

Boston Medical Center and Boston University Medical Campus
Institutional Review Board

General Responsibilities of the Principal Investigator

The Principal Investigator is required to:

1. Understand what research activities are overseen by the HRPP and consult with HRPP staff if in doubt about whether submission to the IRB is required; and
2. Personally log into the electronic system using their individual username and password as an electronic signature; and
3. Provide information to the HRPP that is complete and accurate to the best of their knowledge; and
4. Design studies to protect individuals conducting the study, to adhere to ethical principles and standards appropriate to his or her discipline, to safeguard the rights and welfare of all human subjects, to minimize risks, to have adequate provisions to monitor the data for safety, to draw subjects from a population selected to distribute the risks and benefits fairly, to employ additional safeguards necessary to protect vulnerable populations, to safeguard research data, and to meet all applicable HIPAA requirements; and
5. Determine that adequate resources will be available to carry out the study, including facilities, access to an appropriate population, medical and psychological resources for subjects, and sufficient time and staff to conduct the research; and
6. Ensure that prior to beginning work on the study, the Principal Investigator and all members of the research team meet all applicable Boston Medical Center and Boston University requirements for the disclosure and management of conflicts of interest; have all required training, qualifications, credentials, and licenses; and are trained on and appropriately delegated responsibility for study procedures; and
7. Not initiate any human subjects research activities until an IRB final outcome letter has been received and all required institutional approvals have been obtained; and
8. Be responsible for execution and management of the study, including oversight of all study personnel and any sub-awardees/subcontractors under their direction; and
9. Comply with all applicable terms, conditions, assurances and certifications referenced in the application, award (grant or contract), and protocol; and with all applicable state, federal, and local laws, rules, regulations, policies, and guidelines, as well as institutional policies (including those pertaining to IRB requirements, patient confidentiality, HIPAA, debarment, finances and record retention) related to this study; and
10. Follow the IRB-approved research plan by recruiting subjects in a fair and equitable manner; by adhering to the approved inclusion and exclusion criteria and maintaining appropriate source documentation that demonstrates adherence; by employing the approved process for obtaining and documenting informed consent; by meeting all applicable HIPAA and other data security requirements; by maintaining the privacy of subjects and protecting the confidentiality of data; by responding appropriately to and documenting the response to subjects, prospective subjects, and family members who request information or have concerns or complaints; and by providing aggregate and/or individual study results to subjects if promised; and
11. Maintain all required records, including documentation (regulatory documents, source documents, and study data) that demonstrates compliance with the IRB-approved study application and/or protocol, and cooperate with any request for auditing by the HRPP, sponsor, or government agency; and

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12. Comply with all requirements for identifying and reporting Unanticipated Problems, Adverse Events, deviations, and safety monitors' reports, and any other new or significant information that might impact a subject's safety or willingness to continue in the study; and
13. Ensure that IRB approval is obtained prior to making any change to the approved study plan, consent form, or study personnel unless the change is immediately necessary for the safety of subjects; that IRB approval for continuation is obtained prior to the study expiration date; that a status check-in is proved before the due date for studies without expiration dates; and that a Final Report is submitted to close the study at the appropriate time.