1.0 POLICY

1.1 Background.

1.1.1 Sponsors and the institutions receiving research monies have obligations to protect research participants. As an institution receiving research funds from private and public sources, The University of Alabama must identify and address human research protection requirements with all sponsors.

1.1.2 The Office for Sponsored Programs (OSP) reviews, approves and provides the institutional signature for proposals, awards, and contracts. OSP is responsible for:

1.1.2.1 The dissemination and monitoring of Federal laws and regulations, state laws and regulations as well as University policies and procedures regarding the management of sponsored programs.

1.1.2.2 Submitting all proposals for externally funded projects, which includes receiving appropriate assurances and approvals from university administrators for submission of proposals.

1.1.2.3 Furnishing reports on key statistics applicable to all sponsored projects.

1.1.2.4 Reviewing awards receive for accuracy and acceptability of terms and verifying compliance prior to establishing the award. The award is then given to the OSP Financial Services Office which is responsible for creating proper accounts and ensuring that financial transactions comply with fiscal and reporting requirements established by Federal and State law, agency regulations, University policies and procedures and generally accepted accounting principles.

1.1.2.5 Monitoring compliance from proposal creation to award final close out of externally funded projects.

1.1.3 NOTE: This policy deals only with Human Research Protections aspects of sponsored research. Other University and OSP policies on financial and legal aspects of sponsored research are available on the OSP website.

1.2 Policy Statement

1.2.1 It is the policy of the University of Alabama Office for Sponsored Programs that:
1.2.1.1 The Human Research Protections Program (HRPP) applies to all sponsored research, projects, and other scholarly activities using human research participants, regardless of the student or faculty status of the investigator/director, the nature of the investigation/project, or the source, size, or duration of the award or other support.

1.2.1.2 All sponsored programs are subject to appropriate state and Federal laws and regulations, as well as University of Alabama policies and procedures. The University shall require compliance with its policies and procedures on all sponsored projects to receive assurance of adequate protection for human research participants. The University of Alabama IRB will not deviate from its policies and procedures pertaining to the protection of human research participants at the request of a sponsor.

1.2.1.3 The OSP shall establish written agreements with research sponsors that obligate sponsors to promptly report to the organization any findings (no longer than within 30 days) of study monitors that could affect the safety of subjects or alter the IRB's approval to continue the study; any findings that influence the conduct of the study, the safety of participants, the provision of information about the dissemination of new study, related information that might influence willingness of participants to continue with the study, or the willingness of IRB to grant approval for continuation of the study.

1.2.1.3.1 Written agreements shall describe the communication of results from a research study to subjects when those results directly affected their safety or medical care.

1.2.1.4 Written agreements shall address arrangements for the definition, provision and payment for medical care needed from a research-related injury.

1.2.1.5 The University of Alabama shall adhere to sponsor requirements set forth in the protocol or research agreement regarding the reporting of any adverse event experienced by a research participant.

1.2.1.6 No sponsored project involving human research participants may begin nor an account be established without confirmation that IRB approval has been received and that other regulatory requirements for the protection of human research participants have been met.

1.2.1.7 Sponsored research agreements for clinical trials negotiated by OSP shall include reference to the written protocol and language allowing the sponsor and regulatory authorities the right to inspect the University’s property and documents related to the performance of a trial to ensure it is being conducted in accordance with the protocol and applicable law.

1.2.1.8 In nonclinical research agreements the responsibility for human research protections shall be included in the work statement or the sponsored research agreement.

1.2.1.9 OSP shall monitor compliance with agency policies, guidelines and award terms including verifying appropriate regulatory approvals and assurances are in place,
prior to submitting a proposal. OSP monitors compliance with reporting requirements upon notification of the receipt of an award and serves as the authorized institutional contact for late technical report notices. OSP notifies appropriate officials of non-compliance when they are discovered, or when they have been reported to OSP.

1.2.1.10 Investigators will keep both OSP and the DRC informed of all developments that affect the welfare of human research participants.

1.2.1.11 OSP and the Office for Research Compliance (ORC) shall communicate with each other about aspects of sponsored research that affect human research participants and investigator compliance with OSP and IRB requirements. A dual system of investigator reporting, and OSP/DRC verification will strengthen the protection of human research participants.

