1.0 POLICY

1.1 Background.

1.1.1 Federal regulations and AAHRPP standards require that protocols must be re-reviewed for continuation at least annually depending on the degree of risk.

1.1.2 This review should be meaningful rather than perfunctory. **Meaningful review** includes not only the assessment of risks and benefits to participants but also investigators’ assessments of participants’ comprehension of informed consent, the nature and management of participants’ questions or complaints about the study, reports of modifications and unanticipated events, and, in community-based research, the efforts made toward participatory research in which the community is benefited in some way.

1.2 Policy Statement

1.2.1 It is the policy of the University of Alabama that all investigators with approved protocols (including exempt protocols) must submit them for continuing review at least annually or more often if required by IRB based on the degree of risk. See GUIDANCE: General Responsibilities of Investigators. **Continuing review is allowed to stop only when the research is permanently closed to the enrollment of new participants, all participants have completed all research-related interventions, collection and analysis of private identifiable information has been completed, and the data have been de-identified.**

1.2.2 The Office for Research Compliance shall send a courtesy notice to alert investigators to renew or close studies 90 days before their expiration dates, inform them about what information must be submitted for continuing approval, describe procedures used by IRB to perform continuing reviews, inform investigators of IRB decisions in writing, and notify investigators of changes in the procedures.

1.2.3 Investigators shall submit renewal applications in time to be reviewed by IRB before the expiration date for the proposal. If they do not and the proposal approval expires, they shall stop recruitment and data collection until IRB review and approval for continuation are received. Failure to renew applications before their expiration date may be considered noncompliance with IRB requirements.

1.2.4 The current consent document is still accurate and complete.
1.2.5 Any significant new findings that arise from the review process and that might relate to participants’ willingness to continue participation will be provided to participants.

1.2.6 The approval year begins on the day of (1) the convened IRB meeting when the proposal was approved, (2) an expedited reviewer’s approval, or (3) the day when an exemption is granted unless the Board approves a shorter approval period.

1.2.7 The expiration date and time for a proposal receiving approval for one year is at 5:00 p.m. of the day before the anniversary date of the last IRB approval. That is, a proposal approved for one year on June 10th expires on June 9th of the next year at 5:00 p.m., regardless of whether or not this date falls on a business day.

1.2.8 If the IRB granted approval for less than one year, the expiration date will be at 5:00 p.m. on the day before the date specified by the IRB in the approval letter to the investigator.

1.2.9 Continuing review is not required for studies in which data collection from human participants has ended if the data can no longer be linked to persons and any means of re-establishing the linkage have been destroyed and an application requesting study closure for this reason has been submitted. If data remain identifiable by the investigator, investigators must continue to file for continuing renewal. Investigators are urged to state in their applications how long they will retain the data and whether data will remain identifiable as this affects reviewer consideration of privacy and confidentiality. See POLICY CLOSURE OF IRB PROTOCOLS.

1.2.10 Applications not submitted for continuing review in time to be reviewed before the expiration data will be administratively withdrawn and considered noncompliant with IRB policies. In this case the investigator must stop all project activity immediately and must submit a new application to IRB in order to continue the research. (Research Compliance will send a courtesy notification that the approval expires in 90 days and a notice of pending administrative withdrawal when the expiration date passes without investigator response.) See POLICY CLOSURE of IRB PROTOCOLS.

1.2.11 Applications for continuing review may be combined with a request for modifications, provided that the modifications will not take effect until after continuing approval is granted.

1.2.12 The IRB holds continuing authority and discretion in the assignment of type of review for any particular proposal.

1.2.13 Proposals which initially receive full board review must be reviewed by the full board again unless the Director of Research Compliance determines that continuing review may be managed by expedited review. This may be appropriate when:

1.2.13.1 The research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related interventions, and the research remains active only for long-term follow-up of subjects; or

1.2.13.2 No subjects have been enrolled and no additional risks have been identified; or
1.2.13.3 The remaining research activities are limited to data analysis and manuscript preparation. (*NOTE: Journals often ask manuscript authors if they have an active IRB approval.*)

1.2.13.4 The research does not involve an investigational new drug application or investigational device exemption and the convened IRB has documented that the research does not involve other categories of exemption, is of no more than minimal risk, and no additional risks have been identified.

1.2.14 Proposals which initially receive expedited review may be submitted for expedited review, unless proposed modification removes it from this category. Therefore, a proposal originally approved as expedited may be assigned to full board review if the DRC, IRB chair, or an expedited reviewer deems it necessary.

