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. Use the electronic system only through his or her individual login; and
3. Provide information to the HRPP that is complete and accurate to the best of his or her knowledge; and
4. Design studies to protect individuals conducting the study, to adhere to ethical principles and standards appropriate to their 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, and to meet all 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 from himself or herself and staff to conduct the research; and
6. Ensure that prior to beginning work on the study, all personnel under his or her direction have an accurate conflict of interest disclosure on file with Boston University or Boston Medical Center; have all required training, qualifications, credentials, and licenses; and are trained on and appropriately delegated responsibility for study procedures; and
7. Not initiate any study 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 his or her 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 research plan by recruiting subjects in a fair and equitable manner; by applying approved inclusion and exclusion criteria; by employing the approved process for obtaining and documenting informed consent; by meeting all HIPAA requirements; by maintaining the privacy of subjects and protecting the confidentiality of data; by responding promptly and appropriately to subjects, prospective subjects, and family members who request information or have concerns or complaints; and by providing any promised overall and/or individual study results to subjects; and
11. Maintain all required records and cooperate with any request for auditing by the HRPP, sponsor, or government agency; and
12. Comply with all requirements for identifying and reporting Unanticipated Problems, Adverse Events, protocol 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; and that a Final Report is submitted when the study has been completed.