Harvard Pilgrim Health Care

Harvard Pilgrim Health Care IRB
Investigator's Responsibilities

The IRB would like to remind you of some of your most important responsibilities as an investigator. Please share this information sheet with your co-investigators and data managers. These guidelines are consistent with Good Clinical Practice guidelines and DHHS regulations (45 CFR 46) and FDA regulations (21 CFR Parts 50, 54, 56, 312, 314, 601, 812, 814).

1. Obtain and document informed consent from subject or, if appropriate and approved per protocol, subject's legally authorized representative using current IRB-approved consent form(s). The subject must sign and date the consent form at the time consent is obtained. IMPORTANT NOTE: Do not use outdated (expired) consent forms. Check IRBNet for the current approved consent form before obtaining consent. Replace and dispose of all copies of outdated versions.

2. Keep the executed consent form with the original subject's signature in your study records, and give the subject a copy.

3. Obtain prior IRB approval of all protocol deviations or exceptions by submitting an amendment request form prior to initiation. Implement only after you have received written notification of IRB-approval of the protocol deviation/ exception.

4. Request in writing IRB approval of all changes to protocol or consent form by submitting an amendment request form through IRBNet prior to initiation of changes. Implement changes only after notification of IRB-approval has been received.

5. Complete and submit continuing review reports on time to fulfill the federal requirement for IRB review at least once every 12 months.

6. If IRB approval of the study lapses, all study activities MUST STOP. DO NOT USE OUTDATED CONSENT FORMS OR CONTINUE TO ENROLL SUBJECTS IN THE STUDY UNTIL STUDY IS REAPPROVED.

7. Report Unanticipated Events, Protocol Violations, and Adverse Events to the IRB within the required timeframe for adverse event reporting. These guidelines can be found under the IRB external webpage.

8. If a Data Safety Monitoring Board (DSMB) has been established for the trial, submit a written summary of DSMB periodic review to the IRB for review.

9. If the study involves an investigator-held IND or IDE, the investigator assumes all of the responsibilities of the sponsor, i.e., adverse event reporting to FDA and participating sites (multi-center trials) and submission of annual reports (21 CFR 312 Subpart D).

10. Keep good records. You should have a study file that contains all study-related information, e.g., all correspondence and protocol information from the sponsor and all IRB correspondence. In general, each subject enrolled or screened for a study should have a file in which documents are placed including a copy of the signed consent form, copies of case report forms, etc. After the study is completed, retain records as required by the sponsor and/or other applicable record keeping requirements.