1.0 POLICY

1.1 Background.

1.1.1 A test article is any drug, biological product, or medical device for human use; any human food or color additive; any electronic product or any other article subject to regulation under the FDA or sections 351 or 354-60 of the Public Health Service Act [CFR § 50.31(j) or 21 CFR §56.102(l)].

1.1.2 This policy deals only with drugs or biologicals. See POLICY: Conformity of Investigational or Unlicensed Test Articles (Devices) for information about using devices.

1.2 Policy Statement.

1.2.1 It is the policy of the University of Alabama that investigational or unlicensed test articles will conform to federal regulations.

1.2.2 All initial requests for IRB approval of a study that includes the use of an investigational drug, agent, or biologic will be reviewed by the full Medical IRB.

1.3 Objective

1.3.1 Implementation of this policy will ensure conformity of UA research with federal regulations, thus advancing the protection of human research participants.

1.4 Responsibility.

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

2.0 PROCEDURE

2.1 The investigator will follow relevant federal regulations (see GUIDANCE: Regulatory Requirements for Investigators Who Hold INDs or IDEs) and provide the following information regarding the use of investigational drugs, agents, and biologicals in the IRB application or the appendixes:

2.1.1 The IND number;
2.1.2 IF the investigator holds the IND, a copy of the FDA approval letter;

2.1.3 Investigator Statement FDA Form #1572;

2.1.4 Any supplemental information about the drug, agent, or biologic supplied by the sponsor;

2.1.5 Justification for the conditions required for a drug, agent, or biological to be exempt from the requirements of an IND;

2.1.6 A description of the inventorying, storage, handling, and dispensing of the products. This may include such information as a log of all drugs dispensed, storage in a double-locked cabinet or refrigerator; and disposition of the drug/product upon completion of the study;

2.1.7 A description of the informed consent process and documentation, unless a waiver has been requested;

2.1.8 NOTE THAT AS OF MARCH 7, 2012, the FDA requires the following language in all consent forms for drug or device clinical trials that are initiated on or after that date: “A description of this clinical trial will be available on [http://www.ClinicalTrials.gov](http://www.ClinicalTrials.gov) as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search the website at any time.”

2.1.9 Notification of the IRB of any modifications, serious adverse events, or unanticipated problems to participants or others that occur during the research or follow-up period. See POLICY: Modification of Approved Protocols; POLICY: Continuing Review of Approved IRB Protocols; POLICY: Reportable Events: Protocol Deviations, Unanticipated Problems, and Adverse Events Involving Participants Or Others; FORM: Reporting of Study Problem; POLICY: Closure of Approved Protocols.

2.1.10 Complete and submit applications for continuing reviews at IRB-designated intervals;

2.1.11 Notify FDA and the sponsor of closure of the study and return all unused products in accordance with the sponsor’s instructions;

2.2 The Research Compliance Specialist (RCS) will pre-review applications and request any necessary revisions or additional materials. The RCS will also verify that the IND is valid. This involves ascertaining that the number supplied by the investigator matches the sponsor’s protocol, a letter from the FDA, or a letter from the sponsor. Once the application is complete, it will be assigned to reviewers and placed on the agenda for the next IRB meeting.

2.3 The IRB will review the application in accordance with usual procedures for full board review but paying special attention to the following: The process to control investigational drugs so that they were used only in approved research protocols and under the direction of approved investigators.
2.3.1 If the investigator is requesting that the article be exempt from IND requirements, the IRB will discuss each of the conditions for an exemption and determine if the justification offered is adequate for an exemption.

2.3.1.1 Exemption 1:

2.3.1.1.1 The drug product is lawfully marketed in the United States.

2.3.1.1.2 The investigation is not intended to be reported to FDA as a well-controlled study in support of a new indication for use nor intended to be used to support any other significant change in the labeling for the drug.

2.3.1.1.3 If the drug that is undergoing investigation was lawfully marketed as a prescription drug product, the investigation was not intended to support a significant change in the advertising for the product.

2.3.1.1.4 The investigation does not involve a route of administration or dosage level or use in a patient population or other factor significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product.

2.3.1.1.5 The investigation is conducted in compliance with 21 CFR 50 and 56.

2.3.1.1.6 The investigation is conducted in compliance with the requirements of 21 CFR 312.7.

2.3.1.2 Exemption 2:

2.3.1.2.1 A clinical investigation is for an in vitro diagnostic geological product that involves one or more of the following: Blood grouping serum, reagent red blood cells, or anti-human globulin.

2.3.1.2.2 The diagnostic test is intended to be used in a diagnostic procedure that confirms the diagnosis made by another medically established, diagnostic product or procedure.

2.3.1.2.3 The diagnostic test is shipped in compliance with 21 CFR 312.160.

2.3.1.3 Exemption 4:

2.3.1.4 A clinical investigation involving use of a placebo if the investigation does not otherwise require submission of an IND.

2.3.2 Determination of the scientific soundness of the study as it relates to the risk/benefit ratio. This includes design, study population, trial phase, and mechanisms for data analysis and surveillance.

2.3.3 Concerns that affect the risk/benefit assessment. This may include prior reviews by the FDA, other institutions, scientific review committees, and funding agents. The
Board may also seek expert consultation or a literature review from the medical librarian.

2.3.4 The adequacy of the consent document, whether it meets the criteria for informed consent, including the notification that the FDA may have access to the participants’ study records, and procedures for obtaining informed consent.

2.3.5 The maintenance of the distinction between therapy and research and the investigator’s recognition of any conflicts between status as an investigator and the participant’s personal physician. The IRB may require the investigator to inform the patient/prospect of this potential conflict.

2.3.6 Applications for renewals or modification of the protocol will be reviewed at the level for which the criteria are met.

3.0 REFERENCES

3.1 45 CFR 46.111; 21 CFR 56.111


3.3 21 CFR §312.61,62,69

3.4 21 CFR §812.100, 110, 140 (a)

4.0 RELATED SECTIONS

4.1 GUIDANCE: Regulatory Requirements for Investigators Who Hold INDs or IDEs

4.2 GUIDANCE: IRB Application Guide

4.3 POLICY: Continuing Review of Approved IRB Protocols

4.4 POLICY: Modification of Approved Protocols

4.5 POLICY: Reportable Events: Protocol Deviations, Unanticipated Problems, and Adverse Events Involving Participants Or Others

4.6 FORM: Reporting of Study Problem

4.7 POLICY: Closure of Approved Protocols