POLICY

1.1 Background.

1.1.1 The University of Alabama holds an Office for Human Research Protections (OHRP) approved Federal Wide Assurance (FWA). As part of this agreement with OHRP, the University of Alabama is required to ensure that investigators conducting U.S. Department of Health and Human Services (HHS) human subjects research or HHS sponsored research complete ongoing human subjects training in accordance with the HHS regulations. According to the FWA, the responsibility of establishing educational training and oversight lies with the Institution and the designated Institutional Review Boards (IRBs). The training must encompass ethical and federal regulations pertaining to human subjects research, guidance established by OHRP and other entities, local and state law and institutional policies of the University of Alabama. Those individuals subject to that training and application of the knowledge of human subjects research protection include the following groups: IRB members and staff, research investigators and other appropriate study personnel. In addition, individuals responsible for review of human subjects research protocols in any capacity, including the Institutional Official and Office for Sponsored Programs staff are also subject to job specific training.

1.1.2 All efforts to provide research education and training for persons involved in human research and outreach to research participants and community members comprise the UA Human Research Protection Program (HRPP). The HRPP is broader than the IRB, which is responsible for the actual oversight of research studies. That is, the HRPP is IRB plus education, training, and outreach efforts of the Office of Research Compliance.

1.1.3 This policy deals with the education and improvement of university-affiliated persons with responsibility for the conduct of research or its review. See PARTICIPANT OUTREACH listing (Accreditation Domain V) for policies, procedures, and resources for protecting and educating research participants and members of the larger (non-university) community.

1.2 Policy Statement.

1.2.1.1 It is the policy of the University of Alabama that the Human Research Protection Program (HRPP) shall provide education and assistance to all persons
responsible for the review and/or implementation of research applications in any capacity, in order to assist those persons with acquiring and increasing the knowledge needed to discharge their responsibilities. In addition the HRPP hopes to encourage these persons to participate in self-development activities as well.

1.2.1.2 The training program of the IRB chairs and members, research compliance staff, investigators, sponsored programs staff, and the Institutional Official shall be developed or selected, evaluated periodically, and improved as needed.

1.2.1.3 The Office for Research Compliance will identify those persons who are subject to completion and implementation of the duties of this policy and will implement specific training guidelines for them.

1.2.1.4 Education or information for investigators on how to identify relevant community members, would could include lists of local community resources with expertise in hard-to-reach populations.

1.2.1.5 Various training resources will be made available to those subject to this policy, either through the use of the IRB website or through direct consultation with Office for Research Compliance staff.

1.2.1.6 Data about training activities content, participation, and evaluation will be included in evaluations of the HRPP and may be addressed in quality improvement plans.

1.3 Objective

1.3.1 Implementation of this policy will ultimately lead to improved protection of human research participants by increasing the knowledge of persons involved in that protection. The specific objective is to ensure that University-affiliated personnel are adequately trained to appropriately carry out their responsibilities for the protection of human research participants, as determined by regulations of OHRP and that UA is able to achieve and maintain voluntary accreditation by the Association for the Accreditation of Human Research Protection Programs (AAHRPP).

1.4 Responsibility

1.4.1 The ultimate responsibility for this policy rests with the Vice President for Research, or the otherwise designated Institutional Official. Enabling parties include the Director of Research Compliance and staff, the chairs and members of IRB, the Director of Sponsored Programs and staff, principal investigators, and faculty members who supervise student research or teach research ethics/conduct to students.

2.0 PROCEDURE

2.1 The enabling parties will collaborate to identify educational needs of those concerned with protecting human research participants and ensuring compliance with federal regulations and legislation. Strategies for this collaboration include but are not limited to:
2.1.1 Discussions at IRB and departmental meetings;

2.1.2 Solicited or voluntary suggestions from research administrators, sponsored programs or compliance staff, IRB chairs and members, investigators, faculty teaching research ethics and the conduct of research to students;

2.1.3 Analysis of changes in federal regulations or guidance, AAHRPP requirements, and UA policy;

2.1.4 Results of evaluative surveys sponsored by the University, the HRPP evaluation committee, the IRB, or the Office for Research;

2.2 Training Resources and Methodology

2.2.1 Personnel subject to this policy will have online access to or hard copies of a UA Statement of Principles, the Belmont Report, the Helsinki Declaration, and federal regulations and legislation relevant to the conduct and oversight of research with human participants.

