1.0 POLICY

1.1 Background

1.1.1 Federal regulations (45 CFR 46.110, 21 CFR 56.110 and 38 CFR 16.110) allow the IRB to review certain applications on an expedited basis if they meet specified criteria. The Secretary of HHS has established and published in the Federal Register a list of categories of research that may be reviewed by an IRB using an expedited review procedure. See http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm for these categories.

1.2 Policy Statement

1.2.1 It is the policy of the University of Alabama that qualifying research may be reviewed using an expedited procedure.

1.2.2 To qualify for expedited review the research activity must:

1.2.1.1 Present no more than minimal risk to human subjects. That is, any harms or discomforts are not greater in magnitude than those encountered in ordinary daily life or during routine physical or psychological examinations or tests.

1.2.1.2 Not expose subjects, when identified, to risk of criminal or civil liability, or be damaging to the subjects' financial standing, employability, insurability, reputation or be stigmatizing, unless reasonable and appropriate protections will be implemented in order to reduce such risks to a minimal level.

1.2.1.3 Not be federal classified research involving human subjects

1.2.1.4 Fall into one or more of the categories listed by OHRP in “Categories of Research That May Be Reviewed by the Institutional Review Board through an Expedited Review Procedure.”

1.2.1.4.1 Clinical studies of drugs and medical devices if:

1.2.1.4.1.1 It is research on drugs for which an investigational new drug application is not required, or

1.2.1.4.1.2 It is research on medical devices for which an investigational device exemption application is not required, or the medical device is cleared.
1.2.3 The UA IRB will consider some studies involving prisoners (usually those that would qualify for exempt review if the participants were not prisoners, such as record reviews of de-identified data) for expedited review. The Director of Research Compliance will make the decision that such applications qualify for exempt status and the prisoner representative will be a reviewer.

1.2.4 Expedited review will take place independently of full-board meetings of the IRB.

1.2.5 Expedited review shall be carried out by the IRB Chair or one or more designated voting members of the IRB possessing sufficient scientific and other expertise to evaluate the proposed research.

1.2.6 Materials required for expedited review shall be the same as those for protocols undergoing full-board review. All expedited reviewers will receive all materials.

1.2.7 Expedited reviews shall be conducted with the same criteria for approval and the same depth as for full-board review.

1.2.8 Expedited reviewers will declare any conflict of interest and decline to review applications with which they are in conflict.

1.2.9 Reviewers performing expedited reviews may request that the research undergo full-board review if they do not believe the research meets criteria for expedited review or if they are unable to reach a decision or approve the application with modifications.

1.2.10 Reviewers performing expedited reviews may request additional resources from the ORC, such as consultants who have expertise beyond that of the IRB members.

1.2.11 Research may not be disapproved via expedited review. If the reviewer(s) is unable to approve the research (with or without modifications), it shall be referred for full-board review.

1.2.12 Research approved via expedited review may be approved for no more than one year. If the study lasts longer, the principal investigator is responsible for applying for continuing renewal.

1.2.13 Investigators are responsible for submitting requests for modification of an approved expedited review study and for study closure to the IRB. If the principal investigator is a student and fails to close the study, the faculty supervisor is responsible for doing this.

1.2.14 The Office for Research Compliance shall inform the IRBs each month of applications that have been approved using an expedited procedure.

1.2.15 Research approved via expedited review, like full-board reviewed studies, are subject to routine monitoring and monitoring for cause.

1.2.16 Expedited review may be used for applications originally approved under full board review IF:
1.2.16.1 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

1.2.16.2 No subjects have been enrolled and no additional risks have been identified; or

1.2.16.3 The remaining research activities are limited to data analysis and manuscript preparation. (NOTE: Journals are beginning to ask manuscript authors if they have an active IRB approval.)

1.2.16.4 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.

1.3 Objective

1.3.1 Compliance with this policy will promote prompt and appropriate review of research which by its nature does not necessarily warrant full-board review by the IRB.

1.4 Responsibility

1.4.1 The Vice President for Research is ultimately responsible for this policy. Enabling parties include the Director of Research Compliance, Research Compliance Specialists, IRB members, and principal investigators.

