1.0 POLICY

1.1 Background.

1.1.1 Conflicts of interest (COI) for investigators, immediate family, or research staff members may adversely affect the protection of human research participants in terms of the criteria for IRB approval or the integrity of the research.

1.1.2 The regulations of the Public Health Service, Food and Drug Administration, and the National Science Foundation apply to the University of Alabama.

1.1.3 This policy deals only with the investigator’s responsibilities to IRBs and IRB’s responsibilities to investigators in regard to declared or undeclared investigator COI. See POLICY: Conflict of Interest for IRB Chairs, Members, and Consultants for these persons’ responsibilities.

1.2 Policy Statement.

1.2.1 It is the policy of the University of Alabama that all UA investigators conducting research with human research participants shall comply with the University of Alabama Policy on the Conflict of Interest/Financial Disclosure in Research and Other Sponsored Programs and that all Research Compliance staff and IRB chairs and members will be familiar with that policy for use in evaluating research applications.

1.2.2 Evaluation of the existence, nature, or effects of COI shall be a consideration in all levels of review (exempt, expedited, full board) and upon both initial and continuing review.

1.2.3 In many cases the investigator’s financial interests will be identified and managed prior to IRB approval. However, the IRB has the final authority to identify COIs not previously declared by an investigator, disagree with the approved management plan, require changes in the research plan, impose additional or different disclosure requirements to human research participants, and to determine whether the research will be approved.

1.2.4 Objective
1.2.4.1 Adherence to this policy will insure that investigator conflict of interest (COI) does not adversely affect the protection of human research participants or the integrity of research conducted under the auspices of the University of Alabama.

1.3 Responsibility.

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

2.0 PROCEDURE

2.1 Investigator Responsibilities

2.1.1 The investigator follows the procedures described in The University of Alabama Policy on the Conflict of Interest/Financial Disclosure in Research and Other Sponsored Programs for reporting COI and working with the Director of Research Compliance on the management of COI.

2.1.2 The investigator prepares the IRB application and includes:

2.1.2.1 Disclosure of any COI and an explanation of how s/he will or might gain from that interest;

2.1.2.2 A description of the management plan specified by the Director of Research Compliance (DRC) or Legal Counsel (if any);

2.1.2.3 A description of how the COI may affect the protection of human participants or the integrity of the research and how those impacts may be avoided, reduced, or monitored;

2.1.2.4 A description of any disclosure made to prospective human participants in the consent process and documentation. This may include use of a statement similar to the following: The researcher owns stock [or has some other financial interest] in the company sponsoring this study which creates a conflict of interest. This conflict of interest has been reviewed by the University of Alabama IRB and the University of Alabama Conflict of Interest Review Board. A Conflict of Interest Management Plan has been put in place to ensure that the financial interest of the researcher does not create additional risk to participants or have any other adverse impact on this study.

2.1.3 The investigator responds to any requirements or recommendations by the IRB after review of the application.

2.1.4 The investigator submits notice of any change in COI issues to the IRB within ten working days of his/her awareness of the issue by filing FORM: Modification of an Approved Proposal.

2.2 IRB Responsibilities
2.2.1 The primary reviewer and other IRB members review the application using FORM: IRB Checklist for Reviewers and Investigators, attending to the COI question applicable to all levels of review. For initial review: Is there an undeclared or declared conflict of interest (COI) for the investigator or staff that may adversely affect the protection of participants in terms of criteria for IRB approval or the integrity of the research? For continuing renewal, has new information about COI become available? If so, does it affect participant risk or research integrity?

2.2.2 Discussion of COI issues covers the possible impact of the COI on risk to or protection of human participants and the integrity of the research, the need for a management plan if none was supplied (e.g., the board identifies an undeclared COI), adequacy of the management plan proffered, and the nature and adequacy of disclosure to participants.

2.2.3 The actions the IRB may take in regard to COI include the following:

2.2.3.1 Request for revision and resubmission of the application to include management of a COI identified by the board but not disclosed by the investigator; (NOTE: This may require the investigator to file a COI disclosure and work through the steps described in POLICY: UA Policy on Conflict of Interest/Financial Disclosure in Research and Other Sponsored Programs.)

2.2.3.2 Approval of the application as submitted (COI has been handled satisfactorily);

2.2.3.3 Requirement of changes in the research design to protect human participants;

2.2.3.4 Requirement of changes in the disclosure process and informed consent document to inform prospective participants more fully;

2.2.3.5 Requirement for changes in the management plan;

2.2.3.6 Requirement that the consent process be observed on some schedule by an IRB member or Research Compliance staff member;

2.2.3.7 Recommendation that the study be monitored within the approval period;

2.2.3.8 Specification of a schedule for more frequent continuing review;

2.2.3.9 Disapproval of the application

2.2.3.10 The IRB has the final authority over the approval of applications involving COI.

2.3 Research Compliance Staff Responsibilities.

2.3.1 The minutes will reflect IRB discussion and decisions about COI issues.

3.0 REFERENCES
3.1 DHHS: 42 CFR 50.603; 42 CFR 50.606(a), 45 CFR 690

3.2 FDA: 21 CFR 54.1,2; 21 CFR 54.4; 21 CFR 312.64(d); 21 CFR 812.110(d)

4.0 RELATED SECTIONS

4.1 POLICY: UA Policy on Conflict of Interest/Financial Disclosure in Research and Other Sponsored Programs

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

4.3 FORM: IRB Checklist for Reviewers and Investigators

4.4 GUIDANCE: Responsibilities of Investigators