AAHRPP DOCUMENT # 27

UNIVERSITY OF ALABAMA
HUMAN RESEARCH PROTECTIONS PROGRAM

GUIDANCE: GENERAL RESPONSIBILITIES OF INVESTIGATORS

It is the policy of the University of Alabama Institutional Review Board (IRB) that Investigators be knowledgeable about their roles and responsibilities as investigators and conduct research involving human subjects in accordance with Federal, State, and University rules and regulations.

This list is a broad guideline. These responsibilities are detailed in specific policies or other guidance documents available online.

I. Human Subjects Protection

1. Investigators are responsible for compliance with all Federal, State, and institutional rules and regulations related to research involving humans and, if applicable, to the Good Clinical Practice Guidelines adopted by the Food and Drug Administration.

2. Investigators are the ultimate guardians of participants’ rights and safety. They must create a research environment that supports the highest standards of participant welfare and ethical behavior for all staff.

3. Investigators are responsible for reducing risk to participants by taking all reasonable precautions for their safety and well-being.

4. Investigators will ensure that Office of Research Compliance approval or IRB review and approval has taken place before research using human subjects is started or before modifications to approved protocols are implemented.

5. Investigators are obligated to be certain that each participant is adequately informed about the study and has freely consented to participate in the research.

6. Investigators are responsible for providing participants with contact information for themselves and the Director of Research Compliance on the consent form in case participants or their LAR(s) have questions, complaints, or concerns about the research study.

7. Investigators will respond to prospects’ or participants’ questions and complaints and maintain a record of these for use in applications for continuing review or study modification or for reporting to IRB if the event is a reportable event.
8. Investigators are responsible for reporting inappropriate activities connected with the research process (their own or that of others) to the Director of Research Compliance.

9. Investigators are responsible for helping improve the functioning of IRB and the Human Research Protection Program by asking questions and making suggestions.

10. Investigators (both faculty and students) are responsible for formally closing their studies with the IRB.

II. Investigator Training

1. Investigators are responsible for completing initial and ongoing UA IRB human research protections training requirements for remaining up-to-date with federal regulations, state and local laws, UA and IRB policies and procedures, and compliance expectations.

2. Principal investigators are responsible for assuring that key study personnel—including but not limited to principal investigators, co-investigators, study coordinators, project directors, recruitment coordinators and schedulers, interviewers, statisticians and data analysts working with identifiable data, students, consultants, and persons with other titles who have contact with study participants in any capacity—are adequately trained in human research protections and have completed continuing education requirements.

III. Appropriate Delegation of Study-Related Task and Supervision of Staff

Principal investigators are responsible for:

1. Providing sufficient resources (personnel, equipment, etc.) that the study can be executed safely and according to protocol and ethical requirements;

2. Selecting staff qualified by training (courses, certifications, degrees, or licensure) or experience to perform the desired study tasks or for providing such training to them if that is feasible and legal for the desired tasks;

3. Providing staff with general information about the nature of the study and detailed information about their specific tasks, including events that require reporting to the investigator, sponsor, IRB, or Office of Sponsored Programs;

4. Supervising study personnel in the performance of their tasks through such means as routine meetings, response to staff-identified problems, direct observation of performance, and independent verification (replication) of staff’s findings;

5. Arranging for coverage by a qualified person if s/he cannot be available for some period during the study;
6. Informing staff that they may be surveyed by the Office for Research Compliance about appropriate delegation of tasks, the adequacy of study resources; fidelity to the protocol and IRB requirements, and accessibility of the principal investigator as part of routine study audits or evaluation an improvement of the Human Relations Protections Program.

7. Informing staff that they may request information, offer suggestions about IRB policies and procedures, or report concerns and complaints about studies to the Office of Research Compliance using any medium, including the online FORM: Report of Complaint or Concern About Research Study.

IV. Investigator and Key Personnel Conflicts of Interest (COI)

Each investigator is responsible for:

1. Reading and understanding the UA Policy on COI.

2. Disclosing all actual or perceived conflicts of interest as defined by institutional policy for self or key personnel to the UA Office for Research for review to determine if and what disclosure to human research participants is needed.

3. Supplying information on conflicts of interest as directed by the Director of Research Compliance in the IRB application for initial and continuing review relation to possible harm to participants or effects on the integrity of the research.

4. Responding to IRB as requested in regard to additional information about COI or additions to or modifications of the informed consent document.

5. Updating IRB on COI as issues of financial interest arise or terminate.

V. Congruence of IRB Applications with Funding Proposals

1. Investigators are responsible for seeing that the IRB application is consistent with the proposal for funding for extramural or intramural support.

