1. Overview

A UI-IRB or the Vice Chancellor for Research may suspend or terminate a research study for reasons including that:

a) Serious or continuing non-compliance has taken place; and/or

b) An unanticipated problem involving harm to subjects or others has occurred; and/or

c) Research is not conducted in accordance with the IRB-approved protocol and poses possible risk of harm to subjects.

2. Definitions

a) **Suspension:** Temporary withdrawal of IRB approval. The UI-IRB or CUNY administration can suspend approval of an entire human subject research study, or aspects of the study, such as suspending subject recruitment.

b) **Termination:** Permanent withdrawal of UI-IRB approval of a human subject research study.

c) **Voluntary Suspension**: The Principal Investigator or sponsor may voluntarily decide to suspend or terminate human subject research.

3. Authority to Suspend or Terminate

3.1. Administrative Suspension or Termination

a) Administrative action to suspend human subject research activities may be implemented by the Vice Chancellor for Research or the University Director for Research Compliance or his/her designee. The suspension of a study by CUNY administrative action may be taken if it is deemed immediately necessary to ensure the safety of human subjects.

The Institutional Official may terminate a study when s/he determines the action to be in the best interest of the subjects.

b) The Principal Investigator shall be promptly notified in writing of a decision to suspend or terminate a study, the reasons for the suspension or termination, and any required steps for corrective action and/or closure.

c) All actions taken by CUNY Administration shall be promptly reported to the convened UI-IRB for review.

3.2. Suspension by an IRB Chair or his/her Designee

a) The UI-IRB Chair or his/her designee may suspend human subject research if s/he deems that such prompt action is necessary to ensure the safety of human subjects and that it is inappropriate to await action by the convened UI-IRB. The Chair or his/her designee's determinations will subsequently be forwarded to the UI-IRB for further review.

b) When suspending a study, the UI-IRB Chair or his/her designee may make any of the following determinations:

   i. Request an investigation by the Office of the Vice Chancellor for Research prior to convened UI-IRB review;

   ii. Initiate an inquiry by requesting specific information from the Principal Investigator prior to convened UI-IRB review;

   iii. Refer the report directly to the convened UI-IRB for review, in which case an unscheduled IRB meeting may be called.

c) The Principal Investigator shall be promptly notified in writing of the UI-IRB Chair or designee's determination, any required steps for corrective action, and the reasons for such requirements.

d) An IRB Chair or designee may NOT make a determination to terminate a study. The decision to terminate a human subject research study shall be made by a convened UI-IRB or by the Institutional Official.

3.3. Suspension or Termination by a Convened IRB

a) The convened UI-IRB has the authority to suspend or terminate its approval of any study that it has reviewed and approved.

b) The UI-IRB may make any of the following determinations:

   i. Request an investigation by the Office of the Vice Chancellor for Research;

   ii. Initiate an inquiry by requesting specific information from the Principal Investigator;

iii. Require corrective actions including but not limited to:

1) Mandating additional training in the protection of human subjects for the principal investigator and/or other research team members;

2) Requiring investigator supervision by a qualified mentor and/or hiring of new, qualified staff;

3) Imposing a probationary period for an investigator, pending remedial action(s);

4) Suspending individual investigators from participation in the research protocol;

5) Suspending an investigator's right to perform human subjects research studies, pending remedial action(s);

6) Transferring responsibility for the protocol to another principal investigator;

7) Notification to subjects of non-compliance;

8) Requiring modifications to the protocol or consent documents;

9) Requiring the re-consenting of currently enrolled subjects;

10) Mandating additional safeguards such as more frequent IRB continuing review; audits; monitoring of research or consent/recruitment process; and/or research site visits by the Office of the Vice Chancellor for Research or designee(s);

11) Notifying college administration, partners, sponsors, or collaborators of the findings of non-compliance which lead to suspension/termination, and/or required corrective actions, if applicable;

12) Additional decisions may be necessary regarding the status of data and the appropriateness of publication of study results.

c) When the UI-IRB determines that a suspension is appropriate, criteria for lifting the suspension must be defined. Terms for lifting the suspension must be included in the UI-IRB determination letter to the Principal Investigator.

d) The Principal Investigator shall be promptly notified in writing of a decision to suspend or terminate a study, the reasons for the suspension or termination, and any required steps for corrective action and/or closure.

3.4. Voluntary Suspension by Researcher or Sponsor

The Principal Investigator or the sponsor of a study may voluntarily suspend an IRB-approved study. The Principal Investigator or sponsor can suspend an entire human subject research study, or aspects of the study, such as suspending subject recruitment.

a) Subject Safety Considerations

The PI must submit a recommendation regarding the continuation of any study-related activities with subjects for safety purposes during the suspension. A UI-IRB Chair or designee will review the reason for the voluntary suspension along with the recommendation for subject safety. The UI-IRB Chair or designee will determine whether the subject safety recommendation is adequate, whether any additional actions are required, or refer the review to the convened UI-IRB.

b) Subsequent Suspension "For Cause"

A study under voluntary suspension may be suspended "for cause" either by CUNY administrative action or by UI-IRB determination. If a suspension is imposed administratively or by the UI-IRB, this suspension shall override the voluntary suspension and shall carry with it the reporting requirements defined in Section 8 of this Policy.

4. IRB Responsibility: Subject Safety Considerations

a) When considering suspension or terminations the UI-IRB shall evaluate:

i. Whether currently enrolled subjects should continue certain research procedures for safety reasons; whether and how subjects should be transitioned off research procedures; and/or whether it is safe to suspend all human subject research procedures immediately.

ii. Study interventions or interactions with currently enrolled subjects should only continue when these are in the best interest of the individual subjects.

5. Principal Investigator Responsibilities

a) The principal investigator, or other key personnel in the absence of the principal investigator, shall implement an administrative suspension or termination of a study in accordance with the UI-IRB's determination letter.

b) The principal investigator shall consider the effect of the suspension on the rights and welfare of current subjects, and if appropriate, provide a plan outlining the action(s) that will be taken to protect subjects. If appropriate,

the principal investigator shall include how the subjects will be informed of the study suspension or termination.

6. Process to Appeal a Suspension or Termination

a) A principal investigator may appeal to the convened UI-IRB about a decision to suspend or terminate a study. This appeal must be made in writing **within 10 working days** following receipt of the written notice of suspension or termination.

b) If the principal investigator chooses to appeal the suspension or termination, s/he must submit a corrective action plan addressing the reasons leading up to suspension or termination of the study.

7. Lifting of a Suspension

a) The convened UI-IRB shall lift a suspension when the previously defined terms to lift a suspension have been met.

b) If additional information becomes available, the convened UI-IRB will reconsider the terms of the suspension, in accordance with the overall safety of the study and the risks to currently enrolled and future subjects.

8. Reporting Suspensions/Terminations

The Office of the Vice Chancellor for Research will report determinations of suspension or termination to federal agencies and/or sponsor(s), when required.

a) **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 which was suspended or terminated;
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 any non-compliance; and
vi. Any additional pertinent details related to the suspension or termination, including corrective action plans

Reference

Code of Federal Regulations, Title 45 – Public Welfare DHHS, Part 46 – Protection of Human Subjects