CUNY HRPP Policy: Researcher Responsibilities

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.

2. Researcher Defined

For the purposes of CUNY HRPP/IRB, a researcher is any individual who i) serves as the Principal Investigator (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.

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. 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[1] receive either HRPP exemption or IRB approval prior to its initiation (including any subject recruitment)
- Ensure that all IRB approved protocols receive continuing review before the expiration date set forth by the IRB, if any
- Ensure that changes to exempt or IRB approved protocols receive HRPP/IRB review, and exemption or approval, prior to their implementation

[1] To determine whether an activity constitutes human subjects research, please refer to the guidance document, "When is CUNY HRPP or IRB Review Required?"

- 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.

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 HRPP Policies & Procedures.

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*.

2. DHHS Food and Drug Administration (FDA) *Guidance for Industry: Investigator Responsibilities – Protecting the Rights, Safety, and Welfare of Study Subjects*.