International Research Guidance and Worksheet

When research takes place in a foreign country, procedures normally followed in the foreign country to protect human subjects may differ. According to the NIH, when research takes place in a country with human subjects protection laws equivalent to or more stringent than those of the United States, researchers should conform to local law. Where local human subjects protections are less stringent, researchers should conform to United States law. To ensure that your research is sensitive to local customs/rules and is compliant with the relevant laws, the IRB expects that you understand and demonstrate cultural understanding and sensitivity and that you understand the research ethics guidelines of the country in which research will be conducted. If you have not already, please review HRPP/IRB [SOP 31.0](http://research.unc.edu/files/2014/05/2014-04-24-OHRE-Standard-Operating-Procedures-FINAL-CLEAN.pdf), International Research.

There are several ways to obtain this knowledge, depending on the nature of the proposed research and location.

1. It should first be determined whether a local IRB or other analogous review body exists. It may be required to use the local IRB, if they have jurisdiction over the site where research will be performed (e.g., the IRB for a collaborating investigator or a ministry for the entire country).
2. Even when local IRB approval is not required, the local IRB may be an appropriate source for local context and guidance. If a local review body does not exist or is not available to review the protocol, information can be obtained from appropriate consultant(s), e.g., an in-country expert with direct knowledge of the local context. This can be submitted to the IRB as a letter from the expert that confirms that the study has been reviewed and is compliant with local laws and is sensitive to local customs and rules. This generally only applies to research that is determined to be of minimal risk (the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests) to subjects.

[The International Compilation of Human Research Standards](http://www.hhs.gov/ohrp/international/index.html) is a listing of over 1,000 laws, regulations, and guidelines on human subjects protections in over 100 countries and from several international organizations. Many of the listings embed hyperlinks to the source document. These laws, regulations, and guidelines are classified into seven categories:

1. General, i.e., applicable to most or all types of human subjects research
2. Drugs and Devices
3. Research Injury
4. Privacy/Data Protection
5. Human Biological Materials
6. Genetic
7. Embryos, Stem Cells, and Cloning
8. In some cases, investigators and faculty advisors or their on-site collaborators may be able to provide sufficient insight to the IRB. In this case, please provide a justification for not including local IRB approval or a letter from an in-country expert by responding to question #7 on the attached worksheet.

**All applicants must complete the following worksheet and upload in the Attachment section of the IRB application.**

**Delete page 1 (guidance and instructions) prior to submitting the International Research Worksheet.**

**International Research Worksheet:**

1. **Provide a description of the context of cultural norms or local laws and differences with U.S. culture with respect to autonomy of individuals or groups, consent procedures, recruitment techniques and age of majority. Include an explanation of what cultural sensitivities will be required to conduct the study.**
2. **Describe the qualifications the researcher has in relevant coursework, past experience or training to justify his/her international research capabilities.**
3. **Explain the researcher’s ability to speak, read or write the language of the potential participant.**
4. **Describe what knowledge or expertise the researcher has of the local, state or national laws that may impact the research.**
5. **Describe if the researcher was invited into the community or how the researcher will gain culturally appropriate access to the community.**
6. **If the researcher is a student, describe how the student will communicate with the faculty advisor while conducting the research. Describe how the advisor will oversee research activities.**
7. **If you have not obtained documentation of local IRB or other ethics approval, please provide justification.**

**Please submit the completed worksheet as an “Attachment” in IRBIS. Select Document Type “International Research”. When naming your document, please include the word “worksheet”.

Documentation of local IRB or other ethics approval: Please upload as “Attachment”. Select Document Type “International Research”. When naming your document, please include the word “worksheet”.**