BC 10.850 - Research Regulatory Document Maintenance and Archiving

I. POLICY:

Federal regulations require documentation of all study-related activities. The regulatory files and subject records, which are periodically reviewed by the study sponsor and upon request by regulatory agencies, serve as the site's record of compliance with regulations, policies, and Good Clinical Practices. It is the policy of Baystate Health to fulfill all regulatory and clinical requirements for collecting filing, storage, and retention of study-related documents and records.

II. PURPOSE:`

This policy describes the documentation and storage of source data, and regulatory documents for clinical research studies and trials at the site and in Florence eBinders™ system. It also describes BH Principal Investigator and study staff responsibilities.

Investigators are responsible for maintaining study documents in accordance with applicable federal regulations, International Conference on Harmonization (ICH), Good Clinical Practice (GCP) Guidelines, Health Insurance Portability and Accountability Act (HIPAA) requirements, and departmental procedures.

At all times, study documents must be readily accessible for review and/or inspection by the regulatory agency (i.e. US Food and Drug Administration (FDA), US Department of Health and Human Services (DHHS), study sponsor/designee, approving Institutional Review Board (IRB), other regulatory authorities and/or organizational personnel as appropriate).

III. SCOPE:

This policy applies to all employees, medical staff, associate professional staff, teachers, students, residents, fellows, volunteers, contractors, consultants, agents, and others associated with BH who are involved in Research or any professional scholarly activities at any BH affiliated entities including but not limited to: Baystate Medical Center ("BMC"), Baystate Wing Hospital ("BWH"), Baystate Franklin Medical Center ("BFMC"), Baystate Noble Hospital (BNH), and the University of Massachusetts Chan Medical School – Baystate.

IV. DEFINITIONS:

Certified Copy: A copy of original information that has been verified, as indicated by a dated signature, as an exact copy having all the same attributes and information as the original.

Electronic Signature: An electronic sound, symbol or process that is attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record.

Legacy Studies: Studies that were activated prior to the use of Florence eBinders™ system.

Regulatory/Essential Documents: Those documents which individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor and monitor with the standards of GCP and with all applicable regulatory requirements.

Source Data/Documentation: All information in original records and certified copies of original records of clinical findings, observations, or other activities (in a clinical investigation) used for the reconstruction and evaluation of the trial. This typically comes down to the first place that a data point is recorded.

V. PROCEDURES:

A. Data Collection and Storage

Documentation of source data is necessary for the reconstruction, evaluation, and validation of clinical findings, observations, and other activities of a clinical research study. Source documentation serves to corroborate the integrity of study data and confirm observations that are recorded.

According to the Food and Drug Administration (FDA), data should meet certain fundamental elements of quality. Whether they're recorded on paper or electronically, source data should follow ALCOA-C, an acronym used in clinical research for:

- Attributable
- Legible
- Contemporaneous
- Original
- Accurate
- Complete

These best practices for documentation must be followed, to provide valid evidence of the test article performance.

B. Paper-based Records

When recording data on paper, every written element needs to be traced back to the authorized individual responsible for recording it. This requires a signature or initials, the date, and an identifier to a subject visit. Similarly, if something needs to be changed on the record, the change must be initialed, dated, and explained.

Everything written on paper must be legible and recorded in a permanent medium – not in pencil. Handwriting must be clear to reduce the likelihood of transcription errors and allow accurate study re-creation.

Data should be recorded, signed, and dated at the time of trial conduct, rather than risk an individual recalling the wrong information from memory. On paper, data needs to be documented in real time and dated with the current date – no pre- or post-dating.

The source is the earliest record, the first-place data is documented. If corrections or revisions need to be made, changes should not be obscure prior entries. Paper source documents should be preserved and kept in their original form.

It's important the source completely reflects true observations and findings. This means an honest, accurate, and thorough representation of facts describing the study conduct. There will

be times when source documents are incomplete, inconsistent, or wrong. If changes need to be made, modifying a paper record must be done in a compliant manner.

To ensure that data is accurate and complete, the study team must **record data as soon as possible**. This will help minimize audit findings due to incomplete or missing data.

C. Electronic Records

The audit trails are important aspects of the electronic system. Audit trails make it clear:

- who created a record,
- when it was created,
- who made a change,
- when the change was made,
- the reason a change was made

A compliant system will track this information and enable electronic signatures. Data is attributable to a unique user with a secure password and role-based permissions, preventing unauthorized users from making changes. There are few illegible handwriting problems in electronic source records, because data and information are presented in a clean and standardized format. Additionally, automatic edit checks can immediately alert when missing data points or out-of-range data are entered.

The electronic record will provide automatic date and time stamps every time clinical data is entered, edited, or modified in an electronic system with appropriate controls in place to fully support FDA requirements for electronic signatures, also known as 21 CFR Part 11.

D. Florence eBinders™ System

BH employees who are using this system are engaged in the collection, creation, completion, maintenance, and/or storage of Essential Documents from the planning and study startup stage through study completion/archival, effective with studies starting on or after **March 14, 2021**.

