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1. CUNY UI-IRB Authority

1.1. 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).

1.2. 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 Federal-wide Assurance (FWA) for the Protection of Human Subjects with the US Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP).

1.2.1. 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.

1.3. IRB Review

1.3.1. 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:

a. 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.

b. 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.

c. 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.

d. **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 overtime and items must be pushed to another agenda; when a protocol has been submitted for UI-IRB review in an un-applicable state; or as deemed necessary by the UI-IRB Chair.

e. **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).

f. **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.

### 1.3.2. 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.

a. **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.

b. **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.

1.4. **Additional UI-IRB Authorities**

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

1.4.1. **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.

1.4.2. **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.

1.4.3. **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.

1.4.4. **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


2. Code of Federal Regulations, Title 21 – Food and Drugs, Part 50 – Protection of Human Subjects


2. HRPP Staff Responsibilities

2.1. Overview
CUNY HRPP Staff (“Staff”) is responsible for facilitating and supporting the CUNY Human Research Protection Program (HRPP), including the IRB review process, through the implementation of the duties described herein.

2.2. Staff Responsibilities
All HRPP staff is responsible for the following:

2.2.1. Regulatory and Policy Expertise
- Providing guidance to CUNY researchers and IRB members with regards to regulations and CUNY policy concerning human subject protection
- Assisting researchers in applying relevant regulations and CUNY policy when preparing their IRB applications
- Reviewing research submissions to evaluate whether they require CUNY HRPP or IRB review, and issuing related determinations
  - Goal: It is suggested that the determinations of whether an activity requires CUNY HRPP or IRB review be completed within 1-2 business days\(^1\).
  - Performing administrative pre-review of research submissions to ensure that the submission is complete, consistent and

\(^1\) This may vary by College depending on workload and other duties assigned at the College level.
addresses all regulatory and Policy requirements prior to review by IRB member(s) or the convened IRB

- **Goal**: It is suggested that pre-reviews be completed within 2-3 business days of receipt.

  - Keeping current with changes in federal and State regulations and guidance to ensure best practices and to make recommendations regarding their implementation to the University Director for Research Compliance

2.2.2. Communication

- Promptly responding to investigators’ inquiries by telephone or e-mail

- Serving as a liaison between the IRBs and the researchers

- Communicating the IRB’s concerns to the researchers in a clear and concise manner, including references when appropriate

  - **Goal**: It is suggested that IRB communications to the researchers during the expedited review process be relayed within 2-3 business days of review completion.

  - IRB communications to the researchers regarding reviews conducted at a convened IRB meeting shall be relayed within 5 business days.

- Notifying researchers and CUNY Administrators, when relevant, in writing of the IRB’s decisions to approve, disapprove, require modifications to, terminate or suspend human subject research activities.

- Maintaining active communication with IRB members to ensure timely completion of reviews

2.2.3. Administrative Duties

- Promptly responding to investigators’ inquiries by telephone or e-mail

- Assigning research submissions to appropriate reviewer(s), identifying the need for additional reviewer(s) or consultant(s), when appropriate

- Supporting IRB members in their responsibility to conduct a timely review of all applications for the use of human subjects in research

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2 This may vary by College depending on workload and other duties assigned at the College level.

3 This may vary by College depending on workload and other duties assigned at the College level.
• Ensuring compliance with HRPP Procedures
• Maintaining adequate IRB records, as delineated in federal regulations and CUNY Policy
• Reporting to the University Director for Research Compliance on all matters related to HRPP

2.2.4. HRPP Coordinators
HRPP Coordinators have the following additional responsibility:
• Reviewing research submissions that meet the criteria for exemption from IRB review, and issuing related determinations
  o Goal: It is suggested that exempt reviews be completed and determination sent to the researcher within 1-2 days of submission.

2.2.5. IRB Administrators
IRB Administrators have the following additional responsibilities:
• Scheduling IRB meetings, maintaining meeting attendance and ensuring quorum at IRB meetings
• Preparing and distributing meeting agendas, meeting minutes and lists of approvals granted via the expedited review procedures
  o Meeting agendas and related materials shall be provided to the IRB members a minimum of one week in advance of the meeting
• Attending IRB meetings, providing regulatory and Policy guidance to facilitate convened IRB discussions, and documenting convened IRB deliberations by taking meeting minutes and recording any controverted issues
  o Meeting minutes shall be completed no later than 5 business days after the meeting
• Ensuring review of draft correspondence to researchers by the IRB Chair, Vice Chair or designee prior to researcher notification
  o Correspondence resulting from convened IRB meetings shall be completed and delivered to the Chair, Vice Chair or designee no later than 2-3 business days after the meeting
• Identifying IRB member training and education needs, devising plans to address these needs and implementing these plans

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4 This may vary by College depending on workload and other duties assigned at the College level.
3. **IRB Member Roles and Responsibilities**

### 3.1 Composition

IRB members are selected based on appropriate diversity, including consideration of race, gender, cultural backgrounds, specific community concerns, in addition to representation by multiple, diverse professions, knowledge and experience with vulnerable subjects, and inclusion of both scientific and non-scientific members. Every effort has been made to have member representation that has an understanding of the areas of specialty that encompass most of the human subjects research performed at CUNY. On an annual basis, the Vice Chancellor for Research and the University Director for Research Compliance will review the membership and composition of the IRB to determine if they continue to meet regulatory and institutional requirements.

### 3.2 Duties

#### 3.2.1 IRB Chairs and Vice Chairs

- Direct IRB meetings proceedings and discussions to ensure that each submission is reviewed in accordance with the Belmont Report, all applicable regulations and CUNY Policies
  - Keep discussions during IRB Meetings focused on topic and IRB issues
  - Lead an efficient and effective meeting
- Become familiar with members on their panel and each member’s expertise
- Seek subject-matter consultations when needed
- Represent the CUNY UI-IRBs in discussion with researchers, administration, the government, and other external parties as needed
- Review and approve IRB correspondence to be issued to the researchers within 2-3 business days
- Attend all meetings for which they are scheduled; inform the IRB Administrator of all expected absences as early as possible in order to provide sufficient time for a replacement and to ensure quorum
- Review all materials related to each item on the agenda in order to participate fully in the discussion and review of each proposed protocol
- Treat the research protocols and supporting data confidentially
- Review and submit review determinations for all expedited review protocols assigned to them within 3-5 business days of receipt
3.2.2 Primary and Alternate Members
- Attend all meetings for which they are scheduled; inform the IRB Administrator of all expected absences as early as possible in order to provide sufficient time for a replacement and to ensure quorum
- Review all materials related to each item on the agenda in order to participate fully in the discussion and review of each proposed protocol
- Treat the research protocols and supporting data confidentially

3.2.3 Expedited Reviewers
- Review and submit review determinations for each expedited submission assigned to them within 3-5 days of receipt
- Treat the research protocols and supporting data confidentially

3.3 Training and Education
CUNY is committed to providing initial and continuous training and education for IRB members throughout their service on the IRB. This is to ensure that oversight of human subjects research is ethically grounded and the decisions made by the IRB are consistent with current regulatory and policy requirements.

- Members must attend an initial orientation session held by the Office of the Vice Chancellor for Research’s research compliance staff prior to serving as a reviewer.
- Members must complete the HSR for IRB Members’ Module of the on-line training in the protection of human subjects within 30 days of their appointment. CUNY subscribes to CITI training for this purpose. Instructions on completing this training are available at http://www.cuny.edu/research/compliance/training-education/citi-training.html
- Members will be asked to attend additional training, such as workshops, lectures and conferences as directed by the University Director for Research Compliance

3.4 Conflict of Interest
No IRB member may participate in the review (initial, continuing, or modification) of any research project in which the member has a conflict of interest (COI), except to provide information as requested. It is the responsibility of each IRB voting member to disclose any COI in a study submitted for review and recuse him/herself from the deliberations and voting by leaving the room. COI may include, but is not limited to: IRB members’ or their immediate family members’ involvement in the design, conduct and reporting of research, IRB members’ or their immediate family
members’ significant financial interest related to the research, and any other situation where an IRB member believes that a financial COI or a conflict of commitment exists that may affect his or her ability to deliberate objectively on a protocol. The Chair will poll IRB members as each convened meeting to determine if a COI exists regarding any protocol being reviewed at the meeting.

3.5 Reporting Allegations of Undue Influence
If an IRB Chair, member or staff person has a reason to believe that the IRB has been unduly influenced by any party, they shall make a confidential report to the Institutional Official (IO) via the University Director for Research Compliance. The official receiving the report will conduct a thorough investigation and corrective action will be taken to prevent additional occurrences.

4. Researcher Responsibilities

4.1. Overview
Researchers are responsible for i) the ethical conduct of their research, including the protection of human subjects; ii) complying with all applicable regulations and CUNY policies; and iii) adhering to CUNY UI-IRB’s stipulations. Though the research team shares these responsibilities, the Principal Investigator (PI) is ultimately held responsible for the ethical conduct of research and for compliance with applicable regulations, policies and IRB stipulations.

4.2. Researcher Defined
For the purposes of CUNY HRPP/IRB, a researcher is any individual who i) serves as the PI or co-investigator; ii) interacts directly with the research subjects for research purposes; or iii) has access to identifiable private information about the human subjects for research purposes.

4.3. Protection of Human Subjects
Researchers are responsible for protecting human subjects throughout the research process: recruitment, screening, consenting, study procedures and end of study considerations. Specifically, researchers should:

- Develop research studies using sound research design, which minimizes risks to subjects, does not unnecessarily expose subjects to research-related risks, and maximizes benefits
- Planning and implementing fair and equitable recruitment practices, which avoid the potential for coercion and undue influence
- Obtaining legally effective informed consent for subject participation
• Ensuring availability of adequate resources (including personnel, time commitment, facilities, funding, etc.), such that the research may be conducted in a manner that protects the rights and welfare of human subjects and that ensure integrity of the research

• Responding promptly to subject complaints, concerns or request for information and reporting any significant complaints or concerns to the IRB

4.4. Complying with Regulations, Policies and IRB Stipulations

To ensure compliance, researchers must:

• Seek HRPP guidance if uncertain about HRPP/IRB review requirements

• Ensure that all human subjects research receive either HRPP exemption or IRB approval prior to its initiation (including any subject recruitment)

• Ensure that all IRB approved protocols receive continuing review by the IRB at least annually

• Ensure that changes to exempt or IRB approved protocols receive HRPP/IRB review, and exemption or approval, prior to their implementation

• Promptly report any unanticipated problems involving risks to subject or others to the IRB

• Promptly report any serious or continuing non-compliance with applicable regulations or CUNY policies

• Accurately and thoroughly complete all relevant IRB application materials

• Comply with all applicable regulations

• Comply with all applicable CUNY policies

• Comply with all sponsor requirements, when applicable

• Comply with IRB’s determinations and stipulations

• Cooperate with the HRPP staff and IRB members during any inquires or audits concerning human subject research review and oversight

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5 To determine whether an activity constitutes human subjects research, please refer to Section 7 of this document “When is CUNY HRPP or IRB Review Required?”
In order to prevent a lapse in IRB approval, it is required that researchers submit all continuing review applications at least 30 days prior to the expiration date of the study.

4.5. Training and education
Researchers must be qualified by education, training and experience to conduct the research they are proposing. Additionally, researchers are required to complete the CUNY-required modules of the Collaborative Institutional Training Initiative’s (CITI) on-line training in the protection of human subjects. Detailed CUNY policy concerning this requirement is available at http://www.cuny.edu/research/compliance/human-subjects-research-1/hrpp-policies-procedures.html.

4.6. Recordkeeping
Researchers are required to retain research records in accordance with applicable regulations, CUNY policies and sponsor requirements. Specifically, researchers must:

- Retain records of all IRB approved submissions, including:
  - All correspondence between the IRB and the researcher
  - All IRB approved documents, including but not limited to IRB application, sponsor protocol (if any), recruitment materials, screening documents, consent documents and data collection tools
  - Documentation of subject eligibility, when applicable
  - Documentation of consent process for each subject, when applicable
  - All signed consent documents, when applicable

- Retain all records for a minimum of three years after the end of the study; OR a minimum of six years for studies involving Protected Health Information (HIPAA applicable); AND in accordance with sponsor requirements.

- Maintain confidentiality of research records in accordance with IRB approved protocol and sponsor requirements.

References

1. DHHS Office for Human Research Protections (OHRP) Investigator Responsibilities – FAQs.

5. Principal Investigator Responsibilities and Qualifications

5.1. Full time CUNY faculty and staff and RF-CUNY staff

Full time CUNY faculty and staff, and RF-CUNY staff, may serve as Principal Investigator (PI) on IRB applications. The faculty or staff member listed as the PI on the application form is ultimately responsible for the protection of human subjects, for compliance with applicable regulations and CUNY policies, and for adherence with CUNY UI-IRB stipulations.

5.2. CUNY adjunct faculty

CUNY adjunct faculty who wish to conduct human subject research as part of their institutional responsibility at CUNY should obtain an approval from their Provost prior to submitting an IRB application.

CUNY adjunct faculty who wish to serve as PI for non-exempt human subject research must obtain prior written approval from the Vice Chancellor for Research. To request an approval, the adjunct faculty must submit the following documents to the University Director for Research Compliance:

- A completed CUNY Adjunct Faculty Request to Serve as a Principal Investigator (PI) on an IRB Application form;
- Documentation of approval from the Provost of the CUNY college where the adjunct faculty has an appointment; and
- Current CV of the adjunct faculty member requesting the approval.

When approved to serve as a PI, the approved adjunct faculty member is ultimately responsible for the protection of human subjects, for compliance with applicable regulations and CUNY policies, and for adherence with CUNY UI-IRB stipulations.

5.3. CUNY students and postdoctoral scholars

CUNY students and postdoctoral scholars may serve as PIs on IRB applications ONLY with the supervision and permission of their faculty advisor or research program director. The faculty advisor or research program director who signs off on the given project and the PI are both responsible for the protection of human subjects, for compliance with applicable regulations and CUNY policies, and for adherence with CUNY UI-IRB stipulations.

6. Faculty Advisor Responsibilities

6.1. Overview
A faculty member or research program director who agrees to serve as the faculty advisor to a student or postdoctoral researcher is an active mentor to the student and shares responsibility for ethical conduct of the research and compliance with applicable laws, regulations and CUNY policies.

6.2. Ethics and compliance

- Prior to the student’s or postdoctoral researcher’s involvement in human subject research, the faculty advisor or research program director is responsible for:
  - Discussing general principles of research ethics with the student or postdoctoral researcher;
  - Discussing the principles of The Belmont Report with the student or postdoctoral researcher, with the intent of guiding the student or postdoctoral researcher in ethical conduct of research involving human subjects;
  - Ensuring that the student or postdoctoral researcher is familiar with any federal regulations, State laws and CUNY policies that are applicable to his/her research;
  - Assisting the student or postdoctoral researcher in determining whether his/her research requires CUNY HRPP or IRB review and approval; and
  - Guiding the student or postdoctoral researcher through the IRB application and review process.

- During the conduct of the research, the faculty advisor or research program director is responsible for ensuring that the research is being conducted in compliance with:
  - Applicable federal regulations, State laws and CUNY policies; and
  - CUNY UI-IRB approved protocol; and
  - Any stipulations imposed by the CUNY IRB.

6.3. Research Design and Planning

During the research design and planning phase, the faculty advisor or research program director must:

  - Assist the student or postdoctoral researcher in designing a research project that is appropriate to the student’s or postdoctoral researcher’s level of training and experience;
  - Ensure that the student or postdoctoral researcher allocates sufficient time to obtain HRPP exemption from IRB review or IRB approval, as appropriate; and
  - Oversee the student’s or postdoctoral researcher’s preparation of the HRPP or IRB application. A clear, complete and consistent application package will result in a more efficient review process.

