SOP 2.6.2 Project Completion/Project Close-Out Procedures

General Description:

For projects that require annual review, Principal Investigators (PI) must submit a continuing review/closure form through IRBNet when a protocol is completed or otherwise no longer meets the federal definition of research with human subjects. This form formalizes and documents the closure of a study file, but also provides the IRB with information pertinent to its review and status. By submitting a continuing review/closure form in IRBNet, specifically requesting study closure, the researcher confirms that the study is finished and that researchers will have no further interaction with subjects or their data in ways that would require ongoing IRB approval. If a project does not have an expiration date, the PI must email the IRB office to inform IRB staff that the project should be administratively closed in IRBNet when the project is complete or when they are leaving GMU.

An investigator should only close a study when the research is permanently closed to the enrollment of new subjects, all participants have completed all research-related interventions or activities, and collection and active analysis of private identifiable information has been completed or if they are leaving GMU. Additional research projects using data acquired in the approved study might constitute new human subjects research studies subject to separate IRB review.

Procedures (Closure By PI):

1. For studies requiring annual review, investigators submit a continuing review/closure form through IRBNet requesting closure of the study. This should be submitted by or before the expiration date of the study or when the investigator has completed the study. The continuing review/closure form must be completed in full.
2. If no annual review is required, investigators must email the IRB office at irb@gmu.edu to inform staff that the project has been completed or that they are leaving GMU.
3. The IRB staff will review the IRB Project Closure Form/email to determine whether closure of the protocol is appropriate.
    a. If further information is required for review, the IRB will communicate to the Principal Investigator those steps needed to close the study.
    b. If closure is deemed appropriate, the PI will be formally notified of the study closure through IRBNet.
4. All documents relating to the closure of the protocol will be maintained by the IRB for a period of not less than 5 years after closure.

Investigators are expected to continue to honor confidentiality protections for data and other commitments made to the subject such as:

- notifying the subject of study completion;
- communicating research results and/or additional significant findings to the subject
- ensuring appropriate data protection is provided for legacy data at Mason, as well as any data taken with the Investigator;
- providing compensation to subject.

Procedures (Closure by IRB):

The Mason IRB may close projects without a request from the PI in the following circumstances:

1. If it is determined that the PI is no longer affiliated with GMU.

2. In response to unanticipated problems involving risk to subjects or others, serious or continuing non-compliance, findings presented during an IRB review; or problems identified in a monitoring process.
3. If the investigator has not responded to the IRB's requests for revisions and/or clarifications to obtain IRB approval within 3 months (for projects that have not yet received initial IRB approval, continuing review submissions, or amendment submissions that are awaiting response from the investigator).
4**.** If an approved project expires and the PI does not submit the appropriate documents for continuation of the project.

The IRB will provide written notification of all closure circumstances through IRBNet to the PI, the PI's Department or another entity as appropriate. IRB Records will be maintained per IRB policies and are outlined in GMU IRB SOP 1.6.3. Documentation and record keeping procedures.

Related Forms, Guidance, and SOPs:

- 45 CFR 46.109
- 21 CFR 56.109
- 45 CFR 46.103
- 1.5.3. Suspension/termination of IRB review
- 1.6.3. Documentation and record keeping procedures

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:	February 24, 2016
Revision Date:	August 11, 2020
Current Version #:	3

Approved By	Title and Division	Date Approved
Rebecca Hartley	Assistant Vice President, Research Integrity and Assurance	August 11, 2020
Laurie Meamber	IRB Chairperson	August 11, 2020