Changes to Approved Research - Amendments

I. Purpose

To define policies and procedures for reviewing an amendment to previously approved non-exempt research.

II. Revisions from Previous Version

None.

III. Definitions

Amendments are defined as changes in the Institutional Review Board (IRB) approved protocol and project documents. The words amendment and modification are often used interchangeably.

IV. 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 when necessary to eliminate apparent immediate hazards to the participant. Some exempt studies may also require IRB approval for changes (see Exempt Review SOP). Examples of amendments that require IRB review include, but are not limited to, changes in:

- Advertising materials (flyers, social media, 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 participant(s) without prior IRB approval, the researcher must immediately report the changes to the IRB for review (within 24 hours) and a determination will be made as to whether the changes eliminate hazard and are related to 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 Project Closure SOP for procedures on closing a study with the IRB.

V. Procedure

Submission of Amendments

1. The Principal Investigator (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 form and supporting documents according to the instructions on the form and submits the package to the IRB via WRG-HS using the tracked changes function for any revised documents.

3. Continuing Reviews and AMs should not be submitted at the same time. Submitting both may cause delays in approval.
Screening of Submissions
1. IRB staff pre-reviews the submission package according to Staff Processing of Submissions SOP.
2. If the request is incomplete, IRB staff will request revisions from the PI. Once a submission is complete, IRB staff will forward the AM to the IRB, expedited reviewer, or designated staff reviewer.
3. AMs for studies under FDA purview where the changes impact FDA related determinations will be forwarded to the fully convened IRB for review.
4. If the AM adds vulnerable populations or requires documentation of protocol specific justifications, IRB staff will notify the reviewer of the required necessary determinations. For example, if the PI adds children as participants, the IRB staff will notify the reviewer of the need for 45 CFR 46 Subpart D related determinations and protocol specific justifications.
5. If the AM requires consent/assent form changes, the IRB staff will ensure all necessary elements of consent are included. The IRB staff will also screen the consent/assent form(s) to reflect any recent changes in the IRB template. The IRB staff will alert the IRB reviewer if the consent/assent form(s) are inconsistent with the template.

Determining Mechanism of Review
1. The IRB staff will determine the most applicable type of review (e.g. full board, expedited, or administrative).
2. If the sponsor or the PI specifically requests full board review procedures, the IRB staff will place the AM on an agenda for full board review following the procedures outlined in the Initial Full Review SOP.
3. If the AM does not require a full board review, the IRB staff will conduct the review (if an administrative change as described below) or send the AM to an expedited reviewer.
4. The reviewer will document their determinations on the Reviewer Checklist. If the project is more than minimal risk but the change is minor, IRB staff, the IRB Chair, or a member will conduct the review using expedited review 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 IRB 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 there is no increase in risk to participants;
   • 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); or
   • Any other changes that would not require a risk/benefit analysis or reassessment of approval criteria.

Review Procedures
1. Expedited reviewers exercise all the authority of the IRB except disapproval.
2. IRB staff, the IRB Chair, or a designated IRB member will document determinations on the reviewer checklist regarding:
   • Eligibility for expedited, exempt, or limited IRB review,
   • Whether the research meets the criteria for IRB approval at 45 CFR 46.111 or 21 CFR56.111;
   • 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. If a non-staff reviewer is unable to respond within a week, IRB staff may forward the protocol to another reviewer.
4. If the project requires or the reviewer recommends full board review, the IRB staff will assign the AM to an agenda following procedures outlined in the Initial Full Review SOP.
5. The convened IRB will review the AM following procedures outlined in the Initial Full Review SOP, applying the federal criteria for approval, as applicable.
6. For an AM involving prisoner research, a prisoner representative will be assigned as a primary reviewer if it is reviewed at a fully convened meeting.

Review Outcome(s)
1. If conducted outside of a fully convened meeting, the listing of the submission on the quarterly report supplement serves to advise the IRB of the review.
2. For expedited review, the outcomes of the review are the same as the options outlined in the Initial Expedited Review SOP. The IRB staff will notify the PI of the IRB's decision in writing.
3. For full board review, the outcomes of review are the same as the options outlined in the IRB Meeting Conduct SOP. The IRB staff will notify the PI of the IRB's decision in writing.
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, including a justification for changing the IRB's decision.

VI. 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)