Florence eBinders™ system digitizes all the study binder workflows and provide remote access for start-up, monitoring and source data review for the sponsors.

1. The system has the ability to maintain the following GCP and regulatory requirements, including but not limited to:

    - Signed Protocol and Amendments, if applicable (all versions)
    - Investigator's Brochure (all versions)
    - FDA 1572 Statement of Investigator Form
    - FDA 3454/3455 Certification & Disclosure of Financial Interests
    - FDA 3674 Certification of Compliance with ClinicalTrials.gov (If applicable)
    - Informed Consent Form & information given to subjects
    - IRB Approvals and Correspondence
    - Safety committee approval(s), if applicable
    - Laboratory certification/accreditation
    - Operations Manuals (all versions)
    - Information for Use (all versions)

- Monitoring reports/correspondence with sponsor
- Investigator/staff curriculum vitae, licensure, training certifications, etc.
- Subject screening and enrollment logs
- Delegation of Authority Log
- Approved Recruitment and Retention materials Fully executed Clinical Trial Agreement (CTA)
- Laboratory normal ranges
- Study financial records

Investigators are encouraged to contact the Baystate Human Research Protection Program for questions regarding eBinders™ system templates and training needs.

2. **Legacy studies** are studies that were activated prior to the use of Florence. Legacy study documents may be: Scanned documents stored in Florence ebinders™ system or not scanned documents stored following institution recommendations.

3. Study Team Responsibilities for the Use of Florence eBinders™

   All BH investigators and their designee(s) engaging in research at the trial site, or at external participating sites (when BH is the Coordinating site) are responsible for maintaining study documents in a timely and organized fashion.

   The Principal Investigator (PI) or designee conducting an industry-sponsored study (ISS) activated after **03/14/2021** are responsible for incorporating the one-time institutional Florence fee into the study budget. This one-time fee off-sets institutional costs in establishing a local account which allows the sponsor secure remote access to essential documents and study records in Florence for the purpose of study monitoring. Federally funded research, research funded by non-profit entities, Investigator-initiated trials (IITs), and/or consortium-led studies are not subject to the institutional fee.

   Organizational Administrators in the BH Office of Research with the Team Set Up Role, or their designee, develops the eBinders™ structure template for indexing the storage of electronic study documents. The institution maintains the right to request alterations to the structure or template and require study teams to utilize these structures as needed. Those with the Team Set-Up role will have the capability to access all records in the system. All document views are automatically recorded in the audit trail, which is not alterable.

   The Principal Investigator (PI) or their designee, is responsible for ensuring that the appropriate Users (including external monitors and auditors), have the necessary access and permissions to conduct document management, completion, review, and archiving.

E. Archiving Study Records

Following completion of a clinical study, the study records may be examined and subject to review by internal departmental monitors/auditors, or externally by the study sponsor or FDA inspectors in compliance with regulatory and contractual requirements.

The local PI and institution must retain secure possession of the study records on-site after study completion by following HRPP guidelines and contractual obligations for potential review. Additional considerations are required for studies subject to the Privacy Rule, State and Federal requirements as applicable.

After maintaining the study records on-site, the clinical research records may be moved for long-term archiving to BH Archives and Records Management, or another appropriate and secure archive system approved by BH.

When archiving paper files ensure:

- Storage boxes are labeled clearly and completely. Keep a list of box numbers/receipts available to study staff.
- Maintain documentation of inventory within storage boxes.
- Store in a Baystate contracted, and/or approved, secure location for the required period of time.
- Obtain written permission from the sponsor prior to destroying any study records.
- Maintain log documenting destruction date of study documents.
- Maintain storage according to the Human Research Protection Program (HRPP) SOP Investigator records or seven years to ensure Health Information Portability and Accountability Act (HIPAA) is met.

VI. REFERENCES:

BH HRPP SOP October 28, 2022
March 2018 E6 (R2) Good Clinical Practice: Integrated Addendum to ICH E6 (RI) Guidance for Industry
21 CFR 312.60 General Responsibilities of investigators
21 CFR 312.62 Investigator recordkeeping and record retention
21 CFR 312.64 Investigator Reports
21 CFR 312.68 Inspection of investigator's records and reports
21 CFR 812. 110 Specific Responsibilities of Investigators
21 CFR 812.140 Records
45 CFR 46.115 institutional Review Board Records
45 CFR 164.528 Accounting of disclosures of Protected Health Information
BC 4.200- Record Retention Policy

APPROVALS:

		Date:
Approved:	Policy Management Committee	11/21/2023
Policy Owner:	Shemetra Owens, Human Research Protection Program & Gerard Coly, Clinical Trials Program	
Originating Author/Title:	Gerard Coly, Clinical Trials Program & Jennifer Pacheco, Chief Research Compliance and Integrity Officer	
Reviewers:	Jennifer Pacheco	
Replaces:		
Original Effective Date:		NEW
Review Dates:		
Revision Dates:		