

CUNY HRPP Policy: CUNY UI-IRB Authority

1. Purpose

The purpose of this policy is to establish the authority and to define the responsibilities of CUNY's University Integrated Institutional Review Boards (UI-IRBs).

2. IRB Authority and Responsibility

Pursuant to CUNY's commitment to protect human subjects, CUNY has established one or more panels each called the University Integrated Institutional Review Board. Each UI-IRB shall have responsibilities to review assigned human subject research in accordance with applicable federal regulations, State laws and CUNY policies and procedures. In addition, each UI-IRB shall be guided by the principles of the Belmont Report and the terms of CUNY's Federalwide Assurance (FWA) for the Protection of Human Subjects with the US Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP).

2.1. Protection of the Rights and Welfare of Human Subjects

The UI-IRB's responsibility to protect the rights and welfare of human research subjects extends to all human subject research in which CUNY is engaged, including pilot studies and feasibility studies.

3. IRB Review

3.1. Possible Outcomes of IRB Review

Upon its review of human subject research, the UI-IRB is authorized to take any of the following actions on each submission:

1. Approval

If a proposal is approved, the principal investigator (PI) will be notified in writing, at which time research may begin. Approvals are given for no more than 12 months after the date on which the IRB reviews and approves the research.

2. Conditional Acceptance or Deferral

If a protocol receives a conditional acceptance or deferral, the PI must address the UI-IRB's conditions or requests for modifications and provide revised study documents to the UI-IRB as necessary. After the conditions are deemed by the UI-IRB to have been met, or removed by the UI-IRB after discussion with the PI, and modifications have been accepted, the research will receive an approval in writing.

3. Referred for Convened IRB Review *by an expedited reviewer*

If an expedited reviewer refers a protocol for convened IRB review, this means that the expedited reviewer believes the study confers an element(s) of risk, or involves procedures that require convened UI-IRB discussion.

4. **Tabled by the convened IRB**

The convened UI-IRB may table items on an agenda in instances when quorum is permanently lost; when the meeting has run over-time and items must be pushed to another agenda; when a protocol has been submitted for UI-IRB review in an un-approvable state; or as deemed necessary by the UI-IRB Chair.

5. **Consultant Review**

An expedited UI-IRB member or the convened UI-IRB may request a consultant review when additional expertise is necessary in order to make an adequate determination. The UI-IRB or the Office of the Vice Chancellor for Research will identify a consultant based on the required expertise. Consultant's comments will be considered by the requesting UI-IRB reviewing entity (expedited member or convened UI-IRB).

6. **Disapproval by the convened IRB**

The convened UI-IRB may disapprove a protocol when a study does not meet the criteria for IRB approval, including unmitigated risks to human subjects, unqualified study team members/principal investigator, poor study design, etc.

If the UI-IRB decides to deny approval, the investigator will receive this determination in writing. The investigator will have 15 business days to respond to any questions or comments included in the UI-IRB's decision. Responses and/or new information from the PI that were not considered in the initial protocol should be submitted to the HRPP for submission to the UI-IRB.

3.2. Considerations During UI-IRB Review

The UI-IRB may consider recommendations from other institutional or extramural review committees, but the UI-IRB has the responsibility and sole authority to carry out its review responsibilities in accordance with these policies and procedures.

1. **Approval and Disapproval Authority**

The UI-IRB shall determine whether proposed research is acceptable based on CUNY's [Criteria for IRB Approval](#). The Institutional Official or CUNY administration may disapprove the conduct of human subject research that has been approved by a UI-IRB. However, no one at CUNY may approve a study that the UI-IRB has disapproved. When appropriate, each UI-IRB may require research to be reviewed and approved by ancillary committees.

2. **Materials for Review**

In order to approve human research studies, the UI-IRB shall review the full proposal, the consent form and all supplemental information such as, but not limited to, the sponsor's protocol (if applicable), and recruitment materials.

4. Additional UI-IRB Authorities

The UI-IRBs have the authority to take the following actions when appropriate:

4.1. Authority to Require Progress Reports and to Oversee the Study

The CUNY UI-IRB has the responsibility and the authority to review the progress of human subject research studies; to monitor the activities of approved studies including, regularly scheduled continuing review at least annually; and to require verification of compliance with approved research protocols through means such as audit, observation or third party review. The authority to review the progress of studies includes the authority to require prompt reporting to the UI-IRB of any planned changes in approved projects prior to the implementation of those changes and the authority to require prompt reporting to the UI-IRB of any unanticipated problems (including adverse events) occurring in, or related to, approved protocols.

4.2. Authority to Suspend or Terminate Approval of Research

The CUNY UI-IRB may suspend approval of a UI-IRB approved protocol in its entirety or it may suspend selected human subject research activities for reasons such as unanticipated problems involving risks to human subjects, serious or continuing non-compliance with any federal regulation, State laws, UI-IRB approved protocol or stipulations of the UI-IRB. The UI-IRB may also terminate approval of a research study for the same reasons. Such actions by the UI-IRB shall be reviewed at a convened meeting of the UI-IRB with a quorum present and shall be incorporated into the minutes of the meeting. The UI-IRB shall consider the rights and welfare of current and future research subjects when suspending or terminating approval of active studies.

4.3. Authority to Observe, or Have a Third Party Observe, the Consent Process

The UI-IRB has the authority to observe or have a third party observe the consent process, and/or require periodic reports on this process from the PI or others.

4.4. Authority to Observe, or Have a Third Party Observe, the Conduct of the Research

The UI-IRB may observe the conduct of the research, or have a third party observe the conduct of the research and/or perform compliance audits and/or conduct site visits.

References

1. [Code of Federal Regulations, Title 45 – Public Welfare DHHS, Part 46 – Protection of Human Subjects](#)
2. [Code of Federal Regulations, Title 21 – Food and Drugs, Part 50 – Protection of Human Subjects](#)
3. [Code of Federal Regulations, Title 21 – Food and Drugs, Part 56 – Institutional Review Boards](#)