BC 10.170 - Research Subject Enrollment and Study Visits

I. POLICY:

The safety and well-being of subjects is of paramount concern to a research team. This policy describes how staff conducting research related activities at Baystate Health meet the regulatory and clinical requirements to ensure adherence to study procedures for the evaluation of a subject's response to the investigational article. Careful attention is paid to subject well-being and to the integrity of data.

II. PURPOSE:

The purpose of this Policy is to ensure that sites at BH are organized and prepared for the proper conduct of the research study. The policy also describes the requirements for the conduct of a study and necessary steps related to the study termination or suspension.

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:

Case Report Form (CRF): A printed, optical, or electronic document designed to record all of the protocol-required information to be reported to the sponsor or entered into the research database for each clinical trial participant.

Concomitant Medications (CCM): Any prescribed or over-the-counter medications, folk and herbal treatments, vitamin supplements, and drugs or agents used on the street to alter body or mind function.

Documentation: All records, in any form (including but not limited to written, electronic, magnetic, and optical records; and scans, x-rays, and electrocardiograms) that describe or record the methods, conduct, and/or results of a clinical trial, the factors affecting a clinical trial, and the actions taken.

Source Data: All information in original records or certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies) and serve to verify the research record.

Source Documents: Original documents, data, and records, including: hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or questionnaires, evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at

the pharmacy, laboratories, and at medico-technical departments involved in the conducting the clinical trial.

Subject Identification Code: A unique identifier assigned by the investigator to each trial subject to protect the subject's identity and used in lieu of the subject's name when the investigator reports adverse events and/or other trial related data.

V. PROCEDURE:

A. Study conduct

A research study should be initiated at a site only after investigator and Sponsor/CRO involved in the study is satisfied that essential documents, agreements, and approvals are all in place. The site initiation process is designed to ensure that.

- The site has all essential documents in place for the site to conduct the study in compliance with the approved protocol and applicable regulatory guidelines.
- The site is aware of all the sponsor's procedures and SOPs for study conduct (such as safety recording and reporting, amendments, notification of any urgent safety measures/ violations or serious breaches) and has read and understood each.
- The site is met with all the required regulatory and sponsor requirements.

Once the site is activated and starts recruiting patients, the Investigator and the research team will ensure the following:

- All study activities are accomplished according to the protocol and applicable regulatory regulations.
- Subjects sign the correct version of the consent form before any study-related procedures are accomplished.
- The study team performs the required clinical evaluations for the assigned protocol to include, but not limited to the following:
    - ✓ physical assessment
    - ✓ medical history
    - ✓ review of signs and symptoms
    - ✓ new diagnoses
    - ✓ hospitalizations
    - ✓ medication changes
    - ✓ adherence to study medications, tolerability, and side effects
    - ✓ laboratory tests and/or procedures.
- Enrolled subjects are registered in CIS alerts and in the CTMS (OnCore) system with 48 hours after the study visit.
- When appropriate, complete a V08 request sheet (if subject is considered admitted/inpatient at the time of enrollment)
- Each subject's eligibility must be confirmed by the PI or designated staff prior to the randomization and study entry. Reasons for ineligibility must be documented, treatment alternatives must be discussed with the subject and the sponsor must be notified appropriately.
- Data collected in the Case Report Form (CRF) are supported by source documents.

- The Subject Identification Code is used in the communications/correspondences instead of the subject's name
- Protocol deviations/non-compliance/violations/waivers if any should be notified to the IRB and the same must be documented in the source documents and appropriate CRF.
- Adverse events are reflected in the source documents and captured in the CRF. (With appropriate term, grade, causality, start and stop date and CCM given if any.)
- Serious Adverse events (SAEs) are reported to the Sponsor/CRO and IRB within specified time frame (refer IRB SOP for SAE reporting).
- Anticipated study visits that are missed or out of the protocol specified timeframe (window) must be documented as missed study visits.
- Suspected Unexpected Serious Adverse Reaction (SUSAR) and Council for International Organizations of Medical Sciences (CIOMS) should be notified in the timely manner to the IRB.
- The Investigational Product (IP)/device is being dispensed correctly and IP/device accountability records are being maintained appropriately.
- The Sponsor/CRO is informed of all significant study events and staff members are documenting critical interactions with the Sponsor/CRO.
- Biological samples are being obtained, handled, stored, and shipped appropriately.
- Study supplies remain adequate. Study records remain confidential.
- All equipment is calibrated regularly, and maintenance records are being kept.

B. Premature Termination or Suspension of a Study

If the trial is prematurely terminated or suspended for any reason, the investigator/institution should promptly inform the trial subjects, should assure appropriate therapy and follow-up for the subjects, and, where required by the applicable regulatory requirement(s), should inform the regulatory authority(ies). In addition:

- If the investigator terminates or suspends a trial without prior agreement of the sponsor, the investigator should inform the institution, where applicable, and the investigator/institution should promptly inform the sponsor and the IRB and should provide the sponsor and the IRB a detailed written explanation of the termination or suspension.

- If the sponsor terminates or suspends a trial, the investigator should promptly inform the institution where applicable and the investigator/institution should promptly inform the IRB, and provide the IRB a detailed written explanation of the termination or suspension

- If the IRB terminates or suspends its approval/favorable opinion of a trial, the investigator should inform the institution where applicable and the investigator/institution should promptly notify the sponsor and provide the sponsor with a detailed written explanation of the termination or suspension.

C. **Final Report(s) by Investigator**

Upon completion of the trial, the investigator, where applicable, must inform the institution; the investigator/institution should provide the IRB with a summary of the trial's outcome, and the regulatory authority(ies) with any reports required.

VI. POLICY REFERENCES:

BH HRPP SOP October 28, 2022

VII. REGULATORY OR JOINT COMMISSION REFERENCES:

March 2018 E6 (R2) Good Clinical Practice: Integrated Addendum to ICH E6 (RI) Guidance for Industry
21 CFR 50.20 General requirements for informed consent
21 CFR 50.27 Documentation of informed consent 21 CFR 56.109 IRB review of
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 312.66 Assurance of lRB review
45 CFR 46.109 IRB review of research
45 CFR 46.116 General requirements for informed consent
45 CFR 46.117 Documentation of informed consent
45 CFR 46.408 Requirements for permission by parents or guardians and for assent by children
October 2008 Guidance for Sponsors, Clinical Investigators, and IRBs-Data Retention When Subjects Withdraw from FDA Regulated Clinical Trials
January 2009 Guidance for Clinical Investigators, Sponsors, and IRBs Adverse Event Reporting to IRBs - Improving Human Subject Protection

APPROVALS:

		Date:
Approved:	Policy Management Committee	1/16/2024
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Originating Author/Title:	Gerard Coly, Clinical Trials Program Jennifer Pacheco, Chief Research Compliance and Integrity Officer	
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