6.4. Oversight
The faculty advisor or research program director is responsible for monitoring student and postdoctoral researcher’s progress, so as to ensure that:

- The research is being conducted in a compliant and ethical manner, as defined in section 2 above;
- All modifications to the HRPP exempt or IRB approved protocol are submitted for review and approval prior to their implementation; and
- Any unanticipated problems or adverse events are reported to the IRB in accordance with CUNY HRPP policy.
- A complete and accurate Final Report is submitted to the IRB at the conclusion of human subject research activities.

7. When is CUNY HRPP or IRB Review Required?

7.1. Purpose

The purpose of this guidance document is to assist the CUNY research community in determining when CUNY HRPP or IRB review is required.

7.2. When is CUNY HRPP or IRB review required?

CUNY HRPP or IRB review is required when **ALL** of the following criteria are met:

a. The investigator is conducting research or clinical investigation;

b. The proposed research or clinical investigation involves human subjects; AND

c. CUNY is engaged in the research or clinical investigation involving human subjects.

7.3. CUNY HRPP human subject determinations

When researchers are not certain whether their activities constitute human subject research, they should submit a Human Subject Research Determination form in IRBNet to their College’s HRPP Office. The HRPP Coordinator will issue a determination of whether the proposed activities constitute human subject research.

7.3.1. If the HRPP Coordinator determines that the research does NOT constitute human subject research, the researcher should retain this documentation in their research files.

7.3.2. If the HRPP Coordinator determines that the research DOES constitute human subject research, and CUNY is engaged in the research, the researcher
must submit a CUNY Initial Application in IRBNet to their College’s HRPP Office.

7.4. Definitions

7.4.1. Research
A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

7.4.2. Clinical investigation
Any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration (FDA) under the Federal Food, Drug and Cosmetic Act (the Act), or is not subject to requirements for prior submission to the FDA under the Act, but the results of which are intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit.

7.4.3. Human subject
A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. When FDA regulations apply, human subject is an individual who is or becomes a participant in research, either as a recipient of the test article or as a control.

7.4.4. Intervention
Both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.

7.4.5. Interaction
Communication or interpersonal contact between investigator and subject

7.4.6. Identifiable
The identity of the subject is or may readily be ascertained by the investigator or associated with the information.

7.4.7. Private information
Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).

7.4.8. Test article
Any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to FDA regulations.

7.5. Engaged
CUNY is considered engaged in a particular human subjects research project when CUNY employees or agents⁶ obtain, for the purposes of the research project, (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research.

**Note:** CUNY applies *OHRP Guidance on Engagement of Institutions* to determine CUNY’s engagement in all research, regardless of funding.

7.6. Examples

7.6.1. Example: Oral History Projects

<table>
<thead>
<tr>
<th>Activity</th>
<th>HRPP/IRB Review Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Open-ended interviews, that ONLY document a specific historical event or the experiences of individuals without intent to draw conclusions or generalize findings</td>
<td>NO</td>
</tr>
<tr>
<td>Systematic investigations involving open-ended interviews that are designed to develop or contribute to generalizable knowledge (e.g., designed to draw conclusions, inform policy, or generalize findings)</td>
<td>YES</td>
</tr>
<tr>
<td>Creation of archives for the purpose of providing a resource for others to do research. The <em>intent</em> of the archive is to create a repository of information for other investigators to conduct research.</td>
<td>YES</td>
</tr>
</tbody>
</table>

7.6.2. Example: Scholarship of Teaching & Learning (SoTL) and Educational Activities

<table>
<thead>
<tr>
<th>Activity</th>
<th>HRPP/IRB Review Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>SoTL activities designed for localized improvement efforts that will result in changing the design of a course at CUNY, changing the kinds of assessments used in courses at CUNY, changing student</td>
<td>NO</td>
</tr>
</tbody>
</table>

⁶ For the purposes of this document, *employees or agents* refers to individuals who: (1) act on behalf of CUNY; (2) exercise institutional authority or responsibility; or (3) perform institutionally designated activities. *Employees or agents* can include staff, students, contractors, and volunteers, among others, regardless of whether the individual is receiving compensation.
expectation at CUNY, etc., where the results will be limited to dissemination or implementation within CUNY.

<table>
<thead>
<tr>
<th>Systematic SoTL inquiry designed to produce knowledge that is available to those outside CUNY to use and build on.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>YES</strong></td>
</tr>
<tr>
<td>Activities designed for educational purposes ONLY. Results will NOT contribute to generalizable knowledge (e.g., published outside classroom, presented in an article, result in a dissertation or poster session).</td>
</tr>
<tr>
<td><strong>NO</strong></td>
</tr>
</tbody>
</table>

### 7.6.3. Example: Quality Assurance / Quality Improvement Activities

<table>
<thead>
<tr>
<th>Activity</th>
<th>HRPP/IRB Review Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evaluation of a specific program, procedure, etc. when the primary <em>intent</em> is solely for internal assessment or improvement, with no plans to publish or present the results outside of CUNY.</td>
<td><strong>NO</strong></td>
</tr>
<tr>
<td>Systematic evaluation to determine whether an existing, new or modified procedure or program is effective and can be applied to environments outside CUNY.</td>
<td><strong>YES</strong></td>
</tr>
</tbody>
</table>

### References

2. Code of Federal Regulations, Title 21 – Food and Drugs, Part 50 – Protection of Human Subjects

### 8. Human Subjects Research Exempt from IRB Review

#### 8.1. Applicability

These procedures apply to CUNY research involving human subjects that meets the criteria for exemption from IRB review, as outlined in the federal regulations at 45 CFR 46.101(b).

#### 8.2. Determination of Exemption
The HRPP Coordinator, not the Principal Investigator (PI), determines whether a research study meets the criteria for exemption from IRB review. Please refer to section 8.7 below for submission and review procedures. Researchers may not initiate exempt research until and unless they have received a determination of exemption from the local HRPP Office.

8.3. Exemption Criteria
Research that falls within one of the following categories may qualify for exemption from IRB review:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects’ responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation. [NOTE: See Section 2 for limitations on this exemption category for research involving children.]

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2), if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. [NOTE: In order to be eligible for this exemption, all of the materials have to exist at the time the research is proposed.]

5. Research and demonstration projects which are conducted by or subject to the approval of federal department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those
programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed; or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

8.4. Limitations on Exemptions

8.4.1. Children
Research involving survey or interview procedures or observations of public behavior with children does not qualify for exemption, except for research involving observations of public behavior when the investigator does not participate in the activities being observed.

8.4.2. Prisoners
Research involving prisoners does not qualify for exemption.

8.4.3. FDA
Exemption Criteria Category 6 (Taste and food quality evaluation as described in section 8.3(6) above) is the only allowable category that is exempt from the requirements of FDA regulations for IRB review. For research that falls within FDA’s oversight, if category 6 does not apply, the study cannot be considered as exempt from IRB review.

8.4.4. Belmont Report Applies
Although exempt research does not require IRB review, this research is not exempt from the ethical guidelines of the Belmont Report. The individual making the determination of exemption has the authority to require additional protections for subjects in keeping with the guidelines of the Belmont Report, even though the research falls within an exempt category.

8.5. Validity of the Determination of Exemption
Determinations of exemptions are valid until the expiration date noted on the Exempt Determination Letter, up to a maximum of three years from the decision date. Investigators wishing to continue exempt research beyond the period specified on the determination of exemption must submit a Request for Extension of Exemption Determination.

8.6. Amendments to Exempt Research
8.6.1. Investigators shall not implement any changes to the exempt protocol without prior review and new determination of exemption from the local HRPP Office, even if the changes are planned for the period for which approval has already been given.

8.6.2. If the HRPP Office determines that, with the proposed changes, the research continues to meet the criteria for exemption from IRB review, the HRPP Office shall issue an Exemption Determination Letter for the amendment.

8.6.3. If the HRPP Office determines that the research no longer meets the criteria for exemption from IRB review, the submission shall be forwarded to the IRB for expedited or convened IRB review, as appropriate.

8.7. Process for Submission and Determination of Exempt status


8.7.2. The HRPP Coordinator of the PI's primary campus reviews the submission for completion and determines whether the research qualifies for exemption from IRB review.

8.7.3. The HRPP Office issues an Exempt Determination Letter to the PI, which conveys whether the research qualifies for exemption from IRB review.

8.7.4. If the research does not qualify for exemption from IRB review, the PI must re-submit the research using the Initial Application Submission form.

8.8. Exemption Period

Unless otherwise indicated, exemptions are valid for a three year period. The investigator must submit a continuing review request 30 days prior to their expiration date if they wish to continue their research.

References


9.1. Applicability
These procedures apply to CUNY research involving human subjects that meets the criteria for expedited review, as outlined in the federal regulations at 45 CFR 46.110.

9.2. Criteria for Expedited Review

9.2.1. Initial Review
A new human subjects research protocol may be processed on an expedited basis if the research poses no more than minimal risk\(^7\) to subjects, as assessed by the reviewer; AND the research involves only those procedures listed in the following categories:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met:
   a) Research on drugs for which an investigational new drug application [21 CFR Part 312] is not required. [NOTE: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.]
   b) Research on medical devices for which (i) an investigational device exemption application [21 CFR Part 812] is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
   a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8

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\(^7\) 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
week period and collection may not occur more frequently than 2
times per week; or

b) from other adults and children, considering the age, weight, and
health of the subjects, the collection procedure, the amount of blood
to be collected, and the frequency with which it will be collected. For
these subjects, the amount drawn may not exceed the lesser of 50 ml
or 3 ml per kg in an 8 week period and collection may not occur more
frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes
by noninvasive means.

**Examples:** (a) hair and nail clippings in a nondisfiguring manner; (b)
deciduous teeth at time of exfoliation or if routine patient care
indicates a need for extraction; (c) permanent teeth if routine patient
care indicates a need for extraction; (d) excreta and external
secretions (including sweat); (e) uncannulated saliva collected either
in an unstimulated fashion or stimulated by chewing gumbase or wax
or by applying a dilute citric solution to the tongue; (f) placenta
removed at delivery; (g) amniotic fluid obtained at the time of rupture
of the membrane prior to or during labor; (h) supra- and subgingival
dental plaque and calculus, provided the collection procedure is not
more invasive than routine prophylactic scaling of the teeth and the
process is accomplished in accordance with accepted prophylactic
techniques; (i) mucosal and skin cells collected by buccal scraping or
swab, skin swab, or mouth washings; (j) sputum collected after saline
mist nebulization.

4. Collection of data through noninvasive procedures (not involving
general anesthesia or sedation) routinely employed in clinical
practice, excluding procedures involving x-rays or microwaves.
Where medical devices are employed, they must be cleared/approved
for marketing. (Studies intended to evaluate the safety and
effectiveness of the medical device are not generally eligible for
expedited review, including studies of cleared medical devices for new
indications).

**Examples:** (a) physical sensors that are applied either to the surface
of the body or at a distance and do not involve input of significant
amounts of energy into the subject or an invasion of the subject's
privacy; (b) weighing or testing sensory acuity; (c) magnetic

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8 *Children* means persons who have not attained the legal age for consent to treatments or procedures involved in
the research, under the applicable law of the jurisdiction in which the research will be conducted. 45 CFR 46.402
resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

9.3. Continuing Review

9.3.1. When initial review was conducted on an expedited basis
Research that received initial review on an expedited basis may be expedited at the time of continuing review, as long as the research continues to pose minimal risk to the subjects and research procedures continue to fall within categories 1-7 listed in section 9.2.1 above.

9.3.2. When initial review was conducted by the convened IRB
Research that received initial review by a convened IRB may be reviewed on an expedited basis at the time of continuing review if it meets one of the following criteria outlined in regulatory categories 8 or 9:

8.a. Research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related interventions; and research remains active only for long-term follow-up of subjects.

8.b. No subjects have been enrolled and no additional risks have been identified.
8.c. Remaining research activities are limited to data analysis. 

[NOTE: For a multi-center protocol, an expedited review procedure may be used by the IRB at a particular site whenever the conditions of category 8 (a), (b), or (c) are satisfied for that site. However, with respect to category 8(b), while the criterion that "no subjects have been enrolled" is interpreted to mean that no subjects have ever been enrolled at a particular site, the criterion that "no additional risks have been identified" is interpreted to mean that neither the investigator nor the IRB at a particular site has identified any additional risks from any site or other relevant source.]

9. Research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified. 

[NOTE: The determination that "no additional risks have been identified" does not need to be made by the convened IRB.]

9.4. Modifications to IRB-Approved Protocols

9.4.1. 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:

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

b. Proposed modifications involve only those procedures listed in categories 1-7 in Section 9.2.1 above.

9.4.2. 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:

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

b. Proposed modifications constitute a minor change to previously approved research.
9.5. **Exceptions and Limitations**

9.5.1. 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.

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

9.6. **Review and Reviewers**

9.6.1. 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 review, including the complete protocol, funding applications, and recruitment and consent documents.

9.6.2. Expedited review is conducted by the UI-IRB members affiliated with the CUNY College with which the Principal Investigator, or faculty advisor of student Principal Investigator, has primary affiliation.

9.6.3. CUNY UI-IRB members from other campuses may serve as additional expedited reviewers as needed.

9.6.4. 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.

9.7. **Possible Outcomes Of Expedited Review**

9.7.1. **Approval**

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

9.7.1.1. **Approval Period**

Unless otherwise indicated, the approval period will end 364 days from the date of the review.

9.7.2. **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.

9.7.3. **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.

9.8. **Convened IRB Notification and Review**

9.8.1. As part of the meeting agenda for UI-IRB meetings, the Board members will be notified of all expedited approvals issued since the date of the previous notification.

9.8.2. 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. All subsequent reviews, including continuing reviews and modifications may be conducted under expedited review, provided the risk level does not change and the protocol continues to meet the eligibility criteria for expedited review.

**References**


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

**10. Convened IRB Review**

10.1. **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.

10.2. Meeting Proceedings

10.2.1. 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.

10.2.2. 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

10.2.3. 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.

10.3. 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.

10.4. 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.

### 10.5. 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.

### 10.6. Possible Outcomes of Convened IRB Review
IRB members are responsible for the following:

• **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.

  • **Approval Period**
    Unless otherwise indicated, the approval period will end 364 days from the date of the IRB meeting during which the approval was granted.

• **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**


2. [Code of Federal Regulations, Title 21 – Food and Drugs, Part 56 – Institutional Review Boards](#)

11. **IRB Appeals Process**

11.1. **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.

11.2. **Appeals process**

11.2.1. **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.

11.2.2 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.

12. Study Closure

12.1. Purpose
The purpose of this policy document is to define the various ways in which a research study may be closed, either by the principal investigator (PI) or the HRPP/IRB. Please note that this Policy does not cover suspensions or terminations. For information regarding suspensions or terminations, please refer to CUNY HRPP Policy: Suspension or Termination of Human Subject Research.

12.2. Study Closures by the PI

12.2.1. End of Study or End of Human Subject Involvement
A PI may close out a study that no longer involves human subjects, and therefore no longer requires continuing review, when BOTH of the following criteria are met:

a. The investigators have finished obtaining data through interaction or intervention with subjects or obtaining identifiable private information about the subjects; AND

b. The investigators have finished using, studying, or analyzing identifiable private information.

For example, A PI may close out a study when the only remaining activity of a research project involves the analysis of aggregate data sets without individual subject identifiers.

12.2.1.1. Study Closure Process
When an investigator has completed a research project involving human subjects, or when human subjects are no longer involved in a research project, the PI must submit a Final Report Form. Upon review of the Final Report Form, the PI will receive either an acknowledgment of study closure or a request for additional information from the HRPP Office. The PI remains responsible for retaining research records in accordance with applicable regulations, CUNY policies and sponsor requirements.

12.2.2. Withdrawal
A PI may withdraw a submitted HRPP/IRB application as follows:

12.2.2.1. Submissions Pending HRPP/IRB Review
A PI may withdraw a submission related to an exempt protocol that has not yet received HRPP review, or an IRB application prior to review by the IRB at any time.

