1. Overview

The CUNY UI-IRBs approve, disapprove or require modifications to new and ongoing research protocols that involve human subjects. In addition, an IRB may suspend or terminate a previously granted IRB approval.

CUNY UI-IRB approved human subjects research may be subject to further review and approval, disapproval, termination or suspension by CUNY administration. However, CUNY administration may not approve a human subject research protocol that has not been approved by the IRB, or that has been disapproved or terminated by the IRB.

Researchers may appeal CUNY UI-IRB's decisions or determinations by requesting a review by the Appeals Committee.

2. Appeals Process

2.1. IRB Review Process

The IRB review process involves dialogue between the IRB and the researcher. At each step of the review, the IRB provides written communication to the researcher, indicating approval, request for modifications or disapproval of the given submission. In its communication, the IRB indicates any concerns it has regarding the protection of human subjects, or compliance with applicable regulations and CUNY policy, and provides suggestions on how the researcher may address these concerns. In response, the researcher is expected to address each of the IRB's concerns in writing. The researcher may agree or disagree with the IRB. Any statement of disagreement should be accompanied by a written justification for the disagreement.

2.2. Appeals Regarding Research that Underwent Expedited Review

If a submission is reviewed on an expedited basis, and after two rounds of written communications between the IRB and the researcher, the IRB and the researcher remain at an impasse, the researcher may request, in writing, that the protocol be referred for review by a convened UI-IRB. The request must include justification for the appeal.

2.3. Appeals Regarding Research that Underwent Convened IRB Review

If, after two rounds of written communications between the convened IRB and the researcher, the IRB and the researcher are unable to reach an agreeable resolution, the researcher will be invited to the convened IRB meeting to address the IRB's concerns. If the IRB and the researcher do not come to an agreeable resolution during this meeting, the researcher may choose to request review by an Appeals Committee.

2.3.1. Requesting a Review by the Appeals Committee

If the conditions in Section 2.3 above apply, a researcher may request review by an Appeals Committee by submitting a written request to the University Director for Research Compliance. The request must include justification for the appeal. The University Director for Research Compliance, in consultation with the Vice Chancellor for Research, determines whether the case warrants an Appeals Committee review.

2.4. Appealing CUNY UI-IRB Decisions or Determinations Concerning Issues of Non-Compliance

A researcher may appeal a CUNY UI-IRB's decision or determination regarding issues of non-compliance by requesting, in writing, a review by the Vice Chancellor for Research. The request must include justification for the appeal. Upon review of the case, the Vice Chancellor for Research will determine whether further review by an Appeals Committee is warranted.

2.5. Referral by a CUNY UI-IRB

A reviewing IRB may refer any matter before it for review by an Appeals Committee at any time.

3. Appeals Committee

3.1. Charge

The charge of the Appeals Committee is to review the history of the case at hand, evaluate the concerns of both the reviewing IRB and the researcher and recommend possible resolution to the reviewing IRB. The Appeals Committee serves an advisory role; as such, the reviewing IRB is not required to accept the Appeals Committee's recommendations.

3.2. Membership

The University Director for Research Compliance, in consultation with the Vice Chancellor for Research, will determine the membership of the Appeals Committee based on the nature of the appeal, the type of research, and the nature of the IRB's concerns. The Appeals Committee must have faculty and community representation from the CUNY UI-IRBs, and may include internal or external subject-matter expert(s), as deemed necessary.

Reference

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