

SOP: 302	ADMINISTRATIVE REVIEW AND DISTRIBUTION OF MATERIALS
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Approved by IRB Executive Committee: November 12, 2008
 Supersedes Document Dated: November 15, 2005, May 1, 2004
 AAHRPP Elements II.1.A. and II.1. F.

POLICY

The efficiency and effectiveness of the IRB is supported by administrative procedures that ensure that IRB members not only have adequate time for thorough assessment of each proposed study, but that the documentation they receive is complete and clear enough to allow for an adequate assessment of study design, procedures, and conditions.

PROCEDURES

1. Procedures for Administrative Review

An administrative review (pre-review) of all new study, continuing review and amendment applications is conducted by an IRB administrator or IRB coordinator using checklists developed to determine if sufficient information has been provided for IRB review.

An IRB administrator or IRB coordinator is assigned as the administrative reviewer based upon the type of application (i.e. new study application, continuing review or amendment) and the date of submission.

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 administrator as outlined in SOP 401a.
Exempt	Forwarded to IRB Chair, IRB Vice-Chair or IRB Director for final review and determination as outlined in SOP 401b.

Primary Risk Assessment	Review Requirements
Minimal	<p>Assigned to a Primary Reviewer for Convened Board Review (see SOP 403) unless eligible for Expedited Review. Primary and Secondary Reviewers are assigned to review studies involving vulnerable populations.</p> <p>If eligible for Expedited Review (see SOP 402), assigned to IRB Chair or a designated expedited reviewer for review.</p>
Greater than Minimal Risk	Assigned to Primary and Secondary Reviewers for Convened Board Review (see SOP 403).

- 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 Expedited Review of Research Guidance on the IRB website).

Determined Risk Assessment	Review Requirements
Minimal	<p>Assigned to a Primary Reviewer for Convened Board Review (see SOP 404) unless eligible for Expedited Review.</p> <p>If eligible for Expedited Review (see SOP 402), 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 (SOP 404) unless eligible for Expedited Review.</p> <p>If eligible for Expedited Review (see SOP 402), 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	Forwarded to IRB Chair or IRB Vice-Chair for re-determination of exempt status. Substantial changes which alter exempt status will be reviewed using initial review procedures.
Amendments proposing minor changes and involves no more than minimal risks to the participant	Forwarded to Chair or IRB Vice-Chair for review and approval. Full 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 SOP 405) regardless of the determined risk assessment of the study (i.e. minimal, greater than minimal).

2. Procedures for the 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 coordinator. The IRB coordinator makes assignments with the help of the Reviewer Assignment Sheet and IRB Internal Roster. The IRB coordinator 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 coordinator assigns reviewers who are knowledgeable about or experienced in working with vulnerable participants, if necessary. If the IRB coordinator finds there is no IRB member with appropriate scientific and scholarly expertise to conduct an in-depth review, IRB coordinator will consult with the IRB administrator or IRB Director for assistance in obtaining consultation or whether it will be required to be deferred to another IRB meeting.
- 2.2. The assignment of convened board reviewers (primary and secondary reviewers) are made at least seven (7) calendar days in advance of the convened board meeting. If the assignment is made less than seven (7) calendar days before a convened meeting, extenuating circumstances must exist and the assignment must be made no less than two (2) working days prior to the meeting. The assignment of designated expedited reviewers is conducted concurrently with the assignment of convened board reviewers.

All reviewers receive an e-mail automatically generated from the ERICA system stating the assignment.

- 2.3. The ERICA online system creates an electronic agenda for convened meetings based upon the reviewer assignments. The IRB coordinator is responsible for the accuracy of the agenda and for completing any other components of the agenda (see IRB Agenda/Minutes Template) in the ERICA system. A copy of the agenda and attached materials is maintained with the meeting minutes within the ERICA online system.
- 2.4. Complete applications as described in SOP 301 (Research Submission Requirements) are available to all IRB members, via the electronic agenda beginning at least seven (7) 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.