BC 10.250 - Research Study Closeout

I. POLICY:

The research project must complete an appropriate close out process. This includes the study close out visit, notification to the Institutional Review Board (IRB) and funding agencies and ensure proper storage of research data and specimen. The visit is performed to ensure that all data has been collected and verified, the final accounting has been completed, investigational product has been destroyed or returned to sponsor, and to verify that the investigator's files are complete and accurate after all subjects have completed the study.

Among the reasons for closing out a study, the closure report updates the IRB on the conduct and outcomes of the study, any new risks, safety issues or problems that may have arisen since the last study renewal and informs the IRB of the final disposition of research records and data.

II. PURPOSE:

This Policy explains the circumstances in which a study may be closed from IRB oversight, as well as ongoing Principal Investigator and Institution responsibilities that apply to a closed study.

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. PROCEDURE:

A. Criteria for Study Closure

A study can be closed when:

- ✓ All research participants have completed all study-related interventions and procedures, including any follow-up; AND
- ✓ The research team has obtained all private identifiable data and/or specimens from all participants (or from data/specimen sources if your study involves secondary analysis of data/specimens); AND
- ✓ The research team has completed analysis of all private identifiable data and specimens, as described in the IRB application.

Therefore, a study may be closed, as long as identifiable private data or identifiable specimens are not being obtained, used, or analyzed, and Sponsored Programs has indicated all financial components of a project are complete and all contractual obligations with external sponsors are met.

Studies must remain active and continue to receive ongoing IRB review and approval if any of the six conditions listed below occur:

1. Enrollment is on-going.
2. Research-related interventions and/or follow-up is ongoing.
3. Participant follow-up is ongoing.
4. Biological specimens containing personally identifiable information are being maintained in a repository that has been approved as part of this study or upon which analysis or research is ongoing. If, however, specimens were transferred to a separate repository that has ongoing IRB approval, the study may be closed.
5. Data analysis or manuscript preparation that involves the use or access to personally identifiable information is ongoing.
6. If there is an external study sponsor and the sponsor has not provided permission to close the study with the IRB.

B. Relationship to Data Use and Analysis

- Maintaining identifiable private data/specimens. If human subjects activities have been completed but identifiable private data/specimens will be maintained (as approved by the IRB), then IRB review and approval is no longer necessary, and the study may be closed. If the research team plans to make available a list or database of the study participants to multiple PIs and/or multiple projects for potential recruitment into future research studies, a new project to establish a registry/subject pool must be submitted to the IRB for review and approval.

- Secondary analysis of existing data/specimens. Should the Study team plan to continue a secondary analysis of existing data or specimen, they must consult with the IRB office prior to closing research study. This includes if the original investigators seek to use the data/specimens to investigate new research questions/topics OR if other investigators wish to use those data/specimens to study a new research question or topic, as this may constitute new human subjects research requiring IRB exemption or approval.

- Data sharing. If a study team plans on sharing data or specimens with individuals or entities not previously described in the IRB application, the study team must consult with the IRB office to ensure that the conditions under which the IRB approved the collection and use of the data/specimens are met.

C. PI Responsibilities

- Submit a closure report to the IRB within 30 days of completion or termination of all research activity, even if the current approval period has expired. The PI is encouraged to reference the Baystate Human Research Protection Program Standard Operating Procedures, Section 3.12 “Closure of Protocols”, to review and understand the Study Closure Report process of the Baystate IRB. Along with the closure report form to the Baystate IRB, the PI team should also include closure notice from the sponsor (as applicable) and approval to close from the reviewing IRB.

- Store the research records for the required length of time in accordance with federal regulations, and any additional requirements stipulated by research sponsors and/or

investigators' professional associations. The PI is encouraged to reference the Baystate Human Research Protection Program Standard Operating Procedures, Section 4.10 "Investigator Records", to review and understand the required storage periods such as the privacy rule. In addition, PI's working with external sponsors need to review their contractual obligations which may have additional terms and conditions for data storage and destruction approvals.

- Continue to follow data security measures and assure confidentiality of records and data**.** If the research team, collaborator or funding source proposes to move data to a new location at study close, please contact the Information Security Office and Institutional Review Board for approval of the method and storage location.

- Report to the IRB any information learned after study closure that could affect subject safety or medical care, including but not limited to serious adverse events or unanticipated problems reported by the Sponsor or others responsible for study monitoring.

- If terminating employment or other association with BH, the Principal Investigator is obligated to either:

  - ✓ Transfer the protocol to another BH investigator who must then be approved by the BH IRB (required), Department or Division head (where applicable) as the new Principal Investigator, and Sponsored Programs Administration, as applicable; or
  - ✓ Close the study and submit a study closure to the BH IRB. If closing the study, the Principal Investigator is responsible for making arrangements with the department/division to assure data and records are stored properly and remain confidential.

- Submit financial disclosure (FDF) to the sponsor one (1) year following study completion.

D. ClinicalTrials.gov

- Any trial which is listed by a Baystate PI on ClinicalTrials.gov will need to have the project results uploaded (as applicable) before the trial status can be modified to indicate project closure. The PI is responsible for ensuring ClinicalTrials.gov records have all required documents uploaded before the record indicates project completion. The record owner may contact an IRB Chair or the Baystate Chief Research Compliance Officer with any questions regarding record closure on ClinicalTrials.gov.

E. Post Award Closure

Post-Award Closure is the clinical trial close-out process required by the BH Office of Research and Sponsored Programs Administration, to ensure that all financial and cost standards have been met with institutional guidelines, sponsor guidelines, and federal regulations.
The research team must closely work with SPA during the trial close-out process.

F. Archiving Records

Archiving records refers to retaining and maintaining documents associated with a study after the completion of the research.

- The trial can be archived when all the end of trial documentation and end of trial reports have been written, submitted, and filed
- Any publications received after the files have been archived will be added to the archive at that time
- The trial documentation must be archived in accordance with federal, state and Baystate health regulations and policies.

V. POLICY REFERENCES:

BH HRPP SOP October 28, 2022

VI. REGULATORY OR JOINT COMMISSION REFERENCES:

45 CFR 46.102(f)
21 CFR 54 Financial Disclosures
21 CFR 56.115(b) IRB records
21 CFR 312.62 Investigator recordkeeping and record retention
21 CFR 312.66 Assurance of IRB review
21 CFR 312.68 Inspection of investigator's records and reports
21 CFR 812.110 Specific responsibility of Investigators
February 2013 Guidance for clinical Investigators. Industry, and FDA staff
Financial Disclosure by Clinical Investigators
August 2013 FDA Guidance Oversight of Clinical Investigations-A Risk Based Approach to Monitoring
December 2016 E6(R2) Good Clinical Practice: Integrated Addendum to ICHE6 (RI) Guidance for Industry

APPROVALS:

		Date:
Approved:	BH Policy Management Committee	9/19/2023
Policy Owner: (department name)	Office of Research	
Originating Owner:	Gerard Coly, Clinical Trials Program Director Shemetra Owens, Director Human Research Protection Program	
Reviewers:	Peter Friedmann, MD, Chief Research Officer Jennifer Pacheco, Chief Research Compliance Officer	
Replaces:	NEW	
Original Effective Date:		9/19/2023
Review Dates:		
Revision Dates:		