1.2.15 Proposals approved as exempt will continue to be reviewed by the Director of Research Compliance who may renew it at that level or change it to expedited or full board review.

1.2.16 A research study which deviates from that approved by the IRB for a non-safety reason is at risk of suspension by the IRB and may be considered research noncompliance or misconduct, in which case policies governing these events shall apply.

1.2.17 Investigators of all approved protocols shall notify the IRB promptly when a proposal closes. If student investigators fail to close their studies upon graduation or to transfer their data to the faculty supervisor, faculty supervisors should file the appropriate request for closure (FORM: Closure of Approved Protocols).

1.2.18 Statistical and qualitative information from the IRB and investigators shall be made available to those conducting the annual evaluation of the Human Research Protection Program/IRBs.

1.3 Objective.

1.3.1 Implementation of this policy will aid university and IRB compliance with federal regulations and AAHRPP standards and will assure continuing oversight of approved research, protection of human participants, 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 include the Director of Research Compliance and staff, the IRB chairs and members, associate deans for research, and principal investigators.

2.0 PROCEDURE

2.1 Renewal of an Approved Protocol That Received Full Board Review
2.1.1 The Office for Research Compliance will notify principal and co-investigators and faculty supervisors for student research in writing 90 days in advance that their protocol approval expires on a certain date.

2.1.2 For proposals approved for less than one year, the approval letter will state the expiration date and the date on which the renewal application is due in order to be included on the agenda for a scheduled IRB meeting.

2.1.3 The PI completes the two application face pages and the FORM: IRB Renewal Application and sends it and a copy of the previously approved protocol and appendices to the Office of Research Compliance. The application should be received in the Office of Research Compliance by the 15th of the month prior to the month that it is to be reviewed. (The schedule for IRB meetings is posted on the IRB website.)

2.1.4 Proposals not submitted in time for review before their expiration date lose their approval. If approval is expired, the investigator must stop participant recruitment, intervention, advertisement, new enrollment and data collection until the proposal receives continuing review and approval. SEE POLICY CLOSURE OF IRB PROTOCOLS.

2.1.5 The IRB may grant emergency continuance to research in the case that there is an overriding safety concern or ethical issue involved such that it is in the best interests of individual participants to continue participating. For example, abrupt cessation of a support group, home health monitoring, or a drug regimen might be harmful to a participants' mental or physical health. If the PI believes this to be the case, s/he must notify the DRC immediately. The DRC and the IRB Chair may approve the request if both concur. The approval period will be granted for a period sufficient to allow formal review by the next scheduled full board meeting.

2.1.6 The PI may combine modification of a proposal with an application for renewal. The PI should complete FORM: Modification of an Approved Protocol and also follow the procedures described in POLICY: IRB Application for Modifying Approved Protocols.

2.1.7 A Research Compliance Specialist will work with the PI to determine that the application for renewal is completed two weeks before a scheduled IRB meeting and will place the application on the agenda for the next scheduled meeting.

2.1.8 All IRB members will receive all materials submitted by the PI and are expected to participate in the discussion. Although a primary reviewer is not routinely assigned for renewal applications, the IRB chairs may appoint one at their discretion. The IRB will review the renewal application using FORM: IRB Checklist for Reviewers and Investigators. In addition to standard criteria for review of applications (e.g., FORM: IRB Checklist for Reviewers and Investigators, and the information provided on FORM: IRB Renewal Application), the discussion will consider factors that involve specific regulations or the investigator’s history with the IRB, such as:

2.1.8.1 The use of vulnerable populations;

2.1.8.2 Novel or geographically remote performance sites;
2.1.8.3 Involvement of recombinant DNA (including gene transfer);

2.1.8.4 Use of waivers in the informed consent process;

2.1.8.5 Protocols with potential for heightened risk to subjects;

2.1.8.6 Previous problems with the research or investigators, including occurrence of unanticipated problems, non-compliance, administrative actions, and complaints of participants;

2.1.9 Recommendations from units supplying special approvals of the research (e.g., Radiation Safety committee, research pharmacy review.)

2.1.10 The board will use the following criteria to determine which projects need verification from sources other than the investigators that no material changes have occurred since the previous IRB review:

2.1.10.1 Protocols randomly selected for monitoring by the Manager of Research Compliance;

2.1.10.2 Complex protocols involving unusual levels or types of risks to subjects;

2.1.10.3 Protocols from principal investigators who have previously failed to comply with federal regulations or the determinations of the IRB; and/or

2.1.10.4 Protocols with indications that material changes may have occurred without IRB approval. Such indications may be noted in the submitted materials or may arise from information from other sources.