2.2.2 The HRPP/IRB website will contain lists of UA policies and procedures for research and review; forms to be used for research applications, reviews, and reports; templates for consent forms and IRB applications; and guidance documents.

2.2.2.1 These documents will be reviewed and revised as circumstances require and at least every three years on a rotating schedule.

2.2.2.2 The Office for Research Compliance will provide investigator guidance and announce new documents or major policy revisions on the website within the section called “IRB NOTES”. Investigators are responsible for using this information in their applications.

2.2.3 Continuing education sessions will be presented in at least 4 IRB meetings per year and at the annual IRB retreat. Members will evaluate the usefulness of these sessions and will be encouraged to suggest topics for future education or to volunteer to present educational sessions for the IRB.

2.2.4 IRB chairs, members, research compliance staff, sponsored programs staff, and investigators expressing interest will be available to make educational presentations about research and research protection to UA faculty and students and community groups.

2.2.5 The IRB chairs’ and members’ annual self-evaluations will include opportunity to identify self-development of activities in addition to those offered by the HRPP/IRB.

2.2.6 The University may request policy enablers to attend relevant conferences and to share their learning upon return.

2.3 Required Training of Subject Parties

2.3.1 IRB Member Training
2.3.1.1 The new member orientation period is defined as the time between appointment to the board and completion of six months of service.

2.3.1.2 All IRB chairs and members will complete the CITI training “IRB Member, Basic Course” (if they are not investigators) or the CITI Investigator training (if they are also investigators) prior to reviewing human subjects research as board members and will recertify every two years on that program.

2.3.1.3 All new IRB members regardless of prior experience on IRBs will:

2.3.1.3.1 Receive a new member packet called “Responsibilities of IRB Membership”, a copy of the Guidance Document: Training for New IRB Members, a copy of FORM: IRB Member Job Description, the UA Statement of Principles, the Belmont Report, and the Institutional Review Board Guidebook (45 CFR 46, CFR Title 21 (Volumes 1 and 2), the Nuremberg Code, and the most recent version of the Declaration of Helsinki, prior to their first IRB meeting.

2.3.1.3.2 Receive a reading list of selected IRB policies, forms, and guidance (all available on the IRB website) designed to acquaint them as rapidly as possible with how the UA IRB functions. The selected documents are grouped into monthly topics for the learner’s convenience. The learner is free to vary that order and is encouraged to supplement the suggested readings by locating other documents that deal with issues that arise in IRB meetings.

2.3.1.3.3 Have the opportunity to be mentored by a compliance staff person or an experienced board member with at least one year of local service. The member will be available to answer questions about meeting events and applications and to assist the new member with at least the first assignment as primary and expedited reviewer. In addition, the board’s Research Compliance Specialist and the IRB Chair will assist the inexperienced IRB member with information, suggestions, and feedback.

2.3.1.3.4 IRB training will then be individualized, depending on the member’s previous experience serving on IRBs—whether they are considered Inexperienced or Experienced members. This training is described in detail on GUIDANCE: Training for New IRB Members.

2.3.1.3.4.1 The goal of member training is to have all members able to conduct independent primary and expedited reviews of applications within six months of their appointments to the boards.

2.3.1.4 The Office for Research Compliance will also sponsor webinars, conferences, retreats, or other events to advance IRB member training. While members are encouraged to take advantage of these, they will not count toward member CE for members’ other purposes unless a single event provides at least 3 contact hours. (It is the member’s responsibility to submit documentation of the event, sponsor, content, duration and completion to the external party.)

2.4. Principal Investigator and Key Personnel Training
2.4.1 The principal investigator is the person assuming overall responsibility for the conduct of a research study and the protection of human participants in that research. Key Personnel include but are not limited to the following: principal investigators, co-investigators, study coordinators, project directors, recruitment coordinators and schedulers, interviewers, statisticians and data analysts working with identifiable data, consultants, and other personnel who have contact with study participants in any capacity.

2.4.1.1 The following are NOT considered key personnel: Persons responsible for ONLY ONE of these activities: Approval of the conduct of the research in that environment (such as a school principal), entry or analysis of non-identifiable data, or manuscript evaluation or revision.

