

## SOP 2.5.3      **Non-human subjects research review procedures**

### **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. However, some projects that involve human participants do not meet the federal definition of human subjects research and therefore do not require review by the IRB. This determination is not the same as exempt review.

The IRB staff is available to assist researchers with a determination about whether or not a project requires review and also provides a Human Subjects Determination form that can be used to help make this determination. This form can be found in the forms section of IRBNet and per the instructions on the form should be submitted through the IRBNet electronic submission system at [www.IRBNet.org](http://www.IRBNet.org) if the researcher would like an official determination and letter from the IRB office.

Sometimes an IRB application is submitted and during the review process the IRB staff determines that the project does not meet the definition of human subjects research. In these instances, the IRB staff will provide an official determination and letter as part of the IRBNet package for the submission.

### **Procedures:**

If the PI or research team has questions about whether or not the project meets the definition of human subjects research, they should contact the IRB office or use the Human Subjects Determination form to assess their project. Researchers can also choose to submit an IRB application or the Determination form through IRBNet for review and determination by the IRB staff. If documentation is submitted through IRBNet for review, researchers will receive email notification if additional information is needed or when a determination about the status of the project has been made. (See SOP 2.4.1 for guidance on how to submit a new project and/or the Determination form through IRBNet.)

The IRB staff will conduct a preliminary review of all submissions and let the researcher know of any missing materials prior to further review. The IRB staff will review Determination forms that have been submitted through IRBNet and make a determination about whether or not the project meets the definition of human subjects research. If the IRB staff believes that the project may meet the definition of human subjects research, the researcher may be asked to complete the full IRB application so that more detailed information about the research project can be considered.

Note that researchers are not required to complete the CITI human subjects training if the IRB staff determines that their project does not constitute human subjects research.

### *IRB Review of Changes to IRB applications/procedures*

If a PI modifies any study procedures (including changes to the protocol, consent form, instruments, recruitment materials, etc.) that change the scope of the project such that it does meet the definition of human subjects research, he or she must submit an amendment request to the IRB office for review before implementing any changes in the study. Researchers can contact the IRB office at [irb@gmu.edu](mailto:irb@gmu.edu) with questions about whether their proposed changes will affect the review level of their project.

**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
- 2.5.2 Expedited and Exempt Review
- Human Subjects Determination form

**Responsibility:**

Principal Investigators  
Research Team Members  
IRB staff  
Institutional Review Board

**Approval and Version History:**

Please contact [irb@gmu.edu](mailto:irb@gmu.edu) if you have any questions about this policy or the version and approval history.

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