1.0 POLICY

1.1 Background.

1.1.1 Only applications that involve human participants and that meet criteria as research will be reviewed by an IRB. Therefore, the IRB must have policies, procedures, and criteria for making that determination.

1.1.2 The determination of human subjects research at UA is governed by both DHHS and FDA regulations.

1.1.3 There are no Alabama state laws addressing the nature of research or human participants (opinion of University legal counsel).

1.1.4 Key DHHS definitions (45 CFR 46):

1.1.4.1 Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

1.1.4.1.1 Systematic investigation includes surveys and questionnaires, interviews and focus groups, analyses of existing data or biological specimens, epidemiological studies, evaluations of social or educational programs, cognitive and perceptual experiments, and medical chart review studies.

1.1.4.1.2 Generalizable knowledge means investigations designed to allow drawing of general conclusions, inform policy, or generalize findings beyond a single individual or an internal program (e.g., publications and presentations), regardless of whether publication or presentation actually occurs.

1.1.3.2 Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information.

1.1.3.2.1 Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.
1.1.3.2.2 *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is given or may be readily ascertained by the investigator or is associated with the information) in order for obtaining the information to constitute research involving human subjects.

1.1.4 Key FDA definitions (21 §56.102):

1.1.4.1 *Clinical investigation* means any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) or 520 (g) of the act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The terms *research, clinical research, clinical study, study,* and *clinical investigation* are deemed to be synonymous for purposes of this part.

1.1.4.2 *Test article* means any drug for human use, biological product for human use, medical device for human use, human food additive, color additive, electronic product or any other article subject to regulation under the Federal Food, Drug, and Cosmetic Act or under sections 351 or 354-360F of the Public Health Service Act.

1.1.4.3 *Human subject* means an individual who is or becomes a participant in research either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient. For research involving medical devices a human subject is also an individual on whose specimen an investigational device is used.

- When medical device research involves in vitro diagnostics and unidentified tissue specimens, the FDA defines the unidentified tissue specimens as human subjects.

1.1.4. DoD requirements:

The definition of “experimental subject” as an activity, for research purposes, where there is an intervention or interaction with a living individual for the primary purpose of obtaining data regarding the effect of the intervention or interaction. Research involving experimental subjects as defined in DODI 3216.02 is a subset of research involving human participants.

1.2 Policy Statement

1.2.1 It is the policy of the University of Alabama (UA) Institutional Review Board (IRB) to have sole authority to determine whether an activity meets the definition of “Human Subject Research” by either DHHS or FDA regulations.
1.2.2 When activities are conducted that might represent “Human Subject Research”, the activities must be submitted to the IRB for a determination. The UA IRB does not identify any category of study (program evaluation, oral history, etc.) as blanketly exempt from IRB review.

1.2.3 The IRB has designated the Director of Research Compliance (DRC) to make the determination that a proposal is research and involves human subjects.

1.2.4 An investigator may request a determination that an activity is “Human Subject Research” but the final determination will be made by the DRC.

1.2.5 All requests for determinations concerning human subject research must be in writing.

1.2.6 IRB chairs and members have the right to question decisions about human subjects research when assigned to protocols, participating in IRB deliberations, or upon viewing the Protocol Summary Sheet, may request to review listed protocols.

1.2.7 Investigators shall be notified about the classification of their research applications.

1.2.8 The UA IRB shall provide guidance to investigators about the DHHS and FDA definitions of human subjects research/clinical investigations.

1.3 Objective.

1.3.1 Implementation of this policy ensures that protocols involving human subjects research are identified in order to provide IRB review and that federal regulations for IRB review are met.

1.4 Responsibility.

1.4.1 The Vice President for Research is ultimately responsible for this policy. Enabling parties are the Director of Research Compliance (DRC), the IRB chairs and members, Associate Deans/Directors of Research, and investigators.

2.0 PROCEDURE

2.1 Investigators should evaluate whether their studies involve human research by viewing FORM: Human Research Determination Checklist (DHHS and FDA). This form lists DHHS and FDA criteria for this decision. If it is clear to the investigator that the research involves human subjects, s/he should submit the IRB application describing involvement and protection of human subjects.

2.2 If in doubt, Investigators may request determinations of human subjects research in writing by letter or email memos describing the project or may submit a complete application to the IRB.
2.2.1 The Director of Research Compliance (DRC) will review the protocol/information and compare it to FORM: Human Research Determination Checklist (DHHS and FDA).

2.2.2 For DHHS regulated research, the DRC will first decide whether the activity is research and if so, whether it involves human participants.

2.2.3 For FDA-regulated research, the DRC will first decide whether the activity is a clinical investigation as defined by FDA, and if so, whether it involves human participants.

2.3 The DRC will communicate all decisions about human research participation to investigators in writing within one week of receipt of the request/application.

2.3.1 Investigators of projects deemed to involve research and human subjects/participants will be notified by e-mail and instructed to submit a complete proposal if that was not done initially.

2.3.2 Investigators of projects not deemed to involve research or human participants will receive a letter about this decision.

2.4 The investigator proceeds in accordance with feedback about human research participation from the DRC and submits a proposal as directed.

2.5 If circumstances change such that a research study not deemed to involve human subjects does involve them, the investigator shall stop research until an application for involvement of human subjects can be submitted to and approved by the IRB.

3.0 REFERENCES

3.1 45 CFR §46.101(a), 45 CFR § 46.102(d), 45 CFR §46.102(f)

3.2 21 CFR §50.1, 21 CFR §50.3 (a), 21 CFR §50.3(c), 21 CFR §50.3(g), 21 CFR §50.3(j), 21 CFR §56.101, 21 CFR § 56.102(c), 21 CFR §56.102(l); DOJ 28CFR 512.10

4.0 RELATED SECTIONS

4.1 FORM: Human Research Determination Checklist (DHHS and FDA)

4.2 GUIDANCE: IRB Application Guide

4.3 GUIDANCE: General Responsibilities of Investigators