Title: Document Storage and Archival Process

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1.0 Purpose

This Standard Operating Procedure (SOP) defines the system for storing and archiving raw data, technical specifications, protocols, reports, batch production records, Certificates of Analysis (COAs), and other documentation generated in support of project research, development, and manufacturing activities (both GMP and non-GMP).

This procedure is made available through federal funds from the National Cancer Inslitute, NIH, under contract [redacted]

2.0 Scope

This SOP applies to Biopharmaceutical Development Program (BDP) personnel who are involved in the document storage and archival process. This includes BDP personnel who provide documents to Biopharmaceutical Quality Assurance (BQA).

3.0 Overview

Work performed in support of project research, development, manufacturing, and support operations is documented to provide a reliable record of the activities performed. These documents, records, and reports capture information that may be needed to meet regulatory requirements, to reconstruct events at a later time, serve as a foundation for future work, provide a mechanism for troubleshooting, and provide a means to audit the validity of subsequently reported data. The retention of documents in a manner that adequately protects the documents and facilitates retrieval is an important component of the overall documentation management system at the BDP.

In general, BQA maintains recently completed and active documents in the Document Control [redacted] for easy reference purposes. If there is a space limitation, documents may be stored in an off-site location. Documents are considered archived when they are sent to off-site storage. Types of stored documents include, but are not limited to, Standard Operating Procedures (SOPs), Master Production Records (MPRs), Batch Production Records (BPRs), Master Equipment Files (MEFs), Quality Control Test Requests (QCTRs), and Validation documentation.

4.0 Authority and Responsibility

4.1 The Director, Biopharmaceutical Quality Assurance (BQA) has the authority to define this procedure.

4.2 It is the responsibility of BQA to:

- Establish secure archive locations that are protected from foreseeable emergencies (fire, flood, etc.).
- Maintain the on-site Document Control Room to ensure compliance with regulatory Food and Drug Administration (FDA) and BDP requirements.
- Manage off-site contract archive companies to ensure compliance with regulatory (FDA) and BDP requirements.
- Maintain traceability of on and off-site documents.
- Retrieve documents from on and off-site locations as requested.
- Maintain a database of off-site archived documents.
- Maintain documents stored on-site in the Document Control Room by document type or under a project name/number.
- Pack boxes and arrange shipment of documents to the BDP off-site archives.

4.3 It is the responsibility of BDP personnel to:

- Provide BQA with completed documents for controlled storage, along with **Form 21402-01, Archive Request**.
- Transfer to BQA raw data (or reference the location of raw data including any electronic data), protocols, technical specifications, reports, and COAs, and any other pertinent information for archiving at the close of the project.

5.0 Controlled Access

5.1 Access to documents stored on-site in the Document Control Room is limited to BQA and selected BDP staff members who assist with multiple tasks that involve the documents stored in the Document Control Room.

5.2 BQA (and selected BDP staff members) retain the key code and/or keycard access to the Document Control Room, which must be locked whenever BQA personnel (or designees) are not present.

5.3 Access to documents stored off-site is controlled by requests from BQA and/or Regulatory Affairs (RA) to the vendor that manages the off-site storage facility (see Section 6.1.1 for vendor facility requirements).

6.0 Document Storage

6.1 Documents may be stored either in the BQA Document Control Room or in an off-site location depending upon space requirements.

6.1.1 Off-site contract archive companies must be in compliance with regulatory (FDA) and BDP requirements:

- Waterless fire suppression system.
- Secure, climate controlled, fire proof environment (i.e., vault).
- Documents/Boxes available for retrieval within the same day, if needed.
- Delivery.
- Monthly contract with a Pest Control Company.
- 24-hour security.
- Generator back up in case of power failure.

6.2 Unless otherwise specified by the Frederick National Laboratory for Cancer Research (FNLCR), raw data generated by the BDP, records, protocols, technical specifications (as applicable per Current Good Manufacturing Practices (CGMP) regulations), official GMP reports and COAs generated as a result of a project, and any other pertinent documentation will be maintained by BQA in controlled storage. Documents completed recently may be stored on-site in the Document Control Room before being transferred to off-site storage, depending upon storage space available.