12.2.2.2. Submissions Under Review
Once the exempt or IRB review has begun, the PI must request withdrawal by submitting a memorandum to the HRPP Office.

12.3. Administrative Closure by the HRPP

12.3.1. Expired Studies
If a study has been expired for 90 days, and the PI has not submitted a continuing review application or a final report form, the HRPP/IRB will close the study. The IRB will evaluate whether any previously enrolled subjects are at risk, and take any necessary steps to protect the subjects. If a PI wishes to re-open a study after this 90-day closure, s/he must submit a new application, including any modifications, referencing the original study's IRB number.

12.3.1.1. PI Responsibility
If the approval of a given study expires, and continuing review approval has not been issued by the IRB, the investigator is required to stop all subject contact, data collection and data analysis until the continuation is approved by the IRB.

12.3.1.2. Re-opening Expired Study Following Closure
Any new protocols submitted for continuation of a previously closed protocol must indicate whether any research related activities took place since the expiration date. If so, the researcher must clearly describe all such activities and provide a corrective action plan for ensuring that this does not recur.
12.3.2. Failure to Respond for 90 Days
If the HRPP or IRB requests additional information or modifications from the PI, and the PI does not respond for 90 days, the HRPP/IRB will close the study. In case of studies that previously received IRB approval, the IRB will evaluate whether any previously enrolled subjects are at risk, and take any necessary steps to protect the subjects. If a PI wishes to re-open a study after this 90-day closure, s/he must submit a new application, including any modifications, referencing the original study's IRB number.

12.3.2.1. PI Responsibility
In case of studies that previously received IRB approval, the investigator is required to stop all subject contact, data collection and data analysis upon receipt of the closure notice.

12.3.2.2. Re-opening Study Following Closure
Any new protocols submitted for continuation of a previously closed protocol must indicate whether any research related activities took place since the study closure. If so, the researcher must clearly describe all such activities and provide a corrective action plan for ensuring that this does not recur.

13. Criteria for IRB Approval

13.1. Applicability and Purpose
This policy applies to all non-exempt human subjects research in which CUNY becomes engaged. The purpose of this policy is to define the criteria used by the CUNY UI-IRBs in evaluating human subjects research.

13.2. Experimental Design and Scientific Validity
The IRBs must ensure that subjects are not exposed to risks, however minimal, without scientific justification, and that the risks are reasonable in relation to benefits. The IRBs accomplish this by evaluating whether the proposed research involves sound experimental design and has the potential to yield valid results. When necessary, the IRBs may seek expert consultants to assist in the review of research that requires expertise beyond or in addition to that available on the IRBs.

13.3. Risk/Benefit Analysis
The IRBs must ensure that:
• Risks to subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk.

• Risks may be minimized by ensuring that appropriate safeguards are in place, such as (a) adequate training of research personnel; (b) exclusion of populations at increased risk; (c) adequate data protection, including coding of data; and, (d) adequate safety monitoring.

• Risks to subjects are minimized by using procedures already being performed on the subjects for diagnostic or treatment purposes.

• Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.

13.3.1. **Risk/Benefit Considerations**

When performing a risk/benefit analysis, the IRBs take the following into consideration:

• IRBs evaluate the research based on only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research).

• The IRBs do not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks or benefits that fall within the purview of its responsibility.

• Research subjects may be exposed to physical, psychological, social, legal or economic risks as well as risks of an invasion of privacy or a breach of confidentiality. All such risks are considered by the IRBs when assessing the risk/benefit ratio of proposed research.

• The IRBs consider the estimated probability, severity, average duration and reversibility of any potential risks to the subjects when evaluating the risk/benefit ratio of the study.

• Research may benefit the subjects or society in terms of the knowledge expected to result. The IRBs consider the anticipated
benefits to subjects and the importance of knowledge expected to result when evaluating the risk/benefit ratio of a study.

- Financial or other forms of compensation are not considered a benefit, and are not considered when evaluating the risk/benefit ratio of the study.

- The IRBs consider the subject population of a given study when evaluating the risks and benefits, as the degree of risk may vary depending on the subject population.

13.4. **Subject Identification and Recruitment**

The IRBs must ensure that:

- Selection of subjects for each proposed study is fair, and that the risks and benefits of research are distributed equitably. In making this assessment, the IRBs take into account the purpose of the research and the setting in which the research will be conducted.

- Inclusion/exclusion criteria are based on those factors that most effectively and soundly address the research problem, and not on the potential subjects' easy availability, their compromised position, or because of social, racial, sexual, economic, or cultural biases institutionalized in society.

- Any proposed exclusion of populations based on age, gender, reproductive status, ethnicity or other factors not related to the research problem is scientifically and ethically justified.

- Identification and recruitment process for each subject population is free of any coercion, undue influence and invasion of privacy.

13.4.1. **Student/Employee Recruitment**

Enrollment of students and/or employees directly under the instruction or supervision of the investigator must be explicitly justified. The IRBs may require additional protections for these subjects. Additionally, PIs must provide assurances that the willingness of these individuals to participate in research will in no way affect their grades, employment or standing with CUNY. Additionally, some CUNY colleges have policies regarding recruitment of students as research subjects at their campus. PI's are asked to become familiar with any local level requirements at their College.
13.4.2. **Family Member Recruitment**
When recruiting family members of already enrolled subjects, the IRBs recommend that investigators develop a recruitment strategy that allows enrolled subjects to provide recruitment materials to their family members. This method allows family members to contact the research team if they are interested in participation, while minimizing the potential for coercion or undue influence.

13.4.3. **Recruitment Materials**
All recruitment materials must receive IRB review and approval prior to their implementation. Recruitment materials may include, but are not limited to, flyers, newspaper, radio or television advertisements, posters, brochures, press releases, broadcast emails and web site postings. Any changes to IRB approved recruitment materials must be reviewed and approved by the IRB prior to their implementation.

Recruitment materials must not:

- State or imply a favorable outcome beyond what is described in the consent document
- Make claims that investigational drugs and devices are safe and effective.
- Emphasize the payment or the amount to be paid, by such means as larger or bold type, or by use of formatting, graphics or backgrounds that would emphasize payment.
- Include exculpatory or coercive language.

13.5. **Screening Activities**
The IRBs review screening procedures to ensure adequate implementation of the inclusion/exclusion criteria and to ensure appropriate consent for screening procedures is obtained, when required.

13.5.1. **Screening Tools**
All screening tools must receive IRB review and approval prior to their implementation. Any changes to IRB approved screening tools must be reviewed and approved by the IRB prior to their implementation.

13.6. **Informed Consent Process, Documentation, and Waivers**
The IRBs review the informed consent process and documentation in accordance with section 15 of this document, “Informed Consent Process and Documentation.” The IRBs also grant a waiver or alteration of informed
consent, or a waiver of documentation of informed consent, when appropriate, in accordance with the same policy.

13.7. Privacy and Confidentiality
The IRBs must ensure that adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data are in place.

13.7.1. Definitions

- **Privacy** means having control over the extent, timing and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

- **Confidentiality** means the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure without permission.

13.7.2. Privacy and Confidentiality Considerations

- IRBs take into consideration the privacy of subjects during the recruitment, screening, informed consent and study procedures. Examples of issues that the IRB may consider include, but are not limited to: (a) privacy of potential subjects when recruitment, screening, informed consent or study procedures are being conducted in a public place; or (b) privacy of subjects when recruitment, screening, informed consent or study procedures are being conducted via telephone, but someone other than the subject answers the telephone.

- IRBs evaluate the appropriateness of methods used for protecting subject’s data based on the nature of the data being collected. Examples of methods for assuring confidentiality of data include, but are not limited to:
  
  o Coding data instead of storing it with identifiers
  o Removing identifiable information from documents such as survey instruments
  o Limiting access to identifiable data
  o Training research staff in the importance and methods of maintaining confidentiality
  o Securely storing research data
  o Obtaining a Certificate of Confidentiality, or a Privacy Certificate, when appropriate
When recording or photographing research procedures, introducing mechanisms to eliminate possibility of misuse of the recordings or photographs.

13.8. Alternatives To Participation
When appropriate, the IRBs review the alternatives available to subjects outside of research context, and ensure that subjects are informed of all available alternatives during the informed consent process.

13.9. Subject Compensation
Research subjects may be compensated for their time and inconvenience. The IRBs take into consideration whether the type of compensation, the amount of compensation, and the time and proposed method of disbursement, are reasonable, not coercive, and do not present any undue influence.

13.10. Conflict of Interest
The IRBs evaluate the impact of any financial or professional conflicts of interest disclosed by the research team on the protection of research subjects. The IRBs may require disclosure of conflicts of interest to the subjects. Additionally, financial conflicts of interests, as defined in CUNY’s Conflict of Interest Policy, will be forwarded to the CUNY Conflicts Committee for review and oversight in accordance with the Policy.

13.11. Research Staff Qualifications
The IRBs review the qualifications of research team members for conducting the proposed research procedures, and ensure that only those individuals with appropriate qualifications and licensure, when required, carry out the research procedures.

13.12. Vulnerable Populations
When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, pregnant women, prisoners, cognitively impaired individuals, or economically or educationally disadvantaged individuals, IRBs must ensure that additional safeguards have been included in the study to protect the rights and welfare of these subjects, as appropriate.

13.13. Data Safety Monitoring Plan
When appropriate, the IRBs may require a data safety monitoring plan based on the probability and severity of potential risks to subjects. In evaluating a data safety monitoring plan, the IRBs consider the following:

- Adequacy of the study stopping rules;
• Qualifications of the individual(s) performing data safety monitoring;
• Adequacy of the monitoring plan, including monitoring frequency and types of data to be reviewed;
• Adequacy of criteria and statistical methodology for decision-making regarding continuation, modification or termination of the research due to benefit or harm

References


14. Use of Raffles as Compensation for Participation

14.1. New York State Raffle Rules
Raffles, drawings and other games of chance are highly regulated in New York. Pursuant to the New York State General Municipal Law Article 9-A and the New York City Administrative Code § 20-433 et seq., games of chance offered by charitable organizations are permitted under certain circumstances. In order to meet the requirements of those laws, investigators who wish to use a drawing as compensation for participation in a research protocol shall abide by the following rules:

a. The drawing must be run by an “authorized organization” as defined by New York law. CUNY (including its colleges) meets the legal definition of an authorized organization, as do certain other types of religious, charitable, educational and service organizations. A for-profit organization will not.

b. Research participants shall not be required to pay anything in order to take part in the drawing.

c. No one under 18 may participate in or run the drawing. If some research participants may be under 18, another form of incentive should be used.
d. No single prize can exceed $100 in value; no series of prizes awarded for drawings held in connection with a particular research protocol can exceed $1000 in value.

e. The winner must be determined and the prize delivered or otherwise made available to the winner on the same day as the drawing.

f. The drawing cannot be advertised by means addressed to the general public, including newspapers, radio, TV, posters, or flyers.

14.2. Research Conducted Outside of New York State or Over the Internet

If a raffle or drawing is done in conjunction with a survey or other research that will be conducted in one or more locations outside of New York State, or will be conducted over the Internet and open to participants located outside of New York State, the raffle must comply with the games of chance laws of each of those locations. In these situations, in addition to complying with the requirements of New York law described above, the PI must also confirm in writing to the IRB that the raffle complies with the applicable laws of each of the non-New York research locations, including any foreign locations.

15. Informed Consent Process and Documentation

15.1. Purpose and Overview

The purpose of this document is to provide guidance regarding the process of obtaining and documenting informed consent of research subjects. Researchers are required to obtain legally effective informed consent of each research subject or their legally authorized representative, unless the CUNY UI-IRB has granted a waiver or alteration of informed consent.

This document provides guidance regarding the informed consent process and its documentation for adult subjects with the capacity to consent for themselves.

For information on parent or guardian permission for inclusion of children in research and related child assent process and documentation, please refer to CUNY HRPP Policy: Research Involving Children.

If a CUNY researcher is designing a research project that may require the inclusion of adult subjects who do not have the capacity to give informed consent for themselves, the researcher should contact the Research Compliance Staff for specific guidance regarding the process and
documentation of obtaining informed consent from such subject’s legally authorized representative. NOTE: Inclusion of cognitively impaired subjects must be scientifically and ethically justified; such inclusion is generally limited to healthcare related research with potential for direct benefit to the subject.

15.2. Informed Consent Process
It is important to note that the informed consent process involves a dialogue between the researcher and the subject throughout the duration of the research. It is not merely limited to the presentation and signing of the consent document. For long-term/longitudinal studies, consideration should be given to the possibility of re-consenting at appropriate intervals.

15.2.1. Considerations for an Effective Informed Consent Process
Researchers and CUNY UI-IRB shall ensure the following when planning and evaluating an informed consent process:
- The consent process takes place in a manner and at a location that ensures subject privacy;
- Information is provided in a manner and language that is understood by the subject;
- Subject is given sufficient opportunity to consider participation;
- Researcher ensures that subject’s questions are answered;
- Researcher ensures that the subject fully understands the information that is provided;
- Researcher obtains subject’s voluntary consent;
- Researcher provides for sufficient opportunities during the course of the research to address additional questions and to permit voluntary withdrawal without penalty; and
- Individual obtaining consent is qualified to do so, given the nature of the study and the subject population.
  o NOTE: Only those individuals who are approved by the UI-IRB to obtain consent may do so.

15.2.2. Subject’s Legal Rights
Informed consent, whether oral or written, may not include exculpatory language through which the subject or the representative is made to a) waive or appear to waive any of the subject’s legal rights; or b) release or appear to release the investigator, the sponsor, CUNY or its agents from liability for negligence.

15.2.3. Group Consent
For research involving subject populations that require group consent, the UI-IRB may approve this procedure with appropriate description and written justification by the Principal Investigator (PI)
for the use of group consent. The PI should also provide a method to obtain private or individual subject assent, where appropriate, and a method for protecting those who choose not to participate in the study.

15.3. Documentation of Informed Consent

Unless the UI-IRB has granted a Waiver of Informed Consent or a Waiver of Documented Informed Consent in accordance with Section 15.4 or 15.5 below, informed consent must be documented by the use of a written informed consent form approved by the CUNY UI-IRB and signed by the subject or the subject’s legally authorized representative. A copy of the signed informed consent form must be given to the person signing the form.

Unless the UI-IRB has granted a Waiver or an Alteration of Informed Consent in accordance with Section 15.4 below, the informed consent document must include all of the basic elements of informed consent outlined in Section 15.3.2 below.

15.3.1. Use of Appropriate Language

Consent documents must be written in a language understandable to the subject or legally authorized representative.

All technical terms of jargon, not expected to be understood by the subject population, should be explained using lay language.

15.3.2. Basic Elements of Informed Consent

The following basic elements must be present in all informed consent documents, unless the IRB has granted a waiver of specific elements:

- A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject’s participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
- A description of any reasonably foreseeable risks or discomforts to the subject;
- A description of any benefits to the subject or to others which may reasonably be expected from the research;
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- A statement describing the extent, if any, to which confidentiality of records identifying the subject must be maintained;
- For research involving more than minimal risk, an explanation as to the availability of medical treatment in the case of research-related injury, including who will pay for the
treatment and whether other financial compensation is available;

- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

15.3.3. Additional Elements of Informed Consent
When appropriate, the following additional elements should also be included in the consent documents:

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

- Anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s consent;

- Any additional costs to the subject that may result from participation in the research;

- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

- A statement that significant new findings developed during the course of the research which may relate to the subject’s willingness to continue participation must be provided to the subject; and

- The approximate number of subjects involved in the study.

15.3.4. Conflicts of Interest
When a researcher has an existing or potential financial conflict of interest or a conflict of commitment related to a given human subjects research protocol, a disclosure statement informing the subjects of the existing or potential conflict must be included in the consent documents.

