SOP 1.5.1 **Protocol Deviations/Noncompliance**

Purpose:

To provide a procedure for the accurate and timely reporting to the George Mason University Institutional Review Board of deviations and noncompliance from the requirements of approved research protocols.

General Description and Definitions:

Institutions are required to have written procedures for "any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and (ii) any suspension or termination of IRB approval" (46 CFR 46.103(5)). This SOP addresses that need and delineates how George Mason University will handle protocol deviations and noncompliance including serious and continuing noncompliance.

Deviations

Investigators are required to conduct their research according to the plans reviewed and approved by the IRB. Instances where this does not occur which leads to an unapproved temporary change in previously approved research activities, implemented without IRB approval are considered deviations and must be reported to the GMU IRB within 10 working days of awareness of the event.

Major deviations include instances that impact participant safety, substantially alter risks to participants, are non-compliant with applicable federal, state and institutional policies and regulations. Comparatively, minor deviations do not adversely affect subjects rights, welfare, safety, or willingness to continue participation. Major deviations should be reported immediately and in no case later than 48 hours after the incident. Minor deviations should be reported within 10 days of awareness of the incident.

Noncompliance

Noncompliance includes failure to have protocols reviewed by the IRB as required, implementing revisions without IRB approval, including enrolling subjects who do not meet enrollment criteria, failing to obtain Informed Consent when required, and otherwise conducting research activities not approved by the IRB.

Serious noncompliance includes noncompliance that results in substantive harm or damage (or risk of substantive harm or damage) to the safety, rights, or welfare of human subjects, research staff, or others; or b) substantively compromises the integrity or effectiveness of the research.

Continuing Noncompliance

Continuing Noncompliance is defined as a pattern of noncompliance that indicates a lack of understanding or disregard for the regulations or institutional requirements that protect the rights and welfare of participants and others, suggests a possibility that noncompliance will continue without mediation or response, or involves frequent instances of minor noncompliance.

Any instance of serious or continuing investigator non-compliance with federal, state, or GMU regulations or policies will be reported promptly to the GMU Institutional Review Board.

Procedures:

Investigator Responsibilities:

Protocol deviations must be reported by the Principal Investigator within 10 business days of occurrence or identification to the IRB office. This report should include a memorandum to the IRB describing the deviation, any reasons for the deviation, and any corrective actions taken by the investigator. Suspected deviations and noncompliance may be reported by any individual, either verbally or in writing, to the IRB office for processing. This report must be submitted through IRBnet.org.

Principal Investigators are responsible for promptly responding to all IRB communications, including request for action, information, or instructions.

IRB Responsibilities:

I. Upon receipt of a report, IRB staff will begin evaluation to determine if it constitutes a minor deviation, noncompliance, or serious or continuing noncompliance. Minor deviations will typically be reviewed by IRB staff. Noncompliance that is neither serious nor continuing will typically be reviewed by the IRB Chair. If the IRB office believes that the deviation may constitute serious or continuing noncompliance it will be referred to the IRB Chairperson for immediate action and placed on the next IRB agenda for a vote by all convened members.

II. Upon review and evaluation of the reported deviation, the IRB office and/or IRB may take the following actions:
    a. For minor deviations, a letter of acknowledgement will be sent to the Principal Investigator and no further action will be required.
    b. For noncompliance that is neither serious nor continuing, a written warning with instructions may be issued.
    c. If the deviation/noncompliance also involves an unanticipated problem or adverse event, the unanticipated problem/adverse event form must be completed and the unanticipated problem/adverse event SOP will also be followed.
    d. All project team members may be required to complete further education.
    e. For serious or continuing noncompliance, the protocol may be suspended.
    f. The PI may be required to submit an amendment.
    g. The PI may be required to submit a corrective action plan to address rights, safety, and welfare of research subjects.
    h. The PI may be required to submit a data and safety monitoring plan to the IRB.
    i. The IRB may require monitoring by the PI's chair, dean, and/or director.
    j. The PI may be required to submit more frequent continuing reviews to the IRB.
    k. The PI may be required to notify research subjects of the deviation and provide further relevant information to these individuals.
    l. The IRB may require that data be destroyed and not used in reporting research results.
    m. The PI may be required to contact subjects and consent/re-consent them as needed.

III. Deviation letters will typically only be directed to the Principal Investigator. Noncompliance notices will typically be copied to the Principal Investigator's Chair, Dean, and/or Director, and the Institutional Official. Any actions taken by the IRB staff and/or IRB will be clearly communicated to the Principal Investigator, and their Chair, Dean, and/or Director, as necessary, in writing.

IV. For federally funded projects where serious and/or continuing noncompliance is detected, a project has been suspended or serious or continuing noncompliance with 45 CFR 46 by IRB acts or omissions has occurred, the IRB will complete an investigation and where appropriate the Institutional Official will notify the Office for Human Research Protections (OHRP), the funding agency, and/or the FDA. This notice will describe the serious/continuing noncompliance and/or project suspension and remediation measures that have been employed to ensure the noncompliance does not reoccur. If the deviation/non-compliance occurred at another study site,

the PI at that site is responsible for reporting it to the appropriate officials. However, the GMU PI should still submit the information to the GMU IRB for acknowledgement.

V. A copy of all correspondence related to the deviation will be maintained in the IRB project file.

Related Forms, Guidance, and SOPs:

- Adverse Events/unanticipated problems

Responsibility:

Principal Investigators
IRB staff/Research Development, Integrity and Assurance
Institutional Review Board
Chairs, Deans, and Directors
Associate Vice President, Research Development, Integrity and Assurance (Institutional Official)

Approval and Version History:

Please contact irb@gmu.edu if you have any questions about this procedure or the version and approval history.

References:

Guidance on Reporting Incidents to OHRP; http://www.hhs.gov/ohrp/policy/incidreport_ohrp.html
SACHRP Recommendation on Protocol Deviations;
http://www.hhs.gov/ohrp/sachrp/mtgings/2012%20Feb%20Mtg/protocoldeviations.pdf

Date First Effective:	September 17, 2012
Revision Date:	March 26, 2014
Current Version #:	2

Approved By	Title and Division	Date Approved
Aurali Dade	**Associate Vice President, Research Development, Integrity and Assurance**	**March 26, 2014**
Gregory Guagnano	**IRB Chairperson**	**March 26, 2014**