1.0 POLICY

1.1 Background.

1.1.1 The University of Alabama is committed to the identification and management of conflict of interest in all aspects of research and sponsored programs and to ensuring objective review for applications submitted to the IRB.

1.1.2 Key Definitions for IRB Members and Consultants (NOTE: These are more stringent than those that apply to investigators in that members, chairs, or consultants may not receive any financial benefit/equity from an IRB application):

1.1.2.1 Conflict of Interest (COI) for an IRB Member, Chair, or Consultant: Any interest that competes with their ability to provide an objective review of an application. Includes not only personal, professional, or financial conflicts but also those of the immediate family members. IRB members are prohibited from owning equity in the university, if appropriate.

IRB members or consultants are defined when they have a conflicting interest as follows:

Financial Interest Related to the Research means financial interest in the sponsor, product or service being tested. [Or equivalent or stricter.]

Involvement of the IRB member, consultant, or their immediate family in the design, conduct, or reporting of the research.

1.1.2.2 Immediate Family Members: The spouse, parent or parent of a spouse, child or child of a spouse, sibling or sibling of a spouse, or a dependent. This includes "step" relationships.

1.1.2.2.1 A dependent is any person who resides with an IRB member or consultant or who receives 50% or more support from an IRB member, regardless of age. This includes adult children (in Alabama, those aged 18 and over) and "step" relationships.

1.1.2.3 A personal conflicting interest means that the IRB member, consultant, or an immediate family member serves as a contributor to the research project as an investigator, collaborator, consultant, research staff, or faculty supervisor. Also, members or chairs who are uncomfortable with being present for review of an application from a supervisor may regard this as a personal conflicting interest.
1.1.2.4 A **professional conflicting interest** means the IRB member, consultant, or an immediate family member) serves as trustee, director, officer, manager, or scientific advisor of any entity sponsoring the research.

1.1.2.5 A **financial conflicting interest** for IRB members and immediate family means that the IRB member or the spouse or dependent of a member or the spouse has or receives something of monetary value (no minimum amount applies) including, but not limited to, salary or payments for other services (e.g., consulting fees or honoraria), equity interests (e.g., stock, stock options, or any other ownership interests), intellectual property rights (e.g., patents, copyrights, and royalties from such rights) with respect to the research (including the product or service being evaluated) or research sponsors.

1.1.2.6 The above definition applies to consultants and their immediate family members except that the consultant may receive a consulting fee from the University of Alabama.

1.1.2.7 Financial conflicting interest for IRB members, consultant, and immediate family members EXCLUDES an interest arising from investment in a business by publicly traded mutual funds, pension funds, or institutional investment funds over which the IRB member, consultant, spouse, or dependent does not exercise control of investment decisions.

1.2 Policy Statement.

1.2.1 **It is the policy of the University of Alabama that IRB members and consultants must disclose conflicts of interest to the IRB as soon as they realize a conflict exists and shall not participate in discussing, or voting on applications reviewed at any level (exempt, expedited, or full-board), except to provide information requested by the IRB. IRB members with a conflicting interest shall leave the meeting room for discussion and voting.** This policy applies also to meetings at which unanticipated problems involving risk to participants or others arise or at which possible non-compliance with the requirements of the IRB are discussed.

1.2.2 IRB members and consultants will avoid the appearance of COI and exercise their own judgment to absent themselves from review, discussion, or vote on any application or agenda item to avoid the appearance of a COI, bias, or effects of undue influence upon them.

1.2.3 The IRB Chair or Director of Research Compliance (DRC) shall be available as needed to discuss issues of COI with members or consultants.

1.2.4 IRB members or Chairs with conflicts shall not be counted towards quorum for discussion of an application.

1.2.5 IRB minutes shall identify persons who have excused themselves for COI or its appearance, note that a COI was the reason for the absence, and state whether persons with conflicts were allowed to provide information to the IRB.
1.2.6 The IRB shall not retain consultants with conflicting interests unless it is impracticable to get needed information otherwise. **In this case, the consultant shall be excluded from the discussion except to provide information requested by the IRB, shall leave the meeting room for discussion and voting, and the consultant’s COI shall be disclosed to the IRB during its review.**

1.2.7 Objective

1.2.7.1 Adherence to this policy will ensure identification and management of COI among IRB members and consultants and objective review of applications before the IRB.

1.3 Responsibility.

1.3.1 The Vice President for Research is ultimately responsible for this policy. Enabling parties include the Research Compliance staff, IRB chairs and members, and consultants.

2.0 PROCEDURE

2.1 COI for IRB members and chairs

2.1.1 Upon receipt of applications, the Research Compliance staff will review them for the presence of the names of IRB members or chairs in any capacity (co-investigators, student advisors, consultants, etc.) If found, the application will not be assigned to those IRB members, and a Chair in conflict will delegate leadership of the discussion of that application to the Vice Chair or, in the Vice Chair’s absence, to the Director of Research Compliance.

2.1.2 Upon receipt of an assigned application, reviewers will identify any COI or appearance of COI and promptly inform the Research Compliance Specialist that they are unable to review that application by signing and returning the first page of FORM: IRB Checklist for Reviewers and Investigators. (They may discuss the issue with Research Compliance staff if they have doubts about the presence or nature of conflict). The Research Compliance staff will reassign the application if necessary.

2.1.2.1 It is possible that the member with actual or apparent COI may be the only person with certain essential experience or information about the research topic. In such cases the IRB chair (full board) or DRC (expedited or exempt) may ask the member to review the application and provide his information but to abstain from voting on it.

2.1.3 In the event that a member does not realize s/he has a conflict with the application until it is presented in a convened meeting, s/he should immediately state that a COI exists and leave the room.

2.1.4 In the minutes of the meeting the IRB secretary will (a) record the names of members or chairs in conflict and when they leave and return, (b) state that COI was the
reason for the absence, and (c) state whether persons in conflict were allowed to provide information to the IRB.

2.2 COI for Consultants

2.2.1 Research Compliance staff who contact potential consultants about service will briefly describe the proposal and identify the investigator and inquire whether the consultant foresees any COI. If not, they will send the consultant the application, a copy of this policy, and FORM: Agreement to Serve as A Consultant to IRB.

2.2.2 The consultant will be instructed to review the application promptly and notify UA IRB by phone or e-mail of any COI that becomes apparent so that another consultant may be found.

2.2.3 If no conflict is identified, the consultant reviews the application as requested and returns it and the completed FORM: Agreement to Serve as A Consultant to IRB to the Director of Research Compliance.

2.2.4 If the consultant identifies a COI or the possible appearance on one, the Director of Research Compliance will decide whether to invite the consultant to continue and provide information to the IRB. (The FORM: Agreement to Serve as a Consultant to IRB requires identification of the presence or absence of COI and the charge to provide information, regardless of the presence of a conflict.)

2.2.5 The DRC will present the consultant’s information to IRB and inform the IRB orally of the consultant’s conflicting interests. This shall be noted in the minutes.

2.2.6 Consultants do not vote on proposals.

3.0 REFERENCES

3.1 45 CFR §46.107(e)

3.2 21 CFR §56.107(e)

4.0 RELATED SECTIONS

4.1 POLICY: Obtaining Additional Expertise or Expert Consultation for IRB Review

4.2 POLICY: Conflict of Interest for IRB Members, Chairs, and Consultants

4.3 FORM: IRB Checklist for Reviewers and Investigators, page 1

4.4 FORM: Agreement to Serve as Consultant to IRB

4.5 POLICY: UA Policy on COI/Financial Disclosure in Research and Other Sponsored Program