

Amendments	
HSC SOP No:	018
Original Procedure Effective Date:	July 14, 2015
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1. PURPOSE

- 1.1. All amendments (i.e., changes/modifications) to approved research must be submitted to the IRB for review and approval before they are implemented. The only exception to this requirement for prior IRB review and approval is in instances where the changes are "necessary to eliminate apparent immediate hazards to the subject" 45 CFR 46.108(3)(iii).

2. DEFINITION and EXAMPLES

- 2.1. *Amendment* means any change/modification made to an approved protocol. Amendments may include, but are not limited to, procedural changes, adding or removing personnel, requesting additional subjects beyond the originally approved number, new funding sources, new or revised advertisements or recruitment methods, changes to the informed consent process and/or documents, changes to surveys, questionnaires or interview guides changes in design based on new literature or techniques, addition of a research site, or any other changes in the research activity.

3. POLICY and PROCEDURE

3.1. Submission Requirements for Amendment Requests

Investigators must submit request for changes to the IRB in writing. These requests must include the following:

- A description of the changes;
- A revised consent document (if applicable);
- Any revised instruments or other documentation affected by the amendment (e.g., recruitment materials, interview guide, etc.);
- A new disclosure of financial conflict of interest (if applicable);
- Any other relevant documentation required by the IRB.

3.2. Types of Review

The IRB staff will determine the type of review (determination that the amendment still meets the criteria for exemption, expedited review, or full board review procedures) in consultation with the IRB Chair/Designee when appropriate.

- All minor changes in previously approved research may be reviewed by expedited review procedures. Minor changes are defined as changes that, if considered independently from the overall research, involve no significant alteration in the research design or fall into one or more categories allowing expedited review procedures, or a determination of exemption, and involve no more than minimal risk to the human subjects.
- Administrative changes, such as addition of a new funding source, adding or removing personnel, other than the Faculty Advisor or Faculty Principal Investigator, may be reviewed and handled administratively. Administrative

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review may be completed by the IRB staff, provided the IRB staff member is also a voting member of the IRB.

- All changes in previously approved research that are not considered “minor” must be reviewed during a convened meeting of the full board or via expedited review procedures. Changes that fall under the following categories must be reviewed by full board if they meet any of the following:
 - a. Present greater than minimal risk to the human subjects;
 - b. Are not eligible for expedited review procedures based on the Office of Human Research Protections categories of research (as described in HSC SOP 016);
 - c. Significantly alter the study design when the research itself is greater than minimal risk.

3.3. **Criteria for Approval of Amendment**

When considering whether to approve an amendment to a research protocol, the IRB revisits the same criteria used to grant initial approval (as described in HSC SOP 014).

4. **SCOPE**

These policies and procedure apply to all exempt and non-exempt human subjects’ research.

5. **RESPONSIBILITY**

The IRB staff, in consultation with the IRB Chair/Designee when appropriate, are responsible for the initial assessment of level of risk associated with all proposed amendment requests. However the final determination of level of risk must be made by the convened IRB or, if the application is reviewed by expedited procedures, by the expedited reviewers.

The IRB staff member who is also a voting committee member and/or IRB Chair/Designee is responsible for performing the expedited review of an amendment request that involve no more than minimal risk.

6. **PROCESS OVERVIEW**

Amendment Review – Confirmation of Administrative Change

When an amendment request that is considered an administrative change, such as adding new personnel or removing personnel is submitted, an IRB staff member will conduct an initial review of the submission. If the amendment is administrative in nature, the change can be reviewed and handled administratively using expedited review procedures under 45 CFR 46.110(b)(1)(ii).

Amendment Review – Expedited

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When an amendment request that qualifies for expedited review is submitted, an IRB staff member will conduct an initial review of the submission. If additional documentation or information is necessary, the responsible staff member initiates correspondence to the investigator, which may include requests for revisions or clarifications, via the protocol application or occasionally via email.

After the investigator has revised the protocol application or responded to the requested information, the IRB staff member will verify that all items have been addressed and the application can be set-up for expedited review. The application will be reviewed at the next regularly scheduled expedited review meeting. During the expedited review meeting, the IRB Chair/Designee, IRB member, and an IRB staff member, who also serves as a voting member of the committee, will review the amendment. If there are any clarifications or concerns, the application will be returned to the investigator to address the expedited review comments. If there are no comments, clarifications, or concerns, or once these items have been addressed, the amendment can be approved.

After the amendment application is approved, all approved documents, including the protocol, informed consent, parental permission, assent, measures, interview questions, etc., will be made available to the investigator along with the protocol approval letter. If there are any items that cannot be resolved or if it is determined that the amendment does not meet the criteria for expedited review procedures, the application must be reviewed by the convened IRB (i.e., full board). Expedited review procedures may not result in withholding approval, or disapproving a study.

Amendment Review – Convened IRB (Full Board)

When an amendment requiring review by the convened IRB is submitted, it is added to the agenda of the next regularly scheduled full board meeting. An IRB staff member will conduct a preliminary review of the application and may prepare comments for the IRB to review at the convened meeting. The IRB staff will inform the committee members that the amendment is available for review and will assign a primary and secondary reviewer for each amendment set-up for full board review. If an amendment requires special consideration or expertise, the IRB Chair/Designee, IRB staff, and/or Research Integrity Director may arrange for a consultant's participation and the necessary documentation will be forwarded to the consultant for comments.

At the convened meeting, the IRB primary and secondary reviewer presents a summary of the the request for amendment to the committee. The IRB primary and/or secondary reviewer may also elaborate on any aspect of the study they deem appropriate to discuss. All IRB members may ask questions and engage in discussion of the protocol review. The IRB

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may approve the amendment request, require modifications to secure approval, disapprove the amendment, or table the protocol for consideration at future convened meeting. The investigator will be notified in writing of the committee review outcome. If modifications are requested, the IRB will designate the IRB staff who is also appointed as a voting member, and/or IRB member to review the investigator's response and revisions in order to verify that the conditions for approval have been satisfied.

If the requested revisions are substantive or sufficient detail is missing in the amendment application, the IRB will request review at a future convened meeting.

After the amendment is approved, all approved documents, including the protocol, informed consent, parental permission, assent, measures, interview questions, etc. will be made available to the investigator along with the protocol approval letter.

If the IRB does not approve the amendment, an IRB staff member will notify the investigator in writing identifying the reason for withholding approval.

References:

45 CFR 46 Regulations

UC Berkeley Policies and Procedures

The Belmont Report