15.3.5. Non-English Speaking Subjects
When a researcher expects to enroll non-English speaking subjects, the investigator must submit translations of the English language consent documents into all languages spoken by the expected subject population. Additionally, all subject materials, recruitment materials,
and any other materials that a participant will view as a result of their participation in the study must also be translated to the native language when a research expects to enroll non-English speaking subjects. Translations must be performed by one of the following:

- A certified translator
  - A certificate of translation must accompany the IRB submission.
- A bilingual member of the research team, who is fluent in both English and the language of the non-English speaking subject.
  - An explanation of the translator’s qualifications must be included with the IRB submission.

NOTE: It is recommended that the researcher obtain IRB approval of the English language consent documents prior to translating them into other languages. This will prevent the need for multiple rounds of translations should the IRB require revisions.

15.3.6. Illiterate Subjects and Subject Populations without a Written Language

When a researcher expects to enroll illiterate subjects or subject populations with no written language, the UI-IRB may approve a consent process using a UI-IRB approved short form written consent document stating that the required elements of informed consent have been presented orally to the subject or the subject’s legally authorized representative. The following requirements must be met when using a short form written consent document:

- An impartial witness must be present during the oral presentation;
- Researcher must use a UI-IRB approved written summary of what is to be said to the subject or the representative during the oral presentation;
- The subject or the representative shall sign or mark, as appropriate, only the short form;
- The witness shall sign both the short form and a copy of the summary;
- The person obtaining consent shall sign only a copy of the summary; and
- A copy of the signed summary and a copy of the signed short form shall be given to the subject or the representative.

15.4. Waiver or Alteration of Informed Consent

The UI-IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent outlined in Section 15.3.2 above or waive the requirement for informed consent, if it
determines and documents that the research falls within one of the following two categories and meets each of the conditions listed for the category:

**15.4.1. Minimal Risk Research**
The UI-IRB may approve a waiver or alteration of informed consent for minimal risk research when:

- The research involves no more than minimal risk to the subjects;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- The research could not practicably be carried out without the waiver or alteration; AND
- Whenever appropriate, the subjects is provided with additional pertinent information after participation.

**15.4.2. Public Benefit**
The UI-IRB may approve a waiver or alteration of informed consent when:

- A research or demonstration project to be conducted by or subject to the approval of state or local government officials is designed to study, evaluate, or otherwise examine the following:
  - Public benefit or service programs;
  - Procedures for obtaining benefits or services under those programs;
  - Possible changes in or alternatives to those programs or procedures; OR
  - Possible changes in methods or levels of payment for benefits or services under those programs; AND
- The research could not practicably be carried out without the waiver or alteration.

**15.4.3. PI Responsibility**
When requesting a waiver or alteration of informed consent, the PI is responsible for providing sufficient explanation of how the criteria in either Section 15.4.1 or 15.4.2 above are met.

**15.5. Waiver of Documentation of Informed Consent**
The UI-IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it determine and document that the research falls within one of the following two categories and meets each of the conditions listed for the category:
15.5.1. **Minimal Risk Research**
The UI-IRB may approve a waiver of documented informed consent for minimal risk research when:
- The research presents no more than minimal risk of harm to subjects; AND
- The research involves no procedures for which written consent is normally required outside of the research context.

15.5.2. **Consent is the Only Link to the Subject**
The UI-IRB may approve a waiver or alteration of informed consent for minimal risk research when:
- The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality.
- In such instances, each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern.

15.5.3. **Information Sheet for the Subjects**
When the UI-IRB grants a waiver of documented informed consent, it may require that the investigator provide the subjects with information sheet about the research.

15.5.4. **Information Sheet for the Subjects**
When requesting a waiver of documented informed consent, the PI is responsible for providing sufficient explanation of how the criteria in either Section 15.5.1 or 15.5.2 above are met.

**References**

2. Code of Federal Regulations, Title 21 – Food and Drugs, Part 50 – Protection of Human Subjects

16. **Internet or Mobile Technology Based Human Subject Research**

16.1. **Purpose**
The purpose of this document is to provide guidance to CUNY’s research community concerning responsibilities and considerations related to Internet or mobile technology based human subject research.

16.2. Applicability

These guidelines are applicable to the use of the Internet or mobile technology as a tool for subject recruitment; as a tool for data collection, whereby researchers use existing information without engaging source participants; and to the use of the Internet or mobile technology as a tool for data collection, where researchers engage with the source participants.

Examples of Internet or mobile technology sources include: public email archives, blogs, data repositories, cloud data services, Facebook, Twitter, RSS feed, Amazon Mechanical Turk and mobile applications/GPS technology.

16.3. Privacy and Confidentiality Considerations

Researchers and IRBs must ensure that adequate provisions are in place to maintain confidentiality of research data and privacy of research subjects. When evaluating subject privacy, researchers and IRBs must take the following into consideration:

- Depending on the nature of subject data being collected, it may be possible to combine de-identified data with other available datasets to identify the individual subjects. The researchers and the IRBs should consider a) the implications of one’s ability to re-identify subjects; and b) provisions for accurately informing subjects of mechanisms in place for ensuring confidentiality of research data as opposed to ensuring anonymity.

- Potential subjects may not have a complete understanding of the privacy policies associated with their use of the Internet or mobile technology. Therefore, the principal investigators are responsible for a) becoming familiar with the terms of service and privacy policy for each Internet venue or mobile technology to be used in their respective research prior to the implementation of human subject research activities; b) providing the IRB with their assessment of how best to safeguard subject privacy and confidentiality based on the tools being used; c) ensuring that all research team members are trained in adequately safeguarding human subjects of research given the nature of the tools being used; and d) informing subjects of the risks of invasion of privacy and breach of confidentiality associated with the specific use of the Internet venue or mobile technology, and the safeguards the researchers will use to protect the subjects from such invasion or breach.

- Researchers should ensure that research data is kept confidential, both physically and electronically. In doing so, CUNY researchers are required to comply with section 12 of CUNY Policy on Acceptable Use.
of Computer Resources. The HRPP/IRB may require additional safeguards, as appropriate.

- Some Internet venues, such as Amazon Mechanical Turk, store identifying information about their users. When using such a venue for subject recruitment, researchers are strongly encouraged to use a different venue, such as Survey Monkey and Qualtrics, for data collection purposes. This type of strategy allows for separation of subject identifiers from other subject data, and adds another layer of protection from breach of subject confidentiality.
- CUNY researchers are required to use their CUNY email address for communications related to research in which CUNY is engaged; and when registering with online services, databases, cloud services, etc. for CUNY research-related purposes.

16.4. Informed Consent Considerations
The researchers and the IRB must consider the following when evaluating the informed consent process and document associated with non-exempt Internet based human subject research:

- When appropriate, CUNY UI-IRBs may grant a waiver of informed consent or a waiver of documented informed consent in accordance with CUNY HRPP Policy: Informed Consent Process and Documentation. For research that meets the criteria for a waiver of documented informed consent, informed consent may be obtained via a research information site. The information site should provide potential subjects with information about the research, and a button to click to agree to participate. The contents of the information site must receive CUNY UI-IRB review and approval prior to implementation.
  - Other mechanisms for obtaining internet or mobile technology based informed consent may also be used appropriate for the venue and when approved by the IRB.

16.5. Cloud Computing
When using cloud services or applications, where it is typical that virtualization obscures the underlying infrastructure and data protections of the cloud service provider, particular care must be taken. Researchers must nevertheless ensure that:

- Research data remains in possession and control of the researcher;
- Export restrictions are observed;
- Unauthorized individuals do not have access to sensitive and/or confidential research data;
- Unauthorized individuals are not able to store personal copies of the research dataset; and
• The data access and storage mechanisms allow for compliance with CUNY’s Intellectual Property Policy.

16.6. Age Verification
Researchers must incorporate mechanisms to ensure that the subjects enrolled in the research meet the study’s inclusion/exclusion criteria, including age limitations. Thus, researchers are encouraged to use multiple confirmation points for age verification, i.e. asking for a subject’s age in different formats (age, date of birth, etc.) at different points during research participation.

References


17. FDA Regulated Research

17.1. Applicability
FDA regulations apply to all clinical investigations that propose to introduce drugs, biologics or devices to subjects within the United States or that propose to deliver drugs, biologics or devices to subjects for introduction into United States interstate commerce.

17.2. Definitions
17.2.1. Clinical investigation
Any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration (FDA) under the Federal Food, Drug and Cosmetic Act (the Act), or is not subject to requirements for prior submission to the FDA under the Act, but the results of which are intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit.
17.2.2. **Human subject**
An individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient.

17.2.3. **Investigational device**
A device, including a transitional device, which is the object of an investigation.

17.2.4. **Investigational new drug**
A new drug or biological drug that is used in a clinical investigation; the term also includes a biological product that is used in vitro for diagnostic purposes.

17.2.5. **Noninvasive**
A diagnostic device or procedure that does not by design or intention: a) penetrate or pierce the skin or mucous membranes of the body, the ocular cavity, or the urethra; or b) enter the ear beyond the external auditory canal, the nose beyond the nares, the mouth beyond the pharynx, the anal canal beyond the rectum, or the vagina beyond the cervical os.

Blood sampling that involves simple venipuncture is considered noninvasive, and the use of surplus samples of body fluids or tissues that are leftover from samples taken for non-investigational purposes is also considered noninvasive.

17.2.6. **Significant risk device**
An investigational device that: a) is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject; b) is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject; c) is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; OR d) otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

17.2.7. **Sponsor**
A person who initiates a clinical investigation, but who does not actually conduct the investigation, i.e., the test article is administered or dispensed to or used involving, a subject under the immediate direction of another individual. A person other than an individual
(e.g., corporation or agency) that uses one or more of its own employees to conduct a clinical investigation it has initiated is considered to be a sponsor (not a sponsor-investigator), and the employees are considered to be investigators.

17.2.8. **Sponsor-investigator**  
An individual who both initiates and actually conducts, alone or with others, a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject. The term does not include any person other than an individual, e.g., corporation or agency.

17.2.9. **Test article**  
Any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to FDA regulations.

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**INVESTIGATIONAL DRUGS OR BIOLOGICS**

**17.3. When is an Investigational New Drug Application (IND) to the FDA Required?**

17.3.1. The clinical investigation is intended to be reported to the FDA as a well-controlled study in support of a new indication for use or intended to be used to support any other significant change in the labeling for the drug.

17.3.2. For a drug that is lawfully marketed as a prescription drug product, the investigation is intended to support significant change in advertising for the product.

17.3.3. The investigation involves a route of administration or dosage level or use in a patient population or other factors that significantly increase the risks (or decrease the acceptability of risks) associated with the use of the drug.

17.3.4. The clinical investigation requires exception from informed consent requirements for emergency research in accordance with FDA regulations.

**17.4. When is an IND Not Required?**
Investigational use of devices is exempt from FDA’s requirement for obtaining an IDE in the following circumstances:

17.4.1. The clinical investigation of a drug product that is lawfully marketed in the United States does not require an IND if ALL of the following conditions are met: a) none of the criteria in section 17.3 above are met; b) the investigation is conducted in compliance with IRB review requirements and informed consent requirements; and c) the investigation is conducted in compliance with FDA requirements for promotion of investigational drugs.

17.4.2. A clinical investigation involving an in vitro diagnostic biological product (specifically, blood grouping serum; reagent red blood cells; and anti-human globulin) IF: a) it is intended to be used in a diagnostic procedure that confirms that diagnosis made by another, medically established, diagnostic product or procedure; AND b) it is shipped in compliance with FDA requirements for drugs for investigational use in laboratory research animals or in vitro tests.

17.4.3. A drug intended solely for tests in vitro or in laboratory research animals is exempt from IND requirements if it is shipped in accordance with FDA requirements for drugs for investigational use in laboratory research animals or in vitro tests.

17.4.4. A clinical investigation involving use of a placebo is exempt from IND requirements if the investigation does not otherwise require submission of an IND.

**INVESTIGATIONAL DEVICES**

17.5. When is an Investigational Device Exemption (IDE) from the FDA Required?

17.5.1. Clinical investigations of devices to determine safety and effectiveness require an IDE unless any of the conditions in section 17.6 below are met.

17.5.2. Investigation of an off-label use of a device with a 510(k), or substantially equivalent to a legally marketed device, designation by the FDA may require an IDE.

17.6. When is an IDE Not Required?
Investigational use of devices is exempt from FDA’s requirement for obtaining an IDE in the following circumstances:

17.6.1. An investigation of a non-significant risk device if the IRB determines that the device is not a significant risk device and grants an approval for its described use.

17.6.2. A diagnostic device if the testing a) is noninvasive; b) does not require invasive sampling procedure that presents significant risk; c) does not by design or intention introduce energy into a subject; AND d) is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.

17.6.3. A device undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution, if the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk.

17.6.4. A device with a 510(k) designation does not require an IDE for use in a clinical investigation in accordance with the labeling cleared by FDA.

17.6.5. Other less common circumstances described in FDA regulations at 21 CFR 812.2.

**ALL FDA REGULATED RESEARCH**

17.7. **Principal Investigator (PI) Responsibilities**

The PI of a clinical investigation is responsible for the following:

17.7.1. Ensuring that the test article is used in accordance with the IRB approved protocol.

17.7.2. Ensuring that only authorized individuals have access to and use the test article.

17.7.3. Ensuring compliance with the dispensing policies of the dispensing entity.

17.7.4. Ensuring compliance with all applicable FDA requirements.

17.7.5. Maintaining clinical investigation records for the longest of:

17.7.5.1. A period of at least two years following the date on which the results of the clinical investigation are submitted to the FDA in
support of an application for a research Investigational New Drug Number or Investigational Device Exemption or marketing permit; OR

17.7.5.2. A period of at least two years following the date on which an application for research or marketing permit (in support of which the results of the clinical investigation were submitted to the FDA) is approved by the FDA; OR

17.7.5.3. Two years after the investigation is discontinued and FDA is notified of that fact.

17.8. IRB Submission Requirements
When proposing a clinical investigation, the PI is responsible for submitting the following additional materials to the IRB:

17.8.1. For clinical investigations that require an IND, the FDA issued IND number.

17.8.2. For clinical investigations that require an IDE, the FDA issued IDE number.

17.8.3. For clinical investigations involving an investigational drug of biologic, an investigator’s brochure.

17.8.4. For clinical investigations involving an investigational device, detailed information about the device and/or device brochure, if available.

17.8.5. Sponsor’s protocol, where available.

17.9. Informed Consent Requirements
In addition to the informed consent requirements outlined in section 15 of this document, “Informed Consent Process and Documentation,” Informed consent documents for research involving the use of test articles must include the following:

17.9.1. A clear statement that the test article is investigational and has not been approved, or has not been approved for the purpose being studied.

17.9.2. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable.
17.9.3. Anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s consent.

17.9.4. A statement that the FDA and/or the study sponsor may have access to identifiable subject data.

17.9.5. A clear description of the alternatives available to the subjects, including when applicable, access to the test article outside of the research setting.

17.9.6. A clear explanation of the party responsible for the cost of the test article; cost of procedures associated with the use of the test article; and cost associated with treatment required as a result of related adverse events.

17.10. Exception from Informed Consent Requirements for Use of a Test Article (NOT including Investigational In Vitro Diagnostic Devices)

FDA allows for an exception from informed consent requirements in the following circumstances:

a. The human subject is confronted by a life-threatening situation necessitating the use of the test article; AND

b. Informed consent cannot be obtained from the subject because of an inability to communicate with, or obtain legally effective consent from, the subject; AND

c. Time is not sufficient to obtain consent from the subject’s legal representative; AND

d. There is available no alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the subject.

17.10.1. PI is responsible for submitting a report related to such an event and the related independent physician evaluation to the IRB within 5 working days after the use of the article.

