1.1 Policy Statement.

1.1.1 It is the policy of the University of Alabama that in keeping with its assurance from the Office for Human Research Protections principal investigators (PIs) and all personnel identified as investigators on IRB applications involving human subjects research shall be qualified to assume this role and that they will be aware of and fulfill their duties as investigators.

1.1.2 The qualifications for principal and other named investigators are as follows:

1.1.2.1 The investigator holds a regular or temporary full-or part-time paid faculty or staff appointment at the University of Alabama for which the position title or job description includes/identifies the conduct or supervision of research as an expectation.

1.1.2.2 Students of any level at the University of Alabama may identify themselves as the principal investigator as long as a faculty member is named as the Second or Co-investigator on the IRB application and signs the Signature Assurance Sheet or the departmental equivalent.

1.1.2.2.1 Student research that must be reviewed by the IRB includes pilot studies for theses or dissertations; undergraduate honors theses, and all class or other projects that involve human research participants and whose findings contribute to generalizeable knowledge and may be published or otherwise disseminated beyond a classroom setting.

1.1.2.3 Investigators, including faculty supervisors, will have completed the required investigator training as specified on the IRB website and will include documentation of current training on their IRB applications.

1.1.2.4 All investigators conducting human subjects research must be adequately qualified and licensed relevant to the scope and complexity of the research conducted.

1.1.2.5 All investigators shall be cognizant of UA policies on conflict of interest, as research with human subjects requires objectivity in explaining risks, seeking subjects, promoting informed consent, and gathering, analyzing, and reporting data.

1.1.3 Investigators shall be aware of their responsibilities as investigators and fulfill them.
1.1.3.1 These responsibilities cover human subjects protection, investigator training, awareness of federal regulations governing research, delegation to and supervision of research staff, conflicts of interest, congruence of IRB applications and funding proposals, supervision and monitoring of the research process, participant confidentiality and privacy, reporting unanticipated problems and other reportable events, maintaining research records, conforming with federal and IRB requirements for use of investigational drugs and devices, securing approvals from other university committees or other institutions, continuing review, closure of protocols, and improving the Human Research Protections Program, and IRB processes.

1.1.4 The Research Compliance staff shall verify that investigators have completed the required investigator training and assist them in the appropriate reporting of conflicts of interest.

1.1.5 IRB reviewers shall assess investigator qualifications in relation to the scope and complexity of the research study and, if necessary, request additional information or documentation of investigator qualifications.

1.1.6 The Office for Research Compliance shall educate investigators about their rights and responsibilities through the IRB website and through consultation.

1.2 Objective

1.2.1 Implementation of this policy will ensure that investigators are prepared to fulfill their responsibilities for the protection of human research participants and that UA meets its assurance by having compliance and IRB personnel monitor and assess the qualifications of investigators.

1.3 Responsibility.

1.3.1 The Vice President for Research is ultimately responsible for this policy. Enabling parties include the Director of Research Compliance, Research Compliance Specialists, IRB members, and investigators.

2.0 PROCEDURE

2.1 Investigator Responsibilities

2.1.1 Investigators complete initial and continuing required training as described on the IRB website.

2.1.2 Investigators ensure that all key personnel—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—have completed and maintained required human subjects or HIPAA training.
2.1.3 Investigators familiarize themselves with their general responsibilities (GUIDANCE: General Responsibilities of Investigators).

2.1.4 Investigators familiarize themselves with details of their responsibilities through the various policies, forms, and other guidance documents relevant to their work that are available on the IRB website or through consultation with the Director of Research Compliance or a Research Compliance Specialist.

2.1.5 Investigators will maintain study records in accordance with IRB policies (in general, for three years after completion of the study). Study records include all study documents, including applications, IRB correspondence, consent documents, study manuals, brochures, logs, laboratory notebooks, training materials for staff or participants, records of complaints and their resolution, and correspondence with funding agencies concerned with reportable events. Study records must also be maintained in accordance with the requirements of any relevant laws or regulations such as FERPA and HIPAA.

2.1.5.1 Investigators are responsible for keeping abreast of any changes in these external laws and regulations.

2.1.6 Investigators will not conduct research that has not been approved by the IRB or approved as exempt.

2.2 Responsibilities of Research Compliance Specialist (RCS)

2.2.1 The RCS will keep records of training certificates in investigator files and will notify investigator applicants if their certificate has lapsed.

2.2.2 The RCS will assist investigators with the appropriate reporting of conflicts of interest.

2.2.3 The RCS will consult with investigators about questions or issues they raise about their responsibilities, referring them to the Director of Research Compliance if necessary.

2.2.4 The RCS will document discussions about investigator training or qualifications in the IRB minutes.

2.3 Responsibilities of IRB Reviewers

2.3.1 Reviewers will review applications using FORM: Checklist for Reviewers and Investigators, considering investigator and research staff qualifications, the use of sound scientific design, identification and minimization of risks, and declared or undeclared conflicts of interests.

2.3.2 Reviewers will request additional information or documentation of investigator qualifications if necessary.
3.0 REFERENCES

3.1 45 CFR §46.103(b)(4)

3.2 45 CFR §46.103 (b)(5)

3.3 21 CFR §56.108(a)

3.4 21 CFR §56.108(b)

4.0 RELATED SECTIONS

4.1 GUIDANCE: General Responsibilities of Investigators

4.2 All other policies, forms, and guidance documents on the IRB website are related to this policy.