International Research with Human Subjects- Guidance for Researchers
Purdue University Human Research Protection Program (HRPP)

Introduction

Purdue University researchers proposing to conduct human subjects research outside of the US must confirm that their research fits within the applicable national laws and cultural norms of their study population. All international research studies must adhere to recognized Ethics Codes such as Title 45 CFR 46, the Declaration of Helsinki, the Nuremberg Code, and/or the Belmont Report.

HRPP and IRB Scope

All human subjects research activities must be overseen and conducted by Purdue University personnel responsible for participant safety and monitoring. In any case where work is conducted on behalf of Purdue University by another entity or individual, contractual arrangements and all researcher responsibilities should be finalized prior to submission of an Institutional Review Board (IRB) protocol application. Purdue HRPP/IRB does not have oversight responsibility when investigators are conducting research outside of their Purdue University commitments. The HRPP may also require separate Independent Investigator Agreements and a description of the protections to ensure confidentiality and appropriate monitoring.

A determination from the HRPP/IRB does not waive or supersede requirements for any contractual, legal, procedural, or university process (e.g. contracts or consulting arrangements). Researchers should anticipate that other university processes may need to take place for business, legal, export controls, international programs or university policy reasons. These processes are outside of the HRPP/IRB review process. However, any items related to the protections of participants may be requested by the IRB whenever necessary to evaluate the risk/benefit ratio.

Relevant contact information for related Purdue University departments appears in the list below. This list is not intended to be all-inclusive, but gives examples of things to consider before an IRB application for international human subjects research is submitted. The HRPP advises that these separate matters be addressed prior to (or in parallel with) the submission of an IRB protocol application.

- Export Controls and Research Information Assurance
- Office of Global Partnerships
- International Programs
- Sponsored Program Services Contracting
- Travel

In-Country and Cultural Considerations

The HRPP/IRB must assess risk in a local context. All recruitment materials and methods used for informed consent must be in the language understood by the subjects through either written process or a qualified translator. Please note that all materials must be provided to the IRB in English for review.

Please reference the document requirements below for detailed explanations about the content of these documents.

In-Country IRB or Ethics Committee Approval

Approval from an in-country Institutional Review Board (IRB), Ethics Committee (EC), or country specific equivalent is necessary for studies with the potential to be greater than minimal risk. Many international universities have IRBs or ECs to review and approve research. The US DHHS provides a resource to identify sites that hold

Federalwide Assurances necessary for research sponsored by US federal agencies. Separate institutional contracts and budget matters may also be required for external IRB service fees and terms associated with the IRB or EC review.

Confirmation of Local Authority

In some cases, a local governing body (such as the country's ministry of health) must determine if research can be conducted within the country/community. Many of the international requirements can be found from the US DHHS Office of Human Research Protections international human research standards page, but should be verified on a study-by-study basis. The appropriate regulatory official varies based upon country/location. Principal Investigators have a responsibility to consult the guidance and work with the appropriate entity who will make that determination and obtain written documentation of the necessity for review. Alternatively, the PI may provide written documentation from an appropriate official that the local regulations do not require review.

Memo of Cultural Appropriateness

Researchers must obtain written documentation from a cultural expert who is familiar with the culture of the country/local community where the research will take place. The cultural expert must be completely independent from the research team. A Memo of Cultural Appropriateness must contain all of the following:

- Information about their relevant expertise.
- A specific reference to the title of the study.
- A confirmation statement that the study has been reviewed in full by the expert and that the intent, procedures, and practices are understood.
- A statement that clearly affirms and explains that the work is appropriate for cultural and societal norms practiced within the population.
- Contact information, a signature, and a current date of letter issuance.

This document may be combined with the Confirmation of Local Authority described above, provided all items are addressed.

Letters of Collaboration from External Sites

Research studies conducted at an external site (e.g. business, organization, school, university, etc.) require a documented letter of collaboration from the site. The purpose of the letter of collaboration is to document the site's agreement to grant access for research purposes. For guidance, utilize the template found on the IRB website under "External Collaborators" (here).

Required Documents for Review - Categorized by Risk Level				
	In-Country IRB or Local Ethics Committee Approval	**Confirmation of Local Authority**	**Memo of Cultural Appropriateness**	**Letters of Collaboration for research conducted at external sites**
No Greater than Minimal Risk	No	Yes	Yes	Yes
Greater than Minimal Risk	Yes	Yes	Yes	Yes