



IRB Toolbox

IRB Review of International Research

The ever changing and expanding landscape of the university—based research environment is providing an increasing number of opportunities for faculty and students to conduct research in foreign countries. It is important to note that human subject research conducted by OSU investigators in foreign countries remains under the purview of OSU and must be reviewed by the OSU IRB. This poses a challenge to the IRB, because the IRB must evaluate the research based, not only, on Western ethical standards, but also the values and customs of the region where the research is being conducted.

When applying to the IRB for review of research to be conducted internationally, the researcher should address or include the following in the application package (in addition to items required as a standard application):

- Location of the research;
- For research reviewed at the expedited or full board level, documentation of review by the local equivalent of an IRB, or description of how local approval or support of the research will be obtained;
- Description of the consent process;
- Translated versions of any recruiting documents, consent documents and instruments/questionnaires/interview questions.

The requirements and customs for documenting informed consent vary widely among cultures. The IRB cannot exempt human subject research conducted in foreign countries from the consent requirements, but in some instances it may be more appropriate for the IRB to waive some or all of the requirements for written documentation of consent, understanding that in some settings, the process of signing the form is very intimidating and may be riskier than the research itself. In the IRB application, researchers should thoroughly explain their proposed method of documenting consent. The explanation should include a description of local customs or social structures in the foreign country, especially if they constrain the typical informed consent process. Researchers should provide participants in foreign sites local contacts so that they may ask questions about the research or about their rights as a research volunteer.

For research expected to be reviewed at the expedited or full board level, researchers must also provide documentation that their research has been approved by the local equivalent of an IRB. The Office of Human Research Protections (OHRP) has compiled a listing of the laws, regulations and guidelines that govern human subjects research in many countries around the world. This can be found on the OHRP web site at <http://www.hhs.gov/ohrp/international/HSPCompilation.pdf>. Where there is no equivalent board or group, researchers must rely on local experts or community leaders to provide approval.

For assistance in preparing an application for international research, please contact the OSU IRB Manager at 405-744-5700 or dawnett.watkins@okstate.edu.



