

Tip Sheet 17: Review of Research by the Expedited Procedure

Related Accreditation Elements: II.2.F.

Policies and procedures should describe review using the expedited procedure, when an expedited procedure is used.

Recommended Content:

This policy and procedure may stand alone or be part of an umbrella policy and procedure on IRB or EC review.

Application procedure:

1. Describe the materials that must be submitted to the IRB or EC, including information to judge eligibility for review by the expedited procedure.

Reviewers:

1. Define when an IRB or EC member is considered experienced.
2. Describe the process by which the IRB or EC chair designates reviewers.

Pre-Review Procedures:

1. Describe the entity (title of person or office), if any, that checks submissions for completeness and the actions taken when the submission is incomplete.
2. Describe the process used to decide whether the expedited procedure is used.
3. If reviewers using the expedited procedure rely on other supplemental reviews (e.g., consultants, staff, or subcommittee reviews), describe:
 - a. When submissions receive such review.
 - b. The entity that checks submissions to determine whether supplemental reviews are required and have been completed.
 - c. The process by which reviewers learn the results of such reviews.
4. Describe the entity that checks for required special representation, such as a prisoner representative.
5. If more than one person can conduct reviews by the expedited procedure, describe:
 - a. The entity that selects the person that conducts the review.
 - b. The criteria used to make the selection.
6. If each research protocol or plan is reviewed by multiple persons, describe the procedure, including:
 - a. The entity that determines that at least one reviewer has appropriate scientific and disciplinary expertise.
 - b. The documents provided to all reviewers.

- c. The documents provided only to specific reviewers.
- d. The timing of document distribution.
- e. The process used by the multiple reviewers to make a group decision.

Review Procedures:

1. Describe the criteria for approval of research.
2. Describe responsibilities of reviewers, including:
 - a. Conducts reviews with the same depth as that by a convened IRB or EC.
 - b. Uses the same criteria for approval as for review by a convened IRB or EC.
 - c. Declares conflicts of interest.
 - d. Considers the need for additional expertise.
 - e. For initial review:
 - i. Documents the category of approval.
 - ii. Determines that the research falls into one or more categories that allows review using an expedited procedure.
 - iii. For DHHS- and FDA-regulated research, determines that the research meets the applicability criteria. (Include criteria to judge whether research involves no more than minimal risk to participants. Include criteria to judge whether identification of participants or their responses would reasonably place them at risk of criminal or civil liability—or be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing—unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.)
 - f. For continuing review:
 - i. Determines that the research falls into one or more regulatory categories that allow continuing review using the expedited procedure.
 - ii. Documents the category of approval.
 - g. For review of modifications to previously approved research, determines that the proposed modification represents a minor change (include criteria to judge whether a modification represents a minor change).
 - h. Completes checklists or other documentation, if any.
 - i. Documents specific determinations required under the laws or regulations and protocol-specific findings that justify the determinations.
 - j. Communicates with Researchers, if applicable.
 - k. For continuing review, determines:
 - i. That the current or proposed consent document is accurate and complete.
 - ii. If any significant new findings that might relate to a participant’s willingness to continue taking part in the research study need to be provided.
 - iii. Whether verification from sources other than the Researcher is needed to ensure that no material changes have occurred since previous IRB or EC review.

Describe criteria to make such a determination.

1. Other expectations, if applicable.
3. Describe the range of possible actions that can be taken, such as:
 - a. Approval.
 - b. Require modifications in order to secure approval.
 - c. Other applicable actions allowed.
4. Describe actions that cannot be taken, including disapproval.
5. Describe when research protocols or plans are referred to the convened IRB or EC, such as:
 - a. The reviewer cannot approve or approve with modifications.
 - b. The reviewer can approve with modifications, but the Researcher does not agree with the requested modifications.
 - c. Other situations, if applicable.
6. For initial and continuing review, describe:
 - a. The process used by the reviewer determines the approval period including the criteria for which research protocol or plans require review more often than annually.
 - b. The documentation of the approval period in records.

Post-Review Procedures:

1. For initial and continuing review, describe:
 - a. How the start date of the approval period is determined.
 - b. How the last day of the approval period is determined.
2. Describe the process to inform IRB or EC members about research protocols or plans that have been approved using the expedited procedure.
3. Describe the process to report findings and actions from reviews using the expedited procedure to the Organization:
 - a. Specify the organizational offices and officials that are notified.
 - b. Describe the mechanism for notification.
4. If approved research requires further review by the Organization, describe:
 - a. The required reviews.
 - b. The process for communicating the results of those reviews to the IRB or EC.
5. Describe the process by which reports from the review are communicated to the Researcher:
 - a. Date of review.
 - b. What was reviewed.
 - c. The process of review by the expedited procedure.
 - d. The decisions of the reviewer.
 - e. If the reviewer requires modifications in order to secure approval:
 - i. A description of the required modifications.
 - ii. The basis for requiring modifications.

6. When the reviewer requires modifications to the research protocol or plan in order to secure approval, describe the process for review of responsive materials.
7. Describe the process by which Researchers may respond in person or in writing to IRB or EC decisions.

Additional Issues for Continuing Review:

1. Describe the consequences of the Researcher not providing continuing review information to the IRB or EC, or of the IRB or EC not reviewing and approving a research protocol or plan by the expiration date, such as:
 - a. State that all research activities must stop, unless the IRB or EC finds an over-riding safety concern or ethical issue such that the best interests of individual participants are served by continuing.
 - b. Describe the process the IRB or EC uses to determine whether there are currently enrolled participants with safety concerns or ethical issues that may arise if research activities are stopped.
 - c. Describe the process to determine whether the best interests of individual participants are served by continued involvement in the research.
 - d. Describe any other consequence, as applicable.

Additional Issues for Review of Modifications to Previously Approved Research:

1. Indicate the required time frame for submission to the IRB or EC of:
 - a. Changes initiated without IRB or EC review and approval to eliminate apparent immediate hazards to the participant.
 - b. Proposed changes in a research activity.
 - c. The completion of a research study.
 - d. Other changes.
2. Describe the process to review modifications initiated prior to IRB or EC approval to eliminate apparent immediate hazards to determine whether changes are consistent with ensuring participants' continued welfare.

Other Suggestions:

1. If a checklist is used for initial review of research, include:
 - a. Applicability criteria for eligibility for review by the expedited procedure.
 - b. Categories of research eligible for review by the expedited procedure.
 - c. Criteria for approval.
2. If a checklist is used for continuing review of research, include:
 - a. Categories of research eligible for review by the expedited procedure.
 - b. Criteria for approval.
3. If a checklist is used for review of modifications to previously approved research, include:
 - a. The requirement that the modification be a minor change.
 - b. Criteria for approval.
4. Include in supporting forms for Researchers:
 - a. Submission requirements.
 - b. Eligibility criteria for review of research by the expedited procedure.
 - c. The required time frame for submission of study completion.