

INVESTIGATOR GUIDANCE: Investigator Obligations

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1. PURPOSE

- 1.1. This guidance describes the obligations of Principal Investigators conducting <Human Research> overseen by this University's local IRB.
- 1.2. For research overseen by an IRB other than this University'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, submit a New Application form through <https://osu-chs.my.irbmanager.com> and wait for the IRB's determination before commencing the study.
- 2.2. Comply with all requirements and determinations of the IRB, as well as Federal, state, and local laws, regulations
- 2.3. Ensure that there are adequate resources to carry out the research safely. This includes, but is not limited to, sufficient investigator time and oversight of all research team members, 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 human subjects training and continuing training at least every three years through CITI Program (citiprogram.org).
 - 2.4.2. If the study involves Protected Health Information under HIPAA, all research team members must also complete annual training in HIPAA
 - 2.4.3. If the study is a clinical trial, GCP training through CITI Program (citiprogram.org) is also highly encouraged.
- 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. Ensure the research protocol is consistent with the proposal for funding for extramural or intramural support
- 2.8. Protect the rights, safety, and welfare of subjects involved in the research.
- 2.9. Submit proposed modifications 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 in the time frame requested by the IRB.
- 2.11. Submit a study closure to end the IRB's oversight:
 - 2.11.1. When **all** the following apply:
 - 2.11.1.1. The protocol is permanently closed to enrollment;
 - 2.11.1.2. All subjects have completed all protocol related interventions and interactions;
 - 2.11.1.3. No additional identifiable private information about the subjects is being obtained;
 - 2.11.1.4. Analysis of private identifiable information is completed.

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- 2.11.2. When a study has expired or been administratively closed due to a continuing review not being submitted before expiration
- 2.12. If research approval expires, immediately stop all research activities including analysis of identifiable data, and submit a study closure. A new research protocol must be approved before research activities may resume.
- 2.13. Promptly report to the IRB the information items listed in “POLICY: Prompt Reporting Requirements (HRP-071)”.
- 2.14. Do not accept or provide payments to professionals in exchange for referrals of potential subjects (“finder’s fees”).
- 2.15. Do not accept payments designed to accelerate recruitment that were tied to the rate or timing of enrollment (“bonus payments”) without prior IRB approval.
- 2.16. For studies regulated by a federal department or agency, follow the additional obligations, as applicable:
 - 2.16.1. “INVESTIGATOR GUIDANCE: Additional DOD Obligations (HRP-810)”
 - 2.16.2. “INVESTIGATOR GUIDANCE: Additional DOE Obligations (HRP-811)”
 - 2.16.3. “INVESTIGATOR GUIDANCE: Additional DOJ Obligations (HRP-812)”
 - 2.16.4. “INVESTIGATOR GUIDANCE: Additional EPA Obligations (HRP-813)”
 - 2.16.5. “INVESTIGATOR GUIDANCE: Additional ED Obligations (HRP-814)”
 - 2.16.6. “INVESTIGATOR GUIDANCE: Additional FDA Obligations (HRP-815)”
 - 2.16.7. “INVESTIGATOR GUIDANCE: Additional ICH-GCP Obligations (HRP-816)”
 - 2.16.8. “INVESTIGATOR GUIDANCE: Additional ISO 14155 Obligations (HRP-817)”
 - 2.16.9. “INVESTIGATOR GUIDANCE: Additional HHS Obligations (HRP-818)”
- 2.17. For studies where ICH-GCP compliance is required, follow additional the obligations in “INVESTIGATOR GUIDANCE: Additional ICH-GCP Obligations (HRP-816).”
- 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, parental 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. Follow the University’s requirements to disclose financial interests.
 - 2.20.1. Disclose your conflicts of interest on submission of an initial review.
 - 2.20.2. Disclose changes to your conflicts of interest.
 - 2.20.2.1. On submission of continuing review
 - 2.20.2.2. 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
- 2.21. Retain research records for the greater of:
 - 2.21.1. If all participants are adults: at least three years after completion of the research
 - 2.21.2. If participants are children: until all participants are 18 years of age, or for three years after the completion of the research, whichever is longer

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- 2.21.3. If the study involves Protected Health Information, research records must be maintained for a minimum of six years after the completion of the research.
- 2.21.4. 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.
- 2.21.5. 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.
- 2.21.6. The retention period required by the sponsor
- 2.21.7. The retention period required by local, state, or international law.
- 2.21.8. The retention period required by a site that is not part of this University
- 2.22. Employ sound study design in accordance with the standards of your discipline and design studies in a manner that minimizes risks to subjects.
- 2.23. Update the IRB with any changes to study personnel.
- 2.24. 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.

3. REFERENCES

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