SOP 2.5.2 Exempt and Expedited 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 IRB staff and/or the IRB.

If the human subjects research activities described in the IRB application fall into an exempt or expedited review category within the federal regulations, then the protocol will be reviewed via the exempt or expedited procedures as outlined below. The same application forms are used for all levels of review. Determination about the review level of a submission is made by the IRB staff in consultation with the IRB Chairperson as needed. IRB staff will conduct a preliminary review of all submissions (usually done within 7 days) to make sure that there is a complete package and to determine the review level. Submissions are reviewed in the order received. IRB staff is responsible for all communications with the Principal Investigator and/or other researchers.

Procedures:

Exempt Review:

1. If the IRB staff determines that the research meets the definition of human subjects research and that the research activities fall into one of the eight exempt categories listed in 45 CFR 46.104, the project does not require review by the IRB. Because of possible conflicts of interest, the Office for Human Research Protections (OHRP) recommends that researchers not make the determination that the proposed research is exempt for themselves. Therefore, at Mason exempt research is reviewed and categorized by the IRB staff. Research may not pose any more than minimal risk to study participants to qualify for exempt review. The IRB Chairperson or IRB staff can require expedited or full board review at his/her discretion even if the research might otherwise qualify for exempt review.
2. IRB staff will determine that all procedures, including participant activities, recruitment, consent, privacy of participants, confidentiality of data, risks, benefits, and compensation, are all described in the application. IRB staff will compare all documents in the package for consistency. All requested changes, clarification or concerns will be conveyed by IRB staff to the researchers through IRBNet.
3. Certain research projects that collect information which is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, may still qualify for exemption so long as an IRB member conducts a limited IRB review to make the determination that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. For these projects, IRB staff will ensure IRB review of the necessary details of the project prior to exemption. If a study is deemed exempt, the researchers will receive electronic notification and an exemption letter through IRBNet, as well as stamped consent and recruitment documents. An exempt project does not receive an expiration date and researchers are not required to submit annual continuing review forms for these projects.

Expedited Review:

1. If the IRB staff determines that the research activities are not exempt, but present no more than minimal risk to human subjects and fall into one of the expedited categories as described in the regulations at 45 CFR 46.110(a), the project will be reviewed by one or more IRB members outside of the convened IRB meeting. The IRB staff, in consultation with the IRB Chairperson as needed, will determine which IRB member will review the research based on the following: the member's time on the IRB; his/her experience conducting expedited reviews; and/or his/her level of expertise with the proposed study activities.
2. Expedited reviewers will be given access to project through IRBNet. During the review, the expedited reviewer is responsible for ensuring that certain regulatory criteria are met. The reviewer will complete any relevant protocol transmittal forms and/or worksheets and upload them to the IRBNet package. The expedited reviewer may approve the application, require revisions to secure approval, or refer the project to the full board meeting for review (the expedited reviewer cannot disapprove the research application). The expedited reviewer will relay any questions, requests for revisions or concerns to IRB staff, who will then convey the IRB's requests to the researchers through IRBNet.
3. . If the IRB determines that a protocol is no more than minimal risk to participants and the Board does not document a specific justification for requiring continuing review, research that is eligible for expedited review will not generally require annual continuing review (45 CFR 46.109 (f)).
4. Projects in which data collection has been completed and the remaining activities are limited to data analysis will not require continuing review.
5. For projects where continuing review is not required, no expiration date will appear in the approval letter.
6. Automated email notifications will be sent to the research team annually reminding them that any adverse events and changes to the project should be submitted for IRB review. The email notification will also ask whether or not the project has been completed. Investigators should submit the appropriate forms to report events or request any changes to the research as needed. The continuing review form should be submitted to close projects when appropriate. Otherwise, investigators are not required to act on the reminder messages.
7. If applicable, researchers will be responsible for completing a continuing review form prior to the expiration date of their project and submitting it along with any other required documents through IRBNet. Researchers will be sent reminders through IRBNet prior to the expiration date of the approval.

General:

1. 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 IRB expedited reviewer as needed.
2. Any proposed changes to projects reviewed via exempt or expedited procedures must be submitted to the IRB for review and approval prior to implementation in the research. Amendments should be submitted through IRBNet. An amendment to existing research may change the review level of that study. The IRB staff, in consultation with the IRB Chairperson as needed, will determine whether or not an amendment changes the review level.
3. Future continuing reviews of and/or amendments to the project will be reviewed at the level the initial application was reviewed provided that there is no increase in risk to participants.

4. All changes requested by the IRB staff will be noted in IRBNet as part of the reviewer documents in the IRBNet package. IRB staff will communicate the results of the exempt/expedited review to the researcher through IRBNet.
5. 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.
6. IRB staff will provide the IRB with a list of all exempt and expedited projects reviewed each month as part of the IRB meeting agenda available in IRBNet.
7. Human subjects research that does not meet the criteria for exempt or expedited review and/or poses more than minimal risk to study participants will be reviewed by the full board at a regularly scheduled meeting.
8. When the study is exempted/approved, the IRB staff will:
    a) enter the review type, action, effective date, project status, expiration date for expedited and full board studies, initial approval date, and risk level of the study in the IRBNet package. When this information is entered in the IRBNet package, all researchers with access to the package will receive notification about the approval.
    b) stamp the approved versions of recruitment materials, informed consent documents, assent forms, and debriefing materials.
    c) complete the approval letter. The approval letter and stamped documents will be uploaded in the Board Documents section of the IRBNet package for use by the researcher. All researchers with access to the IRBNet package will receive notification that these documents have been published.

Related Forms, Guidance, and SOPs:

- 2.1.1 Types of IRB decisions
- 2.1.2 Study intake and triage
- 2.4.1 Submitting a human subjects project for review
- 2.5.1 Full Board Review
- 2.5.3 Non-human subjects research review procedures
- 2.6.1 Continuing Review
- 2.6.4 Modifications/amendments
- 45 CFR 46.104
- 45 CFR 46.110
- 45. CFR 46.111

Responsibility:

Principal Investigators
Research Team Members
IRB Staff
Institutional Review Board
IRB Chairperson

Approval and Version History:

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

Date First Effective:	December 14, 2016

Revision Date:	January 21, 2019
Current Version #:	2

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