

GUIDELINE FOR CONDUCTING INTERNATIONAL RESEARCH

Procedures followed by foreign countries to protect human subjects may differ from those used in the United States (U.S.). As such, when research takes place in a foreign country the RSRB will require additional safeguards to demonstrate equivalency in ethical standards and cultural norms to protect the rights and welfare of human subjects. This guideline provides researchers and the RSRB with the information necessary to conduct international research.

1. Investigator Responsibilities

Investigators conducting international research are responsible for reviewing the provisions provided in the *International Compilation of Human Research Standards* available through the Office for Human Research Protections (OHRP) at:

<http://www.hhs.gov/ohrp/international/index.html>.

- a) Whenever possible, researchers should collaborate with a research or educational institution, or local community representative or government agency familiar with the local culture and research-related issues, as applicable.
 - i. Federally funded research must comply with the appropriate agency procedures and regulations (e.g., FederalWide Assurance (FWA) requirements). Providing equivalent protections is unacceptable in lieu of providing the protections required under the federal regulations. Also, the research must be approved by an appropriately constituted local IRB or ethics committee that uses an acceptable national or international ethical standard as a basis for review. Examples of acceptable standards include:
 - o International Conference on Harmonization (ICH) guidelines,
 - o World Medical Association Declaration of Helsinki, and
 - o Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Biomedical Research Involving Human Subjects.
 - ii. For un-funded research or research that is not federally funded, the Investigator must obtain documentation from a local IRB or ethics review community as noted under 1a above, or in some circumstances where research may be performed in settings where there are no IRBs, the RSRB will require documentation from an entity not affiliated with the particular research project who is familiar with the customs, practices, or standards of care where the research will be taking place, such as local IRBs or ethics committees, local community leaders, or other experts on the region, acknowledging support of the research. Depending upon the type of research to be communicated, the RSRB may require more detail about the acceptability of research procedures, research methods, or consenting practices in the letter to ensure protection of human subjects.
 - iii. The Investigator must include IRB/Ethics Committee approval, or documentation of local community or government letter of support, as well as any informed consent document(s) to be used in the foreign country, in the ROSS application for RSRB review.
- b) For international research, the following should be considered and descriptions included in the protocol, as applicable:
 - Indication of the research or educational institution where the researcher is collaborating.
 - A description of the research location/population.

- Information about local languages to be used in the consent process and qualification of research personnel or others to communicate with subjects in those languages.
 - When requesting waivers or alterations to obtaining consent or documentation of consent for minimal risk studies, the Investigator must provide information justifying the request and, when applicable, explain what equivalent protections will be provided.
 - Information about any local laws of the host country pertinent to the project, and confirmation to the RSRB that the proposed project will follow all local laws, regulations, customs, and practices.
 - Information about any cultural issues that provide context for the need for specialized procedures to either protect subjects or respect their cultural standards.
 - Information about local requirements or customs for obtaining appropriate access to the population.
 - Information on any additional required qualifications of the Researchers and Research Staff for conducting research in the host country.
 - When Protected Health Information (PHI) will be collected as part of the research study, the Investigator is not required to comply with HIPAA while in the foreign country; however, is required to comply with HIPAA when returning to the United States. The protocol should include the method for complying with HIPAA (e.g., de-identification of data prior to returning to the United States).
- c) Investigators, including collaborating Investigators in the foreign country (co-investigators), must provide timely reports on the progress of the research according to [Policy 502 Types of RSRB Submissions](#), and to report any research events to the RSRB according to [Policy 801 Reporting Research Events](#).

2. RSRB Responsibilities

- a) When reviewing international research, the RSRB will apply all federal regulations, guidelines and University policies as if the study were being conducted domestically. This includes the appropriate expertise and knowledge of the country through RSRB membership or consultants according to [Policy 302 RSRB Membership and Composition](#), as well as application of the appropriate criteria for RSRB approval according to [Policy 404 Criteria for Approval of Research](#). In performing its review of the study, the RSRB will take into account the local cultural context of the location where the study will take place; this “local context” will be obtained through the IRB approval or letter of support from the host location.
- b) The RSRB will review the RSRB Online Submission System (ROSS) application, including the protocol and any consent form(s), to ensure that the study is comparable to U.S. standards, especially with regard to a description of procedures, risks and explanations of voluntariness. If they are not comparable, changes or appropriate justification will be required from the Investigator.