SOP 405: Amendments to Approved Studies

Terms and Abbreviations

Full board meeting: A convened meeting of the IRB at which a quorum of members is present
Full board studies: Research studies that require review by the convened IRB
IO: Institutional Official; individual who is legally authorized to act for the institution and ensures the effective functioning of the IRB
IRB: Institutional Review Board
IRB office staff: the IRB Manager, IRB Administrator, and any other IRB office staff, either collectively or individually
PI: Principal Investigator

Overview

The Principal Investigator must conduct the research in accordance with the specific methods described in the application that was approved by the IRB.

If a PI wishes to make changes to a previously approved research project, these changes must first be submitted to and approved by the IRB. No changes in approved research may be initiated without IRB review and approval, except when necessary to eliminate apparent immediate hazards to research subjects.

The IRB reviews amendments to previously approved research in accordance with:

1. the level of risk of the study as a whole, and
2. the level of risk of the proposed changes.

Amendments may be reviewed at a full board meeting or via expedited procedures.

Details and Procedures

When determining the appropriate review level for an amendment, IRB office staff consider which of the "three P's" are affected by the changes:

1. Purpose
2. Population under study
3. Procedures

Most amendments that impact only one of these and do not involve an increase in risk to participants are considered minor amendments. These are generally reviewed by IRB office staff.

Amendments that affect two or more of the "three P's", or where the risk to participants is increased (including risks related to procedures and methods, and modifications that might negatively impact the statistical analysis of the research), are treated based on the level of review of the initial study.

(Note: in most cases, amendments affecting all 3 P's are usually significant enough to be considered a different study entirely, and the IRB recommends that these be submitted as a new study rather than an amendment.)

- **Exempt studies:** Amendments are reviewed by IRB office staff only, unless the changes are significant enough that the study no longer qualifies for exempt status. In this case, the amendment would receive either expedited or full board review, in accordance with the level of risk of the changes.
- **Expedited studies:** Amendments receive expedited review, unless the changes raise the study to the level of more than minimal risk and full board review is required. Expedited reviews may be conducted by the IRB office staff only, or one or more additional reviewers may be assigned.
- **Full board studies:** Minor changes may receive expedited review by IRB office staff and/or one or more reviewers. Significant changes must receive full board review. IRB office staff, primary reviewer(s), and/or the Chair determine whether a change is "minor" vs. "significant". If there is not consensus, the amendment is sent to the full board.

Expedited Review Process

Applies to amendments for most exempt and expedited studies, and for minor changes to full board studies.

1. The researcher submits an amendment through the electronic submission system. All documents affected by the amendment must be included. Changes should be marked in the documents so the IRB office staff and reviewer(s), if applicable, can clearly see what is different from the currently approved version.
2. IRB office staff conducts an initial review and determine the level of review required. IRB office staff may act as the sole reviewer if they feel they have adequate expertise to complete the review without input from additional reviewers, or may assign additional reviewer(s).
3. The IRB office staff and any additional reviewer(s) complete the appropriate review checklist and recommend one of the following actions:
    a. Approve as submitted
    b. Request revisions
    c. Assign an additional IRB member to review
    d. Refer to the convened IRB for review
    Note: Amendments may not be disapproved using expedited procedures. If the reviewer(s) recommend disapproval, the amendment must be referred to the full board.
4. The IRB office staff communicates any request for revisions to the researcher in writing.
5. Upon resolution of any requested changes, the IRB office staff issues the approval letter.

6. The approval of an amendment does not change the original approval period or the expiration date of the study.
7. IRB office staff includes a list of all expedited actions on the next available meeting agenda and documents the IRB's approval of these actions in the IRB meeting minutes. Agendas and minutes are made available to all IRB members and the IO regularly, and to anyone else in the institution upon request. An IRB member may request that any amendment given expedited approval be brought before the convened IRB for review.

Full Board Review Process

Applies to full board studies where the changes are not minor, or to exempt/expedited studies if the changes involve more than minimal risk.

1. The researcher submits an amendment through the electronic submission system. All documents affected by the amendment must be included. Changes should be marked in the documents so the IRB office staff and reviewer(s), if applicable, can clearly see what is different from the currently approved version.
2. IRB office staff conducts an initial review and completes the reviewer checklist. One or more additional reviewers may be assigned.
3. The amendment is placed on the next available meeting agenda and the PI and/or SPI are invited to the meeting.
4. The convened IRB reviews the amendment and may take one of the following actions, based on the votes of the majority (more than 50%) of the voting members present at a full board meeting.
    a. Approve as submitted
    b. Request revisions
    c. Table, pending additional information
    d. Disapprove
5. The date of approval of an amendment does not change the original approval period or the expiration date of the study, unless the IRB determines that the changes warrant reviewing the study more frequently (*example: a 6 month approval period rather than the usual 12 months)*. In that case, a new expiration date may be issued.
6. The IRB office staff communicates any request for revisions to the researcher in writing.
7. Once any requested changes have been made, the IRB office staff issues the approval letter.
8. The amendment, discussion of any controverted issues, and actions taken by the IRB are documented in the meeting minutes.

References

45 CFR § 46.110

21 CFR § 56.110

Revision History

Version	Date	Summary of Changes
1	2 Jul 2020	Initial version