1.0 POLICY

1.1 Policy Statement.

1.1.1 It is the policy of the University of Alabama that recruitment plans for research projects will ensure appropriate and equitable selection of subjects by age, gender, race, and ethnicity. In order to assess the appropriateness of the proposed research participants, the IRB requires the PI to provide information on the characteristics of the participant population, age ranges, health status, gender and criteria for inclusion or exclusion. The IRB is authorized to review the purposes of the research, the setting of the research, and whether the population to be recruited is vulnerable to coercion or undue influence. Regulatory determinations will be made if a project proposes to recruit pregnant women (45 CFR 56 Subpart B), prisoners (45 CFR 46 Subpart C), 21 CFR 50 Subpart D) or children (45 CFR 46 Subpart D, and 21 CFR 50 Subpart D).

1.1.2 The IRB will assess the recruitment plan to ensure that it is compliant with federal regulations, as well as HIPAA Privacy Policies.

1.1.3 Advertising and subject incentives are covered in POLICY: Subject Recruitment and Compensation.

1.2 Objective

1.2.1 Adherence to this policy will ensure that the burdens and benefits of research are equitably distributed.

1.3 Responsibility.

1.3.1 The Vice President for Research is ultimately responsible for this policy. Enabling parties include the Director of Research Compliance, IRB chairs and members, study investigators, and faculty supervisors of student research.

2.0 PROCEDURE

2.1.1 Study investigators will provide the IRB a description of the proposed participant population in the IRB application.
2.1.1.1 If special or vulnerable populations (children, pregnant women, cognitively impaired persons, prisoners), investigators will complete and attach the appropriate supplementary forms identified in the policies on those populations.

2.1.1.2 If vulnerable populations relevant to the research but not described in the federal regulations are used (students, employees, etc.), they will be named, their use will be justified, and measures for their protection as a vulnerable population (e.g., threats to employment if they expressed critical views) will be described within the protocol.

2.1.2 The investigator will include in the protocol description the characteristics of all proposed participant populations, including the following population characteristics:

A. Gender  
B. Age  
C. Race  
D. Ethnicity  
E. Institutional Status  
F. Health Status  
G. Membership in Special Populations (Children, Cognitively Impaired, Prisoners, Pregnant Women and Fetuses; others specific to study such as employees or immigrants)  
H. Students from Research Subject Pools or specific courses  
I. Subjects’ level of education, English language proficiency, and language preference as appropriate

2.2 The investigator justifies the need for inclusion or exclusion of groups with certain characteristics and the use of Protected Health Information in selection or pre-study screening of potential participants.

2.3 The Research Compliance Specialist communicates with the investigator about any needed additions to or modifications of the recruitment plan, and with the Director of Research Compliance, determines the needed level of review.

2.4 The reviewer/IRB reviews information provided by the investigator and determines whether the research burden is appropriate for the proposed participants.

2.4.1 In assessing the selection of subjects for a research project the IRB considers the following:

A. Requirements of the study setting and study design;  
B. Subjects’ susceptibility to risk;
C. Likelihood that the benefits will be realized by the subjects;
D. Practicability of the proposed research;
E. Fairness of the proposed research design, including inclusion and exclusion criteria;
F. Whether Protected Health Information about prospective participants is justified and adequately protected from access by others.
G. Whether the use of vulnerable populations is appropriate. Vulnerable populations must not be used merely because they are readily available to the investigator.

3.0 REFERENCES

3.1 45 CFR Part 46. 111(a) (3)
3.2 45 CFR 46. 116
3.3 21 CFR Part 56. 111(a)(3)
3.4 OHRP Guidance on Written Institutional Review Board Procedures
3.5 FDA: 21 CFR 56.111(a)(3), 21 CFR 50.20, 21 CFR 556, 111(a) (3)

4.0 RELATED SECTIONS

4.1 POLICY: Subject Recruitment and Compensation.
4.2 FORM: IRB Checklist for Reviewers and Investigators
4.3 GUIDANCE: IRB Application Guide
4.4 GUIDANCE: IRB Advertising Guidelines
4.5 GUIDANCE: Templates for Medical and Non-Medical Informed Consents
4.6 POLICY: Protection of Pregnant Women, Fetuses, and Neonates
4.7 POLICY: Protection of the Cognitively Impaired
4.8 POLICY: Protection of Prisoners
4.9 POLICY: Protection of Children in Research

4.10 POLICY: Protection of Human Research Participants’ Privacy and Confidentiality