SOP 2.6.4 **Modifications/amendments**

General Description:

Amendments are intended to inform the IRB of proposed changes to the research project. The IRB must conduct a review of all amendments/changes to covered human subjects research projects. Review of amendments must take place at a convened meeting at which a majority of the IRB members are present, including at least one member whose primary concerns are in nonscientific areas, unless the research qualifies for review under an expedited or exempt review procedure (45 CFR 46.108(b)).

It is the responsibility of the Principal Investigator or co-investigator to submit all amendments to the IRB for review and approval prior to the implementation of any of the proposed changes.

The IRB review of an amendment uses the same procedures, applies the same criteria for approval, and involves the same possible IRB actions as reviews of initial applications or continuing reviews.

Procedures:

1. **Submission of Amendment/Modification form**. Investigators provide a completed Amendment form through IRBNet prior to implementing any changes in their research (see document 4a in the IRBNet forms section for instructions on how to submit an amendment through IRBNet). The amendment form should describe all proposed revisions. The following information must be submitted in addition to the Amendment Form (if applicable):
    a. A revised IRB application with all revisions to the previous submission marked/highlighted
    b. Any other revised or new study documents (i.e. consent form, instruments, recruitment materials) with all revisions marked/highlighted (if applicable)
    c. Clean copies of any revised consent and recruitment documents (in addition to the marked versions)
    d. Any changes in the investigator's situation, qualifications or affiliations.
    e. If there is a change in funding, the appropriate section of the Amendment form should be marked and the Office of Sponsored Programs proposal number should be included.

2. **Pre-review procedures:** Prior to the IRB review of the amendment, IRB staff will perform a preliminary review, verifying all appropriate information is included in the amendment package. Staff will identify and obtain clarification about any significant issues about the amendment request before review (including missing documents, marked revisions, appropriate training for new researchers).

3. **Assignment to Review.** GMU IRB staff members will schedule review either by a convened IRB meeting or, if the study qualifies, by an expedited or exempt reviewer. The same IRB (or expedited/exempt reviewer) that performed the initial review of a study will generally perform all subsequent amendment reviews.

4. **IRB Review.** The IRB will determine if the criteria for initial approval of the research study are still satisfied. The IRB/IRB staff will also ensure that if the revisions affect risks to participants, the appropriate level of review is conducted. The IRB will determine that the following are still satisfied in light of the requested revisions:
    a. Risk to subjects are minimized;

b. Risks to subjects are reasonable in relation to anticipated benefits;
c. Selection of subjects is equitable;
d. Informed consent will be sought from each prospective subject or the subject's Legally Authorized Representative;
e. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects;
f. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data;
g. Appropriate safeguards are included to protect subjects likely to be vulnerable to coercion or undue influence; and
h. When the research involves pregnant women, fetuses, neonates, prisoners, or children, the research satisfies the additional requirements for IRB approval.

5. **IRB Determination**
    a. Under HHS regulations at 45 CFR 46.109(a), the IRB can take any of the following actions:
        i. Approve the amendment either (a) as submitted without any conditions, or (b) with conditions;
        ii. Require modifications to secure approval and defer or table the research study for further review at a future date after the required modifications are submitted by the investigator; or
        iii. Disapprove the amendment.
    b. Duration of approval period after amendment: the expiration date of the initial/continuing review **does not change** at the time an amendment to the study is reviewed and approved.

6. IRB Communication
    a. The IRB must notify the investigator and the institution in writing of its decision to approve or disapprove the amendment to the research, or of modifications required to secure IRB approval of the research (45 CFR 46.103(b)(4) and 46.109(d)).
    b. For amendments that are approved, the IRB's notification to the investigator will clearly state the period of time for which the project is approved, any conditions of the IRB's approval, and the expiration date of the study (if applicable) (45 CFR 46.103(b)(4) and 46.109(d))

7. IRB Records
    a. A copy of all correspondence concerning amendment review will be kept in the electronic IRB file for the study.
    b. The minutes of the IRB meeting will document the following for projects reviewed at a convened meeting:
        i. Separate deliberations, actions, and votes for each protocol undergoing amendment review;
        ii. The vote on all IRB actions including the number of members voting for, against, and abstaining, recorded in a manner that documents the continued existence of a quorum.
        iii. Conditions of approval or reasons for deferral for each action taken by the IRB;

References

45 CFR 46.108(b)
45 CFR 46.109(e)
45 CFR 46.109(d)
45 CFR 46.109(a)

45 CFR 46.103(b)(4)
45CFR 46.110(b)(2)
21 CFR 56.109(f)
21 CFR 56.108(a)(2)

Related Forms, Guidance, and SOPs:

- 2.5.1 Full Board Review
- 2.5.2 Expedited and exempt review
- 2.6.1 Continuing Review

Responsibility:

Execution of SOP:
Principal Investigator
Study Team Members
IRB Staff
IRB

Approval and Version History:

Please contact irb@gmu.edu if you have any questions about this policy or the version and approval history.

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Approved By	Title and Division	Date Approved
Aurali Dade	Associate Vice President, Research Development, Integrity and Assurance	January 21, 2019
Laurie Meamber	IRB Chairperson	January 21, 2019