17.11. Exception from Informed Consent Requirements for Use of Investigational In Vitro Diagnostic Devices

17.11.1. Before the use of investigational in vitro diagnostic devices used to identify chemical, biological, radiological, or nuclear agents, both the investigator and a physician who is not otherwise participating in the
clinical investigation make the determination and later certify in writing ALL of the following:

a. The human subject is confronted by a life-threatening situation necessitating the use of the investigational in vitro diagnostic device to identify a chemical, biological, radiological, or nuclear agent that would suggest a terrorism event or other public health emergency.

b. Informed consent cannot be obtained from the subject because:
   - There is no reasonable way for the person directing that the specimen be collected to know, at the time the specimen was collected, that there would be a need to use the investigational in vitro diagnostic device on that subject’s specimen; AND
   - Time is not sufficient to obtain consent from the subject without risking the life of the subject.

17.11.1. PI is responsible for submitting a report related to such an event and the related independent physician evaluation to the IRB and FDA within 5 working days after the use of the article.

17.11.2. If the use of the investigational device is, in the opinion of the investigator, required to preserve the life of the subject, and time is not sufficient to obtain the independent determination required in 17.11.1 above in advance of using the investigational device, the determinations of the investigator shall be made and, within 5 working days after the use of the device, be reviewed and evaluated in writing by a physician who is not participating in the clinical investigation.

17.11.2.1. PI is responsible for submitting a report related to such an event and the related independent physician evaluation to the IRB and FDA within 5 working days after the use of the article.

17.11.3. PI is responsible for disclosing the investigational status of the in vitro diagnostic device and what is known about the performance characteristics of the device in a report to the subject’s health care provider and in any report to public health authorities.

17.11.4. PI is responsible for providing the IRB with information (as closely following the requirements of informed consent as possible) that will be provided to the subject and detailed description of the procedures that will be used to provide this information to the subject or the subject’s legally authorized representative at the time the test results
are provided to the subject's health care provider and public health authorities.

**17.11.4.1.** The IRB is responsible for ensuring the adequacy of the information and for insuring that procedures are in place to provide this information to each subject or the subject’s legally authorized representative.

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**EMERGENCY RESEARCH**

**17.12.** FDA regulations allow for mechanisms by which certain types of emergency research may be conducted without the requirement for obtaining informed consent from the subject or the subject’s legally authorized representative. If a CUNY researcher plans to become engaged in such research, s/he must first contact CUNY’s research compliance staff for guidance on how to proceed.

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**HUMANITARIAN USE DEVICES (HUD)**

**17.13.** FDA regulations require the review and approval from an IRB prior to the use of a HUD. If a CUNY researcher plans to administer a HUD, s/he must first contact CUNY’s research compliance staff for guidance on how to proceed.

**References:**

1. [Code of Federal Regulations, Title 21 – Food and Drugs](http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm113709.htm):
   a. [Part 50 – Protection of Human Subjects](http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm113709.htm)
   b. [Part 56 – Institutional Review Boards](http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm113709.htm)
   c. [Part 312 – Investigational New Drug Application](http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm113709.htm)
   d. [Part 812 – Investigational Device Exemptions](http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm113709.htm)
   e. [Part 814, Subpart H – Humanitarian Use Devices](http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm113709.htm)

   [http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm113709.htm](http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm113709.htm)

**18. Department of Defense Conducted or Support Research**
18.1. Applicability
This policy applies to all CUNY research involving human subjects that is supported by or conducted in collaboration with the Department of Defense (DoD). This includes research involving human subjects for which the DoD is:
- Providing at least some of the resources, including but not limited to funding, facilities, equipment or personnel;
- Giving access to or information about DoD personnel for recruitment; or
- Providing identifiable data or specimens from living individuals.
This policy outlines additional requirements for DoD conducted or supported research. All other CUNY policies also apply to DoD conducted or supported research.

18.2. Prohibitions

18.2.1. Testing of chemical or biological warfare
Research involving human subjects for testing of chemical or biological warfare agents is generally prohibited, subject to possible exceptions for research for prophylactic, protective, or other peaceful purposes.

18.2.2. Detainee as a human subject
Research involving a detainee, as defined in DoD Directive 2310.01E, as a human subject is prohibited, except as permitted by the Food and Drug Administration’s regulations at Title 21 of the Code of Federal Regulations when for the purpose of diagnosis or treatment of a medical condition in a patient.

18.3. Scientific Merit
The IRB must consider the scientific merit of all human subjects research conducted in collaboration with DoD or supported by DoD. This is accomplished in the following manner:

The highest-ranking administrator who oversees research at the CUNY College with which the principal investigator has primary affiliation must sign off on the IRB application for the given protocol, indicating that the protocol has sufficient scientific merit to proceed. Please contact your College’s HRPP Coordinator to obtain the contact information for the highest-ranking administrator.

18.4. Risk Evaluation
Minimal risk is defined in the federal regulations as follows: 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.

When evaluating risks to human subjects involved in DoD conducted or DoD supported research, the phrase, “ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests,” may not be interpreted to include the inherent risks certain categories of human subjects face in their daily life, such as the risk faced by active duty personnel serving in a war zone.

For example, the risks imposed in research involving human subjects focused on a special population should not be evaluated against the inherent risks encountered in their work environment (e.g., emergency responder, pilot, soldier in a combat zone) or having a medical condition (e.g., frequent medical tests or constant pain).

18.5. Payment for Participation

18.5.1. On-duty federal personnel as human subjects

18.5.1.1. Compensation for blood draws
Federal personnel participating as human subjects in research conducted by CUNY may be compensated up to $50 for each blood draw if the research is in connection with the care of any person entitled to treatment at Government expense, regardless of funding.

18.5.1.2. General compensation for participation
Federal personnel participating as human subjects in research while on duty may not be otherwise compensated for general research participation, regardless of funding.

18.5.2. Off-duty federal personnel for participation

18.5.2.1. Compensation for blood draws in federally funded research
Federal personnel participating as human subjects in research conducted by CUNY may be compensated up to $50 for each blood draw if the research is in connection with the care of any person entitled to treatment at Government expense and it is federally funded.

18.5.2.2. Compensation for blood draws in non-federally funded research
Off-duty federal personnel may be compensated for blood draws in a reasonable amount as approved by the IRB according to local prevailing rates and the nature of the blood draw.
18.5.2.3. **General compensation for participation**

Federal personnel participating as human subjects while off duty may be compensated for research participation in the same way as human subjects who are not federal personnel. Payment to off-duty federal personnel must not be directly from a federal source.

18.5.3. **Non-federal personnel as human subjects in DoD funded research**

18.5.3.1. **Compensation for blood draws**

Non-federal personnel participating as human subjects in research funded by the DoD may be compensated up to $50 for each blood draw if the research is in connection with the care of any person entitled to treatment at Government expense.

18.5.3.2. **General compensation for participation**

Non-federal personnel participating as human subjects in research funded by the DoD may be compensated for research participation in a reasonable amount approved by the IRB according to local prevailing rates and the nature of the research. Payment for general research participation may come directly from federal or non-federal source.

18.6. **Considerations for Recruitment of Service Members**

- Superiors of service members shall not be present at any human subject recruitment sessions or during the consent process in which members of units under their command are afforded the opportunity to participate as human subjects. When applicable, the superiors so excluded shall be afforded the opportunity to participate as human subjects in a separate recruitment session.

- For greater than minimal risk research involving Service members as human subjects, for which recruitment occurs in a group setting, the IRB must appoint an ombudsman. The ombudsman shall not be associated in any way with the research study. The ombudsman must be present during the recruitment process, in order to monitor that the voluntary involvement or recruitment of the Service members is clearly and adequately stressed, and that the information provided about the research is clear, adequate and accurate.

- For minimal risk research involving Service members as human subjects, for which recruitment occurs in a group setting, the IRB may decide to require an ombudsman, depending on the human subject population, the consent process and the recruitment strategy.
18.7. Legal Capacity to Consent

All active duty Service members and all Reserve Component members in a federal duty status participating as human subjects in DoD supported research are considered to be consenting adults. When Service members are under 18 years of age, students at Service Academies, or trainees, the IRB must carefully consider the recruitment process and the necessity to include such members as human subjects.

18.8. Research Monitor

For greater than minimal risk research involving human subjects, the IRB must approve an independent research monitor by name. The duties of the research monitor will be determined by the reviewing IRB on the basis of the specific risks or concerns about the research. These duties may include, but may not be limited to, one or more of the following:

- Observe recruitment, enrollment procedures and consent process
- Oversee study interventions and interactions
- Review monitoring plans and/or reports of unanticipated problems involving risks to subjects or others
- Oversee data collection and analysis

The research monitor must report their observations and findings to the IRB of record for the given protocol. The IRB will determine, on a protocol-by-protocol basis, the frequency with which the research monitor must report to the IRB.

The research monitor has the authority to:

- Stop a research protocol in progress;
- Remove individual human subjects from a research protocol; AND
- Take any appropriate and necessary steps to protect the safety and well-being of human subjects until the IRB can assess the monitor’s report.

18.9. Waiver of Informed Consent

DoD does not allow research involving a human being as an experimental subject without prior informed consent from the experimental subject or their legal representative. If the consent is to be obtained from the experimental subject’s legal representative, the IRB must determine that the research intends to benefit the individual subject.
NOTE: DoD distinguishes between research involving human subjects and research involving a human being as an experimental subject as follows:

- **Research involving human subjects**: Activities that include both a systematic investigation designed to develop or contribute to generalizable knowledge AND involve a living individual about whom an investigator conducting research **obtains data through intervention or interaction with the individual or identifiable private information**.

- **Research involving a human being as an experimental subject**: An activity, for research purposes, where **there is an intervention or interaction** with a living individual **for the primary purpose of obtaining data regarding the effect of the intervention or interaction**.

### 18.10. Research involving Prisoners

DoD supported or conducted research that fall within one of the categories of research exempt from IRB review or expedited review and includes prisoners as research subjects must be reviewed and approved by a convened CUNY UI-IRB and meet the requirements outlined in the CUNY Research Involving Prisoners Policy.

In addition to the categories of permissible research involving prisoner subjects outlined in the CUNY Research Involving Prisoners Policy, DoD supported research or research conducted in collaboration with DoD may enroll prisoners in the following category of research:

- Epidemiological research that meets the following criteria:
  - The research describes the prevalence or incidence of a disease by identifying all cases, or studies potential risk factor associations for a disease;
  - The research presents no more than minimal risk;
  - The research presents no more than an inconvenience to the human subject; AND
  - Prisoners are not a particular focus of the research.

### 18.11. Reporting

CUNY HRPP will notify the appropriate DoD Human Research Protection Official (HRPO) of the following actions concerning research conducted in collaboration with the DoD or supported by DoD:

- When significant changes to the research protocol are approved by the IRB, including when a subject becomes a prisoner while participating in research;
The results of the IRB continuing review;
When the reviewing IRB changes;
When CUNY is notified by any Federal department or agency or national organization that any part of the CUNY HRPP is under investigation for cause involving a DoD supported research protocol; AND
Unanticipated problems involving risks to subjects, suspensions, terminations, and serious or continuing noncompliance regarding DoD supported research involving human subjects.

References

2. Department of Defense Instruction Number 3216.02, “Protection of Human Subjects and Adherence to Ethical Standards in DoD-Sponsored Research,” issued November 8, 2011
5. United States Code 10 Section 980, “Limitation on Use of Humans as Experimental Subjects”

19. Multisite Non-Exempt Human Subjects Research

19.1. Applicability
These procedures apply to non-exempt multi-site research involving human subjects in which CUNY is engaged. Please refer to section 7, “When is CUNY HRPP or IRB Review Required” for assistance in determining whether CUNY is engaged in a multi-site protocol.

19.2. Multi-CUNY College Human Subjects Research

19.2.1. Principle Investigator (PI) Responsibilities

19.2.1.1. Submitting to the HRPP Office
When a research project is to be conducted in collaboration between two or more CUNY Colleges, or when research procedures are performed at two or more CUNY Colleges, the IRB Application should be submitted to the HRPP Office of the CUNY College with which the PI of the project has primary affiliation. The Application should only be submitted to one CUNY HRPP Office, regardless of the number of CUNY campuses collaborating on the project.

19.2.1.2. Initial IRB Application Form
The PI must provide the following information in the IRB application for all CUNY sites:
- Identify all CUNY sites involved in the research
- Describe each CUNY site’s role in the research

19.2.2. HRPP Staff Responsibility
Upon approval of a multi-CUNY College protocol, the HRPP Coordinator or IRB Administrator overseeing the review of the protocol shall send an informational email to HRPP Coordinators of all approved CUNY sites informing them of the following: a) name of PI; b) title of study; c) IRBNet ID number for the study; and d) list of CUNY sites that are approved under this protocol.

19.3. Collaborative Research with Non-CUNY Sites
CUNY UI-IRB review and approval is required for all non-exempt human subjects research activities for which CUNY affiliated individuals obtain: 1) data about the subjects through intervention or interaction; 2) identifiable private information about the subjects; or 3) informed consent of human subjects for the research.

19.3.1. PI Responsibilities

19.3.1.1. Initial IRB application form for all collaborative research
For all collaborative studies, the PI must provide the following information in the IRB application:
- Identify all collaborating sites and their respective PI’s
- Describe CUNY’s role in the research
- Describe each non-CUNY site’s role in the research

19.3.1.2. Initial IRB application form for federally funded collaborative research where CUNY is the prime awardee and/or coordinating center
For non-exempt federally funded human subjects research, where CUNY is the prime awardee and/or the coordinating center, the PI must include in the IRB application a written assurance that the PI will maintain in their records all of the following:
- Documentation of current Federalwide Assurance (FWA) for each of the collaborating sites engaged in human subjects research
- Documentation of current IRB approval and IRB approved consent documents from the designated IRB of all collaborating sites engaged in human subjects research

19.3.1.3. **IRB application for federally funded collaborative research where CUNY is NOT the prime awardee and/or coordinating center**

For non-exempt federally funded human subjects research, where CUNY is neither the prime awardee nor the coordinating center, the PI must include the following with their IRB submission:

- **Initial Review**: Provide a written assurance in the IRB application that the PI will maintain in their records documentation of current IRB approval and IRB approved consent documents from the designated IRB of the prime awardee and/or coordinating center
- **Initial AND Continuing Review**: Attach the current IRB approval from the designated IRB of the prime awardee and/or coordinating center to the submission package

19.3.1.4. **Initial IRB application form for non-federally funded collaborative research where CUNY PI is the lead PI**

For non-exempt non-federally funded human subjects research, where CUNY PI is the lead PI, the PI must include in the IRB application a written assurance that the PI will maintain in their records one of the following:

- For collaborating sites with a designated IRB, documentation of current IRB approval and IRB approved consent documents from the designated IRB of all collaborating sites engaged in human subjects research
- For collaborating sites that do not have a designated IRB, documentation of appropriate permission/authorization from the responsible institutional authority

19.3.1.5. **Addition of Collaborating Sites**

The CUNY PI must submit an amendment and appropriate supporting documents to obtain CUNY UI-IRB review and approval of additional sites prior to engaging in human subjects research procedures at the new site.

19.3.1.6. **Change in the role of a previously approved collaborating site**
The CUNY PI must submit an amendment and appropriate supporting documents to obtain CUNY UI-IRB review and approval of changes in a previously approved collaborating site’s role prior to engaging in the implementation of these changes.

19.3.1.7. **Discontinuation of a previously approved collaborating site**  
As part of the continuing review submission following the discontinuation of a previously approved collaborating site, the PI shall notify the IRB of any discontinuations during the previous approval period.

19.3.1.8. **Record Keeping**  
All records identified below must be available for audit by the CUNY HRPP/IRB at any time.

