

General Description:

This policy is for establishing the procedures that outside entities or researchers must go through before being able to conduct human subjects research, as defined by DHHS and the FDA, on George Mason University (GMU) campuses. This policy assumes that neither GMU nor any of its researchers are engaged in conducting the research (See [OHRP Guidance on Engagement of Institutions in Human Subjects Research](#)).

Procedures:

1. The outside entity, or researcher, should first contact the IRB staff to inform the office of their intent to conduct the research on GMU campuses.
2. After the IRB staff has confirmed that GMU is not engaged in the conduct of the research, the staff will request the following from the outside researchers/entity:
 - Study recruitment material(s)
 - Copy of their IRB approval letter from their home institution
3. Once these materials have been received, IRB staff will contact the outside researchers/entity with an email indicating that GMU is not engaged in the research and that GMU IRB review is not required for them to proceed.
4. IRB staff will then save a copy of the study documents and correspondence with the outside researchers/entity to store in a secure IRB network drive, in a designated folder.
5. The outside researchers must comply with their own IRB requirements. The outside researchers are also advised to contact any of the various GMU departments they may be specifically working with to ensure the relevant department(s) are willing to cooperate with the conduct of their study, if applicable.

Related Forms, Guidance, and SOPs:

- [ORHP Guidance on Engagement of Institutions in Human Subjects Research](#)

Responsibility:

Institutional Review Board
IRB staff, Research Development, Integrity and Assurance office (RDIA)
Researchers

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

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Approved By	Title and Division	Date Approved
Aurali Dade	Associate Vice President, Research Development, Integrity and Assurance	December 14, 2016
Laurie Meamber	IRB Chairperson	December 14, 2016