1.0 POLICY

1.1 Background.

1.1.1 Assurance: A contract of agreement that establishes standards for human subjects’ research as approved by the Office for Human Research Protections (OHRP).

1.1.2 Department of Health and Human Services (DHHS or HSS): The United States government’s agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves.

1.1.3 Office for Human Research Protections (OHRP): The office under the Department of Health and Human Services responsible for implementing DHHS regulations (45 CFR 46) governing biomedical and behavioral/social science research involving human subjects.

1.1.4 Institutional Review Board (IRB): A specifically constituted review body established or designated by an entity to protect the rights and welfare of human subjects recruited to participate in biomedical or behavioral/social science research.

1.1.5 IRB of Record: An IRB is considered the IRB of record when it assumes IRB responsibilities for another institution and is designated to do so through an approved Assurance with OHRP. A Memorandum of Understanding is required, designating the relationship, for The University of Alabama IRB to serve as the IRB of Record.

1.1.6 Memorandum of Understanding (MOU): A formal agreement between The University of Alabama and another institution that identifies the University of Alabama Institutional Review Board as the IRB of Record for that institution.

1.1.7 Institutional Review Boards (IRBs) are mandated by regulatory agencies and by AAHRPP to have written policies and procedures to authorize IRB activities and to enable IRBs to maintain compliance. These policies are based on accepted ethical principles and reflect the overarching commitment of the University of Alabama to provide protection for all human participants in research conducted by its faculty, staff, and students and supported by the Office for Research Compliance and the Office for Sponsored Programs.
1.2 Policy Statement.

1.2.1 It is the policy of The University of Alabama (UA) to uphold and protect the rights of all human subjects for all research activities conducted within its jurisdiction and authority in accordance with federal, state, and university regulations and AAHRPP standards and elements. The University requires that all UA-linked research studies involving humans as subjects or which use human material must be reviewed and approved by the UA IRB prior to initiation of the research, including recruitment and screening activities. Therefore, all responsible parties for this policy will contribute to the development, implementation, and review of written policies and procedures intended to protect the rights of human subjects and maximize compliance with research-related laws, regulations, institutional requirements, and accreditation standards (I.1.D).

1.2.2 UA hereby establishes and designates its institutional review board (IRB) as the UA IRB to conduct research reviews and the Vice President for Research as the responsible institutional official (I.1.C). The UA IRB shall review all research involving human subjects regardless of the funding source and location of the study if the research is sponsored by UA; conducted by or under the direction of any UA employee, agent, or student acting within his/her institutional responsibilities; is conducted under direction of any UA employee, agent, or student using any property or facility of UA; or involves the use of UA’s non-public information to identify or contact human research subjects. The purpose of review is to ensure that UA-related research is designed and conducted in ways that protect the rights, welfare, and privacy of human participants.

1.2.3 The UA IRB is granted authority to approve, disapprove, require modifications to, monitor, and conduct continuing reviews of new applications and studies in progress as it deems necessary to protect human research participants. It may seek consultation to provide additional expertise about applications. The IRB has the authority to observe or have a third party observe the informed consent process and to monitor studies for routine quality control or for cause. It may suspend or terminate approval of an ongoing study that violates the IRB’s requirements or that has been associated with unexpected serious harm to subjects (I.3.B).

1.2.4 The IRB shall conduct continuing reviews at intervals appropriate to the level of risk but never at intervals longer than one year. NOTE: The approval year commences on the date the application was approved by the IRB. The approval year ends at 5:00 p.m. of the day before the anniversary date that the application was approved. That is, an application approved on June 10th expires on June 9th of the next year. At that time, all work on the study must cease if the application for renewal was not submitted in time for review or if approval has not yet been received from the IRB.

1.2.5 The IRB has a mandate to act as an independent entity within the structure of the University of Alabama. Its decisions are binding and cannot be overturned or overruled by an institutional official at any level, nor may any university officials or employees who are not members of the IRB attempt to influence its decisions. Any such attempts are to be reported at once as detailed in other policies. Although the Vice President for Research has overall responsibility for the IRB, s/he will work with it to establish and implement written policies and procedures, and will receive
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1.2.6 The IRB may consist of one or more boards as needed to properly review and approve UA research involving human subjects. The IRB may also use external IRBs to act in the capacity of the UA IRB as circumstances require (I.2.B). See also POLICY: Review and Oversight of Research Conducted at Multiple Sites.

