SOP 2.1.2 **Study Intake and Triage**

General Description:

Research, as defined by the federal regulations at 45 CFR 46, involving human subjects must be reviewed and determined to be exempt by IRB staff or reviewed and approved by the IRB before any human subject activity begins. Review category is determined by IRB staff, in consultation with the IRB Chair as needed, upon preliminary review of the completed IRBNet submission package. Protocols submitted by researchers that meet the criteria for exempt research are reviewed by IRB staff. Certain exempt projects may require a limited IRB review by a designated IRB member to make the determination that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. Protocols that meet the criteria for expedited research are reviewed by at least one member of the IRB. Protocols that require review by the full board will be reviewed at the monthly IRB meeting. Research that does not meet the definition of human subjects research does not need review by IRB staff or the IRB. IRB staff will review all submissions. Submissions are reviewed in the order received. IRB staff are responsible for all communications with the Principal Investigator or other researchers.

Procedures:

1. When a new IRB application is submitted through IRBNet, IRB staff will assign or tag the study for a member of the IRB staff. A new submission may be assigned to the next available IRB staff member. In some cases, when an IRB staff member has knowledge about the study through interaction with the researcher, the submission may be assigned to that staff member. The submission will be tagged globally for the entire project so that all submissions for that project will be tagged for that staff member.
2. IRB staff will initially conduct a pre-review for completeness of the IRB package. As part of the pre-review, IRB staff will:
   a) Verify that the correct IRB application form, existing data form or human subjects determination form are complete and any necessary supporting documents (i.e. consent/assent forms, recruitment materials, instruments, grant application) are included in the package.
   b) Verify that the Principal Investigator (PI) has access to the IRBNet package and the PI has electronically signed the package either as Principal Investigator or, in the case of student research, Advisor.
   c) Confirm that all researchers have completed the Basic Human Subjects CITI training course required by the IRB.
   d) Verify that the PI listed on the IRB application meets University PI policy: http://universitypolicy.gmu.edu/policies/principal-investigators/ and that the researcher is not acting as PI on research he/she is conducting as a Mason student (for example his/her own thesis or dissertation project).
3. When the pre-review is complete, IRB staff will contact the PI and any other researchers through IRBNet to let them know what changes or information is needed in order for the review process to begin. This is usually done within one week (7days).
4. Once no additional changes or information are needed based on the pre-review, IRB staff will then determine the level of review (exempt, expedited or full board).
5. Exempt research is reviewed by IRB staff. IRB staff will determine that all procedures, including participant activities, recruitment, consent, privacy of participants, confidentiality of data, risks, benefits, and compensation, are all described in the application. IRB staff will compare all documents in the package for consistency. All requested changes, clarification or concerns will be conveyed by IRB staff to the researchers through IRBNet. Certain research projects that collect information which is recorded by the investigator in such a manner that the identity of the

human subjects can readily be ascertained, directly or through identifiers linked to the subjects, may still qualify for exemption so long as a designated IRB member conducts a limited IRB review to make the determination that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. For these projects, IRB staff will ensure IRB review of the necessary details of the project prior to exemption.

6. Expedited research is reviewed by one or more members of the IRB. Based on the subject matter of the proposed study, IRB staff, in consultation with the IRB Chair as needed, will determine which IRB member(s) has the expertise to review the study. The IRB reviewer will relay any questions, changes or concerns to IRB staff, who will then convey the IRB requests to the researchers through IRBNet.
7. Full board review will be conducted at a regularly scheduled IRB meeting. Researchers will be notified by IRB staff when their protocol is going for review by the full board. IRB staff will communicate results of the full board review to the researchers with two business days after the IRB meeting.
8. All changes requested by the IRB staff will be noted in IRBNet as part of the reviewer documents in the IRBNet package.
9. When the study is exempted/approved, the IRB staff will:
    a) enter the review type, action, effective date, project status, expiration date (if applicable) for expedited and full board studies, initial approval date, and risk level of the study in the IRBNet package. When this information is entered in the IRBNet package, all researchers with access to the package will receive notification about the approval.
    b) stamp the approved versions of recruitment materials, informed consent documents, assent forms, and debriefing materials.
    c) complete the approval letter. The approval letter and stamped documents will be uploaded in the Board Documents section of the IRBNet package for use by the researcher. All researchers with access to the IRBNet package will receive notification that these documents have been published.

Related Forms, Guidance, and SOPs:

- 2.1.1 Types of RDIA/IRB decisions
- 2.4.1 Submitting a human subjects research project for review
- 2.5.1 Full Board review
- 2.5.2 Expedited and Exempt Review
- 2.5.3 Non-human subjects research review procedures

Responsibility:

IRB staff/Research Development, Integrity and Assurance
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.

Date First Effective:	December 14, 2016
Revision Date:	January 21, 2019
Current Version #:	2

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