

SOP 2.4.1 **Submitting a human subjects research project for 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 office or the IRB.

After determining that a project requires IRB review (see SOP 2.1.2 Determination of activities that require IRB review), researchers must complete the appropriate IRB application for their research and submit it to the IRB for review in order for the IRB to have sufficient information to make the necessary determinations for approval. The IRB applications for both prospective data collection and analysis of existing data and specimens can be found in the forms section of IRBNet and should be submitted through the IRBNet electronic submission system at www.IRBNet.org.

The Mason IRB uses the same application for exempt and expedited studies and will make a determination of the review level once the application has been submitted.

Procedures:

The PI may not begin human subjects research activities until he or she receives IRB approval of the procedures outlined in the IRB application. The researchers will receive email notification of approval once the application has been approved and an IRB exemption or approval letter will be available in IRBNet.

The following provides guidance for researchers as to how to submit the IRB application:

1. Create an IRBNet account
 - a. Go to www.IRBNet.org and create an account
 - b. Log in and click on Create New Project and fill in the information requested (note: the PI listed in IRBNet and in the IRB application must meet the University PI policy: <http://universitypolicy.gmu.edu/policies/principal-investigators/> and researchers cannot act as PI on research they are conducting as a Mason student, for example their own thesis or dissertation projects).
 - c. Complete appropriate IRB application (answer all items) and upload it along with all other relevant study documents (for example, consent form, recruitment materials, study instruments, questionnaires, grant applications, etc.) to the IRBNet package from the Designer page. Please be sure to use the most current version of the IRB application, which can be found in the forms section of IRBNet.
 - d. The PI on the study must electronically sign the package as PI in IRBNet
 - e. Submit the complete project to the Mason IRB by clicking on the Submit this Package button in the administration menu.

Incomplete applications will not be reviewed by the IRB. The IRB staff will conduct a preliminary review of all submissions and let the researcher know of any missing materials prior to the IRB review. Once the application is complete, it will be reviewed either by IRB staff or the IRB depending on the appropriate review level based on the regulations.

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.), he or she must submit an amendment request to the IRB for review and approval before implementing any changes in the study.

Related Forms, Guidance, and SOPs:

- 2.1.2 Determination of activities that require IRB review
- 2.1.3 Types of IRB decisions
- 2.1.4 Study intake and triage
- 2.5.1 Full Board review
- 2.5.2 Expedited and Exempt Review
- 2.5.2 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, Office of Research Development, Integrity and Assurance	May 13, 2016
Greg Guagnano	IRB Chairperson	May 13, 2016