



Protocol Deviations and Violations

PURPOSE

This policy defines the categories of non-compliance with respect to deviations by investigators from approved protocols and the responsibilities of IRB in resolving matters of non-compliance

SCOPE

All BCOM agents and students involved in human subjects research

RESPONSIBLE OFFICIAL(S)

Authorized Institutional Official for Research, Director of Research, Institutional Review Board

DEFINITIONS

Categories and Definitions of Non-Compliance

Category 1: Non-Compliance

Category 1 Non-Compliance results from failure of an investigator or researcher to comply with applicable Federal Regulations or BCOM IRB Policies that did not result in an increased risk to a human subjects research participant.

Category 2: Serious Non-Compliance

Category 2 Serious Non-Compliance results from an action or omission taken by an investigator or researcher that would be viewed by the general research community as compromising the rights and/or welfare of the research subjects. Violations in institutional, state and/or federal guidelines may result in serious non-compliance. Examples include but are not limited to failure of the investigator to:

- obtain IRB approval prior to initiation of research activities
- notify the IRB of changes in approved procedures
- obtain and/or document informed consent
- notify the IRB of changes in the scope and/or intent of the study

Category 3: Continuing Non-Compliance

Patterns of repeated actions and/or omissions by an investigator or researcher personnel that indicates lack of ability and/or unwillingness to comply with institutional, state, and federal policies may result in further IRB actions.

POLICY

Pursuant to its responsibilities, the IRB oversees and conducts continuing review of all research that it approves. The Office of Research assist the IRB by conducting periodic and for-cause audits of approved protocols. In the course of audits or routine IRB business, incidents of noncompliance with federal regulations by investigators may be identified and must be brought to the attention of the IRB. Incidents of non-compliance are reviewed by the IRB. The IRB plan for managing the violation or deviation will depend on the severity of the violation and determination as to whether the violation represented willful intent of the investigator. A plan will be developed for each incident of non-compliance and communicated to the investigator in writing. The IRB may conduct further audits of the research if they deem it necessary.

Actions that may result during and after investigation of Non-Compliance

The IRB or a designated subcommittee of the IRB is responsible for investigating all reported and/or discovered incidents of non-compliance in human subjects research. A written report is developed that provides the following information will be prepared and distributed to the full IRB for further discussion at a convened meeting. The IRB



Chairperson may choose to convene a special meeting of the IRB that is outside of the normal meeting schedule. The Report on Investigation of Non-Compliance will address the following general headings: 1) Brief description of the incident , 2) Statement of exactly what the IRB determines the non-compliant items to be, 3) Explanation of why the IRB believes that the incident did not comply with BCOM, state and/or federal regulation, and 3) action taken by the IRB as a result of the investigation.

Actions that the IRB may take in response to non-compliance include:

- No Action
- Suspension of Enrollment of New Subjects and/or Research Activities pending:
 - Receipt and review of a response and plan of corrective action from the investigator
 - Modification of the research protocol
 - Modification of the information disclosed during the consent process
- Requiring that current participants in the student re-consent to continue enrollment in the study
- Auditing some or all of the investigator's active protocols
- Termination of the Research



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— at —
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Research and Sponsored Programs
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APPROVAL PAGE

Approved by: _____

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APPROVED

**Signed Copy on
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