

Policies and Procedures

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CHAPTER: Institutional Review Board	ISSUED: 10/2009	LAST REVIEWED/REVISED: 04/2019
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1. PURPOSE

This policy/procedure provides guidelines for investigators who need to modify their research after the research has been approved by the Institutional Review Board.

2. MODIFICATIONS

- 2.1. Investigators shall not initiate changes in research procedures or consent form(s) without IRB review and approval, except where necessary to eliminate apparent immediate hazards to the participant. Examples of modifications that require IRB review include, but are not limited to, changes in:
 - 2.1.1. Study personnel
 - 2.1.2. Advertising materials (flyers, radio spots, etc.)
 - 2.1.3. Research protocol procedures
 - 2.1.4. Participant populations (e.g., inclusion or exclusion criteria)
 - 2.1.5. Location where research will be conducted
 - 2.1.6. Consent form (including translations)
 - 2.1.7. Recruitment procedures
 - 2.1.8. Study design or methods
 - 2.1.9. Funding source
- 2.2. If the investigator makes protocol changes without prior IRB approval to eliminate apparent hazards to the participant (s), he/she shall promptly report the changes to the IRB using IRB Document, "Reporting Form for Reportable New Information," found within the IRB electronic system for review and determination as to:
 - 2.2.1. whether any of the previously approved IRB requirements changed in any way

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- 2.2.2. whether the proposed changes were consistent with ensuring the participants' continued welfare
- 2.2.3. whether the protocol continues to satisfy requirements for IRB approval under HHS/FDA regulations, as applicable
- 2.3. The IRB determines that any significant new findings that arise from the review process and that might relate to participants' willingness to continue participation are provided to participants.

3. CHANGES RELATED TO RADIATION SAFETY OR BIOSAFETY

- 3.1. Changes shall not be approved by the IRB until Radiation Safety Committee (RSC) or Institutional Biosafety Committee (IBC) approval is obtained.

4. EXPEDITED REVIEW

- 4.1. In all cases, modifications shall be reviewed by an IRB administrator to determine whether the modification may be reviewed using the expedited review process or whether the modification requires review at a convened IRB.
- 4.2. The IRB may use the expedited review procedure to review minor changes in previously approved research during the period for which approval is authorized. To determine whether the modifications are minor, the expedited reviewer shall first determine whether the research is currently an expedited study.
 - 4.2.1. For research initially approved by the convened IRB (i.e., not eligible for expedited initial review), a minor change is a modification that, in the judgment of the reviewer, does not fundamentally alter the risk/benefit ratio of the project (see IRB Document, "Samples of Modifications and Type of Review Required.").
 - 4.2.2. For expedited research that was initially approved by expedited review, a minor change is a modification that does not change the study's eligibility for expedited review (see IRB Document, "Samples of Modifications and Type of Review Required").
 - 4.2.3. If an IRB administrator determines the changes are minor, the reviewer shall follow the expedited procedures listed in section 4.4 below.

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4.3. If an IRB administrator determines the changes are not minor, the administrator shall schedule the modification request for a convened IRB meeting following procedures outlined in IRB Policy, “IRB Review Process. “Expedited Procedures”

4.3.1. The Chair or designee shall perform the expedited reviews of modifications. Depending on the study and other factors, other reviewers may be included or substituted in the process.

4.3.2. The Chair or designee shall exercise the authority of the IRB except the reviewer shall not disapprove the modification. The IRB members shall be notified of the expedited approval by the documentation in the minutes under modifications.

4.3.3. After the Chair or designee has reviewed and made his/her recommendations, the IRB administrator shall notify the investigator in writing of the official determination of the modification.

5. REVIEW AT A CONVENED MEETING

5.1. The IRB administrator or any IRB member may invite the Principal Investigator to attend the meeting if the modification is unusually complex, they anticipate a controversial issue will arise during the review, or the Principal Investigator requests to present the modification. The IRB shall review the modification proposal following procedures outlined in IRB Policy, “IRB Review Process,” and apply the federal criteria for approval as applicable to the request.

5.1.1. The modification is reviewed by the appropriate Board: IRB-01 for Biomedical research and IRB-02 for Social-Behavioral research.

6. REVIEW OUTCOME(S)

6.1. For expedited review of modifications, the outcomes of review are the same as those outlined in IRB Policy, “Expedited Categories.” For review of modifications at a convened meeting, the outcomes of review are the same as the options outlined in IRB Policy, “IRB Review Process.”

6.2. If the modification involves the addition of new study personnel who have not completed the mandatory IRB training or have not submitted financial

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disclosures (disclosures required only if study has external funding), the IRB shall not approve the addition of these persons as study personnel until they have completed their training and submitted their financial disclosures.

- 6.3. If the IRB approves the modification, the expiration date of the approval period remains the same, unless the IRB specifically shortens the current approval period (requiring continuing review earlier) as part of the motion voted on by the members.
- 6.4. If the Principal Investigator has concerns regarding the IRB decision, s/he may submit his/her concerns to the IRB in a written document that includes a justification for changing the IRB decision.