19.3.1.8.1. **All Collaborative Research**  
For all collaborative research, the PI is responsible for maintaining the following records in the research files:

- Documentation of all communications with the CUNY UI-IRB
- Documentation of all communications with the collaborators and funding agency (when applicable)

19.3.1.8.2. **Federally funded research where CUNY is the prime awardee and/or coordinating center**  
For non-exempt federally funded human subjects research, where CUNY is either the prime awardee or the coordinating center, the PI is responsible for maintaining the following additional records in the research files:

- Documentation of current FWA for each of the collaborating sites engaged in human subjects research
- Documentation of current IRB approval and IRB approved consent documents from the designated IRB of all collaborating sites engaged in human subjects research
- The PI must ensure that such documentation is received by the PI prior to initiation of research at the non-CUNY collaborating sites

19.3.1.8.3. **Federally funded research where CUNY is NOT the prime awardee or coordinating center**  
For non-exempt federally funded human subjects research, where CUNY is neither the prime awardee nor the coordinating
center, the PI is responsible for maintaining the following additional records in the research files:

- Documentation of current IRB approval and IRB approved consent documents from the designated IRB of the prime awardee and/or coordinating center
- Documentation of all communications with the primary awardee and/or coordinating center

19.3.1.8.4. Non-federally funded research where CUNY PI is the lead PI

For non-exempt non-federally funded human subjects research, where CUNY PI is the lead PI, the PI is responsible for maintaining the following additional records in the research files:

- For collaborating sites with a designated IRB, documentation of current IRB approval and IRB approved consent documents from the designated IRB of all collaborating sites engaged in human subjects research
- For collaborating sites that do not have a designated IRB, documentation of appropriate permission/authorization from the responsible institutional authority

19.3.2. CUNY HRPP Staff Responsibilities

The HRPP Coordinator or the IRB Administrator responsible for overseeing the review of the protocol shall:

- Confirm engagement determinations
- Verify that the PI has submitted required documents and assurances as noted in herein
- For federally funded research where CUNY is NOT the prime awardee, verify and document the current FWA number of the prime awardee institution

19.3.3. CUNY as the IRB of Record

CUNY UI-IRB’s approval of collaborative research serves as an IRB approval for CUNY’s involvement in the research. It does NOT constitute an approval for the collaborating sites, EXCEPT when CUNY has agreed to serve as the IRB of Record for the collaborating institution as described in this section.

19.3.3.1. When will CUNY UI-IRB serve as the IRB of Record for the Collaborating Institution?

CUNY UI-IRB will agree to serve as the IRB of Record for collaborating institutions engaged in federally funded research on a case-by-case
basis depending on the nature of the collaboration and the collaborators' role in the research.

19.3.3.2. **Request for CUNY UI-IRB to serve as the IRB of Record**

The request for CUNY UI-IRB to serve as the IRB of Record for a collaborating institution must be made in writing as a part of CUNY PI's submission of the IRB application. The request should include the following information:

- Role of the collaborating institution in the research
- Whether the collaborating institution has a designated IRB
  - If yes, why the collaborating site's designated IRB will not serve as the IRB of Record for the project in question

19.3.3.3. **Procedures**

The request shall be processed as follows:

1. The HRPP Coordinator or the IRB Administrator responsible for overseeing the review of the protocol will confirm the collaborating site's engagement in the federally funded research.
2. Once confirmed, the HRPP Coordinator or the IRB Administrator responsible for overseeing the review of the protocol will forward the request to the University Director for Research Compliance.
3. The University Director for Research Compliance will determine whether the CUNY UI-IRB will serve as the IRB of Record.
4. If the CUNY UI-IRB will serve as the IRB of Record, the University Director of Research Compliance will draft an Agreement for signature by the Vice Chancellor for Research (VCR).
   
   **NOTE:** VCR is the ONLY individual authorized to sign such Agreements on behalf of the University.
5. Once signed by the VCR, the Agreement will be forwarded to the collaborating institution for their authorized individual's signature.
6. The Agreement will go into effect after both parties have signed the Agreement, and the PI has submitted a copy of the signed Agreement to the CUNY UI-IRB.

19.3.3.4. **Collaborating Institution's Responsibility**

The collaborating institution must obtain a FWA and list CUNY UI-IRB as a designated IRB, when appropriate.
20. Research Conducted in an International Setting

20.1. Applicability and Purpose
This policy applies to non-exempt human subjects research conducted outside the United States in which CUNY is engaged. The purpose of this policy is to define researcher responsibility and CUNY UI-IRB considerations required to ensure adequate protection of human subjects involved in research conducted in an international setting.

20.2. Research and IRB Shared Responsibility
The researcher and the IRB share responsibility for ensuring that:
- Subjects in foreign countries are afforded protections that are at least equivalent to those afforded to human subjects of research within the United States;
- Both researcher and the IRB have sufficient knowledge of local laws and culture in order to adequately plan for and evaluate ethical conduct of research; and
- The recruitment, screening and informed consent processes are consistent with local legal and cultural expectations.

20.3. Research Responsibilities
The principal investigator is responsible for ensuring that the following information is provided to the IRB as part of the IRB application:

a. List of all research sites, including city and country information
b. Provide scientific and ethical justification for conducting the research at the foreign site(s)
c. Describe the researchers’ qualifications for conducting the research at the foreign sites(s), including their knowledge of local regulations and culture.
   i. When relying on local community consultations for research planning, the IRB application should include a detailed description of the community consultation and its outcomes.
d. Describe the informed consent process in terms of the local context, including consideration of the following, where applicable:
   i. Local legal age of consent
   ii. Local status of women’s rights to consent for self or for their children
   iii. Literacy level of the subject population
   iv. Use of translators and translated informed consent documents
e. Provide information regarding local oversight required:
   i. Identify applicable local permissions or approvals that may be required
   ii. Follow CUNY HRPP Procedures for Multisite Non-Exempt Human Subjects Research
1. NOTE: for greater than minimal risk international research, requirements of section 4 of this policy override some of the lesser requirements in the Procedures for Multisite Non-Exempt Human Subject Research.

20.4. Greater than Minimal Risk International Research
Greater than minimal risk international research in which CUNY researchers are engaged must comply with one of the following requirements:

a. The researcher must have a collaborator in the non-US country where research is being conducted, who is familiar with the local regulatory requirements and cultural expectations; and obtain an approval to conduct the proposed research from a local authority, which must be submitted to the CUNY UI-IRB prior to initiation of the research; OR

b. CUNY UI-IRB must obtain expert review from someone knowledgeable about and experienced in the local regulatory requirements and cultural expectations.

References


2. OHRP International Compilation of Human Research Standards and related guidance

21. Accounting for Total Subject Enrollment

21.1. Purpose
The purpose of this guidance document is to assist CUNY researchers in accurately defining the number of subjects expected to be enrolled in a non-exempt human subjects research study at the time of initial submission, and to assist in accurately accounting for subject populations at the time of continuing review.

21.2. Why does the IRB ask for expected number of subjects to be enrolled?
IRB approval of each research study is granted for enrollment of a specific number of subjects, or a range of subjects to be enrolled. The IRB considers the number of subjects to be enrolled in a given study in its risk/benefit analysis of the study as follows:
- To ensure that the minimum number of subjects necessary for the described research are being exposed to the risks of research, however minimal; and
- To ensure that the research is designed such that it will yield valid results.

21.3. **Why does the IRB ask for an accounting of the number of subjects at the time of continuing review?**
At the time of continuing review, the IRB must ensure that the risk/benefit ratio of the study remains favorable. A marked difference between the actual and expected rates of enrollment may indicate a problem with the research project that requires further evaluation, including whether the research project is likely to provide sufficient data to answer the scientific question(s) being posed.

21.4. **How does CUNY HRPP/IRB define subject enrollment?**
Number of subjects enrolled refers to the number of subjects who have undergone research related procedures. These include any of the following:
- Number of subjects who have completed the informed consent process for screening procedures, main study procedures or both
- Number of subjects who have undergone screening procedures
- Number of subjects who have undergone any main study procedures

21.5. **On the continuing review form, what does “number of subjects excluded from research due to ineligibility” mean?**
This refers to the number of subjects that underwent the screening procedures but were found to be ineligible to proceed with further research participation.

22. **Children as Research Subjects**

22.1. **Applicability**
This policy applies to all non-exempt human subject research involving children in which CUNY becomes engaged.

22.2. **Definitions**

22.2.1. **Children**
Persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

22.2.1.1. **New York State Jurisdiction**
According to New York State law, a minor is any person who is not an adult. Relatedly, an adult is any person who is eighteen years of age or older or has married.

22.2.1.1.1. Any person who is eighteen years of age or older, or is the parent of a child or has married, may give effective consent for medical, dental, health and hospital services for himself or herself, and the consent of no other person shall be necessary.

22.2.1.1.2. Any person who has been married or who has borne a child may give effective consent for medical, dental, health and hospital services for his or her child.

22.2.1.1.3. Any person who is pregnant may give effective consent for medical, dental, health and hospital services relating to prenatal care.

22.2.1.2. Other Jurisdictions
When recruiting children as research subjects from a jurisdiction outside of New York State, the Principal Investigator (PI) is responsible for ensuring compliance with the legal age of consent requirements of that jurisdiction. The PI must provide this information to the IRB as part of his/her IRB application.

22.2.2. Assent
A child’s affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

22.2.3. Permission
The agreement of parent(s) or guardian to the participation of their child or ward in research.

22.2.4. Parent
A child’s biological or adoptive parent.

22.2.5. Guardian
An individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

22.3. Criteria for Inclusion of Children in Research
CUNY UI-IRBs may approve research involving children as subjects only when the research meets one of the following criteria:

22.3.1. Research not involving greater than minimal risk
The IRB finds that no greater than minimal risk to children is presented, and adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians.

22.3.2. **Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects**

The IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject’s well-being only if the IRB finds that:

a. The risk is justified by the anticipated benefit to the subjects;

b. The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; AND

c. Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.

22.3.3. **Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject’s disorder or condition**

The IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if the IRB finds that:

a. The risk represents a minor increase over minimal risk;

b. The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social or educational situations;

c. The intervention or procedure is likely to yield generalizable knowledge about the subjects’ disorder or condition which is of vital importance for the understanding or amelioration of the subjects’ disorder or condition; AND

d. Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians.
Research not otherwise approvable under criteria 22.3.1-3.3 above, which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children

Research that the IRB does not believe meets the requirements of 22.3.1-3.3 above only if:

a. The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; AND one of the following consultations have taken place:

i. For federally funded or supported research, the Secretary of the funding agency, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined EITHER:

   (1) That the research in fact satisfies the conditions of 22.3.1-3.3 above, as applicable; OR
   (2) All of the following:
      a) That the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;
      b) The research will be conducted in accordance with sound ethical principles; AND
      c) Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians.

ii. For non-federally funded or supported research, the Vice Chancellor for Research, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law), the sponsor of the research, if any, and relevant community representative(s), has determined that:

   (1) That the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;
22.4. Child Assent

The IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate.

22.4.1. Child Assent Process

When the IRB determines that assent is required, it shall also determine the adequacy of the child assent process. For longitudinal studies, the IRB may require re-assenting procedures at certain age appropriate intervals; and consent process when the child reaches adulthood.

22.4.2. Documentation of Child Assent

When the IRB determines that assent is required, it shall also determine whether and how assent must be documented. In general, when the literacy and maturity of the subject population allows, CUNY UI-IRBs require:

a. Oral assent from children under the age of 7.
b. Simple one-page assent document for children between the ages of 7 and 12.
c. Assent document similar to the consent document used for adults for children between the ages of 13 and 17.

22.4.3. Waiver of Child Assent

The IRB may waive the requirement for obtaining child assent if the IRB determines that:

a. The capability of some or all of the children is so limited that they cannot reasonably be consulted; OR
b. That the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research; OR
c. The IRB finds that ALL of the following conditions are met:
   i. The research involves no more than minimal risk to the subjects;
   ii. The waiver will not adversely affect the rights and welfare of the subjects;
   iii. The research could not practicably be carried out without the waiver; AND
   iv. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

22.5. Parent or Guardian Permission
The IRB shall determine that adequate provisions are made for soliciting the permission of each child’s parents or guardian, as follows:

a. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research that meets the criteria in 22.3.1 and 22.3.2 above.

b. For research that meets the criteria in 22.3.3 or 22.3.4 above and permission is to be obtained from parents, both parents must give their permission, unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

22.5.1. Parent or Guardian Permission Process
All requirements for the informed consent process as outlined in 12. Informed Consent Process and Documentation apply to the parent or guardian permission process.

22.5.2. Documentation of Parent or Guardian Permission
All requirements for the informed consent process as outlined in 12. Informed Consent Process and Documentation apply to the documentation of parent or guardian permission.

22.5.3. Waiver of Parent or Guardian Permission
The IRB may waive the requirement for obtaining parent or guardian permission if the IRB determines that ONE of the following sets of conditions apply:

a. ALL of the following conditions are met:
   i. A research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to
protect the subjects (for example, neglected or abused children); AND

ii. An appropriate mechanism for protecting the children who will participate as subjects in the research is substituted; AND

iii. The waiver is consistent with federal, state or local law.

b. ALL of the following conditions are met:

i. The research involves no more than minimal risk to the subjects;

ii. The waiver will not adversely affect the rights and welfare of the subjects;

iii. The research could not practicably be carried out without the waiver; AND

iv. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

22.6. Wards

22.6.1. Children who are wards of the state or any other agency, institution, or entity can be included in research that meets the criteria in sections 22.3.1 or 22.3.2 above.

22.6.2. Children who are wards of the state or any other agency, institution, or entity can be included in research that meets the criteria in sections 22.3.3 or 22.3.4 above only when:

a. One of the following criteria is met:

i. The research is related to their status as wards; OR

ii. The research is conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

b. The IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child’s participation in the research, and who is not associated in any other way with the research, the investigator(s), or the guardian organization.
22.7. **IRB Responsibilities**

The reviewing IRB is required to make each of the determinations outlined in this policy, as applicable. Each of these determinations, and the basis for each determination, must be documented in the reviewer’s comments for reviews conducted by an expedited review process, and in the meeting minutes for reviews conducted by the convened IRB.

**References**


2. New York State Public Health Law, Article 25, Title 1, Section 2504: *Enabling certain persons to consent for certain medical, dental, health and hospital services.*


23. **Prisoners as Research Subjects**

23.1. **Applicability**

This policy applies to all human subject research involving prisoners in which CUNY becomes engaged.

23.2. **Definitions**

23.2.1. **Minimal risk**

The probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

23.2.2. **Prisoner**

Any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

23.3. **IRB Review**

Research involving prisoners as research subjects must be reviewed and approved by an IRB prior to its initiation.
23.3.1. Research involving prisoners cannot be exempt from IRB review; therefore, section 8, “Human Subjects Research Exempt from IRB Review” DOES NOT apply.

23.3.2. Research involving prisoners may be reviewed on an expedited basis, ONLY when the University Director for Research Compliance or his/her designee concurs that the research meets the criteria for expedited review.

23.3.2.1. At least one of the reviewers conducting the review on an expedited basis must be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity.

23.3.3. In addition to meeting the requirements outlined in section 10, “Convened IRB Review, when reviewing research involving prisoners,” the convened IRB must meet the following requirements:

23.3.3.1. A majority of the Board (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the Board.

23.3.3.2. At least one member of the Board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in the capacity.

23.4. Criteria for Inclusion of Prisoners in Research

23.4.1. Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects.

23.4.2. Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects.

23.4.3. Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after one of the following consultations have taken place:
a. For research that is conducted or supported by the US Department of Health and Human Services (HHS), the Secretary of HHS or his/her designee has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the FEDERAL REGISTER, of his intent to approve such research.

b. For research that is not conducted or supported by the HHS, the Vice Chancellor for Research has consulted with appropriate experts including experts in penology, medicine, and ethics, and provided his/her approval of such research in writing.

23.4.4. Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject.

a. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after one of the following consultations have taken place:

i. For research that is conducted or supported by HHS, the Secretary of HHS or his/her designee has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the FEDERAL REGISTER, of the intent to approve such research.

ii. For research that is not conducted or supported by HHS, the Vice Chancellor for Research has consulted with appropriate experts, including experts in penology, medicine, and ethics, and provided his/her approval of such research in writing.

