

SOP 1.5.2 **Research Participant Complaints**

General Description:

At all times, human subjects involved in research have the right to voice a concern, complaint or question. Researchers, the IRB, and the institution are all responsible for addressing complaints in a timely and suitable manner. Proper resolutions must be identified to protect the rights and welfare of research participants.

A participant may voice a concern or complaint directly, or a representative of the participant may voice the concern or complaint on behalf of the participant by phone, in writing or in person. When addressing participant complaints, appropriate privacy and confidentiality protections must be in place throughout the process to ensure protection of the participant.

The Principal Investigator is responsible for ensuring the IRB-approved consent documents contain accurate information for contacting the Principal Investigator should the subject have questions or research-related problems and contact information for the Mason IRB should the subject have questions about the subject's rights as a research subject or to report research-related problems. (45 CFR 46.116(a)(7)).

Procedures:

Complaints received by the PI/ study team

If the Principal Investigator or the study team receives a complaint, the research team must address and resolve the matter as soon as possible. Complaints must be reported to the IRB as appropriate, according to the following guidelines:

1. If the complaint meets the definition of an Unanticipated Problem (see OHRP reference at the end of this document), the PI must report the complaint promptly to the IRB through IRBNet using the Reportable New Information form available in the IRBNet forms library. Please see GMU IRB SOP 2.6.5 for more information on Unanticipated Problem reporting.
2. If the complaint involves possible non-compliance or research misconduct, the report will be reviewed according to IRB and institutional policy, and must be reported to the IRB through IRBNet or directly to the Associate Vice President, Research Development, Integrity and Assurance as appropriate under the relevant policy. Please see GMU IRB SOP 1.5.1 and university policy 4007 for more information on non-compliance and research misconduct.
3. If a complaint does not meet the definition of an Unanticipated Problem but the investigator is unable to resolve the complaint satisfactorily with the research participant, the complaint should be referred to the IRB office/IRB for additional action. This report should be submitted as soon as it is determined that the issue cannot be resolved without assistance from the IRB or the institution.

If the complaint does not meet any of the three criteria above and the investigator was able to satisfactorily resolve the complaint, the investigator should report the complaint at the time of continuing review. The PI must provide a summary of the complaint, how it was resolved, and why it did not meet criteria for prompt reporting as an Unanticipated Problem or Noncompliance.

If a complaint results in the need to change the IRB approved study, an amendment should be submitted to the IRB for review and approval as soon as the complaint is resolved. The report of the complaint must be included in the amendment submission.

Complaints received by the IRB

If a research subject complaint is received by the IRB office/IRB, the IRB office/IRB will take the necessary steps to address the complaint.

1. In receiving notification of a complaint via phone, in writing or via email, the IRB staff may record the following information:
 - A. The individual's name and contact information. Collection of this information is not required if the person wishes to remain anonymous, but the individual will be informed that without this information, direct follow-up will not occur.
 - B. The IRB project number and name of the Principal Investigator, if available.
 - C. The person's relationship to the study (present or past participant or representative of present or past participant).
 - D. A detailed explanation of the complaint/concern/question.
 - E. Who the person has contacted previously regarding the complaint/concern/question, when the contact was made, and the resolution of the contact.
 - F. A proposed resolution from the individual, if offered.
2. The IRB staff member will communicate to the research participant that an inquiry will be made into the circumstances associated with the complaint/concern/question. The IRB staff member will inform the person about the limits of confidentiality in regards to the inquiry, including who may be informed, what information may be reviewed or disclosed.
3. After consultation with the PI and research team, if the complaint was previously raised with the investigator, the IRB will request submission of the complaint formally either immediately or at the time of continuing review. The investigator should report the complaint formally through IRBNet to document receipt of the complaint as well as the process used to address the complaint in collaboration with the IRB. The IRB will review the complaint report according to IRB policies as appropriate.

IRB Review Procedures

Upon receipt of a complaint/concern, the IRB will determine whether it may constitute an Unanticipated Problem, Noncompliance, or other reportable matter, and if so, proceed with appropriate reporting procedures. The IRB may consult with University legal counsel to seek assistance in the handling of any complaint or concern.

After a complaint report is provided to the IRB, the IRB chair or designee will review the report to determine if it involves potential risks to subjects or others or a change in the risk/benefit ration associated with the study.

- A. If the IRB determines that the complaint/concern/question does not involve potential risk to subjects or others or cause a change in the risk/benefit ratio associated with the study, the IRB may accept the report and provide written acknowledgement of receipt and review. The report and acknowledgement of the report will be included in the project file.
- B. If the IRB determines that the complaint/concern/question does involve potential risk to subjects or others or cause a change in the risk/benefit ratio associated with the study, the following may occur:
 - a. The IRB Chair may request the report and response be placed on the next appropriate meeting agenda for Full Board Convened review.

- b. If an immediate effect to participants is expected, the IRB may contact the Principal Investigator to request establishment of immediate procedures for the protection of subjects until review can be completed by the IRB.
- c. The IRB may require modification of the protocol, recruitment materials, and/or consent materials as appropriate to protect future participants.
- d. The IRB may suspend or request termination of the research.

References:

Unanticipated Problems: <http://www.hhs.gov/ohrp/policy/advevntguid.html>

45 CFR 46.103(b)
 45 CFR 46.116(b)(7)
 21 CFR 56.108(b)

Related Forms, Guidance, and SOPs:

- SOP 1.5.1- Noncompliance and Deviations
- SOP 2.6.5- Adverse Event Reporting Policy

Responsibility:

Principal Investigators
 Research Team Members
 IRB staff
 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.

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Approved By	Title and Division	Date Approved
Aurali Dade	Associate Vice President, Research Development, Integrity and Assurance	06/25/2014
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