2.4.2 Principal investigators and key personnel who plan to work on human subjects research projects must complete the training specified for investigators on the IRB website, prior to applying for IRB approval or conducting research with human research participants and to renew it as necessary.

2.4.3 Key personnel (including students) working with clinical trials or any type of medical or nonmedical research that involves chart review, seeks or verifies information about diagnoses, or makes other use of Protected Health Information (PHI) as defined by the Health Insurance Portability and Accountability Act (HIPAA) are required to complete the relevant HIPAA training. Investigators from CCHS (Medical School) should complete the HIPAA training specified on the college website. All other investigators doing research using PHI must complete either the CITI Training Module on HIPAA or the University of Alabama’s HIPAA training and the HIPAA Acknowledgement, in addition to other required investigator training.

2.4.3.1 IRB members interested in learning about the use of PHI are encouraged to complete this training as well.

2.5 Faculty Research Advisor and Dissertation/Thesis Committee Chair/Member Training

2.5.1 Faculty and staff members supervising student research with human subjects are required to complete the training specified for investigators on the IRB website prior to the student’s submission of an application to IRB or beginning work on the study and to renew it as necessary.

2.5.2 If the student is working with medical record chart review or other activities that require the use of participants’ Protected Health Information (PHI), the faculty or staff supervisor must also complete the HIPAA training and Acknowledgement.

2.5.3 Faculty and staff members supervising student research with human subjects are required to insure that students of any level have completed the appropriate training before students work on a research project in any capacity and that they renew it as necessary.

2.6 Student Investigator Training
2.6.1 Students of any level who submit applications to the IRB are required to complete the appropriate medical or non-medical training specified on the IRB website and to renew it as necessary. This applies to students conducting small studies as learning experiences, to preliminary research for a thesis or dissertation (whether or not the research will be included in the thesis/dissertation, and to theses and dissertations.

2.7 Office for Research Staff Training

2.7.1 The University of Alabama requires Research Compliance staff to complete the training specified for investigators on the IRB website prior to reviewing human subjects research and advising investigators as a compliance staff member and to renew that training as specified.

2.7.2 Research Compliance staff members receive continuing education through attendance at conferences on the protections of human subjects and ongoing review of the federal regulations and updated guidance and through such events as webinars sponsored by major research and HRPP organizations.

2.7.3 Research Compliance staff may request to attend certain meetings approved by the Director of Research Compliance to enhance their personal professional development or may be asked to attend on behalf of the department.

2.7.4 Research Compliance staff are encouraged to acquire additional certifications or other designations appropriate to their positions, such as the CIP (Certified IRB Professional).

2.8 Office for Sponsored Programs Staff Training

2.8.1 Staff in the Office for Sponsored Programs undergo continuing training through attendance at conferences on human research protections relevant to sponsored programs, including the historical development of ethical and regulatory requirements, informed consent issues, modifications of protocols and agreements, reporting of safety information and unexpected events, compensation for research-related injuries, conflict of interest plans, and the responsibilities of each party in agreements. Staff may request to attend certain programs approved by the Director of Sponsored Programs to enhance their personal development or may be asked to attend on behalf of the department.

2.8.2 Sponsored Programs staff also participates in local CE programs with members of other departments.

2.8.3 Staff of Sponsored Programs are expected to accomplish the continuing education requirements specific to their disciplines.

2.9 Institutional Official Training

2.9.1 The Institutional Official must complete training specified for investigators on the Investigator Training on the IRB website and to renew it as prescribed.
2.9.2 The Institutional Official also completes the Human Subject Assurance Training developed by OHRP and available online.

3.0 REFERENCES

3.1 None

4.0 RELATED SECTIONS

4.1 POLICY: Evaluation and Improvement of the Human Research Protection Program
4.2 FORM: IRB Members Job Description
4.3 GUIDANCE: Training for New IRB Members
4.4 FORM: IRB Members Self Evaluation
4.5 FORM: IRB Education Record
4.6 FORM: Evaluation of IRB Continuing Education
4.7 DOCUMENT: Available PowerPoint Shows for IRB and Investigator Education
4.8 FORM: IRB Member Evaluation of HRPP/IRB
4.9 POLICY: Investigator Input into the Human Research Protection Program/IRB Process
4.10 POLICY: Protection of Human Research Participants’ Privacy and Confidentiality