23.5. Criteria for IRB Approval

In order to approve research involving prisoners as subjects, the CUNY UI-IRB must find and document that, in addition to the criteria outlined in section 13, “Criteria for IRB Approval,” research involving prisoners as subjects meets the following criteria:

23.5.1. The research under review represents one of the categories of research outlined in section 23.4 above.
23.5.2. Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired.

23.5.3. The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers.

23.5.4. Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the Principal Investigator (PI) provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project.

23.5.5. The information is presented in language which is understandable to the subject population.

23.5.6. Adequate assurance exists that parole boards will not take into account a prisoner’s participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole.

23.5.7. Where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners’ sentences, and for informing participants of this fact.

23.6. When a Non-Prisoner Subject Becomes a Prisoner

23.6.1. This policy applies whenever any human subject in a research protocol becomes a prisoner at any time during the study.

23.6.2. The PI is responsible for:

   a. Immediately informing the IRB if a research subject who was not previously a prisoner becomes a prisoner while participating in the research;
b. Discontinuing any research related interventions or interactions with, and collecting identifying information about, the now prisoner subject, except in circumstances in which the investigator asserts that it is in the best interest of the subject to remain in the research study while incarcerated; AND

c. Advising the IRB as to whether the PI and the subject wish the subject to continue participation in the research.

23.6.3. If the PI and the subject wish the now prisoner subject to continue participating in the research, the CUNY UI-IRB must re-review the protocol, and determine whether the involvement of the now prisoner subject meets all of the requirements of this policy.

23.6.4. If the IRB determines that the research does not meet all of the requirements of this policy, the now prisoner subject must be withdrawn from the research. Appropriate measures agreed upon by the PI and the IRB must be implemented to ensure adequate protection of the health and welfare of the subject, as they relate to the subject’s prior participation in research.

23.7. Epidemiological Studies

Certain epidemiological studies qualify for a waiver of requirements outlined in section 23.4 above. To qualify for this waiver, the epidemiological study must meet BOTH of the following criteria:

a. The sole purposes of the study are:
   i. To describe the prevalence or incidence of a disease by identifying all cases; OR
   ii. To study potential risk factor associations for a disease.

b. The CUNY UI-IRB approves the research, and documents that:
   i. The research meets the criteria in sections 23.5.2-5.7 above;
   ii. The research presents no more than minimal risk and no more than inconvenience to the prisoner-subjects; AND
   iii. Prisoners are not a particular focus of the research.

23.8. Certifications of HHS Conducted or Supported Research

23.8.1. When a CUNY UI-IRB approves research involving prisoners as research subjects, which is conducted or supported by the HHS, the Office of the Vice Chancellor for Research shall certify to the Secretary of the HHS in writing that the criteria listed in sections 23.4 and 23.5 above, or section 7 when applicable, have been fulfilled.
23.8.2. The certification must include the following:

a. Name and address of the CUNY institution
b. OHRP issued Federalwide Assurance number
c. IRB Registration number
d. Protocol title and CUNY protocol ID
e. Name and Title of the Principal Investigator
f. Attachment: CUNY UI-IRB application form(s)
g. Attachment: CUNY UI-IRB approved consent document(s)
h. Attachment: CUNY UI-IRB approved protocol, when applicable
i. Attachment: HHS grant application or protocol
j. Attachment: CUNY UI-IRB approval letter

23.8.3. HHS conducted or supported research involving prisoners as subjects may not proceed until OHRP issues its approval in writing on behalf of the HHS Secretary.

References

3. Federal Register Volume 68, Number 119 (Friday, June 20, 2003)

24. Pregnant Women, Human Fetuses and Neonates as Research Subjects

24.1. Applicability
This policy applies to all non-exempt human subject research involving pregnant women, fetuses and neonates in which CUNY becomes engaged.

24.2. Definitions

24.2.1. Dead Fetus
A fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord

24.2.2. Delivery
Complete separation of the fetus from the woman by expulsion or extraction or any other means

24.2.3. **Fetus**
The product of conception from implantation until delivery

24.2.4. **Neonate**
A newborn

24.2.5. **Nonviable neonate**
A neonate after delivery that, although living, is not viable

24.2.6. **Pregnancy**
The period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.

24.2.7. **Viable Neonates**
Being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration.

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**PREGNANT WOMEN OR HUMAN FETUSES**

24.3. **Conditions for Inclusion of Pregnant Women or Human Fetuses in Research**
CUNY UI-IRBs may approve research involving pregnant women or human fetuses as subjects only if all of the following conditions are met:

24.3.1. Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses.

24.3.2. The risk to the fetus is:

1. Caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; OR

2. Not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means.
24.3.3. Any risk is the least possible for achieving the objectives of the research.

24.3.4. No inducement, monetary or otherwise, will be offered to terminate a pregnancy.

24.3.5. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.

24.3.6. Individuals engaged in the research will have no part in determining the viability of a neonate.


24.4.1. Informed consent in accordance with section 15, “Informed Consent Process and Documentation” of ONLY the pregnant woman is sufficient when:

1. The research holds out the prospect of direct benefit to the pregnant woman;

2. The research holds out the prospect of a direct benefit both to the pregnant woman and the fetus; OR

3. The research holds out no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means.

24.4.2. Informed consent in accordance with section 15, “Informed Consent Process and Documentation” of the pregnant woman AND the father is required when the research holds out the prospect of direct benefit solely to the fetus.

24.4.2.1. EXCEPTION: the father’s consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or if the pregnancy resulted from rape or incest.

24.4.3. Each individual providing consent must be fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate.
24.4.4. For children who are pregnant, child assent and parent or
guardian permission must be obtained in accordance with section 22,
“Children as Research Subjects.”

24.5. Exclusion of Pregnant Women
If a research requires the exclusion of pregnant women, the Principal
Investigator (PI) is required to include the following information in both the
application to the IRB and the informed consent document(s) for the
subjects:

1. Rationale for the exclusion of pregnant women
2. Description of the pregnancy test that may be conducted at screening
   in order to ensure that potential subjects meet this exclusionary
criterion
3. Description of the repeat pregnancy test(s) and its frequency in order
to ensure that subjects continue to meet this exclusionary criterion
4. Instructions or guidance for subjects on how to avoid pregnancy while
   participating in the research
5. Description of the process by which the PI will withdraw subjects who
   may become pregnant while participating in the research

NEONATES

24.6. Viable Neonates
A neonate, after delivery, that has been determined to be viable may be
included in research only to the extent permitted by and in accordance with
section 22, “Children as Research Subjects.”

24.7. Conditions for Inclusion
CUNY UI-IRBs may approve research involving neonates of uncertain
viability and nonviable neonates as subjects only if all of the following
conditions are met:

24.7.1. Where scientifically appropriate, preclinical and clinical studies
have been conducted and provide data for assessing potential risks to
neonates.

24.7.2. Individuals engaged in the research will have no part in
determining the viability of a neonate.

24.8. Additional Conditions for Inclusion of Neonates of Uncertain Viability
Even when the conditions outlined in section 24.7 above are met, research involving neonates of uncertain viability may not be approved unless the IRB determines that:

a. The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective; OR

b. The purpose of the research is the development of important biomedical knowledge, which cannot be obtained by other means, and there will be no added risk to the neonate resulting from the research.

c. The legally effective informed consent of EITHER parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent’s legally authorized representative is obtained in accordance with Section 15 “Informed Consent Process and Documentation,” except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

i. Each individual providing consent must be fully informed regarding the reasonably foreseeable impact of the research on the neonate.

24.9. Additional Conditions for Inclusion of Nonviable Neonates
In addition to the conditions outlined in section 24.7 above, all of the following conditions must be met in order for the CUNY UI-IRB to approve research involving nonviable neonates:

24.9.1. Vital functions of the neonate will not be artificially maintained.

24.9.2. The research will not terminate the heartbeat or respiration of the neonate.

24.9.3. There will be no added risk to the neonate resulting from the research.

24.9.4. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means.

24.9.5. The legally effective informed consent of BOTH parents of the neonate must be obtained in accordance with Section 15, “Informed Consent Process and Documentation.” Each individual providing consent must
be fully informed regarding the reasonably foreseeable impact of the research on the neonate.

24.9.5.1. The waiver of informed consent and the alteration of informed consent provisions provided for in Section 15, “Informed Consent Process and Documentation” DO NOT apply.

24.9.5.2. If either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of ONE parent of a nonviable neonate will suffice, except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest.

24.9.5.3. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will NOT suffice to meet the requirements of this section.

PLACENTA, DEAD FETUS OR FETAL MATERIAL

24.10. Research Involving, After Delivery, the Placenta, the Dead Fetus or Fetal Material
Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, shall be conducted only in accordance with any applicable federal, state, or local laws and regulations regarding such activities.

24.10.1. If information associated with such material is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects and all pertinent CUNY HRPP policies and procedures are applicable.

WAIVER

24.11. Waiver of this Policy
Research that is not otherwise approvable based on the requirements of this policy, which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates may be approved by a CUNY UI-IRB ONLY if:
a. The CUNY UI-IRB finds and documents that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates; AND

b. One of the following consultations have taken place:

1. For research that is conducted or supported by US Department of Health and Human Services (HHS), the Secretary of HHS, after consultation with a panel of experts (for example: science, medicine, ethics, law) and following opportunity for public review and comment, including a public meeting announced in FEDERAL REGISTER, has determined either:

   a. The research in fact satisfies the conditions of this policy, as applicable; OR

   b. The following:

      i. The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates;

      ii. The research will be conducted in accord with sound ethical principles; AND

      iii. Informed consent will be obtained in accord with the informed consent provisions of HHS regulations at 45 CFR 46.

2. For research that is NOT conducted or supported by US Department of Health and Human Services (HHS), the Vice Chancellor for Research, after consultation with a panel of experts (for example: science, medicine, ethics, law) has determined that:

   a. The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates;

   b. The research will be conducted in accordance with sound ethical principles; AND
Informed consent will be obtained in accordance with Section 15, “Informed Consent Process and Documentation.”

Reference


25. Student Subject Pools

25.1. Purpose
This document provides guidance regarding the creation and operation of student subject pools, as well as guidance on recruiting from existing student subject pools.

25.2. What is a student subject pool?
Student subject pools are generally comprised of undergraduate students enrolled in particular courses that offer course credit (or other incentives) for participation in research projects.

25.3. CUNY HRPP or IRB Review of subject pools
CUNY HRPP or IRB review is required:

a. For the creation and operation of a subject pool; AND

b. For human subject research projects that recruit from student subject pools.

25.4. Subject Pool Criteria and Considerations

25.4.1. Voluntary participation
Student participation in both the subject pool and any research project that recruits from the subject pool must be completely voluntary. Therefore, protocols must include mechanisms for assuring the students:

- That their participation is entirely voluntary; and
- That the students may withdraw their participation at any time without any penalty

25.4.2. Alternatives to participation
In order to minimize the potential for coercion that may arise from granting students course credit in exchange for participation in research, the subjects must be given alternatives to such participation. Alternatives should be comparable in time, effort and fulfillment of course credit. Examples of alternatives include:

- Submission of research papers
- Attendance at research talks

25.4.3. **Recruitment**
Researchers and IRBs must ensure that the recruitment process for participation in the subject pool, as well as participation in individual research projects recruiting from the subject pool, minimizes the potential for coercion. It is, therefore, recommended that students be recruited only through the subject pool, rather than through flyers, announcements, or direct invitation.

25.4.4. **Minors**

25.4.4.1. **Inclusion of Minors**
It is possible that some students at CUNY are minors. Researchers who include minors in subject pools must ensure that these minors are provided the additional required protections as discussed in Section 22, “Children as Research Subjects.”

25.4.4.2. **Exclusion of Minors**
Some research projects that recruit from subject pools may require the exclusion of minors. These projects must provide minors in the subject pool with appropriate alternatives, as discussed in Section 25.4.2 above.

25.4.5. **College-specific requirements**
Individual CUNY Colleges may have specific requirements regarding recruitment of students at the given College. Researchers are responsible for ensuring that they are compliant with any local policies or procedures. Please refer to the CUNY College-Specific Policies Regarding Recruitment of Students as Research Subjects for more information.

25.4.5.1. **Baruch College**
Baruch College allows the recruitment of students for research purposes during classroom time on a case-by-case basis as long as it conforms to established administrative guidelines and adheres to CUNY HRPP Policies and Procedures. Instructors are not allowed to
directly recruit their students and must use a research assistant who will retain the consent documents until the end of the semester. If extra credit is given for student participation in research, the instructor must provide an alternate assignment for those students who choose not to participate. The alternate assignment cannot be more onerous than the research being conducted.

25.4.5.2. College of Staten Island
At CSI, when a course involves research practica – for example, a Psych course focused on research where methods are built into the curriculum, subjects may be recruited during class time. For courses that do not focus on research methods we would prefer the investigator do the recruitment before or after the class, or receive permission from the Chair of the department. However, we expect that the IRB members reviewing the proposed study would take into consideration issues of coercion and undue influence, as well as the precautions to lessen these risks, before making a final decision or recommendation to secure approval.

25.4.5.3. Hunter College
If an investigator wishes to recruit or conduct research with 1) Hunter College students and/or 2) CUNY and RFCUNY employees (at Hunter College), the investigator must demonstrate college-sensitive human subject procedures. While in the research planning stage, investigators are encouraged to contact the Hunter College HRPP office since all research utilizing Hunter College students and employees will be reviewed by Hunter College IRB members and the Hunter College HRPP office. If an investigator wishes to study Hunter College students or employees, several factors will influence whether Hunter College approves the research. Investigators are encouraged to adopt proactive strategies that safeguard independent and voluntary participation by research subjects. The following examples may prove helpful.

a. Voluntary participation, with informed consent, is a basic principle for all research involving human subjects. Subjects must be informed that research participation will not impact academic status, grades, employment, recommendation letters, degree programs or applications, professional advancement, salary, etc.

b. Investigators should clearly identify and inform student subjects of the differences between research activities (that benefit the investigator) versus student learning outcomes (that benefit the student).
c. When an investigator wishes to recruit students or employees, the investigator can ask potential research participants to arrive early (before class or work begins) or remain later (after class or work ends) to learn about the research activity. This will prevent recruitment during instructional time (among students) and work hours (among employees). Additionally, investigators should refrain from data collection during class time unless approved by the IRB.

d. Indirect recruitment methods, (such as bulletin board notices, distributed written flyers, advertisements in newspapers, and e-mail notifications) are preferred so that potential subjects do not feel put on-the-spot or pressured (whether real or perceived) into research participation.

25.4.5.4. Kingsborough Community College
Recruitment of students to participate in research during classroom time is acceptable. In accordance with CUNY's Human Research Protections Program Policies and Procedures that govern the recruitment of students as research subjects (Section 25), investigators must ensure that students’ participation is voluntary and without undue influence on their decision. Approval of research projects conducted within KCC’s classrooms is contingent on safeguards investigators put in place to avoid undue influence and coercion. In addition, in cases in which investigators seek to recruit from their classrooms, they must design their data collection procedures to ensure that students' identities are anonymous.

25.4.5.5. LaGuardia Community College
Recruitment of students is not permitted in classes. This prohibition does not apply to the administration of College-sponsored surveys (e.g. standard student satisfaction surveys; faculty evaluations).

25.4.5.6. Lehman College
It is acceptable to allow recruitment of students in research during class time as long as there are no issues of coercion and undue influence and the study has been approved by the IRB.

25.4.5.7. Queens College
Any determination regarding the recruitment of students to participate in research during classroom time is made on a case-by-case basis. QC HRPP Office works with the PIs regarding their proposed research methods/design to ensure that any issues involving coercion and undue influence are minimized.
25.4.5.8. Queensborough Community College

The provost office allows students to participate in research during classroom time, although the final decision is up to the instructor.

