1.0 POLICY

1.1 Background.

1.1.1 All components of the Human Research Protections Program (HRPP) must be guided by clear, published policies. Once developed, those policies must be disseminated and reviewed periodically to ensure that they are current and adequate for the needs of human research protection. Therefore, a policy and procedure for the development, revision, review, and dissemination of HRPP policies is needed.

1.2 Policy Statement

1.2.1 It is the policy of the University of Alabama that creation, revision, review, and dissemination of policies for the human research protections program (HRPP) of the University of Alabama will be guided by a policy and developed with a uniform template.

1.2.2 Policies and procedures for internal use by the Office for Research Compliance will be available to staff members but need not be disseminated externally.

1.2.3 All policies will be reviewed within the first year of publication and then at least once every three years on a staggered schedule. More frequent reviews may be done if necessary.

1.2.4 All UA faculty members, administrators, and members of the HRPP Evaluation Committee may identify needs for new policies or suggest changes in existing policies.

1.2.5 Policies involving the educational programs of the university will be reviewed by such officials as the Provost or units like the Council of Deans, Council of Associate Deans/Directors for Research, or the Faculty Senate.

1.2.6 New policies will be reviewed and approved by the Vice President for Research before posting.

1.3 Objective

1.3.1 Implementation of this policy will ensure that policies for the HRPP are uniform in appearance; guided by input from relevant persons and groups; undergo regular review and revision as needed; and are disseminated, with necessary education and plans for evaluation, to persons governed by those policies. Creation and refinement
of policies in response to user feedback may also be included in the annual evaluation of the HRPP and be identified as an element in the Quality Improvement Program for the next year (POLICY: Evaluation and Improvement of the Human Research Protection Program).

1.4 Responsibility.

1.4.1 The ultimate responsibility for this policy rests with the Vice President for Research. Enabling parties are the Director of Research Compliance and staff, the IRB chairs and members, the Director of the Office of Sponsored Programs, and UA investigators and faculty.

2. PROCEDURE

2.1 Creation of Policies for the HRPP

2.1.1 The template adopted by the Subcommittee for IRB Accreditation in 2006 will be used for all policies. The template allows adjustment for the needs of specific topics while ensuring that certain required headings appear in all policies and that statements are easily located.

2.1.2 The responsible and enabling parties for a policy will note the need for new policies using a variety of sources, including the standards of the Association for Accreditation of Human Research Protection Programs; federal regulations; their experiences with a policy; observations and input from investigators, IRB members, research participants, the Office of Sponsored Program, and senior UA administrators; and recommendations from the Quality Improvement Team.

2.1.3 Any responsible or enabling party may alert some or all of the other parties about a policy need, depending on its nature. For example, a policy need for investigators may or may not require immediate involvement by the Vice President for Research or the Director of Sponsored Programs but does require contacting the IRB chairs and the Director of Research Compliance. A policy need in Sponsored Programs may require the Director of Sponsored Programs, ad hoc personnel from that office, and the Vice President for Research.

2.1.4 The Director of Research Compliance will appoint committees to create policies and schedule meetings for that purpose. These committees may include faculty members who are not IRB members if their expertise is relevant to one or more policies. These meetings may be live or conducted electronically, depending on the nature of the policy. (NOTE: Meetings may combine creation of new policies and reviews of existing policies if that is more efficient.)

2.1.5 The relevant parties shall consider whether education about the new policy will be needed and by whom. If there is a need for special education or targeted notification of key parties, recommendations for the nature and target of education and the person(s) to
develop the education should be presented to the Director of Research Compliance who will then designate a staff member to meet the educational need.

2.1.6 The new policy shall be forwarded to the Director of Research Compliance, and the IRB Chairs, at a minimum. At their discretion the policy will be forwarded to other persons (including faculty) affected by the policy for discussion and revised if necessary.

2.1.7 The creators of the policy will prepare a final copy of the document, noting the creation date on the document masthead, and obtain approval from the Director of Research Compliance who will then obtain approval of the Vice President for Research.

2.1.8 All new policies will be reviewed within one year of creation. At that meeting, reviewers will assign the policy to Review Cycle 1, 2, or 3, depending on the likely need for early review and the need to distribute policies across cycles for workload issues.

2.1.9 The policy template may itself be reviewed for adequacy as needed.

2.2 Routine Review And Revision of Policies

2.2.1 All policies older than one year will be reviewed once every three years on a staggered basis.

2.2.2 The Director of Research Compliance will appoint members of a policy review committee, make review assignments, and schedule and conduct review meetings. (Review of policies and creation of policies may occur in the same meeting, if feasible.)

2.2.3 Policy reviewers will consider federal and AAHRPP regulations, their experiences with the policy, and input from senior UA administrators, investigators, IRB members, and others in deciding whether the policy is in need of revision.

2.2.4 If the policy is in need of revision, the reviewers shall draft the needed revisions and follow the steps described in Section 2.1.5 and 2.1.6 of this policy.

2.2.5 If the policy is not in need of revision, the reviewers shall add the “R” and date of review after “Approval Date” in the policy masthead.

2.2.6 The Director of Research Compliance will report the actions of all policy meetings in the annual IRB report sent to the Director of Research Compliance, the IRB Chairs, the Vice President for Research, and the Chair of the IRB Evaluation Committee.

2.3 Dissemination of Policies

2.3.1 The heading “Dissemination” is understood to include all publications and disseminations of the creation or revision of policies, the identification of any additional education likely to be needed about the policy, and distribution of reports to specified individuals.
2.3.2 All policies created for the HRPP and IRB that pertain to investigators, human research prospects and participants, and faculty will be published on the IRB website for ready reference by users.

2.3.3 The development of new or revised policies shall be announced to the university community on the IRB website, through the Investigator e-mail list, or through DIALOG within three weeks of approval by the Vice President for Research.

2.3.4 Policies and procedures internal to the functioning the Office for Research Compliance (e.g., policies on IRB records, IRB minutes, management of questions, complaints, concerns) will be made available to research compliance staff as they are created or revised but need not be posted online.