2.1.11 Following review and discussion, the board may vote to approve and specify the approval period, or it may defer the application for additional information, approve with resubmission of additional information for full board review or stipulate that contingent modifications requested by the board but not directly relevant to the determination required by the IRBs may be approved by the IRB chair, a subcommittee of IRB members, or by compliance staff who are also members of IRB.

2.1.12 The Research Compliance Specialist will prepare a letter describing the board decision which the IRB Chair or the Director of Research Compliance will sign. (The IRB Chairs have designated the Director of Research Compliance to perform this function.) This letter will be sent to the PI within 10 working days of the IRB meeting.

2.1.13 Revisions requested by the IRB must be submitted within 60 days of the meeting date or the approval will lapse, and the proposal will be administratively withdrawn. To reactivate it the investigator must submit a new initial application to IRB. See POLICY CLOSURE OF IRB PROTOCOLS.
2.2 Renewal of an Approved Protocol That Received Expedited Approval

2.2.1 The Office for Research Compliance will notify principal investigators and faculty advisors in writing 90 days in advance that their protocol approval expires on a certain date.

2.2.2 The PI completes the application face pages and the FORM: IRB Renewal Application and sends it and a copy of the previously approved protocol and appendices to the Office for Research Compliance. The application should be received in the Office for Research Compliance by the 15th of the month prior to the month that it is to be reviewed. (The schedule for IRB meetings is posted on the IRB website.)

2.2.3 Proposals not submitted in time for review before their expiration date will lose their approval. If approval is expired, the investigator must stop participant recruitment, intervention, advertisement, new enrollment and data collection until the proposal receives continuing review and approval.

2.2.4 The PI may combine modification of a proposal with an application for renewal. If this is done, the PI should complete FORM: Modification of Approved Protocol as well and follow the procedures described in POLICY: IRB Application for Modifying Approved Protocols.

2.2.5 Include a clean copy of the revised application with changes included and clearly marked and a copy of the originally approved application.

2.2.6 A Research Compliance Specialist will work with the PI to determine that the application for renewal is complete and will forward it to the Director of Research Compliance.

2.2.7 The Director of Research Compliance will assign one or more expedited reviewers, who will receive all materials submitted by the investigator.

2.2.8 The expedited reviewers will review the renewal application according to POLICY: Expedited Review and FORM: IRB Checklist for Reviewers and Investigators, consider any issues that suggest the need for information from persons other than the principal investigator, and notify the Director of Research Compliance of their decisions. They may vote to approve the application for a specified period of time, request additional information, request revisions for review by either the expedited reviewers or the full board, or recommend that the application be sent to the full board for review.

2.2.9 Revisions requested by expedited reviewers must be submitted within 60 days of the request or the approval will lapse, and the study will be administratively withdrawn. To reactivate it the investigator must submit a new initial application to IRB.

2.2.10 The Research Compliance Specialist will prepare a letter describing the expedited reviewers' decision which the IRB Chair will sign. This letter will be sent to the PI within 10 working days of expedited review.
2.3 Renewal of a Protocol Approved as Exempt

2.3.1 The procedure is the same as for expedited renewals except that the completed application for continuing approval will be reviewed by the Director of Research Compliance.

3.0 REFERENCES

3.1.1 45 CFR §46.103(b) (4); 45 CFR §46.109; 45 CFR §46.116(b)(5); 21 CFR §50.25 (b)(5); 21 CFR §56.108 (a), 21 CFR §56.109

3.1.2 OHRP Guidance on Written Institutional Review Board (IRB) Procedures

3.1.3 OHRP Guidance on Continuing Review

3.1.4 FDA Information Sheets: Continuing Review After Study Approval, Frequently Asked Questions: IRB Procedures


4.0 RELATED SECTIONS

4.1 GUIDANCE: General Responsibilities of Investigators

4.2 FORM: IRB Renewal Application

4.3 POLICY: IRB Application for Modifying Approved Protocols

4.4 FORM: Modification of an Approved Protocol

4.5 FORM: IRB Checklist for Reviewers and Investigators

4.6 GUIDANCE: IRB Application Guide

4.7 POLICY: Exempt Review

4.8 POLICY: Closure of IRB Protocols