CUNY HRPP Policy: Criteria for IRB Approval

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

6. Informed Consent Process, Documentation and Waivers

The IRBs review the informed consent process and documentation in accordance with CUNY HRPP Policy on 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.

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.

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.

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:
  - Coding data instead of storing it with identifiers
  - Removing identifiable information from documents such as survey instruments
  - Limiting access to identifiable data
  - Training research staff in the importance and methods of maintaining confidentiality
  - Securely storing research data
  - 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

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.

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.

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.

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.

12. Vulnerable Populations

When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired-decision making capacity, 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. 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

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

2. Code of Federal Regulations, Title 21 – Food and Drugs, Part 56 – Institutional Review Boards