2.0 PROCEDURE

2.1 The Research Compliance Specialists (RCS) review submitted applications for expedited review and determine whether materials submitted include sufficient detail to qualify for review by the IRB, using FORM: Completeness of IRB Application. Such detail should be sufficient for the RCS to judge whether the research satisfies the criteria specified in 45 CFR 46.111 and 21 CFR 56.111.

2.2 If the research involves prisoners, the Director of Research Compliance decides if the application qualifies for expedited review.

2.3 The Research Compliance Specialist, with assistance from the Director of Research Compliance, determines whether the proposed research satisfies either of the two conditions necessary for expedited review according to 45 CFR 46.110, 21 CFR 56.110:

2.3.1 Research posing no more than minimal risk and a category of research that may undergo expedited review as listed by the Office for Human Research Protections.

2.3.2 Minor changes in previously approved research within the approval period (Guidance: Minor Changes to Approved Protocols).
2.4 Expedited review consists of a review by the IRB chairperson or by one or more experienced IRB members, or one experienced and one inexperienced reviewer from the IRB membership.

2.5 The Research Compliance Specialist selects expedited reviewers with appropriate expertise to adequately evaluate the proposed research using the following guidelines:

2.5.1.1 Background or experience in the same general field of study as the proposed research as indicated by the IRB Expanded Roster, reviewers’ CVs, and knowledge of the reviewer’s contributions to previous IRB discussions.

2.5.1.2 Sufficient duration of service on the UA or other IRB. *(NOTE: IRB reviewers with six months of experience are considered “experienced”; those with less than six months experience are “inexperienced”)*. Reviewers with less than six months of service may review expedited applications independently but an experienced reviewer will also be assigned and informed that s/he is mentoring an inexperienced reviewer. The two shall discuss their reviews and either reach a joint decision or request an additional reviewer.

2.5.1.3 A prisoner representative is always assigned to review research involving prisoners.

2.5.1.4 Apparent absence of conflict of interest based on staff reading of the application (e.g., the prospective reviewer’s name does not appear in the application, the reviewer is unrelated to the investigator, etc.).

2.6 The Research Compliance Specialist sends the reviewer(s) the following materials regarding the proposed research:

2.6.1.1 A completed IRB application with signature page

2.6.1.2 Entire investigator’s research protocol

2.6.1.3 Consent documents, including telephone scripts

2.6.1.4 Copies of surveys, questionnaires or videotapes

2.6.1.5 Letters of assurance or cooperation, if applicable

2.6.1.6 Advertising intended for subject recruitment

2.6.1.7 For proposed modification of approved protocols the investigator’s letter outlining the proposed changes.

2.6.1.8 FORM for Reviewer Response including the Reviewer Checklist for Expedited Reviews.
2.7 Assigned reviewers read the application to determine if they have an actual conflict of interest or the appearance of a conflict with two working days of receipt of the application. If so, they will sign the response page (page 2) of FORM: Reviewer Response Form indicating a conflict and return it and the application to the Research Compliance Specialist so that the application can be reassigned. If they have a question about whether they are in conflict, they may call the Research Compliance Specialist. In general, the Office for Research Compliance prefers to treat questions about the existence of conflicts as conflicts.

2.8 If reviewers are free of conflict of interest, they proceed with the review.

2.9 If a reviewer deems it appropriate, s/he requests that the Director of Research Compliance provide additional expertise or other resources to aid in reviewing the proposal, using FORM: Request for External Consultation or that the research be referred for full board review at the next scheduled meeting.

2.10 Reviewers communicate requests for additional information, clarification, or modifications to the Research Compliance Specialist. Reviewers do not deal directly with the applicants.

2.11 The Research Compliance Specialist communicates all requests for information or modifications to the investigator and provide all investigator responses to the reviewer.

2.12 Investigators have 60 days to respond to the reviewer's requests for more information, revision, or resubmission. Failure to respond in 60 days will result in administrative withdrawal of the application. If the investigator wishes to obtain approval of the protocol, s/he will need to submit a complete initial application and responding to the board's request.

2.13 Reviewers are expected to complete expedited reviews within seven working days. Completed reviews may be returned by FAX (348-7189) or scanned and sent via e-mail.

