1.0 POLICY

1.1 Background

1.1.1. Quality improvement, investigator education, and protection of human research participants require that IRBs routinely and systematically monitor the conduct of studies after IRB approval.

1.1.2. The identification of investigators' excellent procedures for study monitoring and their minor and major changes (deviations) from approved protocols can lead to improved investigator education and protection of human research participants.

1.1.3. **Minor changes** from approved protocols are those which do not affect the level of risk to subjects, the research design or methodology, the subject population, participant burden, the qualifications of the research team, the facilities available to support the safe conduct of the research, or any other factor which would warrant review of the proposed changes by the convened IRB.

1.1.4. **Major changes** from approved protocols are those that affect the level of risk to subjects, the research design or methodology, the subject population, participant burden, the qualifications of the research team, the facilities available to support the safe conduct of the research, or any other factor which would warrant review of proposed changes by the convened IRB.

1.1.5. This policy applies only to routine monitoring for quality assurance purposes. See POLICY: Allegations and Findings of Noncompliance and POLICY: Monitoring for Cause: Suspension and Termination for monitoring for other reasons.

1.2 Policy Statement

1.2.1. It is the policy of the University of Alabama that the Research Compliance Office staff and chairs and members of the IRBs shall conduct routine monitoring of approved studies for quality control and improvement, investigator education, and enhanced protection of human research participants. This serves not only University protection programs but the obligation to many federal agencies to assess compliance with regulations.

1.2.2. The IRBs have the authority to use whatever methods and frequencies of monitoring that they deem appropriate, including the options to observe explanations of the study to potential participants and the consenting process, the data collection process, and the facilities for data analysis and storage, and to contact participants.
1.2.3. An IRB can request observation of the consenting process in certain selected circumstances, which include but are not limited to:

1.2.3.1. Studies that involve high risk to participants;

1.2.3.2. Studies that involve particularly complicated procedures or interventions;

1.2.3.3. Potentially vulnerable populations (e.g., ICU patients, children);

1.2.3.4. Study staff with minimal experience in administering consent to potential study participants;

1.2.3.5. Situations where the IRB has concerns that the consent process might not be proceeding well.

1.2.4. The IRBs may also choose a specific topic for monitoring across several protocols, such as investigating the general question of whether consent forms in use or the recruiting materials are the currently approved versions.

1.2.5. The IRBs have the option to request external consultation to assist with monitoring.

1.2.6. Stimuli for routine post-approval monitoring include but are not limited to random selection by the Office of Research Compliance, IRB discussions of new protocols suggesting that certain new studies are candidates for additional monitoring because of some characteristic of the study, and renewal applications for which the investigator reports events that suggest monitoring may be desirable.

1.2.7. Post-approval monitoring shall cover exempt, expedited, and full-board reviewed studies.

1.2.8. The Office of Research Compliance shall specify guidelines for the number and frequency of approved studies to be monitored annually.

1.2.9. Investigators shall be given advance notice of post-approval monitoring but the amount of notice may vary with the circumstances of the monitoring.

1.2.10. The monitoring committee shall notify the IRB chair immediately if major deviations from approved protocols or instances of serious noncompliance are found. The IRB chair has the authority to stop the study immediately.

1.2.11. Monitors shall give the investigator a date for the correction of observed deficiencies to be verified by submission of additional materials or another visit.

1.2.12. The Director of Research Compliance (DRC) shall inform the IRBs of the findings from monitored studies at the next scheduled meeting or request scheduling of a called meeting if unexpected serious violations of approved protocols were found and the next scheduled IRB meeting is not timely.

1.2.13. The Director of Research Compliance shall summarize the number and nature of post-approval monitored studies in the annual reports to the Vice President for Institutional Review Board The University of Alabama
Research and to the Evaluation Committee for the Human Research Protection Program.

1.2.14. The Director of Research Compliance and the IRB chairs and members shall review the annual report about monitored studies and identify topics for investigator education and implications for modifying or creating research policies.

1.3 The Vice President for Research and the Director of Research Compliance shall annually review the IRB budget for adequacy of conducting the volume and type of monitoring required.

1.4 Objective.

1.4.1. Adherence to this policy will facilitate investigator training, protection of human research participants, and compliance with federal regulations and accreditation standards.

1.5 Responsibility.

1.5.1. The Vice President for Research is ultimately responsible for this policy. Enabling parties are the Director of Research Compliance, the Manager of Research Compliance, the IRB chairs and members, the Council of Associate Deans for Research, principal investigators, and faculty supervising student research.

2.0 PROCEDURE

2.1 Selection of Approved Protocols for Routine Monitoring

2.1.1 Each month a Research Compliance Manager will randomly select 3-5 protocols for routine monitoring in the next three months from the master list of approved active protocols. Exempt, expedited, and full-board approved protocols will be selected in approximate proportion to their numbers.

2.1.2 At each IRB meeting the Research Compliance Manager will note any protocols suggested by board members for post-approval auditing. These may be protocols up for initial review or for continuing approval. These protocols will automatically be entered on a list for the next quarterly monitoring.

