

Guidance on Amending IRB Approved Projects

Investigators must seek IRB approval before making any changes to the approved research- even though the changes are planned for the period for which IRB approval has already been given. **Changes to the study protocol may not be implemented until approved by the IRB.** However, a change may be implemented with IRB approval when the change is necessary to eliminate immediate hazard to the subject in which case the IRB must then be notified at once. [See Reportable Events Guidance]

Modifications represent changes in the protocol within the scope of what the IRB originally authorized. For example, if a researcher wishes to add a population to existing study, but not alter the study procedures or purpose, a modification request is usually appropriate.

The degree and significance of the changes affect whether the modification receives full or expedited review. The IRB may use an expedited review procedure to review minor changes in ongoing-previously-approved research during the period for which approval is authorized. If a proposed change in a research study is not minor (e.g., procedures involving increased risk or discomfort are to be added), then IRB must review and approve the proposed change at a convened meeting before the change can be implemented.

Amendment(s) to Approved Research Submission(s)

Investigators must submit documentation to the IRB about the changes in the status of the study. The following documents are required, however, additional information may request to complete the review and approval process.

- Completed Application for Amendment Form
- A detailed outline of all changes and a rationale for each change. This may be completed as a separate document or in a letter format from the Principal Investigator.
- Revised Investigator's protocol or sponsor's protocol (if applicable)- 2 copies; one clean copy and one copy showing highlighted or underlined changes.
- Revised approved consent/parental permission/assent documents (if applicable) or other documentation that would be provided to subjects when such information might relate to their willingness to continue to participate in the study- 2 copies; one clean copy and one copy showing highlighted or underlined changes.
- Revised or additional recruitment materials or any additional approach materials or documents given to participants that are affected by the modification, such as approach letters, telephone scripts or questionnaires.
- Any other relevant documents provided by the Investigator.
- Once the request is received, the IRB office will determine the review process the amendment qualifies for: expedited or full board. If an amendment application is submitted for expedited review, the reviewer will determine that the proposed changes may be approved through the expedited review procedure and, if not, must refer the protocol for full board review.
- The following are the determinations that may be made by the expedited reviewer:
- The expedited reviewer may approve the modification request as it has been submitted.
- The expedited reviewer may request additional information from the investigator.
- The expedited reviewer needs additional assistance on the review of the project may appoint an ad hoc subcommittee to review the modification.

- The modification may be referred to the full board for consideration of the expedited review determines it does not fall within the federal regulations requirements for expedited approval.
- The following are the determinations that may be made by the IRB at a convened meeting:
 - The board approves the modification request as it has been submitted.
 - The board may grant a Conditional Approval meaning minor revisions are required, such as wording changes, with replacement language provided. Such revisions are presented to the PI for incorporation by simple concurrence. The chair(s) or certain designated IRB office staff upon receipt may approve the revisions without further action by the IRB.
 - The board may defer the amendment for substantive issues. This action is taken if substantial modification or clarification is required, or insufficient information is provided to judge the application adequately. IRB approval of the proposed amendment will not occur by the convened IRB until subsequent review of the material submitted for by the PI.
 - The board may disapprove the amendment. Questions and issues are of such magnitude that the IRB determines approval of the amendment is unwarranted.

When the modification is approved, a copy of the approval is sent to the investigator.

Approval of a modification does not alter the date of the study's approval period. Renewal notices are sent based on the approval period previously assigned.