SOP 2.5.1 **Full Board Review**

General Description:

All institutions that receive federal funding for research are required to comply with certain regulations regarding the treatment of people in research activities. These regulations can be found at 45 CFR 46. In order to comply with these regulations, research activities at GMU involving humans must undergo some level of ethical review by the IRB.

If the human subjects research activities described in the IRB application do not fall into an exempt or expedited review category within the federal regulations or if the individuals taking part in the research may be put at greater than minimal risk if they participate in the research, the protocol will require review by the Full Board at one of its monthly meetings. Determination about the review level of a submission is made by the IRB staff in consultation with the IRB Chairperson as needed.

Procedures:

1. The IRB staff will conduct a preliminary review of all submissions and let the researcher know of any missing materials prior to further review. If the IRB staff determines that the research activities do not fall into an exempt or expedited review category or that the participants will be at greater than minimal risk by participating in the research, the IRB staff will place the project on the agenda for the next Full Board meeting according to the submission and meeting date schedule available on the RDIA website.

2. PIs will be notified as soon as possible once IRB staff has determined that their project will be reviewed by the full board and they will be invited to attend the meeting either in person or by phone to answer any questions about the project.

3. IRB members will be given access to the IRB meeting agenda and all full board project study materials through IRBNet 5-7 days prior to the convened meeting. All IRB members are responsible for reviewing the full protocol and all supporting documents for full board protocols on the agenda and should be prepared to discuss the details of the projects. If an IRB member has reviewed the full board materials but is unable to attend the IRB meeting due to unforeseen circumstances, the IRB staff will accept written comments about the project from that member and present them to the IRB at the scheduled meeting during discussion of that protocol.

4. During the review, IRB members are responsible for ensuring that certain regulatory criteria are met. The IRB will complete any relevant protocol transmittal forms and/or worksheets. The Full Board may approve the application, disapprove the application, require minor revisions or defer consideration of the project to the next convened meeting. Depending on the nature of the discussion and requests from the IRB, revisions to the study documents may be eligible for final review by the IRB Chairperson or the Chair's designee. In some cases, the IRB may request substantive revisions/information such that the revisions will have to be reviewed by the full board at a future convened meeting.

5. An IRB member who has a conflict of interest cannot participate in the review of the project other than to provide information requested by the IRB and must recuse him/herself during the deliberations and vote.

6. If the research being reviewed involves vulnerable subjects, at least one individual who is knowledgeable about working with this population will be present at the meeting.

7. If the research being reviewed requires special expertise or knowledge outside of the IRB membership, the IRB staff will arrange for an appropriate consultant to review the relevant study documents and provide information to the Full Board as needed.

8. The IRB will determine whether future continuing reviews of and/or amendments to the project can be expedited (as long as there is no increase in risk to participants) or whether future reviews must be reviewed by the Full Board. If the Board decides that a project can be expedited in the future, annual continuing reviews may not be required.

9. The IRB will determine whether the project requires review more often than annually on a case by case basis. The IRB may specify a subject enrollment number as a threshold for determining when continuing review is to occur (for example, after 5 subjects have experienced the study intervention or after 6 months, whichever comes first).

10. IRB staff will communicate the results of the full board review to the researcher within 2 business days after the IRB meeting.

11. PIs and research staff will be notified through IRBNet once their project has been approved and the approval letter and stamped consent/recruitment documents will be available in the IRBNet package.

Related Forms, Guidance, and SOPs:

- 1.2.2 Drug and Device Studies
- 2.1.1 Types of IRB decisions
- 2.1.2 Study intake and triage
- 2.4.1 Submitting a human subjects project for review
- 2.5.2 Expedited and Exempt Review
- 2.5.3 Non-human subjects research review procedures

Responsibility:

Principal Investigators
Research Team Members
IRB staff
Institutional Review Board

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