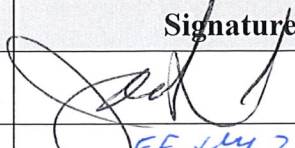


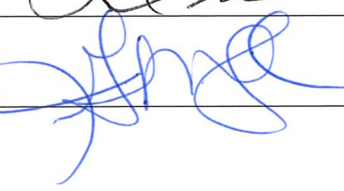


Approvals	Printed Name	Signature	Date
Author	Janel Price-Lutz		20 Nov 2024
Approver	Jenna York	 EE 22 Nov 2024	22 Nov 2024
Approver	Robert Orr		25 Nov 2024
Quality Assurance	Jenise Franch		10 Dec 2024

1.0 PURPOSE

- 1.1 The purpose of this procedure is to describe how training is assigned, conducted and documented at the Biospecimen Management Core (BMC)


2.0 SCOPE

- 2.1 This Standard Operating Procedure (SOP) applies to any employee, consultant or contractor who performs a function at the BMC in accordance with current GxPs or ISBER regulations.
- 2.2 This SOP and associated forms can be used as a guide and record of training for functions that do not fall under the scope of this SOP, if necessary.

3.0 ROLES & RESPONSIBILITIES

Role	Responsibilities
Area Management (AM)	<ul style="list-style-type: none"> Generates, signs and dates Job Descriptions for BMC personnel and provides a copy to QA. Notifies QA of any New Hires and provides the required information. Coordinates new hire training with QA. Performs Company Introduction Ensures that personnel in their areas are trained prior to performing any GxP processes. In collaboration with QA, creates and updates training plans as roles change or get updated.

Role	Responsibilities
Authors	<ul style="list-style-type: none"> Complete form BMC-FRM-06 identifying the Reviewers and Approvers of the document Work with Area Management to identify Trainees and training requirements and document them on form BMC-FRM-06. Submit completed form to QA
Facility Manager	<ul style="list-style-type: none"> Develops and maintains organizational chart and provides it to QA upon being updated.
Quality Assurance (QA) or designee	<ul style="list-style-type: none"> Coordinates new hire training with AM. Provides training documentation to Qualified Trainer/Subject Matter Expert (SME) or Area Manager, as needed. Provides training on BMC's Quality Systems, as needed. Provides or schedules GxP training. Manages and maintains employee training files. With AMs, create Individual Training Plans for each BMC trainee, CBP trainee, contractor or consultant (as needed).
Qualified Trainer or Subject Matter Expert (SME)	<ul style="list-style-type: none"> Trains trainees or contractors, as applicable. Creates or revises training assessments. Reviews completed training assessments, as necessary.
Trainees	<ul style="list-style-type: none"> Following this procedure when completing BMC Standard Operating Procedures. Sign Job Descriptions, as applicable. Provide resume/CV to QA for filing in the appropriate training file, as applicable.


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4.0 REFERENCES AND RELATED DOCUMENTS

Document Number	Title
BMC-FRM-01	Document Change Request Form
BMC-FRM-02	Individual Training Form
BMC-FRM-03	Multiple Trainee Training Form
BMC-FRM-04	Multiple Read and Understand Training Form
BMC-FRM-06	Training for Document Change Requests Form
BMC-FRM-09	Record of Signature and Electronic Signature Agreement Form
BMC-TMP-05	Training Assessment Template
BMC-SOP-03	Good Documentation Practices
BMC-SOP-04	Document Distribution and Archiving
BMC-SOP-06	Controlled Document Management
BMC-SOP-13	Record of Signature, Electronic Signature Agreement and Signature Delegation
N/A	<i>International Society for Biological and Environmental Repositories (ISBER) Best Practices – current edition</i>

5.0 DEFINITION OF TERMS

Term	Definition
Administrative Change	Changes 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.
Trainee	A BMC employee, Collaborating Biobank Personnel (CBP), or contractor (as applicable) who, per their job function or as noted on the company's curriculum, needs to be trained on executing the specified tasks outlined within a document before it can be made effective.
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).
ISBER	International Society for Biological and Environmental Repositories
On the Job Training (OJT)	On-the-job training (OJT) is a form of training where the trainee watches the actual task being performed by the trainer. OJT is an interactive hands-on training method that can be used for training on equipment maintenance, for example.