2.1.3 If the IRB has identified a topic for monitoring, the Research Compliance Specialist will locate protocols for which that topic is relevant and forward them to the Research Compliance Manager.

2.1.4 Enough protocols will be selected for monitoring to ensure that monitoring is spread throughout the year and that the desired number/percent of protocols from each review category are monitored each year.

2.1.5 Protocols selected for monitoring and that are found in compliance will be removed from the monitoring pool for one year.

2.2 Selection of Monitor(s)
2.2.1 The Research Compliance Manager and the IRB chairs will choose one or more monitor(s) for each selected protocol and identify a monitoring team chair if more than one monitor is selected. The size and make-up of monitoring teams may vary depending on the level of review of the selected protocols.

2.2.1.1 Exempt protocols will generally be monitored by the Research Compliance Manager. However, another person from the Office of Research Compliance or an IRB chair or member may be appointed.

2.2.1.2 Expedited protocols will generally be monitored by one or two IRB members, depending on the size and complexity of the study.

2.2.1.3 Full-board reviewed protocols may be reviewed by at least three people, including the Research Compliance Manager, an IRB chair, and an IRB member. An external consultant may also be appointed if considered necessary by the monitoring committee.

2.2.1.3.1 Every effort will be made to distribute the monitoring workload equitably across members while ensuring that team members do not have conflicts of interest with the selected studies. IRB alternates may also be called upon for assistance with monitoring.

2.3 The Monitoring Process

2.3.1 The Director of Research Compliance or Research Compliance Manager will notify the monitor or monitoring team chair and members of the assignment; forward a copy of the assignment, team members' contact information, and the approved protocol to the selected monitor(s); and establish times when they can be available for a monitoring visit.

2.3.2 The appointed monitors will read the forwarded materials and print copies of the appropriate monitoring checklist (FORM: Checklist for Post-Approval Monitoring of Expedited and Full Board Protocols; FORM: Checklist for Monitoring Approved Exempt Protocols). Depending on the nature of the protocol and the IRB's identification of specific topics, the monitor(s) may decide to delete portions of the checklist, use the entire checklist, or add items to it. A division of labor among monitoring team members may be specified if desired.

2.3.3 The Director of Research Compliance or Research Compliance Manager notifies the principal investigator or available key personnel that the study will be monitored. A choice of dates and times (reflecting the availability of the monitors) will be given. The investigator is expected to accept one of the proffered dates or to negotiate another very close to it in time. Failure to do so may be construed as noncompliance.

2.3.4 Principal investigators need not be present at the monitoring visit but some key person on the research team must be. Investigators or the key person will be reminded that the visit will be guided by FORM: Checklist for Post-Approval monitoring of Approved Exempt Protocols or FORM: Checklist for Post-Approval Monitoring of Expedited and Full Board Protocols.
2.3.5 In the absence of any major deviations from the approved protocol, the monitor(s) will complete FORM: Report of Study Investigation by a Monitoring Committee within five working days of the visit that includes the completed checklist, a summary of recommendations and commendations, and guidance for remediation of observed problems. The latter will include a timetable and response format (submission of additional written materials, description of a procedural change, another site visit, a conference with the/a monitor, etc.). The monitor/monitoring team chair will distribute this report to the IRB chair, the principal investigator, and the Manager of Research Compliance (if the Manager was not team chair).

2.3.6 Routine monitoring will be completed within 15 working days from the time the monitor(s) are assigned to the protocol, until the final report is submitted to the Director of Research Compliance.

2.3.7 In the case that major deviations or serious noncompliance are found, the monitoring team will inform the investigator onsite and call the Director of Research Compliance and the IRB Chair immediately. The IRB Chair may determine that the study meets the requirements for an immediate suspension or termination and so inform the investigator. (See POLICY: Allegations and Findings of Noncompliance). The IRB Chair may seek external consultation, order additional investigation, or discuss the matter with a regular or called meeting of the IRB. (See POLICY: Monitoring of Previously Approved Research for Cause: Suspension and Termination).

2.3.8 The IRB provides the investigator with a description of remedial actions to be taken within a specified time period, using FORM: Report of Study Investigation by IRB.

2.3.9 The IRB identifies any commendable practices that may be helpful to other investigators in improving investigator oversight or protection of human research participants. (FORM: Report of Study Investigation by IRB.)

3.0 REFERENCES

3.1 45 CFR §46.109(e)
3.2 45 CFR §46.113
3.3 DOE O 443.1.B (3/17/2011)

4.0 RELATED SECTIONS

4.1 POLICY: Allegations and Findings of Noncompliance
4.2 POLICY: Monitoring for Cause: Suspension and Termination
4.3 FORM: Checklist for Post-Approval Monitoring of Exempt Protocols
4.4 FORM: Checklist for Post-Approval Monitoring of Expedited and Full Board Protocols
4.5 FORM: Report of Study Investigation by a Monitoring Committee