

Investigator Post-Approval Responsibilities

Call the IRB Office ext. 6-7512 with any questions

General

- The PI is responsible for protecting the rights, safety and welfare of each research subject.
- Conduct the research in compliance with the protocol, institutional policies including IRB policy, regulations including 45 CFR 46, other applicable federal and state laws, and the principles of research ethics set forth in [The Belmont Report](#).
- Ensure that adequate resources are available, including staff, equipment, supplies, storage, space etc., to conduct the research at the institution and any other performance site for which the PI is responsible.

Record Retention

- Follow all procedures as approved by the IRB related to confidential storage of documents.
- Ensure the confidentiality and security of all information obtained from and about human subjects, and the privacy of subjects is maintained.
- Maintain written records of IRB reviews, decisions, communications, research records, and current study documents (protocol, informed consent form (ICF), advertisements, etc.) *Keep a copy of everything you submit to the IRB, correspondence with the IRB, and original documents you receive from the IRB.*
- Ensure study documents are organized and available for inspection as may be requested by the IRB, the institution, sponsor, or regulatory authority (FDA, OHRP).
- Maintain current Research Education (CITI) and Conflict of Interest (COI) records for the study team.

Protocol Compliance

- Supervise all research personnel, as specified in the approved protocol, and ensure that all personnel conduct the research in accordance with the approved protocol (including approved modifications) and abide by all applicable laws, regulations and ethical principles.
- Obtain and document participant consent using the **most current and IRB validated** version of the ICF and ensure the informed consent process is followed as described in the protocol. Participants must be provided with a copy of the ICF after it has been signed, unless the IRB has specifically waived this requirement.
- Ensure enrollment goals are not exceeded. The number of subjects you are approved to enroll is noted on the approval letter. To request an increase in this number, submit an amendment to the IRB well in advance.
- Ensure the use of [short forms](#) (up to 5 participants per language per year) or translated documents for the enrollment of all Non-English Speakers.
- Inform subjects of new information that may affect their willingness to continue participating in the study. Updated ICFs & information provided to subjects must be reviewed & approved by the IRB prior to use.

IRB Review Requirements

- Ensure that all research activities have IRB approval and other approvals required by the institution before human participants are involved, and implement the research activity as approved by the IRB.
- Obtain IRB approval (& notify sponsor, if applicable) of any proposed change to the research *before* it is implemented, except when necessary to eliminate apparent immediate hazards to the participants.
- Continuing review is to be conducted before expiration of IRB approval. If IRB approval lapses, research must stop until the IRB re-approves the research or permission is obtained from the IRB to continue.
- Submit [Reportable New Information](#): Promptly report to the IRB any protocol deviations unanticipated problems, or any issues involving risks to participants or others (including adverse events).
- If Tufts is the coordinating site, or acting as Sponsor, verify that IRB approval has been obtained from all participating sites in collaborative activities with other institutions, and ensure continuing review.
- Provide the IRB with audit or inspection reports or findings issued by regulatory agencies, cooperative research groups, contract research organizations, the sponsor or the funding agency.
- Provide the IRB with Data and Safety Monitoring Board or other monitoring group reports (if it meets the criteria for [Reportable New Information](#), submit promptly; otherwise submit at the next continuing review / administrative annual review).
- Inform the IRB when research activity is complete to close out the study.