

SOP 302: ADMINISTRATIVE REVIEW AND DISTRIBUTION OF MATERIALS

PURPOSE

The efficiency and effectiveness of the University of Utah Institutional Review Board (IRB) must be supported by administrative procedures that ensure that University of Utah IRB members have adequate time for thorough assessment of each proposed study, and the documentation received is complete and clear enough to allow for an adequate assessment of study design, procedures, and conditions.

SCOPE

This SOP applies to University of Utah IRB and IRB staff.

POLICY

An administrative pre-review occurs with new study, continuing review, and amendment applications by an IRB staff member using checklists in the University of Utah Electronic Research Integrity and Compliance Administration system (ERICA). Checklists help IRB staff determine if sufficient information has been provided for IRB review.

An IRB staff member is assigned as the administrative reviewer based upon the type of application (i.e., new study application, continuing review, or amendment, etc.) and an initial assessment of the level of review the application is likely to receive (e.g., convened board, expedited review, etc.).

PROCEDURES

1. Administrative Review

The assigned administrative reviewer may request revisions of the investigative staff to ensure sufficient information for the IRB review.

1.1. New Studies

Upon completion of the pre-review for new study applications, an assigned administrative reviewer makes a primary risk assessment. Based on the primary risk assessment, the administrative reviewer proceeds with the appropriate action as described below.

Primary Risk Assessment	Review Requirements
Non-Research/Non-Human Subject Research	Review and determination completed by an IRB administrator as outlined in IRB SOP 401a: Non-Human Subjects Research.

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.



Primary Risk Assessment	Review Requirements
Exempt	Review and determination completed by an IRB administrator (who must be an IRB member) as outlined in IRB SOP 401b: Research Activities Exempt from IRB Review.
Minimal	Assigned to a primary reviewer for convened board review (see IRB SOP 403: Initial Review – Criteria for IRB Approval) unless eligible for expedited review. Secondary reviewers are assigned at the discretion of the IRB administrator. If eligible for expedited review (see IRB SOP 402: Expedited Review), assigned to IRB Chair or a designated expedited reviewer for review.
Greater than Minimal Risk	Assigned to primary and secondary reviewers for convened board review (see IRB SOP 403: Initial Review – Criteria for IRB Review).

1.2. Continuing Reviews

Upon completion of the pre-review for continuing review applications, an assigned administrative reviewer proceeds with the appropriate action based upon the determined risk assessment and the current status of the study. 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 (see IGS: Expedited Review of Research on the IRB website).

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Determined Risk Assessment	Review Requirements
Minimal	<p>Assigned to a primary reviewer for convened board review (see IRB SOP 404: Continuing Review) unless eligible for expedited review.</p> <p>Unless determined otherwise continuing review is not required for a study eligible for expedited review if the study was approved on or after the implementation of the Final Rule (January 21, 2019), or the study was transitioned to the Final Rule. If Expedited Review (see IRB SOP 402: Expedited Review) is appropriate it is assigned to IRB Chair or a designated expedited reviewer for review.</p>
Greater than Minimal Risk	<p>Assigned to primary reviewer for convened board review (IRB SOP 404: Continuing Review) unless eligible for expedited review.</p> <p>If eligible for expedited review (see IRB SOP 402: Expedited Review), assigned to IRB Chair or a designated expedited reviewer for review.</p>

1.3. Amendments

Upon completion of the pre-review for amendment applications, an assigned administrative reviewer proceeds with the appropriate action based upon whether the administrative reviewer determines that the amendment proposes minor changes and involves no more than minimal risk to the participant. Amendments to exempt studies will be reviewed to determine whether the changes alter the initial exempt determination.

Amendment Type	Review Requirements
Amendments to exempt studies	Substantial changes which alter exempt status will be reviewed using initial review procedures.
Amendments proposing minor administrative changes and involve no additional risk to participants	Assigned to an IRB staff member for review and to a designated expedited reviewer for approval.

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Amendment Type	Review Requirements
Amendments proposing changes which have been requested by a convened board	Assigned to a designated expedited reviewer for review. Convened board discussion is not required for these submissions.
Amendments proposing minor changes and involves no more than minimal risks to the participant	Assigned to designated expedited reviewer for review. Convened board discussion is not required for these submissions.
Amendments proposing substantial changes or may represent a greater than minimal risk to the participant	Assigned to primary reviewer for convened board Review (see IRB SOP 405: Review of Amendments to Research Studies) regardless of the determined risk assessment of the study (i.e., minimal, greater than minimal).

2. Assignment of Reviewers and Preparation of an Agenda

- 2.1. The assignment of designated expedited reviewers, primary reviewers and secondary reviewers is the responsibility of the IRB administrator. The IRB administrator makes assignments with the help of the IRB panel roster. The IRB administrator assigns reviewers with the appropriate scientific and scholarly expertise to conduct an in-depth review of the protocol. Based upon the research proposal, the IRB administrator assigns reviewers who are knowledgeable about or experienced in working with vulnerable participants, if necessary. If the IRB administrator finds there is no IRB member with appropriate scientific and scholarly expertise to conduct an in-depth review, IRB administrator will consult with the IRB manager or IRB Director for assistance in obtaining consultation or whether deferral to another IRB meeting will be required.
- 2.2. The assignment of designated expedited reviewers is made concurrently with the assignment of convened board reviewers (see 2.3) or upon completion of the pre-review. Applications approved using expedited procedures are available to all board members in ERICA on the agenda and minutes.
- 2.3. The assignment of convened board reviewers (primary and secondary reviewers) is made at least seven calendar days in advance of the convened board meeting. If the assignment is made less than seven calendar days before a convened meeting, extenuating circumstances must exist, and the assignment must be made no less than two working

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days prior to the meeting. Reviewers receive an e-mail automatically generated by ERICA stating the assignment.

- 2.4.** ERICA creates an electronic agenda for convened meetings. The IRB administrator is responsible for the accuracy of the agenda and for completing any other components of the agenda in ERICA. A copy of the agenda and attached materials is maintained with the meeting minutes within ERICA.
- 2.5.** Complete applications as described in IRB SOP 301: Research Submission Requirements are available to all IRB members, via the electronic agenda beginning at least seven calendar days in advance of the convened meeting. Complete applications are made available to any alternate members attending the meeting in place of a regular member. Ad hoc consultant reviewers receive copies of material that pertain to their requested input.

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