1.2.1.12 Contracts or other funding agreements require the sponsor to send data and safety monitoring plans and reports to the university. Contracts or other funding agreements specify the time frame for providing routine and urgent data and safety monitoring reports to the university as indicated in the data and safety monitoring plan approved by the IRB.

1.2.1.13 Contracts or other funding agreements describe the steps followed to communicate findings from a closed research study to the investigator or university when those findings directly affect participant safety. Contracts or other funding agreements specify a time frame after closure of the study during which the sponsor will communicate such findings (for example, two years). Alternatively, the time frame may be based on a specific triggering event (such as completion of data analysis) or left open-ended or the requirement can be included or referred to in a survivor clause. This should be based on the appropriate timeframe for each individual study.

1.3 Objective

1.3.1 Adherence to this policy will ensure that sponsored projects at UA meet legal, regulatory, and accreditation standards and follow UA policies and procedures for the protection of human research participants.

1.4 Responsibility

1.4.1 The ultimate responsibility for this policy rests with the Vice President for Research. Enabling parties are the Director of Research Compliance (DRC), the Director and Associate Director of Sponsored Programs, the staff of the Office for Sponsored Programs, the IRBs, Associate Deans/Directors for Research, and investigators.

2.0 PROCEDURE

2.1 Investigator Actions and Responsibilities
2.1.1 The investigator carries out all responsibilities identified in GUIDANCE: General Responsibilities of Investigators as they relate to sponsored research and conforms to all study-relevant IRB policies.

2.1.2 The investigator obtains IRB approval of the proposal at the time required by the sponsor, e.g., before submission of the proposal for sponsor support or upon notification that funding is likely or will follow contingent on IRB approval.

2.1.3 If an investigator received IRB approval for a study identified as unfunded or self-supported and later submits that study for funding, the investigator informs the Director of Research Compliance (DRC) of this action and submits a new IRB application if the study has been changed since the original approval.

2.1.4 If the proposal is revised in response to sponsor feedback and differs from that originally approved by the IRB, the investigator submits a revised application to IRB outlining the changes.

2.1.5 The investigator completes the Internal Coordination Sheet (sometimes called the routing sheet). This sheet is available from the OSP website under “Forms”. This form solicits necessary information about the proposed activity or project seeking an external sponsor, such as key personnel and their contact information, facilities requirements including the safety of the work environment, cost sharing information, and various compliance reviews of interest to IRB (conflict of interest; human subjects; use of blood, blood products, or human tissues; radioactive or hazardous materials) and the relevance of Federal Export Control Regulations. Directions for consulting other policies and other forms to attach are provided.

2.1.5.1 Investigators are welcome to call OSP if they have questions about proper completion of the Internal Coordination Sheet.

2.1.5.2 The status of the application’s IRB approval—either the number of the policy and the date of IRB approval or the word “pending”—must be indicated on the Internal Coordination Sheet.

2.1.5.3 Currently, the investigator can complete the Internal Coordination Sheet online but must print the completed form and return it to the Office for Sponsored Programs.

2.1.6 Once approved and funded, the investigator complies with all IRB policies regarding protection of human research participants, including continuing review, reporting of unanticipated problems, and study closure. (See online list of IRB policies).

2.1.7 The investigator communicates with the sponsor and OSP about study progress and problems.

2.1.8 The investigator notifies the ORC when the sponsor makes changes in the study that affect human research participants and submits IRB applications for protocol modification when needed.

2.2 IRB and OSP Actions and Responsibilities
2.2.1 Upon receipt of an award OSP staff will verify the Internal Coordination Sheet report of IRB status with the Office for Research Compliance to determine that the IRB approval is current.

2.2.2 OSP staff will inform the DRC of sponsor audits of approved sponsored studies.

2.2.3 The DRC will inform OSP of any gaps in approval and of closure of the study to data collection.

2.2.4 The DRC may request to review the grant file of an approved sponsored study to verify that the application is the same as that received by IRB, to review investigator and sponsor communications, or for any other matter possibly related to the protection of human research participants.

2.2.5 If the IRB monitors the study for cause and suspends or terminates the study, the DRC will notify the OSP.

3.0 REFERENCES

3.1 45 CFR §46.116(a)(6), 45 CFR §46.116(a)(7)

3.2 21 CFR §50.25(a)(6), 21 CFR §50.25(a)(7)

4.0 RELATED SECTIONS

4.1 GUIDANCE: General Responsibilities of Investigators

4.2 GUIDANCE: Informed Consent Template