References


5. Code of Federal Regulations, Title 21 – Food and Drugs, Part 50 – Protection of Human Subjects


26. Unanticipated Problems and Adverse Events

26.1. Purpose

The purpose of this policy is to define unanticipated problems and adverse events associated with non-exempt human subject research, and to establish the reporting process and timeline for each.

26.2. Overview

Unanticipated problems and adverse events both involve undesirable experiences with the research protocol and/or subjects. Some unanticipated problems and adverse events may involve risks to subjects or others. These require prompt reporting to the IRB. Others can be reported at the time of continuing review.

26.3. What is an Unanticipated Problem Involving Risks to Subjects or Others (UPIRTSO)?

An unanticipated problem or an adverse event is considered to be an UPIRTSO when it meets ALL of the following criteria:

a. It is unexpected (in terms of nature, severity, or frequency) given:
   a. The research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and
   b. The characteristics of the subject population being studied;

b. It is related or possibly related to participation in the research:
a. A UPIRTSO is related or possibly related to participation in the research when there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research; AND

c. It suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

26.4. What is an Adverse Event?
An adverse event is any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign, symptom, or disease, temporally associated with the subject’s participation in the research, whether or not considered related to the subject’s participation in the research. Examples include emotional distress, exacerbation of an existing mental disorder, a breach of confidentiality, or a complication from use of a medical device.

a. An adverse event is considered a UPIRTSO when it meets ALL of the following three criteria:

i. The adverse event was unexpected. An unexpected adverse event is defined as any adverse event occurring in one or more subjects in a research protocol, the nature, severity, or frequency of which is not consistent with either:
   - The known or foreseeable risk of adverse events associated with the procedures involved in the research that are described in (a) the protocol-related documents, such as the IRB-approved research protocol, any applicable investigator brochure, and the current IRB-approved informed consent document, and (b) other relevant sources of information, such as product labeling and package inserts; OR
   - The expected natural progression of any underlying disease, disorder, or condition of the subject(s) experiencing the adverse event and the subject’s predisposing risk factor profile for the adverse event.

ii. The adverse event was related or possibly related to participation in the research. An adverse event is related or possibly related to the research when there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research.
iii. The adverse event places the subject or others at a greater risk of harm than was previously known or recognized. These adverse events fall in one of two categories:

- **Serious Adverse Event**: An adverse event is serious when medical or surgical intervention is required to prevent any of the following, or when any of the following occur:
  - Death
  - A life-threatening situation
  - Inpatient hospitalization
  - Prolongation of existing hospitalization
  - A persistent or significant disability/incapacity or congenital anomaly/birth defect

- **Life Threatening Adverse Event**: A situation or circumstance which places a subject at substantial risk of dying at the time of the problem; or the use or continuance of an intervention, a drug and/or a device that could possibly result in the death of a subject.

### 26.5. Reporting UPIRTSOs Other Than Those Involving Subjects Deaths and/or Life Threatening Events

Unanticipated problems and adverse events, which meet all three criteria for UPIRTSOs, but which do not involve a subject death and/or life threatening event, must be reported to the IRB (and to sponsors and/or a central or independent monitoring committee [i.e. DSMB] as applicable) **within 5 working days**.

### 26.6. Reporting: Subject Deaths and Life Threatening Events

a. The unanticipated death of a subject that is related or possibly related to the research must be reported to the IRB **within 24 hours**. If the cause of death is not available, this should not delay the report.

b. An adverse event that is life threatening and related or possibly related to the research must be reported **within 24 hours**.

c. Subject deaths that meet any of the following criteria must be reported to the IRB **at the time of continuing review**:

i. The death is due to the nature of the subject’s underlying disease or condition, or is identified as due to a possible risk
of the study procedure or intervention as described in the protocol and consent form;

ii. The death occurs more than 30 days after the subject stopped or completed all study procedures or interventions, or required research related follow-up;

iii. The death is that of a subject who did not complete the protocol for whatever reason, including voluntary withdrawal or removal by the PI;

iv. The death is that of a subject participating in a study which does not include a research intervention (for example, an observational study tracking outcomes).

26.7. Reporting: Other Unanticipated Problems and Adverse Events

Unanticipated problems and adverse events that do not require prompt reporting to the UI-IRB (per criteria defined in Sections 26.4 and 26.5 of this Policy) must be submitted as a summary of events at continuing review.

26.8. Principal Investigator Responsibilities

When reporting unanticipated problems and adverse events, the Principal Investigator shall assess the cause and seriousness of the event and advise whether:

a. A change in the protocol is necessary to minimize the risks to subjects;

b. The consent form should be revised to reflect the risk, and/or

c. Subjects previously enrolled in the study should be re-consenting in the light of the risk(s).

26.9. Authority to Review

26.9.1. Review by CUNY Administration

a. If immediate risks to subjects are involved, the University Director for Research Compliance or his/her designee, in consultation with the Vice Chancellor for Research and/or UI-IRB Chair, may take one or more actions prior to IRB review which may include (but are not limited to):

i. Immediate suspension of human subject research activities to ensure the ongoing safety of subjects;

ii. Request additional information from the Principal Investigator or others;
iii. Refer the report to a UI-IRB Chair or Vice Chair for review;
iv. Convene an emergency meeting of the UI-IRB, or a UI-IRB subcommittee, to review the report.

b. The principal investigator shall be promptly notified in writing of the determination and any required steps for corrective action.

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

26.9.2. Review by an IRB Chair or his/her Designee

a. A UI-IRB Chair or his/her designee may review events where only slight changes in risk have been reported, such that only minor changes in the study protocol or informed consent documents are required. The UI-IRB Chair or his/her designee may ask investigators and/or Data Safety Monitoring Boards or others for additional clarifying information and may require corrective actions.

b. The principal investigator shall be promptly notified in writing of the UI-IRB Chair or his/her designee’s determination, and any required steps for corrective action.

c. Any suspensions shall be reported to the convened UI-IRB in accordance with CUNY Policy.

26.9.3. Review by a Convened IRB

a. A convened UI-IRB or a UI-IRB subcommittee must review UPIRTSOs and adverse events that meet the criteria for reporting within 24 hours or 5 days.

b. The principal investigator shall be promptly notified in writing of the IRB’s determination, and any required steps for corrective action or termination.

26.9.4. Corrective Actions
Corrective actions that may be required by either the convened UI-IRB or the UI-IRB Chair or his/her designee include (but are not limited to):
26.10. External Reporting Requirements
The Office of the Vice Chancellor for Research will promptly communicate in writing to federal agencies and/or sponsor(s), as required, the details and corrective actions related to the UPIRTSO(s).

26.10.1. Information to be included in the report:

a. Name of the CUNY institution(s) conducting the research;
b. Title of the research project and/or grant proposal in which the UPIRTSO(s) occurred;
c. Name of the principal investigator on the protocol;
d. Number of the research project assigned by the IRB and the number of any applicable sponsored program or project;
e. A detailed description of the UPIRTSO(s); and
f. Any additional pertinent details related to the UPIRTSO(s), including corrective actions

References


27. Disposition of Allegations of Non-Compliance

27.1. Overview and Purpose
All human subject research must be conducted in full compliance with applicable regulations, State law, University policies, CUNY UI-IRB approved
protocol and stipulations imposed by the CUNY UI-IRB. This document describes CUNY HRPP’s policy and procedures for addressing allegations of non-compliance.

27.2. Definitions

a. **Non-Compliance**: Any situation, incident, or process during the conduct of human subject research that is inconsistent with any of the following: applicable federal regulations, State law, CUNY policies, any IRB-approved protocol or any stipulations imposed by the CUNY UI-IRB.

b. **Serious Non-Compliance**:
   i. Conducting non-exempt human subject research without prospective IRB review and approval.
   ii. In IRB-approved protocols: Any incident of non-compliance that significantly increases risks to subjects; jeopardizes the safety, welfare, or rights of subjects or others; or decreases potential benefits of the study, including the scientific integrity of the research.

c. **Continuing Non-Compliance**: A pattern of repeated non-compliance which continues after initial discovery and approval of a corrective action plan that suggests that non-compliance will continue if there is no intervention; or if continued, could significantly increase risks to, or jeopardize the safety, welfare, and/or rights of subject(s) or others; or if continued, could decrease potential benefits (including the scientific integrity of the research).

27.3. Reporting Allegations of Non-Compliance

Allegations of non-compliance may be brought to the University’s attention as follows:

a. Self-report by the principal investigator (PI) or study team

b. Any individual may report suspected non-compliance against one or more persons orally or in writing. Such allegations should be addressed to the University Director of Research Compliance (UDRC) or his/her designee.

c. If an allegation is received by another University administrator or identified in the course of another University process, such as
an internal audit, the responsible administrator should immediately notify the UDRC or his/her designee of such an allegation.

27.4. Initial Evaluation of Non-Compliance

a. The HRPP will forward allegations of non-compliance to a UI-IRB Chair or designee for review.

b. The UI---IRB Chair or designee must determine whether there is non-compliance, and if so, whether the non-compliance is serious and/or continuing.

c. Upon completion of an initial evaluation, the UI---IRB Chair or designee may make one or more of the following determinations:

   i. Determine that there is no non-compliance

   ii. Determine that the non-compliance is neither serious nor continuing, and acknowledge the non-compliance without requiring any further action

   iii. Determine that the non-compliance is serious and/or continuing

      1. Determinations of serious and/or continuing non-compliance must be referred to the convened UI-IRB

   iv. Require corrective actions in accordance with section 27.6 of this policy

   v. Refer the allegation to the UDRC for further investigation

27.5. Investigations by the UDRC and Findings of Non-Compliance

a. Upon receipt of a request for investigation, the UDRC or his/her designee will review the allegation, and based on the nature and substance of the allegation or expertise required, and in consultation with the Vice Chancellor for Research (VCR) and/or the UI-IRB, identify appropriate membership of the investigative team. When appropriate, allegations of non-
compliance will be promptly reported to the VCR.

b. The investigation of non-compliance allegations will be documented. The PI and others who may have relevant information should have the opportunity to provide input during the investigation. Every effort must be made to protect the identity of whistle blowers before, during and after investigation. Retaliation against good faith whistle blowers will not be tolerated. Those against whom allegations of non-compliance have been made will be provided a description of the allegations, reasonable access to evidence, and opportunity to respond and provide input.

c. Upon completion of the investigation, the investigative committee will provide a written report to the UDRC to include, at a minimum, the following:

- A detailed description of the allegations;
- Summary of the research records and evidence reviewed;
- For each separate allegation of non-compliance identified during the investigation, a recommendation as to whether the non-compliance did or did not occur;
- Root cause analysis;
- Recommendations for corrective action(s)
- For any recommendation for a finding of non-compliance, a recommendation as to whether or not the non-compliance is serious or continuing.

d. The investigation of non-compliance allegations will be documented. The PI and others who may have relevant information should have the opportunity to provide input during the investigation. Every effort must be made to protect the identity of whistle blowers before, during, and after investigation. Retaliation against good faith whistle blowers will not be tolerated. Those against whom allegations of non-compliance have been made will be provided a description of the allegations, reasonable access to evidence, and opportunity to respond and provide input.

27.6. Review by the Convened UI-IRB

a. For allegations of non-compliance that are referred to the convened UI-IRB, the UI-IRB will make the final determination of whether the allegation constitutes non-compliance. If the determination is made that there is non-compliance, the UI-IRB
must determine if the non-compliance is serious and/or continuing. The UI-IRB may rely on the recommendations of the investigative team, the UDRC, and any other resources deemed appropriate in making this determination.

b. The Office of Vice Chancellor for Research will promptly notify the principal investigator in writing of the UI-IRB's determination along with a statement of the reasons for its decision. Investigators will be offered an opportunity to respond to the UI-IRB in writing.

27.7. Corrective Action Plan

a. The UI-IRB may require corrective actions to protect human subjects. Such actions may include, but are not limited to:

   i. Temporarily suspending new enrollment in a protocol;

   ii. Suspending or terminating all human subject research activity; (NOTE: Only the convened IRB may terminate a study.)

   iii. Mandating investigator and/or staff training in the protection of human subjects;

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

   v. Suspending individual investigators from participation in the research protocol;

   vi. Notification to subjects of non-compliance;

27.8. Reporting Non-Compliance

a. The University Director for Research Compliance will promptly report determinations of serious and/or continuing non-compliance made by the convened IRB to the Institutional Official.

b. The Office of the Vice Chancellor for Research will promptly report serious and/or continuing non-compliance to federal agencies and/or sponsor(s), when required.
c. 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 in which the non-compliance occurred;

   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 the non-compliance; and

   vi. Actions the institution is taking or plans to take to address the non-compliance.

Reference


28. Suspension or Termination of Human Subjects Research

28.1. 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.

28.2. 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.

### 28.3. Authority to Suspend or Terminate

#### 28.3.1. 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.

#### 28.3.2. 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.

28.3.3. 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.

28.3.4. **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.

28.4. **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.

28.5. 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.

28.6. 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.

28.7. 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.

28.8. 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 


29. Training in the Protection of Human Subjects 

29.1. Purpose 

The purpose of this policy is to set forth CUNY's requirements for training in the protection of human subjects. 

29.2. Training Requirements 

All key research personnel involved in human subjects research must complete the CUNY-required modules of the Collaborative Institutional Training Initiative’s (CITI) on-line training in the protection of human subjects (basic course) prior to IRB approval of a new or continuing review application, or an amendment application that requests addition of key personnel. Instructions for completing this training are available at http://www.cuny.edu/research/compliance/training-education/citi-training.html. 

29.2.1. Refresher Course
On-line training certificates will be valid for three years. Key personnel are required to take the CITI training in the protection of human subjects (refresher course) every 3 years following completion of the basic course.

29.3. Definition
Key personnel are defined as the Principal Investigator, co-investigators and research personnel who interact directly with human subjects or who have access to private information related to human subjects during the course of a research project. Key personnel also include faculty sponsors /advisors who provide direct oversight of research with human subjects or research using private information about human subjects.

29.4. Non-CUNY Collaborators
CUNY HRPP will accept training in the protection of human subjects provided by and in accordance with the collaborating institution’s policies. IRB approval from the collaborating institution’s IRB will serve as documentation of completion of such training. Collaborators from institutions relying on CUNY UI-IRBs will be required to complete CITI training described in Section 29.2 above.

30. Mandated Reporting in the State of New York

30.1. Overview
New York State Law and/or CUNY policy may require certain professionals to perform certain types of mandated reporting. This document serves as a general guide to some mandated reporting requirements. Please note that these may not be all inclusive. Researchers are responsible for ensuring compliance with reporting requirements as they relate to their specific professions.

30.2. Role of the IRB

a. In as much as is necessary to fulfill the IRB’s responsibility of ensuring that risks to subjects are minimized; informed consent is adequate; and privacy and confidentiality protections are sufficient; the IRB may require a researcher to:

i. Provide his/her analysis of the possibility of a reportable event occurring during certain types of research; and

ii. Indicate his or her legal obligations to report.
b. Based on the information provided by the researcher in 30.2.a. above, the IRB may require that researchers inform subjects, in research consent documents or otherwise, of the investigator’s duty to report to appropriate authorities, and an explanation of how this may affect subject confidentiality.

30.3. **Child Abuse or Maltreatment**

Reference: New York State Social Service Law, Article 6, Title 6, Section 413: *Persons and officials required to report cases of suspected child abuse or maltreatment.*

30.4. **Communicable Disease**
New York State Department of Health’s summary guide for Communicable Disease Reporting is available at https://www.health.ny.gov/professionals/diseases/reporting/communicable/.


30.5. **Wounds**
Certain wounds must be reported regardless of whether they were obtained during the course of the research

Reference: New York State Penal Law, Title P, Article 265, Section 25: *Certain wounds to be reported.*

Reference: New York State Penal Law, Title P, Article 265, Section 26: *Burn injury and wounds to be reported.*