Institutional Review Board
Management of Suspected Noncompliance

Complete Information regarding Compliance with IRB requirements can be found in the IRB Policy and Procedure Manual. Additional information is also available in the Research Handbook.

Noncompliance with Human Research Protection Regulations or IRB Requirements
Investigators are required to report noncompliance with human research protection regulations, or the requirements and determinations of the IRB, including protocol violations to the IRB. A protocol violation is defined as any deviation from the IRB-approved protocol that is not approved by the IRB prior to its initiation or implementation. The Principal Investigator is responsible for reporting the noncompliance and any corrective action taken, as described below.

1. Minor Noncompliance (Minor Violation)
A minor violation is a violation that does not impact participant safety, compromise the integrity of the study data and/or affect the participant's willingness to participate in the research. Minor violations/noncompliance are to be reported at the time of continuing review. If the IRB or IRB Chairperson finds the violation to be continuing or serious additional action may be taken, as described below.

2. Serious or Continuing Noncompliance (Major Violation)
A major violation is a violation that may impact participant safety, affect the integrity of the study data and/or affect the participant's willingness to participate in the research or continuing issues of noncompliance. Major violations and any corrective action taken must be reported to the IRB within 14 days of discovery of the noncompliance. The IRB will review the report and may take one or more of the following actions:

- Accept the report, with no further action required;
- Require additional information or modifications to the protocol and/or consent form;
- Require notice to participants, which may include re-consent;
- Modify the approval period;
- Require remedial education and/or oversight by a senior investigator;
- Restrict, suspend, or terminate research privileges and/or the research;
- Require periodic audits by the Office of Compliance;
- Other actions deemed appropriate by the IRB.

The findings and actions of the IRB are communicated in writing to the Principal Investigator (PI), as well as the Institutional Official, dean of the appropriate school, department chairperson, sponsor, FDA, OHRP, Office of Integrity and Compliance, Office of Research, Grants and Contracts and IRBs relying on UMMC's IRBs for review and oversight of the protocol, as applicable.

Examples of major violations

This list is intended as a guide and **<u>is not</u>** all-inclusive

- Beginning a study before receiving IRB approval
- Continuing to conduct a study beyond the expiration date
- Performing study procedures that have not been approved by the IRB
- Failure to obtain informed consent, or obtaining informed consent AFTER initiation of study procedures