6.3 Correspondence and GMP-supporting documentation relating to the conduct of a study and the interpretation and evaluation of data, other than those documents contained in the final report, will also be retained.

6.3.1 Records related to regulated production or testing, (e.g., reagent batch preparation logs, equipment maintenance and calibration records, etc.), will be maintained in material or equipment-specific files. Environmental monitoring data is maintained in files identified by Process Analytics (PA) number (QCTR).

6.3.2 All BPRs that have been issued a lot number, must be returned to BQAD for archival. Those issued but not used will be placed in a green file binder.

6.3.3 Validation documentation for utilities, equipment, and process validation (including computer programs that are in production) are to be returned to BQA for storage. When computer programs, equipment, utilities, or process validations are retired, the validation documentation will be archived.

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract [redacted].

6.4 Upon request, documents may be electronically scanned (see ***SOP 21416 - Creation and Use of Electronic Copies of GMP Documents***) before they are archived and sent to off-site storage.

7.0 Organizing and Logging Documents into Storage

7.1 Project-specific documents stored in the on-site BQA Document Control Room are organized in numerical order by project number. Items that are not associated with a specific project are labeled as appropriate. Non-project specific documentation (i.e., environmental data, facility validations, equipment logbooks, etc.) are organized by document type.

7.2 BQA logs the documentation into the off-site archives using a computerized tracking system. When a document is added to the archives, the document number, document title, and date archived are entered in the Archived Documents Database. Additional information will be entered in the database depending on the type of document being archived and on the additional information provided to BQA on **Form 21402-01, Archive Request**. Descriptive additional information will assist with future searches for the document.

8.0 Submitting Documents to be Archived

8.1 Documents that are not maintained in the Document Control [redacted] by BQA (e.g., laboratory notebooks, equipment logbooks, etc.) and are ready to be archived must be submitted to BQA along with **Form 21402-01, Archive Request**.

8.2 The requestor completes **Form 21402-01, Archive Request** as indicated below and sends an email to the NCI BDP BQAD (NCIBDPQAD@mail.nih.gov) inbox with the attached form (**Form 21402-01**):

- **Document Information (Number, Title, etc.) –** document number and title, if neither is applicable provide pertinent information regarding a description of the document. This information will be included in the description of the document in the Archived Documents Database, so it is important that it contains enough information that a reasonable search of the database would locate the document.
- **Submitted By –** name of person submitting request.
- **Date Submitted –** date request is submitted.
- **Project Name –** project name, if applicable.
- **Project Number –** project number, if applicable.
- **Attached List of Documents with Dates –** only used if multiple documents are submitted using one form.
- **Reason for Archival –** provide as much detail as possible for the reason the document is being archived (e.g., inactive document, project closed, etc.).
- **Additional Information –** provide any additional information that will assist in future searches for the document (this information will be included in the Archived Documents database).

8.3 The requestor forwards the document and sends an email to the NCI BDP BQAD [redacted] inbox along with the attachment **Form 21402-01, Archive Request**.

8.4 BQA enters the information into the Archived Documents database according to the information provided on the Archive Request form and archives the document.

8.5 BQA completes the bottom portion of **Form 21402-01, Archive Request**, BQA enters the information into the Archived Documents database if the document is being archived off-site. BQA scans the completed form and e-mails a copy of the form to the requestor as confirmation of receipt of the document. The original form is then filed in the "Archive Requests, Form 21402-01" binder located in the High-Density File Room.

8.6 BQA will not archive documentation related to a closed project off-site without approval from the Director, RA.

9.0 Retrieving and Returning Documents to Storage

9.1 The individual requiring document retrieval sends an e-mail to the NCI BDP BQAD inbox [redacted]. The email should include the name, date, and number of the document requested (as applicable), and the date the document is needed.

