

CUNY HRPP Policy: Disposition of Allegations of Non-Compliance

1. Overview and Purpose

All human subject research must be conducted in full compliance with applicable regulations, State law, University policies, CUNY UI-IRB approved protocol and stipulations imposed by the CUNY UI-IRB. This document describes CUNY HRPP's policy and procedures for addressing allegations of non-compliance.

2. Definitions

- a) **Non-Compliance:** Any situation, incident, or process during the conduct of human subject research that is inconsistent with any of the following: applicable federal regulations, State law, CUNY policies, any IRB-approved protocol or any stipulations imposed by the CUNY UI-IRB.
- b) **Serious Non-Compliance:**
 - i. Conducting non-exempt human subject research without prospective IRB review and approval.
 - ii. In IRB-approved protocols: Any incident of non-compliance that significantly increases risks to subjects; jeopardizes the safety, welfare, or rights of subjects or others; or decreases potential benefits of the study, including the scientific integrity of the research.
- c) **Continuing Non-compliance:** A pattern of repeated non-compliance which continues after initial discovery and approval of a corrective action plan that suggests that non-compliance will continue if there is no intervention; or if continued, could significantly increase risks to, or jeopardize the safety, welfare, and/or rights of subject(s) or others; or if continued, could decrease potential benefits (including the scientific integrity of the research).

3. Reporting Allegations of Non-Compliance

Allegations of non-compliance may be brought to the University's attention as follows:

- a) Self-report by the principal investigator (PI) or study team
- b) Any individual may report suspected non-compliance against one or more persons orally or in writing. Such allegations should be addressed to the University Director of Research Compliance (UDRC) or his/her designee.
- c) If an allegation is received by another University administrator or identified in the course of another University process, such as an internal audit, the responsible administrator should immediately notify the UDRC or his/her designee of such an allegation.

- d) A funding agency or sponsor should forward allegations of non-compliance to the UDRC or his/her designee.

4. Initial Evaluation of Non-Compliance

- a) The HRPP will forward allegations of non-compliance to a UI-IRB Chair or designee for review.
- b) The UI-IRB Chair or designee must determine whether there is non-compliance, and if so, whether the non-compliance is serious and/or continuing.
- c) Upon completion of an initial evaluation, the UI-IRB Chair or designee may make one or more of the following determinations:
 - i. Determine that there is no non-compliance;
 - ii. Determine that the non-compliance is neither serious nor continuing, and acknowledge the non-compliance without requiring any further action;
 - iii. Determine that the non-compliance is serious and/or continuing.
 - 4.c.iii.1. Determinations of serious and/or continuing non-compliance must be referred to the convened UI-IRB.
 - iv. Require corrective actions in accordance with Section 6 of this policy;
 - v. Refer the allegation to the UDRC for further investigation.

5. Investigations by the UDRC and Findings of Non-Compliance

- a) Upon receipt of a request for investigation, the UDRC or his/her designee will review the allegation, and based on the nature and substance of the allegation or expertise required, and in consultation with the Vice Chancellor for Research (VCR) and/or the UI-IRB, identify appropriate membership of the investigative team. When appropriate, allegations of non-compliance will be promptly reported to the VCR.
- b) The investigation of non-compliance allegations will be documented. The PI and others who may have relevant information should have the opportunity to provide input during the investigation. Every effort must be made to protect the identity of whistle blowers before, during and after investigation. Retaliation against good faith whistle blowers will not be tolerated. Those against whom allegations of non-compliance have been made will be provided a description of the allegations, reasonable access to evidence, and opportunity to respond and provide input.
- c) Upon completion of the investigation, the investigative committee will provide a written report to the UDRC to include, at a minimum, the following:
 - A detailed description of the allegations;
 - Summary of the research records and evidence reviewed;

- For each separate allegation of non-compliance identified during the investigation, a recommendation as to whether the non-compliance did or did not occur;
- Root cause analysis;
- Recommendations for corrective action(s)
- For any recommendation for a finding of non-compliance, a recommendation as to whether or not the non-compliance is serious or continuing.

d) The UDRC will forward the investigation report to the UI-IRB.

6. Review by the Convened UI-IRB

- a) For allegations of non-compliance that are referred to the convened UI-IRB, the UI-IRB will make the final determination of whether the allegation constitutes non-compliance. If the determination is made that there is non-compliance, the UI-IRB must determine if the non-compliance is serious and/or continuing. The UI-IRB may rely on the recommendations of the investigative team, the UDRC, and any other resources deemed appropriate in making this determination.
- b) The Office of Vice Chancellor for Research will promptly notify the principal investigator in writing of the UI-IRB's determination along with a statement of the reasons for its decision. Investigators will be offered an opportunity to respond to the UI-IRB in writing.

7. Corrective Action Plan

- a) The UI-IRB may require corrective actions to protect human subjects. Such actions may include, but are not limited to:
- i. Temporarily suspending new enrollment in a protocol;
 - ii. Suspending or terminating all human subject research activity; (NOTE: Only the convened IRB may terminate a study.)
 - iii. Mandating investigator and/or staff training in the protection of human subjects;
 - iv. Requiring investigator supervision by a qualified mentor and/or hiring of new, qualified staff;
 - v. Suspending individual investigators from participation in the research protocol;
 - vi. Notification to subjects of non-compliance;
 - vii. Requiring modifications to the protocol or consent documents;

- viii. Requiring the re-consenting of currently enrolled subjects;
 - ix. Mandating additional safeguards such as more frequent IRB continuing review; audits; monitoring of research or consent/recruitment process; and/or Office of the Vice Chancellor for Research or designee site visit(s)
 - x. Notifying college administration, partners, sponsors, or collaborators of the findings of non-compliance and/or required corrective actions, if applicable.
 - xi. Additional decisions may be necessary regarding the status of data and the appropriateness of publication of study results.
- b) The Office for the Vice Chancellor for Research will follow-up with the Investigator periodically to ensure and document that all corrective actions have been completed in a satisfactory manner and timeframe. The Vice Chancellor for Research or his/her designee and the UI-IRB will be provided with follow-up documentation and may impose additional corrective actions or sanctions for investigators who fail to satisfactorily complete required corrective actions in the allotted timeframe.

8. Reporting Non-Compliance

- a) The University Director for Research Compliance will promptly report determinations of serious and/or continuing non-compliance made by the convened IRB to the Institutional Official.
- b) The Office of the Vice Chancellor for Research will promptly report serious and/or continuing non-compliance to federal agencies and/or sponsor(s), when required.
- c) **Information to be included in the report:**
 - i. Name of the CUNY institution(s) conducting the research;
 - ii. Title of the research project and/or grant proposal in which the non-compliance occurred;
 - iii. Name of the principal investigator on the protocol;
 - iv. Number of the research project assigned by the IRB and the number of any applicable sponsored program or project;
 - v. A detailed description of the non-compliance; and
 - vi. Actions the institution is taking or plans to take to address the non-compliance.

Reference

[Code of Federal Regulations, Title 45 – Public Welfare DHHS, Part 46 – Protection of Human Subjects](#)