SOP 2.1.4 **Reliance Agreements**

General Description:

GMU researchers may sometimes be engaged in non-exempt human subjects research that involves co-investigators and/or human subjects at other institutions. In accordance with 45CFR46.114, GMU may rely on the review of another qualified IRB or allow another institution to rely on the GMU IRB. This is done through an IRB Reliance Agreement (also referred to as an IRB Authorization Agreement). The scope of the agreement is usually limited to a specific protocol and on a case-by-case basis.

Procedures

Requests to rely on another IRB for review or for an outside institution to rely on the GMU IRB will be considered on a case-by-case basis based on the research protocol being proposed, the risk level of the project, the involvement of each institution, and as the Institutional Official allows. Generally, GMU will rely upon or serve as the IRB of record for federal agencies, other Commonwealth of Virginia Institutions of Higher Education and other institutions with whom MOUs have been executed.

Requests for reliance agreements are reviewed by the IRB Manager/administrative staff. IRB Office staff will review the details of the project, obtain any additional information needed from the investigator and consult with the Institutional Official to determine whether or not the request can be accepted. Once a determination is made that the request can be approved, any necessary reliance documentation will be executed by all involved institutions. All research under a reliance agreement will follow all applicable federal and state regulations and institutional policies of the IRB of record regarding human subjects research. The IRB staff will add a tag to the project in IRBNet indicating that there is a Reliance Agreement in place for the project.

The Principal Investigator (PI) at each institution is responsible for ensuring that the research is conducted according to the approved protocol and overseeing research personnel at his/her site. The PI from the IRB of record/reviewing site is responsible for all sites and personnel, regardless of the location of the research.

Investigator Responsibilities for projects provided a Reliance Agreement by the Mason IRB office

If a GMU student, employee/faculty member plans to work on a human subjects protocol that has been or will be approved by an outside IRB and the GMU IRB has agreed to allow a Reliance Agreement to cede review to that institution's IRB, the following steps must be taken:

1. The GMU researcher will collect the most recent IRB approval letter along with the current protocol, consent document(s) and other relevant study documents from the outside institution and submit a complete package of documents, including the signed Reliance Agreement, through the IRBNet system. This submission will not be reviewed by the IRB, but will be used to track research activities and maintain a record of the project.
2. All researchers involved in the proposed research activity must follow their institution's requirements for training in human subjects protection. The GMU researcher may be required to provide documentation of his/her CITI human subjects training to the outside IRB.
3. Even though the GMU IRB will not serve as the IRB of record in these cases, it is still responsible for verifying that other compliance and educational requirements are met. Each

site must ensure that local review of conflicts of interest, biosafety review, radiation safety review and other compliance-related reviews and approvals are obtained as applicable. The GMU PI may need to submit documentation of such approvals to the IRBs.

4. When GMU is not the IRB of record, the Mason PI is still responsible for submitting project approvals from the IRB of record (for example, continuing review approvals, amendment approvals) and closure documents through IRBNet, so that Mason IRB office is aware of the status of the project.
5. GMU will cooperate with the IRB of record regarding review of non-compliance and unanticipated problems/adverse events.

If another institution is relying on the GMU IRB, the following steps must be taken:

1. A standard protocol submission to GMU's IRB through IRBNet is required and other documents related to the reliance agreement may be required as part of the submission as well. Researchers may need to submit documentation of the project to the other IRB depending on their processes and further information should be obtained from that IRB's office. Once the research is approved by the IRB, the GMU PI is responsible for oversight at all research sites and should report events from any site to the GMU IRB.
2. When GMU is the IRB of record, it will review all initial and continuing reviews, amendments, unanticipated problems involving risk to participants or others, and non-compliance. All documentation should be submitted through IRBNet. The GMU IRB has the authority to suspend or terminate the research.
3. All researchers involved in the proposed research activity must follow their institution's requirements for training in human subjects protection. The GMU researcher should describe the human subjects training of the non-GMU researchers as part of addendum J of the GMU IRB application.
4. Each site must ensure that local review of conflicts of interest, biosafety review, radiation safety review and other compliance-related reviews and approvals are obtained as applicable.
5. The relying site is responsible for investigating issues of non-compliance/other reportable events that occur at their site and/or involve their study staff and reporting information related to the incidents back to the Mason IRB.
6. The GMU IRB office will keep copies of all IRB records relating to the research and will provide relying institutions with specific documentation pertaining to the protocol and/or its review as requested.

For more information or questions about a possible Reliance Agreement, please contact the IRB office at irb@gmu.edu.

Related Forms, Guidance, and SOPs:

- 45 CFR 46.114

References:
Based on guidance from UC Berkeley's IRB: IRB Reliance (http://cphs.berkeley.edu/policies_procedures/rr412.pdf) .

Responsibility:

Execution of SOP:
Principal Investigator
Study Team Members
IRB Staff

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:	August 24, 2016
Revision Date:	November 28, 2017
Current Version #:	2

Approved By	Title and Division	Date Approved
Aurali Dade	Associate Vice President, Office of Research Development, Integrity and Assurance	November 28, 2017
Laurie Meamber	IRB Chairperson	November 28, 2017