NOTE: The standard turnaround for document retrieval from off-site storage is 24 hours if BQA receives an e-mail request before 2:00 pm. Same day delivery is an option for critical documents. Determination of document criticality requires approval from Director, RA/BQA

9.2 Documents may only be removed from on-site storage in the Document Control Room by BQA personnel (or designee). Requests for off-site archived documents will be made by BQA to the vendor that manages the off-site storage facility.

9.3 Photocopies of documents may be requested by sending an e-mail to NCI BDP BQAD. Original documents may be viewed in the Document Prep Area [redacted] or in the Conference Room [redacted], if necessary, or photocopies provided as requested. Only under exceptional circumstances will the original documents be allowed out of the BQA area.

9.4 Whenever an original document is signed out of BQA, an "Out" card is completed by BQA (or designee) and placed in the location or box where the document was stored. The "Out" card captures the date the document was checked out of BQA, to whom it was checked out to, and the document number or title. If the document was in an off-site storage box, the box remains in the BQA Document Control Room until the checked-out document is returned.

9.5 If a second individual needs the document, this individual must send an e-mail to BQA requesting the document be transferred to them. **The document may not be transferred to another individual without reassigning the "Out" card to the BQA (or designee) personnel.**

9.6 When the document is returned, BQA removes the "Out" card and returns the document to the location or box where it was originally stored. Off-site boxes are stored in the BQA Document Control Room until the next time boxes are sent to the off-site location.

NOTE: Data cannot be added, nor changes made to any document that has been archived. An addendum or copy will be issued for the document for the purpose of making additional entries, changes, etc. The changes will be documented.

9.7 When documentation is returned to off-site storage, BQA lists the items to be returned and obtains the signature of the courier on **Form 21402-02, Archived Document Pickup**.

10.0 Document Retention

10.1 Archived paper documents will be retained for each project for at least ten (10) years (refer to the ***SOP 21407 - Records Retention***), or in the case of fragile documents, until they no longer afford evaluation, whichever comes first. At the end of the ten (10) years, the NCI may be contacted and provided with a list of documents for destruction. The NCI and BQA must approve any destruction of documents.

10.2 BQA shall retain other records on-site such as personnel training, equipment maintenance and calibration records, batch records, etc., as long as they pertain to any active BDP project documents still retained by NCI.

11.0 References and Related Documents

11.1 **SOP 21407** *Records Retention*

11.2 **SOP 21416** *Creation and Use of Electronic Copies of GMP Documents*

12.0 Attachments

12.1 **Attachment 1** Form 21402-01, Archive Request

12.2 **Attachment 2** Form 21402-02, Archived Documents Pickup

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract [redacted].

Attachment 1

Form 21402-01; Archive Request

FNLCR, BDP
Form No.: 21402-01
SOP No.: 21402
Revision 04: FEB 20 2019

Biopharmaceutical Development Program
Biopharmaceutical Quality Assurance Documentation (BQAD)

Archive Request

Document Information (Number, Title, etc.): _____

_____

Submitted By: _____ **Date Submitted:** _____

Project Name: _____ **Project Number:** _____

Attached List of Documents with Dates: ☐ Yes ☐ No

Reason for Archival:

Additional Information:

Final Disposition (to be completed by BQAD):
Location, and Identification Codes, if any:
Archived By/Date:

NOTE: GMP Documents are kept for a minimum of 10 years.

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract [redacted].

Attachment 2
Form 21402-02; Archived Documents Pickup

FNLCR, BDP
Form No.: 21402-02
SOP No.: 21402
Revision 04: FEB 20 2019

Biopharmaceutical Development Program
Biopharmaceutical Quality Assurance Documentation (BQAD)

Archived Documents Pickup

Iron Mountain Account Number		
New or Refile	Box Number	Box Size (Standard, Letter, Legal)

Box Total for New: _____
Box Total for Refile: _____
Box Total for Pickup: _____

_____ _____
Iron Mountain Staff Signature Date

_____ _____
BQAD Signature Date

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract [redacted]