Amendments/Modifications: Making Changes After IRB Approval

Does Not Need Additional Review

Only correcting grammatical or typographical errors.

Submit revised materials at the next continuing review.

May Use Expedited Review Procedures

Minor changes that, if considered independently from the overall research, involve no significant alteration in research design or fall into one or more categories allowing exempt or expedited review, and involve no greater than *minimal risk* [Note 1] to participants [Note 2 for examples].

Submit an amendment application through eProtocol: Amend/ Modify an Approved Protocol

Expedited amendment applications are reviewed in the order that they are received.

Requires Full Board Review

Major changes to approved research which:
a. Present greater than minimal risk to participants
or
b. Are not eligible for expedited review
or
c. Significantly alter the study design, and the research itself is already greater than minimal risk [Note 3].

Submit an amendment application through eProtocol: Amend/Modify an Approved Protocol

The amendment application will be reviewed at the next available meeting according to the applicable CPHS calendar [Note 4].

Notes on Amendments/Changes After IRB Approval

1. “Minimal risk” definition: The probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of routine physical examination. The definition of minimal risk for research involving prisoners differs somewhat from that given for non-institutionalized adults (see CPHS/OPHS Glossary of Terms).

2. Examples of minor modifications include personnel changes; minor procedural changes; changes that reduce risks; changes that add minor risks (e.g., risks of small blood draws); changes to wording in the application, consent form, or other documents; modifications to questionnaires/surveys that don’t increase risk, etc. Note that changes to research that was initially approved through expedited review will qualify for expedited review unless the change increases the overall risk level of the research to greater than minimal.

3. Examples of major modifications for studies that initially required Full Committee review include adding vulnerable populations, significantly altering the study design, adding investigational devices and/or investigational drugs, adding serious privacy risks (e.g., asking participants about abusive behavior or current illegal activities), etc.

4. Applications that are likely to require Full Committee review must be submitted prior to the submission deadline for a scheduled meeting date of the appropriate committee (see Committee Directory and Meeting Calendars). All other applications are reviewed as they come in and in the order that they are received. Investigators should allow extra time for projects that require additional review from other UCB regulatory programs (e.g., Radiation Safety Committee, Conflict of Interest Committee, etc.).

Note: The level of review is determined by OPHS analysts in consultation with the IRB Chair as needed. Should you have any questions, please do not hesitate to contact OPHS staff at ophs@berkeley.edu or 510-642-7461.