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6.0 PROCEDURE

6.1 Description of Training Levels

Note: The level of training required is governed by the type of document, the employee's or contractor's or consultant's (as applicable) job function and previous training or experience.

Note: Administrative changes made to controlled documentation do not necessitate training.

6.1.1 Read and Understand Training

6.1.1.1 At a minimum, procedures related to job responsibilities require Read and Understand training.

6.1.1.2 Read and Understand trainings may fall into the following categories:

- Documents that provide general instructions in the conduct of BMC processes.
- Individual has been trained in a previous version and current document has not had major changes to content.
- Informational literature, such as materials obtained at or from a conference.

6.1.1.3 Document training using Forms BMC-FRM-02 (Individual Training Form), 03 (Multiple Trainee Training Form), or 04 (Multiple Read and Understand Training Form).

Note: BMC-FRM-04 is used when trainee is training on multiple documents that require Read and Understand training. This form cannot be used for any other type of training.

6.1.1.4 Trainee signs and dates the form and forwards it to QA when complete.


6.1.1.5 Trainee's signature and date designate the effective date of training.

6.1.2 Lecture/Instructor Led Training

6.1.2.1 The AM, in collaboration with the Author, determines the need for Lecture/Instructor Led training.

6.1.2.2 Lecture/Instructor Led training may be required for complex procedures, On-the-Job Training (OJT) formats, or multi-step procedures that require use of controlled forms.

6.1.2.3 If presentation materials are handed out or created in-house, QA files any hardcopy and/or electronic copies in QA.

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6.1.2.4 Document training using BMC-FRM-02 or 03 depending on if one or multiple trainees are trained.

6.1.2.5 Trainee and Trainer sign and date the form. The Trainer forwards to QA when complete.

Note: If the Trainer's signature cannot be obtained, as in the case of an off-site training, check the "Not Available" box and attach any associated handouts or certificates.

6.1.2.6 Trainee's signature and date designate the effective date of training.

6.1.3 Training Assessments

6.1.3.1 The Trainer in collaboration with the AM determines the need for an assessment as part of training.

Note: All Standard Operating Procedures require assessments.

6.1.3.2 The Author and/or Trainer design the assessment to accurately reflect the material being presented.

6.1.3.3 The Author or Trainer creates the assessment in the format shown in BMC-TMP-05, *Training Assessment Template*.

6.1.3.4 Trainees must achieve $\geq 80\%$ to pass an assessment.

6.1.3.5 Trainees have a maximum of 3 attempts to achieve a passing grade. If a trainee fails the third attempt, an Instructor re-trains the Trainee (see 6.1.2).


6.1.4 BMC Personnel New Hire Orientation and Training

6.1.4.1 Area Management notifies QA of any BMC New Hires and provides the following to QA.


- Name
- Start date
- Title
- Manager's name

6.1.4.2 BMC New Hire orientation and training occurs during the individual's first two weeks of employment and includes:


- A company introduction (as applicable)
- Providing a signed and dated resume to QA. Resume/CV must include your current position at BMC.

