1.0 POLICY

1.1 Background.

1.1.1 Complete records of IRB applications and approved protocols, including closure, are essential to accomplish the University’s assurances of protection of human research participants.

1.1.2 This policy deals only with closure of protocols requested by the investigator or administrative withdrawal initiated by the Office for Research Compliance for investigator non-response.

   1.1.2.1 For studies closed for other reasons such as matters of noncompliance or risk to participants, see POLICY: Allegations and Findings of Noncompliance, POLICY: Reportable Events: Protocol Deviations, Unanticipated Problems, and Adverse Events Involving Risk to Participants and Others, and GUIDANCE: Reportable Events.

   1.1.2.2 Situation-specific letters to investigators will be generated for these events.

1.2 Policy Statement

1.2.1 It is the policy of the University of Alabama that all approved studies must be formally and actively closed by the investigator and the Office for Research Compliance or they will be administratively withdrawn by the Office for Research Compliance. “Active Closure” is initiated by the investigator and confirmed by the ORC. “Administrative Withdrawal” is initiated by the Office for Research Compliance for non-responsiveness by the investigator to IRB requests or notices of study expiration.

1.2.2 Investigators may not continue to collect or use data from studies that have not been renewed (have expired) or have been administratively withdrawn for any reason.

1.2.3 The Office for Research Compliance (ORC) may notify investigators in writing or electronically of the impending expiration of their approved applications well in advance of the date and, if necessary, of the administrative withdrawal of their studies and the reason(s) for it.

1.2.4 Investigator failure to respond to communications from ORC about IRB requests or study expiration in a timely fashion with subsequent administrative withdrawal is considered to be in noncompliance with UA IRB policies. The first administrative withdrawal for an investigator will be noted as administrative noncompliance. The second shall provoke a notice that a third administrative withdrawal will be
Institutional Review Board  The University of Alabama

considered continuing or persistent noncompliance. If a third administrative withdrawal occurs, the Research Compliance Officer shall notify the IRB in accordance with the policy on noncompliance and may refuse to review new applications from the investigator or his/her students for a specified period of time. SEE POLICY: Allegations and Findings of Noncompliance.

1.2.5 The principal investigator (PI) is responsible for promptly closing a study (active closure) if any of the following conditions apply:

1.2.5.1 All research/clinical investigation activities including data analysis and reporting are complete;

1.2.5.2 Subject accrual is finished and data collection is complete. The only remaining study activity is data analysis, and the data are de-identified, and there are no identifying links or codes to the de-identified data.

1.2.5.3 The study was never initiated;

1.2.5.4 The study has been open for one or more years, no subjects have been enrolled, and the investigator sees no likelihood of doing so.

1.2.5.5 The investigator plans to graduate from the University, to leave University employment and to continue the research activities at another institution, or to transfer responsibility for the study to another UA investigator.

1.2.5.5.1 In the event that a student investigator leaves the University without filing the appropriate renewal or closure, the faculty research supervisor is responsible for doing this.

1.2.6 The investigator cannot close out an active protocol if:

1.2.6.1 Subjects are still being followed;

1.2.6.2 Identifiable data (data with codes or links to identifiers, allowing identification of individual participants) still exist.

1.2.6.3 Renewal applications must be filed if either of the above circumstances applies.

1.3 The Office of Research Compliance is responsible for the administrative withdrawal of a study if either of the following apply:

1.3.1 The investigator has not responded to IRB requests for information, revisions, or a resubmission of a protocol within the specified time period;
1.3.2 The investigator has allowed approval to lapse without responding to the IRB notice about expiration of an approved protocol and warning of administrative withdrawal.

1.4 Investigators may reinstate actively closed or administratively withdrawn studies by submitting complete new IRB applications for the appropriate level of review (exemption, expedited review, full board review.)

1.5 Objective

1.5.1 Implementation of this policy will enable the IRB to fulfill its obligation to monitor research, protect human subjects, and comply with accreditation standards.

1.6 Responsibility

1.6.1 The ultimate responsibility for this policy rests with the Vice President for Research. Enabling parties include the Director of Research Compliance, staff of the Office for Research Compliance, principal investigators, and faculty supervisors.

2.0 PROCEDURE

2.1 Active Investigator Study Closure: All Study Activities Completed

2.1.1 The Investigator completes and signs FORM: Closure of an Approved Study, identifying study completion as the reason for closure and including a brief description of the major findings.

2.1.2 This option may be chosen by both investigators who remain at UA and those who graduate or leave UA for other employment.

2.1.3 A Research Compliance Specialist or the Research Compliance Manager will review the closure application for completeness. For example, a completed study without a description of the findings will be returned to the investigator.

2.1.4 When closure requests are complete, the Research Compliance Manager will send the PI a notice that the study has been actively closed on the IRB database for this reason.

2.2 Active Investigator Study Closure: Data Analysis of De-Identified Data

2.2.1 The investigator completes and signs FORM: Closure of an Approved Study, choosing indicating that analysis of de-identified data remains to be done. His/her signature certifies that the data have been de-identified.