2. Investigators will act as liaisons between the IRB and the research sponsor. Acting in this capacity, the PI will work with the Office for Sponsored Programs Pre-Award office to:

   a. Assure compliance with and negotiate contracts to align with university, federal, and state standards;

   b. Compare and align informed consent and contract language, e.g. patient injury;

   c. Facilitate final negotiation of the study budget, payment schedule, and initiation funding by assuring that the budget submitted is accurate and the consts are reasonable and consistent with current pricing;
d. Obtain institutional sign-off on final contract.

VI. Supervision and Auditing of the Research Process

Investigators are responsible for:

1. Assuring adherence to the study protocol, monitoring the informed consent process, overseeing research staff, and assuring the presence of appropriate facilities and resources to conduct the research.

2. Identifying and addressing any deficiencies or deviations from protocol and contacting the IRB as necessary for study modifications or for reporting unanticipated or adverse events.

3. Cooperating with IRB in routine monitoring or monitoring for cause or noncompliance.

VII. Confidentiality and Privacy

1. Investigators must assure participant privacy and confidentiality of data according to HIPAA guidelines, IRB policies, and the IRB-approved application.

VIII. Unanticipated Problems Involving Risk to Participants or Others

1. Investigators are responsible for reporting unanticipated problems involving risks to participants or others that occur in the course of the research to the IRB, Data Safety Monitoring Boards, sponsors, the Office of Sponsored Programs, and appropriate Federal agencies in a timely manner, depending on those units’ requirements and the seriousness of the unanticipated problem.

IX. Research Records

1. Investigators are responsible for maintaining and providing research records according to the specifications of IRB, federal regulations, and research sponsors.

2. Investigators who leave UA must notify the IRB, the Office of Sponsored Programs, and their research sponsors. Their options include having another UA scientist assume principal investigator responsibilities, closing all of their active studies with the IRB, or taking the research studies to the new location.

X. Use of Investigational Drugs and/or Investigational Devices
1. Investigators are responsible for obtaining the Investigational New Drug (IND) or Investigational Device Exemption (IDE) from the FDA in accordance with federal regulations.

2. Investigators considering the emergency use of a test article must comply with FDA and IRB regulations about doing so.

XI. Approvals From Other University Committees or Other Institutions

1. Investigators are responsible for seeking review of and approval from other university committees and other institutions as required prior to the initiation of any research.

2. Investigators will document the need for required external committee or institutional applications and approvals in the IRB application form. Once approval is granted by these committees or institutions, investigators should forward copies of the approval letters and approved consent forms to the UA IRB.

XII. Federalwide Assurances (FWA), Memos of Understanding (MOU), Other IRB Approvals and Letters of Cooperation

1. Investigators are responsible for assuring that the proper approvals and agreements are in place before research begins. This includes research at performance sites “engaged” or “not engaged” that are not a legal entity of UA.

2. Investigators are responsible for submitting copies of all IRB approvals or letters of cooperation, whichever is applicable, for all performance sites indicated in the IRB application that are not a legal entity of UA.

3. Investigators must assure that each performance site indicated in IRB applications as “engaged” in research has a current FWA and IRB approval, both initially and throughout the conduct of the research.

4. If the UA IRB has agreed to serve as the IRB of Record for a performance site “engaged” in research as evidenced by an executed MOU, investigators are responsible for assuring that the MOU is current and that they uphold the terms and conditions defined within the MOU.

XIII. Continuing Reviews And Modifications of Approved Protocols

1. Principal investigators are responsible for ensuring that all subject participation and other research activity occurs only within IRB approval periods. Therefore, they must submit applications for continuing review and modifications of the protocols to the IRB in time for allow continuous approval.

2. Principal investigators are responsible for requesting and reporting modifications, unanticipated events, adverse events, the nature of any new literature that may
affect participant risk or benefit to the IRB, and the nature and resolution of participant questions or complaints when requesting continuing review in order to facilitate substantial and meaningful review.

XIV. Closure of Protocols

1. Investigators (including students) are responsible for notifying the IRB that an approved protocol has been completed and completing FORM: Request for Study Closure (Investigator). If students fail to close studies, their supervising professors must do so for them.

XV. Improving the Human Research Protection Program and IRB Processes

1. Investigators are responsible for knowing how to obtain answers to questions about the Human Research Protection Program and IRB requirements and processes, how to express concerns about the Human Research Protection Program or IRB processes, and how to make suggestions for the improvement of the Human Research Protection Program or IRB processes.