BC 10.950 - Principles of Documentation and Data Management

I. POLICY:

Baystate Health (BH) must demonstrate adequate preparation and retention of records of research data to enable appropriate responses to questions about accuracy, authenticity, primacy and maintain compliance with laws and regulations governing the conduct of the research. Sponsors, federal and state agencies, or journals and other colleagues may need, or be, legally entitled to review research data well after study activities have been concluded.

II. PURPOSE:

The purpose of this policy is to:

- clarify responsibilities and accountability
- ensure that research data are recorded and used properly, are retained under responsible custody for a reasonable length of time and are made available for review under appropriate circumstances.

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:

Principal Investigator (PI): The individual or individuals primarily responsible for and in charge of a research project.

Research Data: Recorded factual material commonly accepted in the scientific or scholarly community as necessary to validate research findings). Research data include, but are not limited to, laboratory notebooks, as well as any other records that are necessary for the reconstruction and evaluation of reported results of research and the events and processes leading to those results, regardless of the form or the media on which they are recorded. Included in this term are unique research resources such as novel compounds synthesized by the investigator, organisms, cell lines, viruses, cell products, cloned DNA as well as genetic sequences and mapping information, crystallographic coordinates, plants, animals, and spectroscopic data.

V. PROCEDURE:

A. Responsibility of Baystate Health

BH ownership and stewardship of the scientific record for projects conducted by faculty and staff, using Baystate Health facilities and resources, is based on state law, federal regulation, and sound management principles.

The responsibilities of BH in this regard include, but are not limited to:

- Complying with the terms of sponsored project agreements.

- Ensuring the appropriate use of animals, human subjects, recombinant DNA, biological agents, radioactive materials, and the like.
- Protecting the rights of faculty, students, postdoctoral scholars, and staff, including, but not limited to, their rights to access to data from research in which they participated for their programs of study.
- When appropriate, securing the intellectual property rights of BH.
- Facilitating the investigation of charges, such as scientific misconduct or conflict of interest.

B. Responsibility of the Principal Investigator

- PIs are responsible for ensuring that critical, high-value research data under their stewardship are preserved.
- Unpublished data, confidential data, or other secured data must be accessible to authorized users but protected from unauthorized access or use.
- The PI is responsible for determining what needs to be retained in sufficient detail and for an adequate period of time to enable appropriate responses to questions about accuracy, authenticity, primacy, and compliance with laws and regulations governing the conduct of research.
- PIs must retain research data for at least the minimum period required by applicable laws and regulations, sponsorship requirements, or other agreements. PIs may choose to retain the data beyond the minimum period, up to any deadline specified by laws, regulations, or other agreements.
- PIs must destroy research data when required by laws, regulations, or other agreements, on or before a specified deadline, and follow the applicable process for destroying research data. PIs are reminded to review their data destruction plans approved by the IRB, funding agency contract and Institutional Privacy Rule obligations before destruction may occur. (Destruction of data must be done thoroughly and effectively. Paper records should be shredded. Electronic records must be erased in a manner that completely eliminates the file, potentially by multiple pass erasures.)
- The PI is responsible for educating all participants in the research project of their obligations regarding the research data, and for protecting BH's rights and ability to meet obligations related to the research data.
- The PI must comply with all public access requirements that are laid out by the funding agency sponsoring the research.
- PI must alert Sponsored Projects Administration (SPA) if a grant or contract may require management of research data that go beyond the standard requirement.

C. Collection and Retention

Data is the central focus of the research effort. It involves acquisition, management, sharing, and ownership of the data. Collection of research data involves clear, concise collection of multiple forms of data. Best practices include means to document the research experiment and result as well as who did the work, when, and what the interpretation of the experimental outcome was at that time.

Regarding the clinical research data, the PI must ensure that the procedures for retention and/or destruction of participants' research data are conducted in accordance with the provisions of the written informed consent document signed by the research participant, as well as applicable regulations and the clinical trial agreement. If the study includes medical

treatment, the PI must ensure that the medical records are retained in compliance with state law and Baystate Health policy for medical record retention.

Routine published data should be retained for an appropriate period consistent with standard practices or requirements within a discipline, funding agency, or department, or for a fixed period of time.

Clinical Trials data must be stored in the Oncore Clinical Trials Management System and Florence eBinders™ to reduce mistakes, promote the safety of study subjects, and allow for greater efficiency in conducting studies. See BC 10.850 Regulatory Document Maintenance and Archiving Policy.

Clinical Trials information that is required to be retained should not be retained in the Baystate email system. See BC 6.825 Email Retention Policy.

D. Sharing Data with Project Partners

A clear agreement regarding research data management and sharing should be put in place before any project start date.

Details of data sharing; type, frequency, format, and transfer arrangements should be noted within your data management plan and agreed at the project outset. If project data contains personal identifiers or detailed private health data, then additional data protections may be required to ensure that privacy is maintained. If an "honest broker" is engaged to assist in sharing data among project partners, the Baystate Honest Broker Agreement should be signed and followed (see Baystate Honest Broker Agreement attachment).

E. Ownership

Unless superseded by specific terms of sponsorship or other agreements, Baystate health owns all research data generated or acquired by employees (faculty and staff) or non-student trainees or fellows (not employed by Baystate health) through research projects conducted at or under the auspices of Baystate Health, regardless of funding source.

The PI is the steward of the research data that are under their control. PIs are responsible for managing access to research data under their stewardship. PIs will select the vehicle(s) for publication or presentation of the data. PIs decide whether or not to share research data, including placing research data in public repositories, unless specific terms of sponsorship or other agreements supersede this right. As a reminder, the PI must follow any contractual and grant agreements made to the institution and funder of the study.

F. Access in the Event the Investigator leaves Baystate Health

Although Baystate Health retains ownership of the research data, PIs will be granted access to and may request permission from the organization to create copies of research data if the PI is leaving Baystate Health. The organization will need to review patient authorization, contractual and grant obligations when weighing its decision. Preference will be given when a research project is to contractually accompany the PI to a new institution, as long as Baystate Health, the PI, and any funding agencies have access to the data when necessary and upon reasonable notice.

VI. REFERENCES:

BH HRPP SOP October 28, 2022
2 CFR 200.315
21 CFR Part I Electronic Records; Electronic Signatures
21 CFR 312.50 General responsibilities of sponsors
21 CFR 312.56 Review of ongoing investigations
21 CFR 312.60 General responsibilities of investigators
21 CFR 312.62 Investigator recordkeeping and record retention
21 CFR 3 12.64 Investigator reports
21 CFR 312.68 Inspection of investigator's records and reports
21 CFR 312.70 Disqualification of a Clinical Investigator
August 2003 Part II, electronic Records; Electronic Signatures-Scope and Application
May 2007 Guidance for Industry -Computerized Systems Used in Clinical Investigations
September 2013 Guidance for Industry Electronic Source Data in Clinical Investigations
December 2016 E6 (R2) Good Clinical Practice: Integrated Addendum to ICH E6 (RI) Guidance for Industry

APPROVALS:

		Date:
Approved:	Policy Management Committee	11/21/2023
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Originating Author/Title:	Gerard Coly, Clinical Trials Program & Jennifer Pacheco, Chief Research Compliance and Integrity Officer	
Reviewers:	Jennifer Pacheco	
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