International Research

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Policy Statement

Research with human subjects conducted by University investigators in foreign countries remains under University purview and requirements including IRB approval. University researchers seeking to conduct research with human subjects in foreign countries should be mindful that the requirements for prior review and approval of research is not obviated by the location of the study.

Description and Procedures

A. International Human Research Standards

The Office of Human Research Protections has compiled a list of laws, regulations, and guidelines on human subjects protections in over 100 countries and from several international organizations: https://www.hhs.gov/ohrp/international/compilation-human-research-standards/. This compilation should be consulted to determine country-level guidelines applicable to the planned research project. The IRB proposal should include information about the ethics requirements of the country and community where the study will be conducted and provide contact information for that body. The IRB will require additional information and documentation if the research is federally funded.

B. Documentation of International Research Considerations

Researchers will be expected to document relevant experience and expertise related to the cultural norms and conditions of the participants:

1. researcher qualifications (coursework, experience, training, etc.) that demonstrate international research capabilities;

2. description of cultural norms, local laws or regulations that govern the conduct of research at the proposed location (e.g. age of majority, parental consent requirements, prior approvals, conditions for continuation, etc.). The researcher(s) must understand that local requirements may influence the design of the inquiry but compliance with U.S. and UIW regulations for the conduct of research is expected and cannot be waived.

3. researcher identification of the language(s) of the community and ability to read, speak, or write the language of the proposed participants;

4. description of how researcher(s) have appropriate access to the proposed community (e.g. invitation);

5. description of the steps to be taken to minimize risk associated with participation in the proposed study in regards to the cultural, political, religious or economic (or other) climate of the community/country where the research is proposed to be conducted;

6. a translated copy of the consent/assent form (as appropriate) and description of the means by which that translation was conducted;

7. description of the means of communication with the IRB in the event of reportable events or required changes; and

8. if the researcher(s) is a student, description of the means of communication with and supervision by the faculty advisor.

C. Review of International Research Protocols

At UIW, research projects falling under the Expedited and Full Board review categories must have been approved by the local equivalent of an IRB before they are submitted to the UIW IRB. Where there is no equivalent committee, investigators must rely on local experts or community leaders to provide approval. The IRB requires documentation of this "local approval".

D. Informed Consent Requirements

While the IRB at UIW cannot impose standards for written documentation on other cultures, the requirements for consent, assent, cultural responsiveness and ethical conduct of research cannot be waived. However, in some instances the IRB may waive some or all requirements for written consent. Research proposals for which this is requested should include explanations of cultural, religious, or other norms or conditions requiring such as waiver.

Effective Date

August 24, 2020

Revision History

References

International Compilation of Human Research Standards