CUNY HRPP Policy: Research Conducted in an International Setting

1. Applicability and Purpose

This policy applies to non-exempt human subjects research conducted outside the United States in which CUNY is engaged[1]. 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.

2. Researcher 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

3. Researcher 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[2]
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] For the purpose of this policy, engagement is determined in accordance with OHRP guidance at http://www.hhs.gov/ohrp/policy/engage08.html.

[2] Refer to Section 3.5 of CUNY HRPP Policy: Informed Consent Process and Documentation for requirements regarding acceptable translations

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.

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

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

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