SOP 2.1.3 Verification of No Material Changes from Other Sources

General Description:

Protecting the rights and welfare of research participants sometimes requires that the IRB verify independently, utilizing sources other than the investigator, that no material changes have occurred during the IRB designated approval period. This policy outlines the circumstances in which the George Mason University IRB may require this type of verification. Examples of additional sources include, but are not limited to: post approval monitoring by the IRB staff in the Research Development, Integrity and Assurance office, investigational records, incident reports, radiation safety reports, source documents, as well as information from staff, research participants, families, sponsors or others.

Procedures:

1. The need for verification from independent sources that there have been no material changes to the approved project will be initiated on a case by case basis and may be requested by the convened IRB, IRB Chair, or an IRB member during the course of an expedited review.

2. Criteria for determining if verification is required includes, but is not limited to:

    a. Complex protocols involving unusual levels or types of risks to subjects.
    b. Protocols conducted by Principal Investigators who previously have failed to comply with Federal regulations or the requirements or determinations of the IRB.
    c. Protocols where concern about possible material changes occurring without IRB approval have been raised based on information provided in continuing review reports or from other sources.

3. The individual(s) requesting the verification will indicate the specific reason for the request and the subject matter to be verified. This information will then be conveyed to the study team as well as to the person(s) responsible for conducting the verification process or providing the information needed to verify no material changes have occurred.

4. The verification process will focus on assessing relevant research documents and/or observing the conduct of the research to help ensure that no material changes have been initiated without IRB approval.

5. The results of the verification process will be reported back to the IRB in the form of a written summary, which will also be uploaded into IRBNet under the relevant protocol by IRB staff. The findings may also be reported to the Institutional Official.

6. If the evaluation established that material changes to the project may have been made, the IRB Chair or convened IRB will follow the procedure for reviewing allegations of suspected or actual noncompliance, or refer the report to the convened board to determine whether the unapproved change rises to the level of serious or continuing noncompliance. If applicable, the IRB Chair or IRB staff will notify the investigator and direct the investigator to submit a modification to their study via IRBNet.

7. Findings that present increased harm to participants or others or that require immediate action, such as suspending the study, will be presented to the convened IRB at the next possible meeting.

Any necessary corrective actions and decisions made by the IRB will be communicated to the Principal Investigator in writing through IRBNet.

Related Forms, Guidance, and SOPs:

- SOP 1.5.1 Noncompliance and deviations
- SOP 1.5.2 Research Subjects Complaints
- SOP 1.5.4 Investigation
- SOP 2.6.1 Continuing Review
- SOP 2.6.4 Modifications/amendments
- SOP 2.6.5 Reportable Events
- SPO 2.6.6 Post-Approval Monitoring and Education Visits
- 45 CFR 46.108(a)(4)(2)

Responsibility:

IRB staff/Research Development, Integrity and Assurance
Institutional Review Board

References:

Based on guidance from University of Pittsburgh IRB: Verification from Other Sources; guidance from Princeton University: Independent verification that no material changes have occurred; and from the Mayo Clinic IRB: Verification of No Material Changes Since Previous IRB Review.

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	December 14, 2016
Laurie Meamber	IRB Chairperson	December 14, 2016