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- Signing and dating individual's Job Description (as applicable) and providing it to their Manager for signature
 - BMC SOP training as defined in training matrix.
- 6.1.4.3 During the employee's/contractor's/consultant's (as applicable) first week, QA, in collaboration with AM, initiates a training curriculum based on the New Hire's job responsibilities.
- 6.1.4.4 Upon completion of signing and dating the Job Description, the New Hire's Manager provides the completed document to QA for filing into the appropriate training file.
- 6.1.5 SSF Collaborating Biobank Personnel (CBP) Training
- 6.1.5.1 The Collaborating Biobank (CB) notifies Area Management of CBP requiring SSF facility access.
- Form SF-2-3 Appendix E required
 - Verify that access requested aligns with the CBs equipment housed in the SSF (i.e. CB with no MRU housed in the SSF cannot request personnel be trained to access MRU rooms.)
- 6.1.5.2 Within one week of receipt of SF-2-3 Appendix E, QA, in collaboration with the New Hire and/or the New Hire's AM, initiates a training curriculum based on access requested via SF-2-3 Appendix E.
- 6.1.5.3 Area Management notifies QA of any CBP New Hires and provides form BMC-FRM-09 (Record of Signature and Electronic Signature Agreement Form) to QA upon training completion. AM provides the completed training documents to QA for filing into the appropriate training file.
- 6.1.6 Contractor and Consultant Training
- 6.1.6.1 QA maintains files for all contractors/consultants involved in conducting or advising on operations at the BMC.
- 6.1.6.2 Contractor/Consultant files minimally consist of:
- Name and contact information of contractor/consultant
 - Description of services to be provided to the BMC such as Consulting Agreement, Service Agreement, job description, etc.
- 6.1.6.3 Contractors/Consultants only advising the BMC on operations, are not required to complete training or attend BMC's SOP trainings.


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- 6.1.6.4 Contractors are required to complete SOP trainings in addition to the training required per their job function or as noted on the company's curriculum.
- 6.1.7 SSF Collaborating Biobank Personnel Annual Training
 - 6.1.7.1 Training on critical safety and security procedures occurs annually. QA conducts or arranges the training.
 - 6.1.7.2 SSF CBP employees and contractors (as applicable) receive annual safety and security training to ensure understanding of how safety and security directives apply in the BMC.
 - 6.1.7.3 Annual training may consist of a lecture, seminar, webinar or course and may include a training assessment.
 - 6.1.7.4 Document training on BMC-FRM-02 or 03.
- 6.1.8 Webinars and Off-Site Training
 - 6.1.8.1 Document webinar and off-site trainings on BMC-FRM-02 or 03.
 - 6.1.8.2 Attach copies of handouts and/or certificates obtained during the training to the training form and forward to QA for filing.
- 6.2 Qualified Trainer or SME Requirements
 - 6.2.1 The employee/contractor (as applicable) demonstrates the education, relevant work experience, training or a combination thereof, to enable them to train others or be considered a SME.
 - 6.2.2 The employee/contractor (as applicable) demonstrates their Qualified Trainer or SME capabilities through their resume, publications or documented training.
 - 6.2.3 QA maintains a list of Qualified Trainers and SMEs for all documents.
- 6.3 Documentation of Subject Matter Experts (SMEs) and Individual Company Training Requirements
 - 6.3.1 When the Author requests a Document Change Request (DCR) (BMC-FRM-01) for an SOP, QA provides the Author with BMC-FRM-06 (Training for Document Change Requests Form) in addition to the DCR.
 - 6.3.1.1 Individuals identified in Part B of BMC-FRM-06 were involved in the writing and/or review of the document and are considered trained and, where appropriate, SMEs.
 - 6.3.1.2 The Author, with Area Management, completes Part C which identifies Essential Trainees, individual/role/departments training requirements and the level of training.
 - 6.3.2 Upon completion of creation or revision of the document, forward the


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DCR and BMC-FRM-06 to QA.

- 6.3.3 QA provides training forms and assessments (if necessary) to the trainees/departments identified on Part C of BMC-FRM-06.
- 6.3.4 Upon completion of training, Trainees forward forms to QA for filing.
- 6.4 BMC Personnel Role Changes/Updates
 - 6.4.1 If an employee changes roles within the company, QA, in collaboration, with the employee's AM, updates their training curriculum based on their new job responsibilities, as needed.
 - 6.4.2 The AM provides QA an updated Job Description to file in the employee's training file.
 - 6.4.3 The employee submits an updated resume including updated responsibilities to QA for filing in the appropriate training file.
 - 6.4.4 The employee submits an updated form BMC-FRM-09, *Record of Signature and Electronic Signature Agreement Form*, to QA to reflect their new role.
- 6.5 Collaborating Biobank Personnel (CBP) Role Changes/Updates
 - 6.5.1 Upon notification by employee or employee's AM that CBP change roles within their biobank, QA, in collaboration, with the employee's AM, updates their training curriculum based on their new job responsibilities, as needed.
 - 6.5.2 CBP submit an updated form BMC-FRM-09, *Record of Signature and Electronic Signature Agreement Form*, to QA to reflect their new role.
- 6.6 BMC Personnel Training Records Maintenance
 - 6.6.1 QA maintains training files in a restricted access location for all active BMC employees who perform tasks within the scope of this SOP. At a minimum, these training files include:
 - A resume which includes employee's current BMC responsibilities along with employee's signature or initials and date submitted.
 - Current job description with employee's and manager's signature
 - Signature record (BMC-FRM-09; see BMC-SOP-13)
 - Certifications and/or licenses, as applicable
 - BMC training, as applicable
 - Record of training from external training seminars/courses, if applicable
 - Record of training received at BMC

