

Tip Sheet 16: Review of Research by the Convened IRB or EC

Related Accreditation Elements: II.2.D. and II.2.E.

Policies and procedures should describe review of the research protocol or plan by the convened IRB or EC.

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 need to be submitted to the IRB or EC for:
 - a. Initial review.
 - b. Continuing review.
 - c. Review of proposed modifications to previously approved research.

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. If the IRB or EC relies on other supplemental reviews, such as those by consultants, staff, or subcommittees, 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 mechanism by which IRB or EC members learn the results of such reviews.
3. If there are multiple IRBs or ECs, describe:
 - a. The entity that selects the IRB or EC that will review the research protocol or plan.
 - b. The criteria used to make the selection.
4. If a primary reviewer system is used, describe:
 - a. The entity that selects the primary reviewers.
 - b. The criteria used to make the selection.
5. For in depth review of the research protocol or plan:
 - a. Describe the entity that determines that at least one IRB or EC member or consultant conducts such review.
 - b. Describe the criteria used to make the determination.
 - c. If a consultant is used:
 - i. The process to identify any conflicts of interest of the consultant.

- ii. The process to communicate the consultant's findings to the IRB or EC.
6. Describe who checks for required special representation, such as a prisoner representative.
7. Describe the documents provided:
 - a. To all reviewers.
 - b. To specific reviewers (for example, primary reviewers, consultants, or IRB or EC chairs).
8. Describe the timing of document distribution to IRB or EC members.

Review Procedures:

1. Describe the criteria for approval of research.
2. Describe responsibilities of the IRB or EC members, including:
 - a. Declaration of conflicts of interest.
 - b. Consideration of need for additional expertise.
 - c. Depth of review of agenda materials.
 - d. Completion of checklists or other documentation, if any.
 - e. Documentation of required determinations and protocol-specific findings that justify the determinations.
 - f. Communication with Researchers, if applicable.
 - g. For initial and continuing review, determining the review interval.
 - h. For continuing review, determining:
 - i. That the current or proposed consent document is accurate and complete.
 - ii. Whether 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 the criteria to make such a determination.
 - i. For review of modifications, determining whether significant new findings that might relate to a participant's willingness to continue taking part in the research study need to be provided.
 - j. Other expectations, if applicable.
3. Describe the expectations of all IRB or EC members in terms of what documents they are expected to review.
4. Describe additional expectations of primary reviewers.
5. Describe the range of possible actions that can be taken, such as:
 - a. Approval.
 - b. Require modifications in order to secure approval.
 - c. Disapprove.
 - d. Other actions allowed.

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.
 - c. Whether the expiration date is the last date that the research protocol or plan is approved, or the first date that the research protocol or plan is not approved.
2. Describe how the IRB or EC reports its findings and actions to the Organization:
 - a. Specify the organizational offices and officials that are notified.
 - b. Describe how notification to each is accomplished.
3. If research approved by the IRB or EC is subject to further review within the Organization, describe:
 - a. The required reviews.
 - b. The mechanism by which results of those reviews are communicated to the IRB or EC.
4. Describe the reporting of the IRB's or EC's findings and actions to the Researcher. Include:
 - a. The date of review.
 - b. What was reviewed.
 - c. The process of review by the convened IRB or EC.
 - d. The decisions of the IRB or EC.
 - e. If the IRB or EC requires modifications to the research protocol or plan in order to secure approval:
 - i. A description of the required modifications.
 - ii. The basis for requiring modifications.
 - f. If the IRB or EC disapproves research:
 - i. A statement of the reasons for disapproval.
 - ii. A description of how Researchers may respond.
5. When the IRB or EC requires modifications to the research protocol or plan in order to secure approval, describe the process for review of responsive materials:
 - a. The criteria used to determine whether the response by the Researcher is reviewed by the convened IRB or EC or by the expedited procedure.
 - b. Who makes the determination in 5.a.
6. Describe how Researchers may respond in person or in writing to IRB or EC decisions.

Additional Issues for Continuing Review:

1. Describe the consequences of failure to provide continuing review information to the IRB or EC, or failure of the IRB or EC to review and approve 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 to participate in the research.
 - b. Describe how the IRB or EC determines 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.