1. PURPOSE
   1. This policy describes the obligations of investigators conducting <Human Research> overseen by this [Organization].
2. POLICY
   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.
      1. If there are any questions about whether you are conducting research involving human subjects, contact the IRB before commencing the study.
   2. Comply with all requirements and determinations of the IRB.
   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.
   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.
      1. Investigators and research staff are required to complete initial training and continuing training at least every two years.
   5. When submitting a new study to the IRB for initial review, ensure that the principal investigator obtains acknowledgment from his/her Department Head or Chair for the research to take place. This acknowledgment will be obtained by following the requirements of the [Organization’s] Human Research Protection Program.
      1. If the principal investigator is serving as Department Head or Chair, then the acknowledgment must come from the investigator’s acting Dean.
      2. If the principal investigator is staff of a program or institution without a Department Head or Chair, then the acknowledgment must come from the investigator’s acting Dean. If there is no acting Dean, then the acknowledgment must come from the investigator’s supervisor.
   6. Personally conduct or supervise the research.
   7. Conduct the research in accordance with the relevant current protocol approved by the IRB.
   8. Protect the rights, safety, and welfare of subjects involved in the research.
   9. Submit proposed modifications to the IRB prior to their implementation.
      1. Do not make modifications to the research without prior IRB review and approval unless necessary to eliminate apparent immediate hazards to subjects.
      2. A change in funding status or funding organization is considered a modification and requires IRB approval.
   10. Submit continuing reviews when requested by the IRB.
   11. Submit a closure form to close research (end the IRB’s oversight) when:
       1. The protocol is permanently closed to enrollment
       2. All subjects have completed all protocol related interventions and interactions
       3. For research subject to federal oversight other than FDA:
          1. No additional identifiable private information about the subjects is being obtained
          2. Your analysis of private identifiable information is completed
   12. If research approval expires, stop all research activities and immediately contact the IRB.
       * 1. If the IRB approves a research protocol with conditions, and the protocol expires before the conditions are met and verified by the IRB, you are to discontinue all research activities until approval is obtained.
   13. Promptly report to the IRB the information items listed in “POLICY: Prompt Reporting Requirements (HRP-071).”
   14. Do not accept or provide payments to professionals in exchange for referrals of potential subjects (“finder’s fees.”)
   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.

For studies regulated by a federal department or agency, follow any additional obligations, as applicable:

* + 1. “INVESTIGATOR GUIDANCE: Additional DOD Obligations (HRP-810)”
    2. “INVESTIGATOR GUIDANCE: Additional DOE Obligations (HRP-811)”
    3. “INVESTIGATOR GUIDANCE: Additional DOJ Obligations (HRP-812)”
    4. “INVESTIGATOR GUIDANCE: Additional EPA Obligations (HRP-813)”
    5. “INVESTIGATOR GUIDANCE: Additional ED Obligations (HRP-814)”
    6. “INVESTIGATOR GUIDANCE: Additional FDA Obligations (HRP-815)”
  1. If the Principal Investigator is leaving the [Organization] and the research is still open:
     1. Submit a closure form to close the research (end the IRB’s oversight), transfer IRB oversight to another IRB, or transfer to a different Principal Investigator in the [Organization] who is capable and qualified to conduct the research.
  2. For studies where ICH-GCP compliance is required, follow additional the obligations in “INVESTIGATOR GUIDANCE: Additional ICH-GCP Obligations (HRP-816).”
  3. Unless the IRB affirmatively approved a protocol to include the following populations, such subjects may not be enrolled:
     1. Adults unable to consent
     2. Children
     3. Neonates of uncertain viability
     4. Nonviable neonates
     5. Pregnant women
     6. Prisoners
     7. Individuals unable to speak English
  4. 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.
     1. Ensure that the individual(s) obtaining consent are knowledgeable on the areas for which they are discussing with the subject, including—but not limited to—the extent to which confidentiality will be maintained, possible study risks and benefits, and alternatives to participation.
  5. Follow the [Organization’s] requirements to disclose financial interests.
  6. Retain research records (including signed consent documents) for the greater of:
     1. Three years after completion of the research
     2. 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.
     3. 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.
     4. The retention period required by the sponsor
     5. The retention period required by local, state, or international law.
        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.
     6. The retention period required by a site that is not part of this [Organization].
  7. Update the IRB with any changes to study personnel.
  8. 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.
  9. When conducting a clinical trial that is supported by a federal department or agency, or an FDA-regulated trial (except for a Phase I drug trial):
     1. Ensure that an IRB-approved consent form that has been used to enroll a participant in the clinical trial is posted on a website specified by the US federal government. These include clinicaltrials.gov (preferred and required for studies that are registered on clinicaltrials.gov) and a docket folder on regulations.gov.
        1. This must be posted after the clinical trial is closed to recruitment, but no later than 60 days after the last study visit by any participant, as required by the protocol.
        2. Concerns regarding redaction of information (e.g., confidential commercial information) in a consent form that will be posted must be addressed to the Federal department or agency supporting the clinical trial.[[1]](#footnote-2)  Only the Federal agency supporting the clinical trial may permit or require redactions to the information posted. Note that the regulation does not allow for exceptions to the requirement for posting.

1. REFERENCES
   1. 21 CFR §56.103(a)
   2. 21 CFR §56.108(a)
   3. 21 CFR §50.20
   4. 21 CFR §50.25
   5. 21 CFR §50.27
   6. 45 CFR §46.116
   7. 45 CFR §46.117
   8. FDA Guidance for Sponsors, Clinical Investigators, and IRBs Frequently Asked Questions – Statement of Investigator (Form FDA 1572)
   9. AAHRPP Evaluation Instrument for Accreditation

1. For information on how to request an exception to posting the consent form, or redacting sensitive information, contact the administrative grant specialist of the federal department or agency after consulting with University counsel and RESEACH COMMERCIALIZATION? (look up Steve Nappi’s group’s name). [↑](#footnote-ref-2)