1.0 POLICY

1.1 Background.

1.1.1 As part of its mission, the University of Alabama (UA) faculty, staff and students perform research to advance knowledge. UA research includes medical and non-medical research with human research participants. **This policy describes the authority granted to the IRB by the Office of the President in order that the IRB may perform its responsibilities to protect human research participants without interference by University officials to meet federal and other regulations and the ethical standards of the Belmont Report and other ethical guidelines.**

1.2 Policy Statement.

1.2.1 It is the policy of the University of Alabama that IRBs shall be empowered by the President of the University to perform their legally and ethically mandated responsibilities. Specifically:

1.2.1.1 The Vice President for Research is designated as the Institutional Official to work directly with the Office for Research Compliance and the IRBs;

1.2.1.2 Appointment to the IRB as member or chair is considered a University Committee appointment. The appointments for the IRB are made by the Vice President for Research.

1.2.1.3 The IRBs are authorized to approve, modify, or disapprove all human research activities overseen and conducted by the organization. This includes decisions about whether proposed research may be expedited or exempted from federal regulations and guidance. It also covers initial and continuing review and modifications of approved protocols;

1.2.1.4 The IRBs are authorized to suspend or terminate research not being conducted in accordance with the IRB’s requirement or that has been associated with significant harm to participants. The IRBs are authorized to observe, or have a third party observe, the consent process and the conduct of the research;

1.2.1.5 The IRBs are authorized to seek consultation as needed from internal or external consultants;

1.2.1.6 The IRBs shall notify parties in writing of its decisions to approve, disapprove, modify, suspend, or terminate proposed or approved studies;
1.2.1.7  Chairs and members of the UA IRBs will be free of undue influence or coercion from any University official, faculty, or staff member to maintain the integrity and fairness of the IRB review process;

1.2.1.8  The decisions of the UA IRBs about individual research protocols are final. Officials of UA may not approve human subject research that has not been approved by the UA IRB;

1.2.1.9  The UA IRBs shall establish, maintain, and evaluate educational and other outreach efforts for the University and non-university communities about the nature of research, research ethics, and rights and responsibilities of investigators and research participants;

1.2.1.10 To accomplish these purposes the UA IRBs shall develop, maintain, and evaluate the necessary documents (policies, procedures, forms) for use by investigators, Research Compliance staff, and IRB members. These documents shall be reviewed and approved by the Institutional Official and cover:

   1.2.1.10.1 Required training for Office for Research Compliance staff, IRB chairs and members, and investigators and information about research protections for research participants and non-university communities;

   1.2.1.10.1.1 Key personnel—defined as principal investigators, co-investigators, study coordinators, project directors, recruitment coordinators and schedulers, interviewers, statisticians and data analysts who have contact with identifiable data, students, consultants, and persons with other titles who have contact with study participants in any capacity—must complete human subjects training and, if relevant, HIPAA training.

   1.2.1.10.2 Submission and review of research at all levels (exempt, expedited, full board review) for both initial and continuing review and for modifications of approved protocols;

   1.2.1.10.3 Routine monitoring of approved research and monitoring for cause;

   1.2.1.10.4 Detecting or responding to complaints or concerns about noncompliance;

   1.2.1.10.5 Identification and management of complaints about attempts to exert undue influence on Research Compliance staff, IRB Chairs, or IRB members.

   1.2.1.10.6 Prompt reporting to the IRBs, regulatory officials, and institutional officials of unanticipated problems involving risks to subjects or others, and serious or continuing noncompliance with UA policy, federal regulations, or the requirements or determinations of the IRB.

1.2.2  UA will maintain a separate designated budget for the Office for Research Compliance. The Director of Research Compliance will submit a proposed budget annually to the Institutional Official who will finalize it following University procedures for review and adjustment consistent with the overall institutional budget.
1.3 Objective

1.3.1 Adherence to this policy will ensure that the UA IRBs complies with federal and other regulations governing protection of human research participants and accepted ethical principles; that policies and procedures governing research with human participants are developed, maintained, and evaluated; that the IRB functions as an independent organization within the University and is free of undue influence from University officials or faculty; that the work of the IRB is facilitated by the Institutional Official; and that the Office for Research, the Office for Research Compliance, the IRBs, and academic units communicate effectively about research protections and resources.

1.4 Responsibility

1.4.1 The President of the University of Alabama is ultimately responsible for this policy. Enabling parties are the Vice President for Research (appointed as the Institutional Official to work directly with the Office for Research Compliance and the IRB) who is ultimately responsible for the policies and procedures developed by the Department of Research Compliance; the Director of Research Compliance, the Office for Research Compliance staff, and the IRB chairs and members.

1.4.2 Individuals who are responsible for business development are prohibited from serving as members or ex-officio members on the IRB and carrying out day-to-day operations of the review process.

2.0 PROCEDURE

2.1 All documents developed by the Office for Research Compliance and the IRBs and approved by the Institutional Official (Vice President for Research) are relevant to this policy.

3.0 REFERENCES

3.1 The Belmont Report

3.2 University of Alabama Federal Wide Assurance (FWA)

3.3 DHHS Title 45 Part 46 of the Code of Federal Regulations

3.4 FDA 21 CFR Parts 50, 56, 160, 164

3.5 FDA Information Sheets: Non-Local IRB Review

3.6 OHRP Guidance on Knowledge of Local Research Context

3.7 State laws related to consent and reporting