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- 6.6.2 QA files training forms by document type (as defined in BMC-SOP-06, SOP for Controlled Document Management) and revision number.
- 6.6.3 QA copies forms used for multiple trainee trainings and files one in each trained employee's file.
- 6.6.4 QA retains training records of former employees according to BMC-SOP-04, SOP for Document Distribution and Archiving.
- 6.7 Collaborating Biobank Personnel (CBP) Training Records Maintenance
 - 6.7.1 QA maintains training files in a restricted access location for all active CBP who perform tasks within the scope of this SOP. At a minimum, these training files include:
 - Signature record (BMC-FRM-09; see BMC-SOP-13).
 - Record of training received at BMC
 - 6.7.2 QA files training forms by document type (as defined in BMC-SOP-06) and revision number.
 - 6.7.3 QA copies forms used for multiple trainee trainings and files one in each trained employee's file.
 - 6.7.4 QA retains training records of former employees according to BMC-SOP-04.
- 6.8 Organizational Chart, Training Matrices, Individual Training Plans, and Training Tracking
 - 6.8.1 The Facility Manager creates and maintains a current organizational chart(s) which shows the reporting relationships for all employees/consultants/contractors and their job functions.
 - The organizational chart(s) is updated on an as needed basis by the Facility Manager and a copy provided to QA.
 - 6.8.2 BMC Personnel Training Matrix: Create a Training Matrix for each functional area.
 - 6.8.2.1 Each matrix contains the following sections.
 - Job Description (JD)
 - CV/Resume
 - Signature record
 - BMC training requirements
 - Job Specific training requirements

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6.8.2.2 The Area Manager, or designee, in conjunction with QA determines the training requirements for each job description/title.

6.8.3 Collaborating Biobank Personnel (CBP) Training Matrix: Create a Training Matrix for each functional area based on access requested per SF-2-3 Appendix E.

6.8.3.1 Each matrix contains the following sections.

- Signature record
- SSF access-specific training requirements

6.8.3.2 The Area Manager, or designee, in conjunction with QA determines training requirements for each CBP per access requested via SF-2-3 Appendix E.

6.8.4 Individual Training Plans: Area Managers, with QA, assign Individual Training Plans to each employee/CBP/contractor/consultant performing a BMC operation.

6.8.5 Training Tracking: Use the Training Tracking spreadsheet to track the training status by SOP and version # for each individual within a functional area.

6.8.5.1 The Training Tracking spreadsheet contains a list of all the SOPs on the Training Matrix and each individual working within a specific functional area.

6.8.5.2 Upon receipt of completed training forms, QA updates the Tracking Training spreadsheet with the date indicated on the training form and files all hard copies of training documentation within the appropriate individual's training file as indicated in Sections 6.6 – 6.7.

7.0 APPENDICES

7.1 Not Applicable.

8.0 REVISION HISTORY

Revision No.	Section	Change Description/Justification	Date
11.0	All sections	Complete overhaul of SOP to update format, clarify content, move	Current See D-23-08

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Revision No.	Section	Change Description/Justification	Date
		definitions to a central glossary and separate Forms and Template into separate documents to be managed independently of the SOP. Applied new numbering format. Formerly SF-1-05.	
10.0	See SF-1-05	See SF-1-05	15 Mar 2021