SOP 1.3.6 **Collaborative Research**

General Description:

Research may involve more than one institution and fall within responsibility of more than one Institutional Review Board (IRB). If a George Mason University researcher is collaborating on a human subjects research project with a researcher at another university, the Mason IRB must either review and approve the project based on the Mason researcher's role or may possibly rely on the other institution's IRB for the review (see SOP 2.1.4 Reliance Agreements). This document describes the procedures for submitting an IRB application for collaborative research.

Procedures:

1. The Mason researcher involved in the collaborative project should submit the appropriate Mason IRB application through IRBNet for review. The IRB application should include detailed information about the Mason researcher's roles and responsibilities in the research. The application should also provide a basic outline of the research activities being carried out at the collaborative institution.
2. Depending on the role of the Mason researcher and his/her responsibilities in the research project, the IRB staff will determine whether or not Mason is engaged in the research based on guidance from the Office of Human Research Protections (OHRP): http://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/. If Mason is not engaged in the research, the researcher will receive a letter stating this which will be available in IRBNet. If the IRB staff determines that Mason is engaged in the research, the standard IRB review process will continue.
3. The intent to obtain any other necessary IRB approvals/permissions from collaborating institutions should be described in the appropriate section of the application. It is the responsibility of the Mason researcher to ensure that all necessary approvals have been obtained.
4. The Mason IRB does not require researchers to submit documentation of the IRB approval from the collaborating institution. However, if that documentation is available, it is helpful if the researcher provides it as part of the IRB application submission.
5. Each institution is responsible for its own researchers' human subjects training and the Mason researcher is not required to submit training records for researchers at the collaborative institution.
6. If the researchers at either institution are requesting a reliance agreement such that the GMU IRB either relies on the collaborating IRB or the collaborating IRB relies on the GMU IRB for review and approval of the research, the procedures for obtaining a reliance agreement should be followed and the request should be noted in the appropriate section of the IRB application form. Depending on the specific details of the project, the GMU IRB may agree to enter into a reliance agreement with the collaborating institution. Researchers should contact the IRB office for more information about the possibility of entering into a reliance agreement. (Note that all multi-center NIH-funded studies are required to use a single IRB and starting 1/20/20 most federally funded multi-center research projects located in the US will be required to use a single IRB).
7. If a researcher is transferring a human subjects research project to Mason from his/her previous institution, he/she must complete the appropriate GMU IRB application describing his/her role in the project and submit it through IRBNet along with all supporting documentation. It is helpful for the PI to include a memo with the IRB application explaining the transfer of the project. Providing the IRB approvals, consent forms, etc. from the previous institution is also helpful when possible.

8. If a researcher who is new to Mason plans to continue analysis of data that was collected under an IRB approval from another institution and the data collection has been completed, he/she should submit an Existing Data/Specimen application for to seek approval for the continuing analysis of that data.

Related Forms, Guidance, and SOPs:

1.2.3 Existing data
2.1.4 Reliance Agreements
2.4.1 Submitting a human subjects research project for review
45 CFR 46.114
OHRP Guidance "Engagement of Institutions in Human Subjects Research" (2008)

Responsibility:

Execution of SOP:
Institutional Review Board
Research Development, Integrity and Assurance
Principal Investigators

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, Research Development, Integrity and Assurance	January 21, 2019
Laurie Meamber	IRB Chairperson	January 21, 2019