

Guidance on Investigator's Responsibilities

The Institutional Review Board 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). For further information on regulatory requirements for a specific trial, refer to the regulations cited above or for more information contact the IRB Office.

12 Top Investigator Responsibilities

1. Develop and conduct research that is in accordance with the ethical Principles in the Belmont Report
2. Protect the rights and welfare of prospective subjects
 - 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). Sign and date the consent form at the time consent is obtained.
 - IMPORTANT NOTE: Do not use outdated (expired) consent forms. Check the validation and expiration date on the consent form before obtaining consent. Replace and dispose of all copies of outdated versions. File the original of each version of the IRB-approved and validated consent form in the regulatory binder to document IRB approval of consent forms through the life of the study.
3. Obtain and document informed consent as required by the IRB and ensuring that no human subject is involved in the research prior to obtaining their consent
 - Keep the executed consent form with the original subject's signature in your study records, give subject a copy, and place a copy in the subject's medical record only if the study does not involve sensitive personal information, e.g., genetic testing, alcohol or illicit drug use, etc. Refer to confidentiality section of approved consent form for applicability.
4. Have sufficient resources necessary to protect human subjects, including:
 - access to a population that would allow recruitment of the required number of subjects
 - sufficient time to conduct and complete the research
 - adequate numbers of qualified staff
 - adequate facilities
 - a process to ensure that all persons assisting with the research are adequately informed about the protocol and their research-related duties and functions
 - availability of medical or psychological resources that subjects might require as a consequence of the research
5. Develop a research plan that is scientifically sound and minimizes risk to the subjects
 - Develop an eligibility checklist with specific inclusion/exclusion criteria to determine that all eligibility criteria are met. Make sure that source documentation supporting eligibility is available in the subject's medical record.
 - Use objective criteria, e.g., baseline SGPT less than 1.5 times the upper limit of normal.
6. Ensure that all research involving human subjects receives IRB review and approval in writing before commencement of the research
7. Comply with all IRB decisions, conditions, and requirements. Request in writing IRB approval of all changes to protocol or consent form by submitting an amendment form prior to initiation of changes. Implement changes only after written notification of IRB-approval and/or IRB approved consent form has been received.

8. Ensure that protocols receive timely continuing IRB review and approval.
 - Complete and submit continuing review reports on time to fulfill the federal requirement for IRB review at least once every 12 months.
 - If IRB-approval of the study lapses, **DO NOT USE OUTDATED CONSENT FORM OR CONTINUE TO ENROLL SUBJECTS IN THE STUDY UNTIL STUDY IS REAPPROVED.**
9. Have plans to monitor the data collected for the safety of research subjects
 - Report problems that require prompt reporting to the IRB (see: Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events). Report adverse events regardless of the relationship to the study drug/device/procedure to the IRB within the required timeframe for adverse event reporting. Refer to the IRB Reportable Events Guidelines for required timeframe for reporting to the IRB. Refer to the protocol for Adverse Event (AE) and Serious Adverse Event (SAE) reporting requirements of the sponsor. If you hold the IND for the drug being studied and are required to report SAEs to the FDA, use the 7 day/15 day rule as stated in the Code of Federal Regulations (21 CFR 312.32). In addition, investigators must submit all IND safety reports received from the sponsor as soon as you receive them.
 - Have a procedure to receive complaints or requests for additional information from subjects and respond appropriately
10. If a Data Safety Monitoring Board (DSMB) has been established for the trial, submit a written summary of DSMB periodic review to the Human Research Committee for review.
11. Ensure that pertinent laws, regulations, and institution procedures and guidelines are observed by participating faculty and research staff. 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).
12. 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. Keep adequate source documents to corroborate entries on the CRFs. After the study is completed, retain records as required by the sponsor and/or other applicable record keeping requirements.