1.2.7 The University of Alabama’s Assurance currently designates two (2) OHRP-registered Institutional Review Boards (IRBs).

1.2.7.1 The IRBs are appointed as University Committees. As such they serve UA as a whole, rather than a particular school or department, and any institution for which the UA IRB is designated as the IRB of record in an Assurance filed with OHRP with a corresponding MOU.

1.2.7.1.1 The Boards are comprised of at least five members (on average 14-18 members) with varying backgrounds and expertise to promote complete and adequate review of research activities commonly conducted by the institution Board expertise will include persons familiar with the various vulnerable populations involved in UA research, a designated community representative, and a designated prisoner representative.

1.2.7.1.2 The membership will be diverse in terms of race, gender, cultural background, and sensitivity to such issues as community attitudes. No board will be composed entirely of men, women, or members of one profession.

1.2.7.1.3 The membership will include at least one person whose primary concern is in a scientific area, at least one whose primary concerns are in a non-scientific area, and at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution (a "non-affiliated" member).

1.2.7.1.4 The membership will include at least one voting compliance staff member. The role of the staff member is to provide historical data, serve as a resource for the board on federal regulations and institutional policies, and participate as a reviewer (when assigned).

1.2.7.2 The Non-Medical IRB reviews studies designated to contribute to knowledge in behavioral, educational, and social science research that do not involve medical testing. (The reviews may involve health-related topics, however, such as participants’ beliefs or practices about disease management, perceptions of stigma, or coping strategies.) Issues of privacy, confidentiality, coercion, and physical, psychological, social, and economic risk are considered for all applications as well as the scientific validity of the protocol.

1.2.7.3 The Medical IRB reviews studies designated primarily to increase the scientific base of information about normal or abnormal physiology and development and
studies primarily intended to evaluate the safety, efficacy, and usefulness of drugs, biologics, medical products, procedures or interventions. Issues of privacy, confidentiality, coercion, and physical, psychological, social, and economic risk are considered for all applications as well as the scientific validity of the protocol.

1.2.7.4 Every effort will be made to promote consistency of procedure and decision making between the two IRBs.

1.2.8 The UA IRB is guided by the ethical principles regarding research with human subjects as set forth in the Belmont Report (“Ethical Principles and Guidelines for the Protections of Human Subjects of Research”).

1.2.9 In reviewing research protocols the UA IRB shall take into account all applicable federal and state laws and federal guidance, including, but not limited to, the regulations of the Department of Health and Human Services (DHHS) at 45 CFR 46, the Food and Drug Administration (FDA) at 21 CFR Parts 50 and 56 pertaining to human subjects research, and the regulations pertaining to privacy in research under the Health Information Portability and Accountability Act (HIPAA) at 45 CFR parts 160 and 164. Guidance from the Office of Human Research Protection (OHRP) and the AAHRPP shall also be used.

1.2.10 In matters involving non-federal jurisdiction, UA will follow Alabama state law. When more than one set of laws is applicable, UA will apply the most stringent law or regulations. When research is conducted elsewhere, local laws take precedence.

1.2.11 In accordance with federal regulations and as part of the Human Research Protection Program, the IRB shall also respond to allegations of non-compliance with IRB decisions or federal or state regulations, work closely with the Office For Sponsored Programs to assure protection of research subjects, and participate in efforts to improve and evaluate the Human Research Protection Program as described in other policies (I.1.D).

1.2.12 The IRB shall notify parties in writing of its decisions to approve, disapprove, modify, re-review, monitor, suspend, or terminate research. If the application was not approved as submitted, the IRB shall specify what questions must be answered or what changes must be made. When the IRB does not approve or approves with modifications, a statement of the reasons for its decision and an opportunity to respond in person or in writing is given to the investigator. The investigator’s response will be reviewed by the IRB at the next scheduled meeting after its receipt (full board-reviewed applications) or by the IRB Chair and Research Compliance Officer (expedited reviews) with the option to refer the comments to the full board.

