CUNY HRPP Policy: Expedited Review of Human Subjects Research

1. Applicability

This policy applies to CUNY research involving human subjects that meets the criteria for Expedited Review, as outlined in the federal regulations at 45 CFR 46.110.

2. **Criteria for Expedited Review**

A human subjects research protocol may be processed on an expedited basis if the research poses no more than minimal risk[1] to subjects, as assessed by the reviewer(s); AND the research involves only those procedures listed in the OHRP Expedited Review Categories.

2.1. **Modifications to IRB-Approved Protocols**

Researchers are required to submit modifications to IRB-approved protocols prior to their implementation.

2.1.1. **When initial review was conducted on an expedited basis**

Proposed modifications to an IRB-approved protocol that ***initially underwent expedited review*** may be reviewed on an expedited basis if:

2.1.1.1. With the proposed modifications, the research would continue to pose no more than minimal risk to subjects; AND

2.1.1.2. Proposed modifications involve only those procedures listed in categories 1-7 in Section 2 above.

2.1.2. **When initial review was conducted by the convened IRB**

Proposed modifications to an IRB-approved protocol that received ***initial review by a convened IRB*** may be reviewed on an expedited basis if:

2.1.2.1. Proposed modifications do not pose an increased risk to subjects; AND

2.1.2.2. Proposed modifications constitute a minor change to previously approved research.

[1] ***Minimal risk*** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. 45 CFR 46.102

3. **Continuing Review**

3.1. Unless otherwise determined by the CUNY UI-IRB, continuing review of research is not required in the following circumstances:

- Research is eligible for expedited review;
- Research is reviewed by the IRB in accordance with the limited IRB review process;
- Research that has progressed to the point that it involves only one or both of the following, as part of the IRB-approved study:
  - Data analysis, including analysis of identifiable private information or identifiable biospecimens; OR
  - Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

3.2. The IRB must maintain, in its records, a rationale for conducting continuing review of research that otherwise would not require continuing review as described above.

4. **Exceptions and Limitations**

4.1. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability, or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented such that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

4.2. The Expedited review procedure may not be used for classified research involving human subjects.

5. **Review and Reviewers**

5.1. When reviewing research on an expedited basis, the designated reviewer(s) shall receive and review all documentation that would normally be submitted for a convened IRB review, including the complete protocol, and recruitment and consent documents.

5.1.1 Expedited review is conducted by members appointed to the CUNY UI-IRB Expedited Review Panel.

5.1.2 During an expedited review process, the reviewer(s) may exercise all of the authorities of the IRB except that the reviewer(s) may not disapprove the research.

5.2. If reviewer(s) refer research to the convened IRB during the expedited review process, rationale detailing that the research poses more than minimal risk must be provided for studies on the list of OHRP Expedited Review Categories.

6. **Possible Outcomes of Expedited Review**

6.1. **Approval.** The submission is approved, and no changes to the submission are required.

6.2. **Conditional Acceptance.** Reviewer stipulates specific clarifications or modifications to the protocol. The final approval is contingent upon the reviewer's acceptance of Principal Investigator's revisions in accordance with the reviewer's stipulations.

6.3. **Referred for Full Board Review.** The reviewer determines that the submission does not meet the criteria for expedited review, and refers it for review by the convened IRB. The reviewer may choose to request additional information from the investigator prior to review by the convened IRB.

7. **Convened IRB Notification and Review**

7.1. All Board members will be advised of research proposals that have been approved under the expedited review procedures on a regularly scheduled basis.

7.2. If a protocol eligible for expedited review is instead reviewed at a convened IRB meeting, the CUNY UI-IRB may complete the review and may approve the protocol at the meeting. The IRB shall determine that the protocol meets the criteria for expedited review, determine the appropriate category of expedited review, and document this in the minutes. Subsequent modifications to the protocol may be reviewed using expedited review procedures, provided that the risk level does not change and the protocol continues to meet the eligibility criteria for expedited review.

References

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

2. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report*, April 18, 1979

3. US Food and Drug Administration, *Comparison of FDA and HHS Human Subject Protection Regulations*