IRB International Research Requirements

IRB review and approval of international research involves a number of challenges, including local laws and customs, translation of consent and research materials, and the security of subjects and data. The IRB must be convinced that the researcher has the depth of understanding of the ethical challenges, risks and benefits, as well as the ability to deal with unexpected or adverse events in the research locale in order to approve the research. These procedures apply to both minimal risk and greater than minimal risk research.

Research conducted in collaboration with a foreign institution may require a formal agreement delineating the authorities of the local IRB and the ISU IRB to assure the appropriate level of review is taking place. For research projects being conducted under an organization such as the Peace Corps, appropriate approval from the organization must be submitted along with the protocol.

Letters of agreement from the appropriate officials (e.g., government officials, school officials, community officials, Chief Executive Officers, etc.) indicating that the research protocol and any and all instruments to be used (including any biomedical equipment) have been reviewed and are acceptable to those officials are to be submitted.

Local Issues/Concerns

The IRB must ensure that the proposed research is culturally appropriate in the local setting where it is to be conducted. Local community/ethical concerns and laws, subject population, institutional policies and values must be taken into account along with the country's laws regarding human subjects research.

Because the ISU IRB may not be able to be fully aware of the local research context, PIs are responsible for determining if local research and/or ethics reviews are also required. Any required approval should be obtained prior to submission of the ISU IRB protocol and attached thereto. PIs should consult the federal Office for Human Research Protections (OHRP) detailed International Compilation of Human Research Standards database for information regarding many countries at www.hhs.gov/ohrp/international.

PIs should also be aware of any travel warnings or alerts pertaining to their research activities. The U.S. Department of State travel warnings, as well as general information about the country and U.S. embassies therein, may be found at www.travel.state.gov/travel.

PIs will be expected to describe the international site(s) and provide information on local contacts or investigators. They must also describe any cultural, political, religious, or other local influences that may
affect conduct of the proposed research and how these will be addressed (e.g., issues posing potential threats, requiring changes in recruitment methods, etc.). Of particular concern is the privacy and safety of the participants. The PI must be very careful on promises of privacy or safety made to participants. In some countries, just interacting with the researchers may make the participants vulnerable. PIs should be aware that changing political climates affecting the risks and benefits of their research may require changes to or even suspension of their protocols. PIs should also be aware that local concerns may affect the level of risk, and therefore the level of IRB review required.

Researchers should also be prepared to describe their experience with conducting research (or studying or residing) in the research setting, including any relationship(s) with the community from which participants will be recruited. The IRB may require contact information for individuals who are not affiliated with the research (or researchers) who are knowledgeable about the location and population who could serve as a consultant(s) regarding the proposed research. PIs should also describe communication and oversight plans between the researchers(s) who will be on-site and those at ISU.

When appearing before the IRB to answer questions about the research, it is helpful if an individual who is familiar with the culture (unless the researcher is recognized as an "expert") can accompany the researcher.

Translation

Per federal regulations, the consent process and documents as well as study-related documents (e.g., survey instrument, medical release forms) for participants not fluent in English must be presented in a language (preferably native) understandable to them. If it is expected that participants who do not speak English will be enrolled in a study, translated documents should be made available.

PIs will need to list the language(s) in which the research will be conducted on the protocol and indicate whether a member of the research team is fluent in the language of the potential participants so that questions or concerns of the participants may be appropriately addressed.

The IRB must approve non-English language versions of written or oral consent documents and all survey instruments as a condition of approval under 45 CFR 46.117(b)(2) paying careful attention not only to the accuracy of the translation, but the level of understanding of the subject population, as well as any cultural elements specific to the population. For specific requirements, please refer to the IRB Translation Policy and Procedures on the REC website at rsp.illinoisstate.edu/research/human_subjects/
Informed Consent Considerations

PIs should be prepared to describe any local exceptions to the required consent process and how these will be addressed (e.g., a request from outsiders to sign documents would be treated with suspicion based on customs, previous history, etc.). PIs should also be prepared to provide local contact information for participants who have questions or issues with the project.

If the research includes enrollment of children in other countries, the PI is responsible for providing the IRB with sufficient information to verify the age at which participants in such jurisdictions have the ability to consent to participation in research, including any medical treatments or procedures if applicable. The IRB may, if it appears advisable, require the submission of an opinion rendered by an appropriate authority from the applicable jurisdiction on the age at which an individual can consent to participation in research.

If local customs and regulations are such that active parental permission would be culturally inappropriate, the researcher must supply the IRB with proof of this. Examples of such proof would be specific regulations (in English and certified to be accurate) indicating that such permission is not required, an official letter from a ranking official in the country of interest indicating such, or an expert opinion from another ISU employee (preferably a faculty member) who can attest to the cultural inappropriateness of the requirement for active parental permission. In these cases, a waiver of such permission may be granted at the discretion of the IRB, as long as the research does not place the participants at untoward risk. Regardless, the participants in the research retain the right to discontinue participation, without penalty, at any time during the gathering of data.

If a waiver of active parental permission is granted, a letter informing the parents of the research, written at a literacy level that would be understood by the parents, may be required and should be prepared and sent to the parents by the most expeditious method possible.

Data Collection/Security Issues

As with all protocols, issues regarding data collection and security must be addressed both in the protocol and the informed consent process. Specific processes for assuring anonymity and/or confidentiality of all data must be specified in the protocol, particularly if the analysis will occur away from ISU. Issues to be addressed may include encryption procedures and the timing thereof, how and the data will be moved out of the country, and who might intercept the data and the possible consequences thereof.

If data will be collected by someone other than the researcher, that individual or individuals must be included in the protocol and have completed appropriate IRB training. ISU’s participation in the CITI
training program allows for individuals not otherwise affiliated with ISU to complete training through our program. If the data collector(s) will have access to the data, such access must be specified in the protocol and informed consent process as well.

Compensation

If compensation is being offered, it should be appropriate for the setting. What may be considered minimal compensation in the U.S. may be a windfall in another country.

Benefits

Under the Belmont Report principles, subjects should not bear the burden of the research without reaping some benefit therefrom. PIs will be expected to explain any benefits to the local community that will remain with the community once the research is complete.

If the research will involve medical procedures and/or treatment, PIs must indicate if any planned research procedures are considered to be standard of care in the country or location, and to describe provisions for emergency treatment that are available in the location.

For more information, please contact Research Ethics and Compliance at 309-438-2529 or rec@ilstu.edu.