1.0 POLICY

1.1 Background.

1.1.1 The University of Alabama (UA) values student learning about research for both students who will and will not become scientists. Adults with knowledge of the value and processes of research are better prepared for their civic responsibilities in the future than adults who are not. UA also understands that ready access to a large number of research participants is desirable for faculty investigators and graduate students.

1.1.2 A student research pool is defined as a group of students who by virtue of enrollment in a particular course or department or attainment of a certain status (e.g., majors, upper division students) are expected to serve as prospective human participants for faculty and graduate student research as part of their learning. In recognition of the principle of autonomy and the right of prospective research participants to refuse participation, student research pool members are also given alternatives to research participation that will satisfy course requirements.

1.1.3 Students are a vulnerable population in relation to faculty.

1.1.4 An underlying principle of the regulations governing use of human subjects in research is that the subject’s participation is voluntary and based upon full and accurate information. The student-teacher relationship raises the issue of volunteer participation. Students may volunteer to participate in the belief that doing so will place them in a favorable situation with faculty (e.g., better grade, good recommendation, employment possibilities), or that failure to participate will negatively affect their relationship with the investigator or faculty (e.g. lower grade, less favorable recommendation, being "uncooperative" and not part of the scientific community). Care should be taken to eliminate or reduce the risk that undue influence of faculty or coercion affects student participation in research.

1.2 Policy Statement

1.2.1 All student participation in student research pools must be completely voluntary.

1.2.2 Any student research pool offering extra credit to participating students must provide alternative opportunities to earn extra credit to students declining to participate in research. The alternative provided should be a meaningful equivalent to participation in research studies and be evaluated by the appropriate course faculty or PI. When research participation is introduced as part of class curriculum, students must not be penalized for a decision not to participate in
research.

1.2.3 Departments using student research pools should report, or make every effort to ascertain and report, the percentage of students who select the alternative to research participation.

1.2.4 Students should be of the age of majority in the state of Alabama (19 years old). Research involving minors (under 19 years of age) as subjects, (18 or 17 year old college students) in most instances requires a signed parental (or legal guardian) consent, as well as the signed assent of the student. Some types of research may qualify for a waiver of consent (parental permission).

1.2.4 Solicitation of volunteer student subjects for research must be done in a non-coercive manner. To avoid undue influence, subjects should be recruited by a general announcement, or a central posting or announcement mechanism. The announcement should include a clearly written description of the project and a statement of the proposed student participation. In addition to being provided with the traditional information and consent forms, students should also be provided with the name and contact information of the Research Compliance Officer should they feel coerced at any time during the process.

1.2.5 The research must not bestow upon participating UA student subjects a competitive academic or occupational advantage over other UA students who do not volunteer, and the researchers must not impose any academic or occupational penalty on those UA students who do not volunteer.

1.2.6 Academic units establishing and using student research pools shall develop written policies or procedures governing student experience in research pools and alternatives to study participation, provide IRB with copies of these documents, identify the person in charge of the student research pool for the academic year and notify IRB when the policies, procedures, or responsible person are changed.

1.2.7 It is the policy of the University of Alabama that all students in student research pools shall receive information about their rights as research participants and some planned and assessed educational benefit from their research experience or completion of the alternative activity. Studies using deception shall include a description of the debriefing for participants.

1.2.8 Faculty (principal investigators) shall complete and maintain their IRB-required certification as principal investigators for the duration of their research using students.

1.2.9 The Human Research Protection Program (HRPP) shall assist faculty using student pools and students in pools seeking understanding of research ethics and compliance by providing policies, templates, consultation about protocols, and other educational resources.

1.2.10 The HRPP shall include assessments of student research pool experiences and faculty and student use of its educational resources in its procedures and evaluations.
1.3 Objective.

1.3.1 The purposes of this policy are to ensure that the rights of human research participants will be adequately protected for students in student research pools, that pool members will receive education about the nature and benefits of research, that students will be provided with equivalent alternatives to research participation, and that the HRPP facilitates faculty and research students in acquiring the necessary knowledge for the responsible conduct of research.

1.4 Responsibility

1.4.1 The ultimate responsibility for this policy rests with the Vice President for Research, the Provost and Vice President for Academic Affairs. Enabling parties include the Director of Research Compliance, department chairs and faculty investigators, department faculty designated as directors or managers of the student research pool, and students.

2.0 PROCEDURE

2.1 Departments using student research pools will have or create written policies or procedures governing the student research pool. These document(s) should include:

2.1.1 The name and contact information of the person responsible for management of the student research pool;

2.1.2 A statement of who is allowed to request use of the student research pool and the procedure to be used for this;

2.1.3 Objectives for student learning to be gained from research participation and methods by which these objectives will be evaluated by the principal investigator or course professor;

2.1.4 Participation requirements for departmental faculty (for example, four studies or eight hours of participation);

2.1.4.1 If faculties are free to set their own participation requirements, then the document should state whether these requirements will be reviewed by a department chair or associate dean/director of research.

2.1.5 A statement about the allowable level of risk for studies using the student pool;

2.1.6 Methods by which students will be informed of available studies ("live" solicitations, e-mail, list serves, etc.);

2.1.6.1 Include the template for a study information sheet if one is to be used

2.1.6.2 A description of how students will be told about the options to contact IRB with questions, suggestions, complaints, or concerns and to participate in the IRB Survey of Participants in UA-Sponsored Research available online;
2.1.7 A description of the objectives for either a departmental alternative to participation or the requirements for faculty creating their own alternatives.

2.1.7.1 Provide a statement that the alternative assignments are equivalent in time, effort, and learning outcomes to research participation and that the alternative product will be evaluated and graded;

2.1.7.2 Description of the schedule and mechanism for reviewing the departmental student research pool policy and revising it if necessary

2.1.8 Provide the Office of Research Compliance (ORC) with a copy of Student Research Pool policies and document and provide the ORC with an updated document when the policy or procedure is changed

2.1.9 Principal Investigators intending to use students from the student research pool will complete or maintain required IRB investigator training for the duration of the study.

2.1.10 Investigators should avoid direct solicitation of students in their own courses for participation. If personal (“live”) solicitations are used another faculty member should be asked to explain the study and invite student participation.

2.1.11 IRB applications for studies using a student research pool should be submitted, updated, and closed using the regular IRB schedule, forms, or E-Protocol.

2.1.12 Department chairs should discuss/report changes in the nature and workings of the subject pool with/to the Director of Research Compliance.

3.0 REFERENCES

1.3 45 CFR §46.103 (b)(4)
1.4 45 CFR §46.103(b)(5)
1.5 21 CFR §56.108(a)
1.6 21 CFR §56.108(b)

4.0 RELATED SECTION

4.1 POLICY: Faculty Use of Students as Human Research Participants and Paid or Unpaid Assistants in Their Research
4.2 POLICY: Waivers, Alterations, and Exceptions to Informed Consent or its Written Documentation
4.3 GUIDANCE: Use of Deception/Concealment in Research
4.4 FORM: Request for Waiver/Alteration of Informed Consent
4.5 FORM: Request for Waiver of Written Documentation of Informed Consent
4.6 POLICY: Investigator and Staff Response to Participants’ Questions, Complaints, and Concerns

4.7 POLICY: Participant and Community Questions, Suggestions, Complaints, and Concerns About Research Studies.