

## Standard Operating Procedure

**Title: Record of Signature, Electronic Signature Agreement and Signature Delegation**



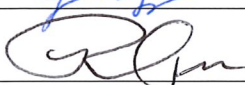
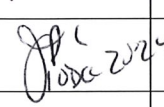
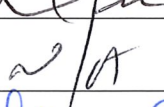
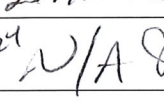
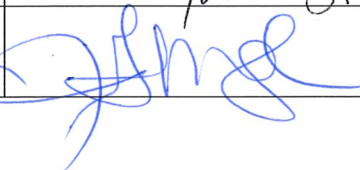
**Document Number: BMC-SOP-13**

**Supersedes Date: First issue**

**Revision: 0.0**

**Effective Date: 12DEC2024**

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Approvals	Printed Name	Signature	Date
Author	Janet Porce-Late		20 Nov 2024
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Approver	N/A  20 Dec 2024	N/A  10 Dec 2024	N/A  10 Dec 2024
Quality Assurance	Jennidee Anush		10 Dec 2024

### 1.0 PURPOSE

To define the system used at the Biospecimen Management Core (BMC) to collect a record of signature, electronic signature agreement and document signature delegation for individuals working in regulated functions within BMC.

### 2.0 SCOPE

This procedure applies to all BMC personnel, including temporary and contract associates working in a regulated function or any BMC personnel participating in regulated activities that have signature authority for controlled documentation, and Collaborating Biobank Personnel (CBP) trained per BMC-SOP-05 (Personnel Training SOP) and working in a regulated function in the BMC.

### 3.0 ROLES AND RESPONSIBILITIES

Role	Responsibilities
BMC Employees	<ul style="list-style-type: none"> <li>Complete BMC-FRM-09, Record of Signature/Electronic Signature Agreement form, if working in regulated areas.</li> <li>Submit a new Record of Signature/Electronic Signature Agreement form when signature changes.</li> </ul>
Collaborating Biobank Personnel (CBP)	<ul style="list-style-type: none"> <li>Complete BMC-FRM-09 if working in regulated areas.</li> <li>Submit a new Record of Signature/Electronic Signature Agreement form when signature changes.</li> </ul>

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Role	Responsibilities
Delegate	<ul style="list-style-type: none"> <li>Confirms signature delegation is established and effective prior to signing.</li> <li>Attaches copy of effective signature delegation form to documents upon signing on behalf of delegator.</li> <li>Fulfills training requirements, as needed, prior to signing on behalf of delegator.</li> </ul>
Delegator	<ul style="list-style-type: none"> <li>Completes BMC-FRM-10, Signature Delegation form, upon initiation, revision or revocation of signature delegation.</li> <li>Submits a new Signature Delegation form when changes are required.</li> </ul>
Quality Assurance (QA), or designee	<ul style="list-style-type: none"> <li>Maintains employee Record of Signature/Electronic Signature Agreement forms.</li> <li>Ensures Delegate training is conducted, as necessary.</li> <li>Assists in securing signature delegations.</li> <li>Submits an executed copy of BMC-FRM-10 to the system owner as notification that delegation during the specified time period is active.</li> </ul>

#### 4.0 REFERENCES AND RELATED DOCUMENTS

BMC-FRM-09	Record of Signature/Electronic Signature Agreement
BMC-FRM-10	Signature Delegation
BMC-SOP-05	Personnel Training

#### 5.0 DEFINITION OF TERMS

Term	Definition
Delegate	One who has been given signature authority on behalf of another individual and is qualified to review and sign the document(s) that have been identified on the Signature Delegation Form.
Delegator	One who gives signature authority to another individual to review and sign documents.
Designee	An individual who performs a specific role or duty when documents are delegated.

<b>Term</b>	<b>Definition</b>
Electronic Signature	An individual's electronic authenticated credentials which have the same meaning as the individual's handwritten signature.
Record of Signature	A document completed to record the handwritten signature of personnel who complete controlled documentation.
Signature Delegation	The process of one employee delegating their signature authority to another employee for a particular process or task.

## 6.0 PROCEDURE

### 6.1 Record of Signature

6.1.1 Personnel working in regulated areas within the BMC or participating in regulated activities provide QA with a completed Record of Signature/Electronic Signature Agreement form (BMC-FRM-09).

**Note:** An updated Record of Signature/Electronic Signature Agreement form is required to be completed and sent to QA when changes are necessary (e.g. name change).

6.1.2 QA or designee maintains BMC-FRM-09 in the employee's Training File within QA.

### 6.2 Signature Delegation

6.2.1 Complete BMC-FRM-10, Signature Delegation Form, to delegate signature authority for the completion of controlled documentation and/or activities to document your agreement that the Delegate may sign on your behalf.

6.2.2 When required, QA works with BMC personnel to secure signature delegation when the signatory is out of the office and cannot sign.

6.2.3 Complete BMC-FRM-10 to retract/revoke your signature delegation.

6.2.3.1 Delegates retract delegated signing authority to Delegates who have changed roles or functional areas for which they are delegated signature authority.

6.2.3.2 Documented retractions are not required for personnel no longer working at the BMC.

6.2.3.3 If a former employee is listed as a delegate for any existing employee, revise BMC-FRM-10 to remove the former employee's name.

6.2.4 Prior to signing on behalf of another individual, verify the Signature Delegation is active.

6.2.4.1 Delegates confirm the delegation by contacting QA.

### 6.3 Requirements for Signature Delegation

6.3.1 If the Delegate is not within the same functional area or department as the individual delegating their authority, the person delegating their signature provides rationale on the Signature Delegation Form.

6.3.2 Prior to signing as a delegate, a Delegate fulfills all training requirements appropriate to the task being performed.

6.3.3 List specific document(s) or actions for which signature delegation is appropriate on BMC-FRM-10. It is not acceptable to specify “all documents”.

6.3.4 Signature delegation is not required when someone at the same level or above performs the same function and they have fulfilled all training requirements related to the process for which they are signing.

6.3.5 A Delegate signs documents or performs activities identified on BMC-FRM-10 in one of the following formats:

- John Smith “on behalf of” Jennifer Doe
- John Smith “for” Jennifer Doe

### 6.4 Signature Delegation as it pertains to Computer Systems

6.4.1 For computer systems that have a mechanism for capturing signature delegation follow the system’s documented procedures.

6.4.2 If the computer system does not have a mechanism or a documented procedure for handling signature delegation, complete BMC-FRM-10. Requirements defined in Step 6.3 are applicable.

6.4.2.1 Give an executed copy of BMC-FRM-10 to the system owner as notification that delegation during the specified time period is active.

### 6.5 Filing Process for Record of Signature/Electronic Signature and Signature Delegations

6.5.1 Personnel send completed BMC-FRM-09 or BMC-FRM-10 forms to QA or designee for verification.

6.5.2 QA or designee maintains the completed Record of Signature form (BMC-FRM-09) in the employee’s training file according to BMC-SOP-05.

- 6.5.3 QA or designee files the completed original Signature Delegation form (BMC-FRM-10) in the Delegator’s training file according to BMC-SOP-05.
- 6.5.4 QA or designee files a copy of the Signature Delegation form (BMC-FRM-10) in the Delegate’s training file.

## 7.0 APPENDICES

- 7.1 Not applicable.

## 8.0 REVISION HISTORY

Revision No.	Section	Change Description	Date
0.0	N/A	New document to provide instructions for documenting employee’s signature, electronic signature and delegation of signature.	Current