



Policy Number: 98.104

**Protocol Deviation Reporting &
Noncompliance**

Adopted: 07/2008

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Human Research Protection Policy

SUBJECT: Protocol Deviation Reporting & Noncompliance

Protocol Deviation

A protocol deviation is **any departure** from the IRB approved protocol procedures, forms, and other attachments.

Any changes in the research protocol may not be initiated without submission of an amendment for IRB review and approval. Amendments must be requested in writing by submitting the IRB Protocol Amendment Form (<http://www.mu.edu/researchcompliance/research/irbforms.shtml>). It is the responsibility of the Principal Investigator to take reasonable steps to avoid deviations from the approved protocol.

If **any** protocol deviation occurs, the deviation **must be reported** promptly by contacting the Office of Research Compliance within 10 business days of the deviation occurrence or identification.

A protocol deviation may be:

- (a) A change intended to eliminate apparent immediate hazards to research subjects;
- (b) A change that does not impact the level of risk to subjects;
- (c) A change that does impact the level of risk to subjects;
- (d) An instance of serious or continued noncompliance

Serious Noncompliance

Serious noncompliance is an act or omission that resulted in increased risk to subjects or others that compromised the subjects' rights, safety, or welfare.

EXAMPLES of serious noncompliance include, but are not limited to the following:

- (a) Deliberate or repeated failure to obtain prior review and approval by the IRB before initiating or continuing human subjects research.
- (b) Deliberate or repeated failure to obtain or document informed consent from human subjects.
- (c) Deliberate or repeated omission of a serious risk when obtaining informed consent.
- (d) Deliberate or repeated failure to maintain accurate research protocol records, report protocol changes to the IRB, or report unanticipated problems to the IRB.

Continued Noncompliance

Continued noncompliance is a pattern of repeated acts or omissions that indicate an inability or unwillingness to comply with the federal regulations governing human subjects research.



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EXAMPLES of continued noncompliance include, but are not limited to the following:

- (a) Consistently late submissions of continuing review protocols or other items that require prompt reporting to the IRB.
- (b) Repeated failure to comply with the IRB requirement that all human subjects research investigators complete the NIH training tutorial prior to involvement in the research.
- (c) Repeated failure to submit required documents to the IRB.
- (d) Repeated refusal to comply with an IRB request.

Protocol Deviation Review

1. Reported deviations are reviewed by a member of the Office of Research Compliance. The ORC may request clarifications or further information from the PI to properly evaluate the deviation.
2. The deviation is evaluated to determine if it had a significant effect on subject's rights, safety, or welfare, and/or on the integrity of the resultant data. The IRB Chair or Vice Chair may be consulted at any time during this deviation review process.
3. If the deviation is determined to be serious or continuing non-compliance, the deviation will be reported to the convened IRB with an evaluation and recommendation from the ORC and IRB Chair or Vice Chair.
4. After review and evaluation of the deviation, the actions that may be taken include, but are not limited to the following:
 - (a) The protocol deviation is acknowledged as submitted and no further action is necessary.
 - (b) The PI is given a warning with instructions on how to avoid further infractions.
 - (c) The deviation is considered an unanticipated problem and/or adverse event, and the PI is instructed to submit a report in accordance with HRPP 98.105.
 - (d) The PI and/or the PI's staff are required to participate in additional training/education for the protection of human subjects in research.
 - (e) The deviation is considered serious or continued noncompliance.
 - (f) The protocol is subject to an audit by the ORC.
 - (g) The PI is required to submit a corrective action plan addressing how the rights, safety, or welfare of the research participants will be protected, and how the research data will be overseen to protect its integrity.
 - (h) The PI is required to submit a protocol amendment.
 - (i) The PI is required to develop and submit for IRB approval a Data and Safety Monitoring Plan.
 - (j) The PI is required to submit periodic status reports.



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- (k) The protocol requires IRB review more frequently than once per year.
- (l) The PI is required to notify current subjects if the information about the noncompliance might affect their decision to continue participation in the research.
- (m) The PI is required to provide relevant information to previously enrolled subjects.
- (n) Some or all of the research protocol may be suspended or terminated.
- (o) The data must be destroyed and may not be used when reporting the research results.