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 site(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](http://www.hhs.gov/ohrp/policy/engage08.html)

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\(^1\) For the purpose of this policy, engagement is determined in accordance with OHRP guidance at [http://www.hhs.gov/ohrp/policy/engage08.html](http://www.hhs.gov/ohrp/policy/engage08.html).

\(^2\) Refer to Section 3.5 of [CUNY HRPP Policy: Informed Consent Process and Documentation](http://www.hhs.gov/ohrp/policy/engage08.html) for requirements regarding acceptable translations.
References


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