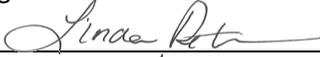


Standard Operating Procedures		
SOP #306.6 Revision 6	TITLE: Review of Changes to Approved Protocols (Amendments)	Effective Date: 1/21/2019
Approved By: OIRB Director	Signature 	Date 1/21/2019
Approved By: IRB Chair	Signature 	Date 1/21/2019

PURPOSE

To define policies and procedures for reviewing an amendment to a previously approved project.

REVISIONS FROM PREVIOUS VERSION

Updates relevant to the revised common rule.

POLICY

Researchers may not initiate any changes in research procedures, consent/assent form(s), or other project related documents for non-exempt research without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to the participant. Some federally funded exempt studies may also require IRB approval for changes related participant privacy and data confidentiality. Examples of amendments that require IRB review include, but are not limited to, changes in:

- Advertising materials (flyers, radio spots, etc.);
- Research procedures;
- Participant populations (e.g. increase in maximum enrollment or change in age range);
- Location where research will be conducted;
- Consent/assent forms;
- Changes in procedures to maintain privacy or confidentiality;
- Recruitment procedures.

If the researcher makes protocol changes (i.e. amendments) to eliminate apparent hazards to the participants(s) without prior IRB approval, the researcher must immediately report the changes to the IRB for review (within 30 days) and a determination is made as to whether the changes are consistent with the participant’s continued welfare.

Researchers must promptly notify the IRB in writing of any change in a project’s status, such as discontinuation or completion of a project. See SOP 410 Project Closure for procedures on closing a study with the IRB.

DEFINITIONS

Amendments are defined as changes in the IRB approved protocol and project documents.

RESPONSIBILITIES

Execution of SOP: Principal Investigator (PI)/project team personnel, IRB Chair, IRB, OIRB

PROCEDURE

Submission of Amendments

1. The PI is responsible for submitting an amendment request (AM) to and receiving approval from the IRB prior to the implementation of any change.
2. To submit the AM, the PI completes the Amendment Application Form and supporting documents according to the instructions on the form and submits the package to the OIRB via IRBNet using version trails for any revised documents.
3. Continuing Reviews and AMs cannot be submitted at the same time.

Screening of Submissions

1. An OIRB staff pre-reviews the submission package according to SOP 109 Staff Processing of Submissions.
2. If the request is incomplete, OIRB staff will request clarifications from the PI. OIRB staff forwards the AM to the IRB, minimal risk reviewer, or designated staff reviewer once the submission is complete.
3. If the AM references an instrument, apparatus, machine, implement or device, OIRB staff discusses the amendment with the OIRB Director to determine if the amendment involves use of a medical device under FDA jurisdiction (collecting safety or efficacy data). If so, the protocol will be forwarded to the fully convened IRB for further review.
4. If the AM references a drug, biologic, therapeutic dietary supplement, substance affecting structure or function of the body, or product intended to diagnose, cure, mitigate, treat, or prevent disease, OIRB staff discusses the amendment with the OIRB Director to determine if the amendment is under FDA jurisdiction (use beyond the course of medical practice). If so, the protocol will be forwarded to the fully convened IRB for further review.
5. If the AM adds vulnerable populations or requires documentation of specific regulatory findings, OIRB staff sends the appropriate checklists to the reviewer with the AM. For example, if the PI adds children as participants, OIRB staff provides the Subpart D checklist.
6. If the AM requires consent/assent form changes, OIRB staff ensures OIRB's contact information appears on the form(s). OIRB staff may also screen the consent/assent form(s) to reflect any recent changes in the IRB template. OIRB staff alerts the IRB reviewer if the consent/assent form(s) are inconsistent with the template. The IRB has final authority for requiring consent/assent changes.

Determining Mechanism of Review

1. An AM will be sent for review following the procedures used for the initial review, unless otherwise specified by the IRB.
2. If the sponsor or the PI specifically requests full review procedures, OIRB staff places the AM on an agenda for full review following procedures outlined in the Initial Full Review SOP.
3. If the AM does not require a full review, OIRB staff conducts the review (if an administrative change as described below) or sends the AM to a minimal risk reviewer.
4. The reviewer documents their determinations on the Reviewer Checklist. If the project is more than minimal risk but the change is minor, the IRB Chair or member conducts the review using expedited or minimal risk procedures. A minor change is one which makes no substantial alterations in:
 - The level of risk to participants;
 - The research design or methodology;
 - The participant population;
 - Qualifications of the PI;
 - The facilities available to support the safe conduct of the research; or

- Any other factor that would warrant review of the proposed changes by the convened IRB.
5. If an AM is an administrative change, it can be reviewed and acknowledged administratively by OIRB staff. Administrative changes include:
 - changes to contact information or formatting in approved documents;
 - new or revised recruitment advertisements or scripts if similar to already approved recruitment materials;
 - changes to surveys or interview questions if no increase in risk;
 - increase or decrease in enrollment numbers in minimal risk projects;
 - changes to improve the clarity of statements or to correct typographical errors provided the requested change does not alter the content or intent of the statement;
 - submission of project or consent documents translated into a foreign language and the required translation certificate(s).
 6. AM to non-federally funded minimal risk research will be conducted according to SOP 205 Review Standards for Minimal Risk Research Not Covered by FWA.

Review Procedures

1. The minimal risk reviewer exercises all the authority of the IRB except the reviewer cannot disapprove the AM.
2. The IRB Chair or designated IRB member documents determinations on the reviewer checklist regarding:
 - Eligibility for expedited (including 45 CFR 46.110(b)(2), if applicable), exempt (for categories 45 CFR 46.104(d)(2)(iii), (d)(3)(i)(C), (d)(7) and (d)(8) or minimal risk review;
 - Whether the research meets the criteria for IRB approval at 45 CFR 46.111;
 - Whether proposed changes to the informed consent/assent process continue to meet requirements as set forth in 45 CFR 46.116 and 117 and 21 CFR 50.25 and 27; and
 - Whether the proposed changes affect any research categories of the currently approved protocol.
3. The IRB Chair or designated IRB member returns the AM and completed reviewer checklists to OIRB staff.
4. If the project requires or the minimal risk reviewer recommends full review, OIRB staff places the AM on an agenda following procedures outlined in the Initial Full Review SOP.
5. The convened IRB reviews the AM following procedures outlined in the Initial Full Review SOP and applying the federal criteria for approval, as applicable, to the request.
6. For an AM involving prisoner research, a prisoner representative will be assigned as a primary reviewer if it is reviewed in a fully convened meeting.

Review Outcome(s)

1. If conducted outside of a fully convened meeting, the listing of the item on the monthly report supplement serves to advise the IRB of the review.
2. For minimal risk review, the outcomes of review are the same as the options outlined in SOP 304 and SOP 205. OIRB staff notifies the PI in writing of the IRB's decision.
3. For full review, the outcomes of review are the same as the options outlined in SOP 303 Initial Full Review. OIRB staff notifies the PI in writing of the IRB's decision.
4. If the IRB approves the AM, the end date of the approval period remains the same as that assigned at initial or continuing review, as applicable.

5. If the PI has concerns regarding the IRB's decision, the PI may submit their concerns to the IRB in a written document that includes a justification for changing the IRB's decision.

REFERENCES

21 CFR 56.110(b)(2)
38 CFR 16.110(b)(2)
45 CFR 46.110(b)(2)
38 CFR 16.111
45 CFR 46.111
21 CFR 56.111
21 CFR 312
21 CFR 812
45 CFR 46.104(d)