/a
26	LN ₂ Systems Post-Fill Log	0*	0*	yes
27	Low O ₂ Alarm Actions/Response & Emergency Contacts (SOP SF-2-2 Appendix F)	0*	0*	yes
28	LN ₂ Weekly System Check	1	1	yes
Controlled Access				
29	Controlled Access Change Form – Current Form, Current Employees	length of employment + 1	length of employ- ment + 1	n/a
30	Controlled Access Change Form – Obsolete Forms, Current Employees	2	2	yes [#]
31	Controlled Access Change Form – Former Employees	2	2	yes [#]
32	Visitor Logs	1	1	yes
33	Access Review Report Checklists (Monthly and Annual) – years indicated in next column, with the following exceptions	1	1	yes
34	Critical access records prior to March 2011 (hard copies)	0*	0*	yes

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Document Description		Overall Retention (Years)	Onsite Retention (Years)	Digital Retention Required
*Only if scanned and retained per BMC-SOP-04		#If Overall Retention and/or Onsite Retention requirements are not met		
35	Digital versions of access logs	∞	n/a	n/a
36	Door Alarm Log	1	1	yes
37	Training Records – Current Employees	length of employment + 3	3	yes [#]
38	Training Records – Former Employees	3	1	yes [#]
39	Audit Reports - Open	∞	∞	n/a
40	Audit Reports - Closed	1	1	yes
41	Deviation Reports - Open	∞	∞	n/a
42	Deviation Reports - Closed	1	1	yes
43	OOS Reports - Open	∞	∞	n/a
44	OOS Reports - Closed	1	1	yes
45	Memos-to-File - Current	∞	∞	n/a
46	Memos-to-File - Obsolete	1	1	yes
47	Billing Records	12	1	yes [#]