

## **International Research Information**

The Office for Human Research Protections (OHRP) website has important information about international research.

It lists laws, regulations, and guidelines on human subjects protections in over 100 countries and from several international organizations. This document should be consulted to determine country level guidelines on human subject research. Many of the listings embed hyperlinks to the source document. These laws, regulations, and guidelines are classified into six 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

## Things to Include In Your Application For International Research

You should state explicitly in your application that you have reviewed the appropriate regulations for the country you plan on doing research in and discuss relevant issues.

All documents/instruments must be submitted to the IRB in English. If they are to be translated, describe the process and the qualifications of the person doing the translation (professional or life experience).

The project should be approved by the local equivalent of an IRB before it is submitted to the Fairfield University IRB. Where there is no equivalent board or group, investigators are expected to consult with local experts or community leaders about the project and to secure their support for the conduct of the research. The IRB requires that there be good faith effort applied to secure local cooperation for the research and to document those efforts as part of the application.

Special attention should be given to local customs and to local social, cultural, and religious realities in drafting written consent documents or proposing alternative consent formats. In some instances it may be appropriate for the IRB to waive some or all requirements for written consent in favor of verbal consent. Research proposals for which this may be reasonable should include explanations of cultural norms or conditions requiring such a waiver. While we cannot impose our standards for written documentation on other cultures, we do not relax our standards for ethical conduct of research or for a meaningful consent process.