1.2.12.1 Investigators may appeal board decisions to disapprove or to implement certain modifications by writing to the board explaining their views and may also request to attend the next meeting and discuss the issue with the board.

1.2.13 The Vice President for Research shall receive the minutes of the IRBs to facilitate his/her knowledge of IRB activities, issues, and needs.

1.2.14 The IRB shall maintain and follow all written policies and procedures consistent with federal regulations, ethical principles, and accreditation standards (I.1.D).
1.2.15 The IRB shall serve as the IRB of Record for other institutions as listed on the University of Alabama’s Federal-Wide Assurance with the Office for Sponsored Programs.

1.2.16 Investigators and their research teams shall protect the rights and welfare of human research participants through knowledge about federal and state laws and regulations concerning human subjects; conformity to UA IRB policies for the protection of human research participants; prompt reporting of adverse events or unanticipated problems involving risks to subjects or others and serious or continuing noncompliance with regulations or IRB determinations; and maintaining documents or providing reports to the IRB in accordance with federal regulations and UA or IRB requirements.

1.2.17 Department chairs and/or associate deans or directors of research, or their designees, shall review research activities within their departments to determine that principal investigators are qualified to conduct the research, the design of studies is consistent with generally accepted scientific principles in the discipline, adequate resources are available to conduct the research, that IRB review and approval are obtained, and that student research is guided by UA, HRPP, and departmental policies and adequately supervised.

1.2.18 The Office for Research Compliance will establish an outreach program to educate participants and the community about research and provide methods for people from the university and the external community to make suggestions, ask questions, and voice concerns or complaints about the IRB or their experiences in research.

1.2.19 The Office for Research Compliance shall conduct periodic evaluations of the Human Research Protection Programs and supply those data to the Institutional Official, the Evaluation Committee for HRPP and university officials and administrative or academic units as requested. Such data may be used to revise the number or structure of IRBs, among other uses.

1.2.20 A quality improvement plan shall be instituted for the Human Research Protections Program. See POLICY: Evaluation and Improvement of the Human Research Protections Program.

1.3 Objective.

1.3.1 Adherence to this policy will ensure that the UA IRB complies with federal regulations governing protection of human research participants and accepted ethical principles; that the IRB functions as an independent organization within the University; that policies and procedures governing research with humans; that institutional officials facilitate the work of the IRB; that protection of human research participants is a shared responsibility of the IRB, UA academic departments, and investigators; and that the Office For Research, the Office for Research Compliance, the IRB, the Office For Sponsored Programs, and academic units communicate effectively about research.

1.4 Responsibility.
1.4.1 The responsibility for the protection of human subjects at UA is a shared responsibility between the UA Institutional Official as the institutional representative, the Research Compliance Office, the UA IRB, the Office for Sponsored Programs, UA academic departments, Associate Deans and Directors of Research, and investigators, including members of their research teams. The responsible parties shall coordinate their activities to develop, implement, and review policies and procedures intended to maximize compliance with human subjects’ research-related laws, regulations, and accreditation standards (I.1.D).

2.0 PROCEDURE

2.0.1 This policy is operationalized through all of the policies and procedures, forms, guidance, templates, and educational programs for investigators, and live and online educational programs for community members.

3.0 REFERENCES

3.0 The Belmont Report

3.1 FDA: 21 CFR 56.108 (c), 56.109, 21 CFR 56.115(a)(5), 56.113

3.2 DHHS: 45 CFR 46.103(b)(3), 45 CFR 46.108(b), 45 CFR 160 & 164

3.3 OHRP Step-by-Step Instructions on Registering an Institutional Review Board (IRB) or Independent EC (IEC)

3.4 FDA Information Sheets: Frequently Asked Questions: IRB Membership, IRB Procedures

4.0 RELATED SECTIONS

4.1 All documents concerning the IRB and investigators are related to this policy.