

INVESTIGATOR GUIDANCE: Investigator Obligations

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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 three 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. Unless the IRB affirmatively approved a protocol to include the following populations, such subjects may not be enrolled:
 - 2.7.1. Adults unable to consent
 - 2.7.2. Children
 - 2.7.3. Neonates of uncertain viability
 - 2.7.4. Nonviable neonates
 - 2.7.5. Pregnant women
 - 2.7.6. Prisoners
 - 2.7.7. Individuals unable to speak English
- 2.8.
- 2.9. Protect the rights, safety, and welfare of subjects involved in the research.
- 2.10. Submit proposed modifications to the IRB prior to their implementation.
 - 2.10.1. Do not make modifications to the research without prior IRB review and approval unless necessary to eliminate apparent immediate hazards to subjects.
- 2.11. Submit continuing reviews when requested by the IRB.
- 2.12. Submit a continuing review to close research (end the IRB's oversight) when:
 - 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. For research subject to federal oversight other than FDA:
 - 2.12.3.1. No additional identifiable private information about the subjects is being obtained
 - 2.12.3.2. Your analysis of private identifiable information is completed
- 2.13. If research approval expires, stop all research activities and immediately contact the IRB.

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- 2.14. Promptly report to the IRB the information items listed in “INVESTIGATOR GUIDANCE: Prompt Reporting Requirements (HRP-801).”
- 2.15. Do not accept or provide payments to professionals in exchange for referrals of potential subjects (“finder’s fees.”)
- 2.16. Do not accept payments designed to accelerate recruitment that were tied to the rate or timing of enrollment (“bonus payments”) without prior IRB approval.
- 2.17. For studies regulated by a federal department or agency, follow the additional obligations, as applicable:
 - 2.17.1. “INVESTIGATOR GUIDANCE: Additional DOD Obligations (HRP-810)”
 - 2.17.2. “INVESTIGATOR GUIDANCE: Additional DOE Obligations (HRP-811)”
 - 2.17.3. “INVESTIGATOR GUIDANCE: Additional DOJ Obligations (HRP-812)”
 - 2.17.4. “INVESTIGATOR GUIDANCE: Additional EPA Obligations (HRP-813)”
 - 2.17.5. “INVESTIGATOR GUIDANCE: Additional ED Obligations (HRP-814)”
 - 2.17.6. “INVESTIGATOR GUIDANCE: Additional FDA Obligations (HRP-815)”
- 2.18. For studies where ICH-GCP compliance is required, follow additional the obligations in “INVESTIGATOR GUIDANCE: Additional ICH-GCP Obligations (HRP-816).”
- 2.19. Unless the IRB affirmatively approved a protocol to include the following populations, such subjects may not be enrolled:
 - 2.19.1. Adults unable to consent
 - 2.19.2. Children
 - 2.19.3. Neonates of uncertain viability
 - 2.19.4. Nonviable neonates
 - 2.19.5. Pregnant women
 - 2.19.6. Prisoners
 - 2.19.7. Individuals unable to speak English
- 2.20. 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.
- 2.21. Follow the [Organization’s] requirements to disclose financial interests.
 - 2.21.1. Disclose your financial interests on submission of an initial review.
 - 2.21.2. Disclose changes to your financial interests.
 - 2.21.2.1. On submission of continuing review
 - 2.21.2.2. 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
- 2.22. Retain research records (including signed consent documents) for the greater of:
 - 2.22.1. Three years after completion of the research
 - 2.22.2. Maintain signed and dated consent documents for at least three years after completion of the research.
 - 2.22.3. Maintain signed and dated HIPAA authorizations and consent documents that include HIPAA authorizations for at least six years after completion of the research.
 - 2.22.4. 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.
 - 2.22.5. 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.

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- 2.22.6. The retention period required by the sponsor
- 2.22.7. The retention period required by local, state, or international law.
 - 2.22.7.1. HIPAA requires signed authorizations to be retained for six years from the date signed or the date when it last was in effect, whichever is later.
- 2.22.8. The retention period required by a site that is not part of this [Organization].
- 2.23. Employ sound study design in accordance with the standards of your discipline and design studies in a manner that minimizes risks to subjects.
- 2.24. Update the IRB with any changes to study personnel.
- 2.25. If you are the lead investigator of a multi-site study, ensure there is a plan to manage of 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.
- 2.26. If you plan to conduct community-based participatory research, you may contact the Community Engagement Group for information about:
 - 2.26.1. Community-based participatory research design
 - 2.26.2. Community advisory boards
 - 2.26.3. Subject advocates
 - 2.26.4. Partnerships with community-based organizations

3. REFERENCES

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