2.2.2 This option may be chosen by both investigators who remain at UA and those who graduate or leave UA for other employment.

2.2.3 The request form will be reviewed for completeness.
2.2.4 When the closure request is complete, the Research Compliance Manager will send the PI a notice that the study has been closed on the IRB database for this reason.

2.3 Active Investigator Study Closure: The Study Was Never Initiated

2.3.1.1 The investigator completes and signs FORM: Closure of an Approved Study, indicating failure to initiate study as a reason for closure and providing a reason for non-initiation of the study, such as withdrawal of funding, unavailability of essential equipment, investigator illness, etc.

2.3.1.2 The request form will be reviewed for completeness.

2.3.1.3 When the request is complete, the Research Compliance Manager will send the PI a notice that the study has been closed on the IRB database for this reason.

2.4 Active Investigator Study Closure: Closure Due to Non-Enrollment

2.4.1 The investigator completes and signs FORM: Closure of an Approved Study, identifying failure to enroll subjects as the reason for closure, stating the period of time the study was open, and providing a reason for failure to enroll subjects, such as inability to hire or replace key recruiters or scarcity of subjects with a rare condition.

2.4.2 The request will be reviewed for completeness.

2.4.3 When the request is complete, the Research Compliance Manager will send the PI a notice that the study has been closed on the IRB database for this reason.

2.5 Active Investigator Study Closure: Investigator (Student, Faculty, Staff) Leaves University

2.5.1 When student investigators graduate, they should complete and sign FORM: Closure of an Approved Protocol, indicating the appropriate reason for closure.

2.5.1.1 If a student leaves without doing so, the faculty supervisor is responsible for closing the study.

2.5.2 If the investigator wishes to continue the research at a new institution and transfer all activity to that site, he should ask the University Office of Sponsored Programs to transfer the award (if any) to the new institution and actively close the study at UA by completing and signing FORM: Closure of an Approved Protocol.

2.5.3 If the investigator (student, faculty, or staff member) wishes to transfer the research to another UA investigator, s/he should write a letter to the Director of Research Compliance requesting to transfer the protocol to a local investigator. This request is likely to entail an application for modification of the study and possibly further IRB review and approval.
2.5.3.1 The new local investigator should send a letter to the Director of Research Compliance, stating willingness to assume the study responsibilities and submit a completed Signature Assurance Sheet, a revised study Personnel Page, and revised consent forms, advertisements, or other study correspondence to the IRB for review.

2.5.4 The request for closure will be reviewed for completeness.

2.5.5 When the request is complete, the Research Compliance Manager will send a letter that the study has been closed on the IRB database for the requested reason.

2.6 Administrative Withdrawal of a Study by the Office of Research Compliance

2.6.1.1 If an investigator does not respond to ORC or IRB requests for additional information, revisions, or resubmission of an application within 60 days of the request, the Research Compliance Specialist will notify the Manager of Research Compliance who will send a letter of administrative withdrawal.

2.6.1.2 If an investigator fails to respond to the notification from the Director of Research Compliance that approval of an existing protocol will lapse (expire) in 90 days and does not file an application for renewal or closure, the Research Compliance Manager will send a letter of Administrative Withdrawal of the study.

2.6.1.3 If an investigator realizes that an application has lapsed and submits a renewal application before the Research Compliance Manager has sent a letter of administrative withdrawal the PI may apply for renewal. This application must have a cover letter in which the PI explains the reason for the expiration, states that no work of any kind has occurred on the study since the expiration date, describes a corrective action plan to ensure that a lapse of approval does not reoccur, and states that no work of any kind will occur on the study until IRB approval has been received. This letter must be received before the application can be reviewed. The first experience of this kind will not be noted as administrative noncompliance; however, a second such lapse will be noted as the first instance of administrative noncompliance for the investigator.

2.7 To reinstate an administratively closed study the investigator must submit a new IRB application for the appropriate level of initial review (exemption, expedited review, full board review).

2.8 Office for Research Compliance Management of Closed Protocols

2.8.1 Upon closure the Research Compliance Manager or designee codes the studies as “terminated” in the IRB database, removes the study materials from the “Active” list,
and files the hard copies alphabetically by PI last name, and month and year of the last review. The protocol is then stored for six years from the closure date.

3.0 REFERENCES

3.1 45 CFR 46.115(b)

4.0 RELATED SECTIONS

4.1 POLICY: Continuing Review of Approved Protocols
4.2 POLICY: IRB Application for Modification of an Approved Protocol
4.3 POLICY: Allegations and Findings of Noncompliance
4.4 POLICY: Reportable Events: Protocol Deviations, Unanticipated Problems, and Adverse Events Involving Risk to Participants and Others.
4.5 FORM: Modification of Approved Protocol
4.6 POLICY: IRB Record Keeping and Management
4.7 FORM: Request for Study Closure (Investigator)