

SOP: 402	EXPEDITED REVIEW
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Approved by IRB Executive Committee: December 10, 2008
Supersedes Document Dated: November 21, 2005; May 1, 2004
AAHRPP Element II.2.B.

DEFINITIONS

- a) Minimal Risk** The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

POLICY

Expedited review procedures consist of a review of research involving human subjects by the IRB Chair, IRB Vice-Chair or by an experienced reviewer designated by the IRB Chair from among IRB members (see SOP 202 for a full description of the procedure used to designate expedited reviewers). In this policy, the IRB Chair designee refers to an IRB Vice-Chair or a designated expedited reviewer.

The IRB Chair or designee may exercise all of the authorities of the IRB, except that he/she may not table or disapprove the research. A research proposal may be tabled or disapproved only after review by the convened IRB.

The categories of research that may be reviewed by the IRB through an expedited review procedure include research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the specific categories listed in the regulations at Federal Register Volume 63, No 216 and (3) the research is not classified. The criteria for approval using the expedited procedure are the same as those for review by a convened IRB.

IRB staff and IRB members follow OHRP guidance concerning expedited review procedures of a continuing review application. The IRB is permitted to use expedited review for initial and continuing review of research that involves solely one or more of the activities published at 63 FR 60364-60367. If research did not qualify for expedited review at the time of initial review, it does not qualify for expedited review at the time of continuing review except in limited circumstances as described in expedited categories (8) and (9) of 63 FR 60364-60367.

The IRB Chair or designee may use the expedited review procedure to review minor modifications to previously approved research during the period for which approval is authorized. Any protocol revision that entails more than a minimal risk to the participants must be reviewed by the full IRB at a convened meeting.

When the expedited review procedure is used, all IRB members shall be informed of actions taken by the IRB at least monthly. A report is generated by way of the ERICA online system and made available to all voting members of the IRB for their review. This report is sent via e-mail or made available within the ERICA online system by an IRB administrator or IRB coordinator.

The approval of research using expedited procedures for a study involving veterans must be reviewed by the Research and Development Committee of the Veteran Affairs Salt Lake City Health Care System before initiation. This review is conducted concurrently or after the approval is granted by the University of Utah IRB. The research study will also be included in the annual review of research projects by the Research and Development Committee of the Veteran Affairs Salt Lake City Health Care System.

PROCEDURES

1. Procedures for Expedited Review

- 1.1. The IRB administrator or IRB coordinator conducts an administrative review of the new study, continuing review or amendment application using the IRB internal checklist within the ERICA online system. If the IRB administrator or IRB coordinator determines the application may qualify for expedited review, documentation is made in the Internal Checklist. Please see SOP 302 – Administrative Review and Distribution of Materials for the full description of the procedure for administrative review.
- 1.2. The IRB Chair or designee is assigned as an expedited reviewer. Assigned expedited reviewers perform an in depth review of pertinent documentation and materials submitted by the Investigator (SOP 301) and IRB staff.
 - For new study and continuing review applications, the assigned expedited reviewer completes a Board Reviewer checklist documenting whether the application meets one or more of the expedited categories and whether the study meets the criteria for IRB approval. The reviewer documents the applicable expedited category.
 - For amendment applications, the assigned expedited reviewer completes a Board Reviewer checklist documenting whether the amendment to the previously approved research is minor and involves no more than minimal risk to participants.
- 1.3. If the expedited reviewer determines the application does not qualify for an expedited review, the reviewer notifies the IRB administrator or IRB coordinator who will assign the study for the next available convened IRB meeting.
- 1.4. If the expedited reviewer recommends that the study be tabled or disapproved, the reviewer notifies the IRB administrator or IRB coordinator who will move the item to the agenda for discussion at a convened IRB meeting. The research may only be tabled or disapproved by the convened IRB.
- 1.5. If the expedited reviewer determines that the criteria for approval of the application have been met, the reviewer may approve the application.

2. Additional Items That May be Reviewed by the IRB Chair or Designee

- 2.1. Conditional Approval Pending Minor Revisions
 - 2.1.1. Revisions to consent documents and other documentation, or clarifications submitted as a result of convened IRB review and as a condition to final approval may be reviewed by the IRB Chair or his/her

designee. Final approval will be issued providing the revisions, documentation or clarifications do not indicate or result in a change to the study or change the risk/benefit ratio.

- 2.1.2. The IRB Chair or designee will not employ the expedited approval process when changes contingent upon clarifications or modifications are directly relevant to judgments required by full board review.