

IRB Review of Modifications

Purpose

- 1) This policy sets forth both the criteria and process to review modifications to research involving human participants, which was approved by the Institutional Review Board (IRB) either at a convened meeting or using expedited review procedures. This policy also applies to research the IRB has deemed exempt.

Policy

- 1) When research involving human participants has already been granted IRB approval, any changes to the research must not be implemented or initiated without Chapman's IRB review and approval.
- 2) In cases of an incident involving an immediate hazard to human participants, Principal Investigators (PIs) may implement an immediate change to the study to avoid harm. Then the PI must submit the following:
 - a) (if the incident constitutes an [unanticipated problem](#)), a modification to the IRB within 5 business days of discovering the matter.
 - b) an incident report within 5 business days of discovering the matter that outlines the circumstances and rationale surrounding the immediate change. See Incident Reports for more information.
- 3) PIs must submit modifications to their approved research through Cayuse IRB using the modification submission.
- 4) The IRB reviews all changes to approved research and determines whether the research continues to satisfy the regulatory criteria for approval ([45 CFR 46.111](#); [21 CFR 56.111](#)), along with any other applicable review requirements (e.g., institutional, state, departmental).
- 5) The IRB utilizes checklists to ensure that human participants will be protected while participating in research. When the IRB Chair and the designated IRB reviewer(s) consider changes to exempt, expedited or full board approved research, they utilize the IRB reviewer checklist for modifications to determine whether the:
 - a) Modifications to previously approved research continue to satisfy the regulatory criteria for the approval.
 - b) Modifications are related to any significant new findings that might affect research participants' willingness to remain in the study.
 - c) Modifications propose to change the PI, and whether that person is qualified with the appropriate background and experience to oversee the research.

- 6) At least one IRB reviewer is required to receive and review the following documents when they review changes to any previously reviewed IRB study:
 - a) Cayuse IRB submission for modifications
 - b) Revised consent, parental permission, and/or assent documents (if modified)
 - c) Other materials used with research participants (if modified) including recruitment materials, surveys, interview questionnaires, etc.
 - d) Other documentation pertaining to the proposed modifications to approved research.

Administrative Review of Modifications to Approved Research

- 1) Chapman's IRB authorizes the IRB administrator(s) to review and acknowledge certain administrative modifications to approved research including:
 - a) Correcting typographical errors, or other similar errors.
 - b) Making minor revisions or updates to contact information for either the IRB or researchers.
 - c) Reviewing changes to research personnel (except for a change in PI), including adding external researchers through a reliance agreement.
 - d) Reviewing changes to the number of participants in research deemed exempt.
 - e) Verifying translator credentials when documents have been translated into languages other than English, and when the IRB has previously approved the English version of the documents.
 - i) **Note:** Changes must not have been made to the previously IRB-approved versions of the translated documents that are reviewed administratively.
 - f) Changes in funding (and reflecting such change in funding to the consent form) may be administratively handled if such change does not trigger any other changes to the study or study documents. Regardless whether the Chapman is the IRB of Record, the Chapman PI must update his Cayuse application to reflect the change in funding. If Chapman is relying on another IRB, the Chapman PI is also responsible for notifying the IRB of Record regarding the change of funding.
 - g) Revision to language (in IRB-approved documents such as consent forms) which does not materially change the meaning/content

Modifications of Exempt Research

- 1) The IRB must assess any modifications requested for exempt research to determine whether the changes would alter, in any way, the exemption category that was previously determined.
 - a) Changes to personnel no longer need submission of a Modification.
- 2) The IRB must determine whether changes in exempt research would disqualify the research from exempt status. When changes alter the research in such a way that it is not eligible for exemption any longer, the research then requires review and approval either through expedited review procedures or full board review.

Expedited IRB Review of Modifications to Approved Research

- 1) The Chapman IRB is authorized to review minor changes to previously approved research using expedited review procedures. The IRB Chair and designated IRB reviewer(s) may conduct expedited reviews and determine whether the research, as modified, continues to satisfy the regulatory criteria for approval ([45 CFR 46.111](#); [21 CFR 56.111](#)).
 - a) **Minor Changes** are those that do not alter the:
 - i) Level of risk to participants
 - ii) Research design or methodology substantially
 - iii) Number of participants enrolled in the research
 - iv) Qualifications of the research team
 - v) Facilities and resources available to support the safe conduct of the research
- 2) Changes to research originally eligible for expedited review can continue to be reviewed through expedited procedures, unless such changes alter the study in such a way that the research is no longer eligible for expedited review. In this case, the modification would need to be reviewed by the convened IRB.

Convened IRB Review of Modifications to Approved Research

- 1) The convened IRB must review changes to previously approved research when those changes are not considered to be minor modifications. In other words, modifications that would potentially increase the risks to or affect the rights, welfare, and safety of research participants will be reviewed by the convened IRB.

IRB Documentation

- 1) The IRB will notify researchers in writing of its decision to approve or disapprove modifications to previously approved research. Should the IRB disapprove a modification, the IRB shall include a statement of the reasons for its decision and give the PI an opportunity to respond in writing.
- 2) All modifications and the resulting IRB determination are maintained in Cayuse IRB. Researchers are encouraged to review determination letters thoroughly and retrieve all newly approved study documents (e.g., informed consent documents, recruitment materials) from the electronic system.

Revision history:

March 4, 2023: added change in wording as a possible modification eligible to be handled by IRB staff

Oct. 16, 2023: clarified that a Mod is needed if an incident constitutes an unanticipated problem; such Mod needs submission to the IRB within 5 business days of awareness of the incident, instead of within 24 hours.

Oct 6, 2023: added description of review workflow for change of funding

May 2023:

- Incident report must be submitted to the IRB within 5 days of discovery (instead of within 24 hours)
- Clarified that exempt studies may also be modified
- Clarified that at least one IRB reviewer (instead of IRB Chair along with other reviewers) is needed to review modifications.
- Clarified that changes to personnel no longer need submission of a Modification

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