2.14 Investigators who disagree with a reviewer's requests for modifications may request a full-board review.

2.15 To grant approval for the research the reviewer must provide the Research Compliance Specialist with:

2.14.1 A signed face page (approval page), specifying aspects of the research which are approved and specifying the date at which approval shall lapse. The approval period may not last longer than one year.

2.14.2 The reviewer may set the approval period shorter than one year if s/he believes the research warrants it.

2.14.3 A signed page two from FORM: Reviewer Response Sheet.

2.14.4 A completed page two from FORM: Reviewer Response Sheet (the review), referenced to the appropriate review criterion.
2.16 The Office for Research Compliance will provide the investigator with notification of approval within two working days of receipt from the reviewer. Approval materials include:

2.15.1 A signed approval page, specifying aspects of the research which are approved and specifying the date at which approval begins and when approval shall lapse.

2.16.1.1 Approval begins on the date the reviewer signs the approval page.

2.16.1.2 Approval lapses the day before the anniversary of the approval date for those projects given a one-year approval period.

2.16.1.3 For research approved for less than one year, approval lapses on the date specified by the reviewer.

2.15.2 A signed and dated letter advising the investigator of approval of their research. Such letter shall indicate the review interval as well as the date on which approval lapses and remind the investigator of the need to file requests for renewal or closure. Either the IRB Chair or the Director of Research Compliance may sign the investigator letter. The IRB Chairs have designated the DRC to perform this function.

2.16 The Office for Research Compliance shall maintain a list of all approved human research proposals. At each meeting of the fully convened IRB the Director of Research Compliance shall provide a printed list of all research approved since the last meeting. The printed list shall include:

2.16.1.1 The category of approval, whether exempt, expedited or full board

2.16.1.2 The title of the research and the name of the investigator

2.16.1.3 The name of the reviewer(s).

2.16.1.4 Reviewers at the meeting may ask to read or discuss applications approved by expedited review.

2.17 If research approved via expedited review continues beyond one year, the investigator must apply for continuing renewal.

2.17.1.1 If no changes are required and no problems have arisen, investigators should follow POLICY: Continuing Review of Approved Protocols and complete FORM: IRB Renewal Application.

2.17.1.2 The designated expedited IRB reviewers will follow standard procedures for continuing review.

2.18 If the investigator needs to modify a proposal approved under exempt review, s/he must apply for modification of an approved protocol.

2.18.1 If the modification falls within the study period of approval, the investigator follows POLICY: IRB Application for Modification of an Approved Protocol and completes
FORM: Modification of an Approved Protocol. If approved, the original period of approval still applies.

2.18.2 If the modification is requested concurrently with the need to apply for continuing review, the investigator applies for continuing review and modification of the proposal simultaneously. If approved, a new period of approval will be specified.

2.18.2.1 The designated expedited IRB reviewers will follow standard procedures for either a request for modification of the proposal or for modification and continuing review. Special attention will be given to whether the modifications affect the original level of risk and the number and nature of reports of study or participant problems. Reviewers may decide that the medications require review by the full board.

2.20 The investigator must also close out studies approved by expedited review using FORM: Request for Study Closure (Investigator).

3.0 REFERENCES

3.1 45 CFR 46.110
3.2 21 CFR 56.110
3.3 45 CFR 46.111
3.4 21 CFR 56.111
3.5 FDA & DHHS Categories of Research That May be Reviewed by the IRB through an Expedited Review Procedure
3.6 OHRP Guidance on the Use of Expedited Review Procedures
3.7 OHRP Guidance on Continuing Review
3.8 FDA Information Sheets: Continuing Review after Study Approval
3.9 DoD: SECNAVINST 3900.39D, para 6e; OPNA VINST 5300.8B

4.0 RELATED SECTIONS

4.1.1 FORM: IRB Checklist for Reviewers and Investigators
4.1.2 FORM: Reviewer Response Sheet
4.1.3 GUIDANCE: Minor Changes to Approved Protocols
4.1.4 FORM: IRB Renewal Application

4.1.5 FORM: Modification of Approved Application

4.1.6 FORM: Request for Study Closure (Investigator)

4.1.7 POLICY: Conflict of Interest for IRB Chairs, Members, and Consultants