1. Applicability

These procedures apply to non-exempt human subjects research that may pose greater than minimal risk to subjects. Initial review, continuing review and amendment submissions involving non-exempt research that may pose greater than minimal risk to subjects must be reviewed by a convened IRB. The convened IRB may also review and takes action on unanticipated problems, allegations of serious or continuing non-compliance, and subject complaints.

Convened IRB also conducts initial review of research that poses no greater than minimal risk to subjects, but that does not appear in any of the categories of research that can be reviewed via an expedited review procedure. The convened IRB may determine that continuing review of such research may undergo expedited review procedures.

2. Meeting Proceedings

2.1. Meeting Frequency

An IRB meeting of the CUNY UI-IRBs is held every week throughout the year. The 4 IRBs meet on a rotation basis. Meeting dates and deadlines for submissions are available at http://www.cuny.edu/research/compliance/human-subjects-research-1.html.

2.2. Quorum Requirements

The following quorum requirements must be met in order for the convened IRB to vote on any determinations:

- Majority of the IRB members must be present (in person or via telephone)
- At least one member whose primary concerns are in a non-scientific area must be present
- Approval of research is by a majority of members present at the meeting
- Should the quorum fail during a meeting, discussion of protocols may continue; however, the IRB may not make any determinations or take any votes unless the quorum is restored

2.3. Conflict of Interest

IRB members may not participate in the discussion or vote related to any research protocol, for which they have a conflict of interest. IRB members are responsible for recusing themselves from the discussion and the vote if they have a conflict of interest. For the purposes of IRB proceedings, a conflict of interest is defined as follows:

- IRB member's, his/her spouse's, dependent child's or close relative's involvement in the design, conduct or reporting of the research.
- IRB member's, his/her spouse's, dependent child's or close relative's financial interest in the sponsor of the research.
- IRB member's, his/her spouse's, dependent child's or close relative's participation as an investigator or research team member of the research protocol.

3. Primary Reviewer System

CUNY IRBs operate on a primary reviewer system as follows:

- The IRB staff assigns primary and secondary reviewers to each agenda item based on the appropriate scientific and non-scientific expertise required. A tertiary reviewer may also be assigned when necessary. For the remainder of this document, primary, secondary and tertiary reviewers are collectively referred to as 'primary reviewers'.

- For studies involving vulnerable populations, a member who is knowledgeable about and experienced in working with the subject population is assigned as a primary reviewer.

4. IRB Staff Responsibilities

IRB staff is responsible for the following:

- Perform an administrative review of all submissions to ensure completeness, to confirm that a convened IRB review is warranted and to provide relevant regulatory and policy guidance to the IRB members
- Distribute all agenda items, including all materials required for the review of a given submission, to all IRB members a minimum of one week prior to the scheduled IRB meeting
- Document attendance and quorum at the meeting and ensuring that quorum is maintained for each vote
- Take minutes during the meeting, to include IRB's discussions of significant concerns; resolutions of controverted issues; regulatory determinations and votes for each agenda item; meeting attendance; and disclosures of any conflict of interest.
- Communicate IRB's concerns, suggestions, and determinations to the PI after the meeting

5. IRB Member Responsibilities

IRB members are responsible for the following:

- All members are expected to review and be familiar with all agenda items prior to the convened IRB meeting

- Primary reviewers provide a brief summary of the agenda item and present any concerns they have identified
- All members participate in the discussion of significant concerns, raise additional concerns, provide necessary clarifications and/or propose resolutions

6. Possible Outcomes of Convened IRB Review

- **Approval**. The submission is approved, and no changes to the submission are required. Criteria for IRB approval are met. IRB may impose specific stipulations on the approval, which are delineated on the approval notice.

- **Conditional Acceptance**. IRB stipulates specific clarifications or non-substantive modifications to the submission. The final approval is contingent upon the reviewer's acceptance of Principal Investigator's revisions in accordance with the IRB's stipulations.

- **Deferral**. Substantive modifications or clarifications are required in order for the IRB to determine whether the submission meets the criteria for IRB approval. Investigator's response must be reviewed by a convened IRB.

- **Consultant Review**: IRB determined that additional expertise is necessary in order to make an adequate determination. Consultant review shall be sought. Consultant's comments will be considered during a future convened IRB meeting. Consultant comments may be received in a written form, in-person during the IRB meeting or by telephone during the IRB meeting.

- **Disapproval**. Criteria for IRB approval are not met.

- **Tabled**. Submission has been tabled for review at a future IRB meeting due to lack of appropriate expertise, lack of sufficient information, or loss of quorum.

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 56 – Institutional Review Boards