SOP 2.6.5 Unanticipated problem/Adverse Event Reporting

Purpose:

To provide a procedure for the accurate and timely reporting to the George Mason University Institutional Review Board (IRB) of adverse/reportable events (referred to as unanticipated problems throughout this document) occurring in approved research protocols.

General Description and Definitions:

Institutions are required to have written procedures for "any unanticipated problems involving risks to subjects or others." This SOP addresses that need and delineates how George Mason University will handle unanticipated problems.

An unanticipated problem is an event or problem occurring during the conduct of the research that meets all three of the following criteria:

- It is unexpected in terms of the nature, severity or frequency given the research procedures that are described in the protocol and other study documents and in the characteristics of the study population.
- It is related or possibly related to participation in research. This means that there is a reasonable possibility that the incident may have been caused by the procedures involved in the research study.
- The incident suggests that the research places the subject or others at greater risk of harm (physical, psychological, economic or social) than was previously known or recognized or results in actual harm of the subject or others. An unanticipated problem generally requires a change in policy or procedure and may warrant substantive changes to the protocol/consent or other immediate corrective actions in order to reduce the risk or eliminate immediate hazard.

Procedures:

Investigator Responsibilities:

Non-serious unanticipated problems that meet all of the criteria listed above (for example, negative non-life threatening physical reactions or unanticipated emotional upset, release of personal information/breach of confidentiality) must be reported by the Principal Investigator or study staff within 5 business days of occurrence or identification to the IRB office. This report should be made through IRBNet using the Reportable Information/Incidents form that can be found in the Forms section of IRBNet.

Serious unanticipated problems (for example, participant death or serious injury to a study participant) must be reported to the IRB office/IRB within 24 hours of when the study team first becomes aware of the event.

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

IRB Responsibilities:

1. Upon receipt of a report, IRB staff will begin evaluation to determine if the unanticipated problem indicates a new or increased risk to study participants or a safety issue. If the IRB Chairperson, in consultation with IRB staff, determines that the reportable event does not qualify as an unanticipated problem, the researcher will be informed of this determination, the report will be acknowledged in IRBNet, and no further action will be taken.
2. If the IRB Chairperson, in consultation with IRB staff, determines that the event does constitute an unanticipated problem upon review and evaluation of the reported deviation, the IRB staff and/or IRB may take the following actions:

    a. If the PI has indicated that the unanticipated problem requires revisions to the study procedures or study documents, the PI may be required to submit an amendment.
    b. If the unanticipated problem or adverse event also involves a protocol deviation or non-compliance, the Protocol Deviation/Non-Compliance SOP will also be followed.
    c. The PI may be required to submit a corrective action plan to address rights, safety, and welfare of research subjects.
    d. All project team members may be required to complete further education.
    e. If the report describes a serious increased risk or safety issue, the protocol may be suspended until that issue has been addressed.
    f. The PI may be required to submit a data and safety monitoring plan to the IRB.
    g. The PI may be required to submit more frequent continuing reviews to the IRB.
    h. The PI may be required to notify research subjects of the unanticipated problem and provide further relevant information to these individuals.
    i. The PI may be required to contact subjects and consent/re-consent them as needed.

3. For federally funded projects where unanticipated problems occur, the IRB staff and 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 as applicable. This notice will describe the unanticipated problem, including any noncompliance and/or project suspension, and remediation measures that have been employed to ensure the unanticipated problem does not reoccur.
4. A copy of all correspondence related to the deviation will be maintained in the IRB project file.

Related Forms, Guidance, and SOPs:

OHRP Guidance on Reporting Unanticipated Problems: http://www.hhs.gov/ohrp/policy/advevntguid.pdf
SOP 1.5.1 Protocol Deviations and Non-compliance
Reportable Information/Incidents form (available in the IRBNet forms library)

Responsibility:

Principal Investigators
IRB staff
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

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Approved By	Title and Division	Date Approved
Aurali Dade	**Associate Vice President, Office of Research Development, Integrity and Assurance**	**May 25, 2016**
Gregory Guagnano	**IRB Chairperson**	**May 25, 2016**