INVESTIGATOR GUIDANCE: Investigator Obligations


1. PURPOSE

1.1. This guidance describes the obligations of investigators conducting <Human Research> overseen by this [Organization’s] local IRB.

1.2. For research overseen by an IRB other than [Organization’s] local IRB, investigators should follow the requirements of that IRB.

2. GUIDANCE

2.1. Do not commence research until you have the IRB approval letter and obtained all other required approvals, such as radiation safety approval, biosafety approval, and approvals of departments or divisions that require approval of the use of their resources.

2.1.1. If there are any questions about whether you are conducting research involving human subjects, contact the IRB before commencing the study.

2.2. Comply with all requirements and determinations of the IRB.

2.3. Ensure that there are adequate resources to carry out the research safely. This includes, but is not limited to, sufficient investigator time, appropriately qualified research team members, equipment, and space.

2.4. Ensure that research staff are qualified (e.g., including but not limited to appropriate training, education, expertise, credentials, protocol requirements and, when relevant, privileges) to perform procedures and duties assigned to them during the study.

2.4.1. Investigators and research staff are required to complete initial training and continuing training at least every two years.

2.5. Personally conduct or supervise the research.

2.6. Conduct the research in accordance with the relevant current protocol approved by the IRB.

2.7. Protect the rights, safety, and welfare of subjects involved in the research.

2.8. Sign all applicable documents submitted to the IRB in order to reaffirm responsibility for oversight.

2.9. Submit proposed modifications (via Form HRP-203) to the IRB prior to their implementation.

2.9.1. Do not make modifications to the research without prior IRB review and approval unless necessary to eliminate apparent immediate hazards to subjects.

2.10. Submit continuing reviews (via Form HRP-202) in the time frame requested by the IRB.

2.11. Update the IRB with any changes to study personnel.

2.12. Submit a study closure to end the IRB’s oversight (via Form HRP-206) within 30 days when all the following apply:

2.12.1. The protocol is permanently closed to enrollment;

2.12.2. All subjects have completed all protocol related interventions and interactions;

2.12.3. No additional identifiable private information about the subjects is being obtained;

2.12.4. Analysis of private identifiable information is completed.

2.13. If research approval expires, stop all research activities and immediately contact the IRB. Submit a study closure report if a continuing review was not submitted prior to the study expiration.

2.14. Promptly report to the IRB the information items listed in “INVESTIGATOR GUIDANCE: Prompt Reporting Requirements (HRP-801)”. 

2.15. For studies regulated by a federal department or agency, follow the additional obligations, as applicable:
2.15.1. “INVESTIGATOR GUIDANCE: Additional DOD Obligations (HRP-810)”
2.15.2. “INVESTIGATOR GUIDANCE: Additional DOE Obligations (HRP-811)”
2.15.3. “INVESTIGATOR GUIDANCE: Additional DOJ Obligations (HRP-812)”
2.15.4. “INVESTIGATOR GUIDANCE: Additional EPA Obligations (HRP-813)”
2.15.5. “INVESTIGATOR GUIDANCE: Additional ED Obligations (HRP-814)”
2.15.6. “INVESTIGATOR GUIDANCE: Additional FDA Obligations (HRP-815)”

2.16. For studies where ICH-GCP compliance is required, follow additional the obligations in “INVESTIGATOR GUIDANCE: Additional ICH-GCP Obligations (HRP-816).”

2.17. Maintain signed consent documents, essential documents, source documentation, and case report forms in a secure location.

2.18. Unless the IRB affirmatively approved a protocol to include the following populations, such subjects may not be enrolled:
   2.18.1. Adults unable to consent;
   2.18.2. Children;
   2.18.3. Neonates of uncertain viability;
   2.18.4. Nonviable neonates;
   2.18.5. Pregnant women;
   2.18.6. Prisoners;
   2.18.7. Individuals unable to speak English.

2.19. When consent, permission, or assent are required by the IRB, ensure that they are obtained and documented in accordance with the relevant current protocol as approved by the IRB.

2.20. Retain research records for the greater of:
   2.20.1. Three years after completion of the research if the research does not involve Protected Health Information.
   2.20.2. Six years after the completion of the research if the research involves Protected Health Information.
   2.20.3. For studies involving a pediatric population, until all participants enrolled in the study are 18 years old.
   2.20.4. For drug studies conducted under an IND, two years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until two years after the investigation is discontinued and FDA is notified.
   2.20.5. For device studies conducted under an IDE or abbreviated IDE, two years after the latter of the following two dates: The date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol.
   2.20.6. The retention period required by the sponsor.
   2.20.7. The retention period required by local, state, or international law.
   2.20.8. The retention period required by a site that is not part of this [Organization].

2.21. Employ sound study design in accordance with the standards of your discipline and design studies in a manner that minimizes risks to subjects.

2.22. For protocols involving investigational product(s), the Investigator must be thoroughly familiar with the appropriate use of the investigational product(s). Investigators are responsible for providing the Investigational New Drug (IND) or Investigational Device Exemption (IDE) from the FDA in accordance with Federal regulations regarding the use of Investigational Articles.
2.22.1. Investigator holding an IND/IDE is considered a sponsor-investigator and assumes additional regulatory responsibilities.

2.23. When the research involves entities within GW that are not under the control of the Principal Investigator, the investigator ensures appropriate communication, education, and training of those staff.

2.24. Permit auditing and monitoring by the sponsor, the [Organization], and regulatory authorities.

2.25. In the event the Investigator leaves [Organization], the GW IRB must be notified. The Investigator may either have another GW investigator assume responsibilities through the submission of a modification to the IRB, close each of his or her research studies with the IRB, or transfer the research studies to the new location. The original research study documents are the property of the GW and must remain at GW.

2.26. Register with ClinicalTrials.gov, if applicable.

2.27. If you are the lead investigator of a multi-site study, ensure there is a plan to manage information that is relevant to the protection of subjects, such as <Unanticipated Problems Involving Risks to Subjects or Others>, interim results, and protocol modifications, and submit that plan to the IRB with your protocol.

2.28. Do not accept or provide payments to professionals in exchange for referrals of potential subjects (“finder’s fees”).

2.29. Do not accept payments designed to accelerate recruitment that were tied to the rate or timing of enrollment (“bonus payments”) without prior IRB approval.

2.30. Follow the [Organization’s] requirements to disclose financial interests.

   2.30.1. Disclose your financial interests on submission of an initial review.
   2.30.2. Disclose changes to your financial interests.

   2.30.2.1. On submission of continuing review

   2.30.2.2. Within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new financial interest that would have required disclosure on initial review

2.31. If you plan to conduct community-based participatory research, you may contact the IRB for information about:

   2.31.1. Community-based participatory research design
   2.31.2. Community advisory boards
   2.31.3. Subject advocates
   2.31.4. Partnerships with community-based organizations

3. REFERENCES

   3.1. 21 CFR §50, §56
   3.2. 45 CFR §46