

IRB GUIDANCE FOR INTERNATIONAL RESEARCH

Human research conducted by University of Dayton faculty, staff or students is reviewed, approved and overseen by the Institutional Review Board (IRB). Here we describe the general process used to review and approve international human research studies. We believe this approach strikes a realistic balance between minimizing risk to human research participants, minimizing liability exposure to UD, and supporting high quality international research experiences for our faculty, staff and students.

In general, the IRB has determined that best practices for international human research dictate the following approval process:

(1) The researcher must become knowledgeable of, and comply with, the foreign country's rules and regulations related to human research studies. If the researcher is a student, it is the responsibility of both the student *and* the faculty advisor to become knowledgeable about, and to comply with, the regulations of the country in which data collection will occur. *The faculty member will be responsible for confirming the student is knowledgeable about the local environment related to human research.* The best resource for such information is the DHHS's International Compilation of Human Research Standards, found at: <http://www.hhs.gov/ohrp/international/intlcompilation/intlcompilation.html>.

(2) The researcher must obtain and document all local approvals in the foreign country prior to applying to UD's IRB for approval. UD's IRB will use the U.S. federal regulations and DHHS guidelines for human research protections in the U.S. as the minimum protection standards when reviewing a protocol. The application package for international research will include foreign approvals, proof of knowledge of local rules and regulations, and additional oversight and contact information (see #3 below). Applications proposing to collect data in a foreign country must include the Additional Information for International Human Research as an appendix (form is attached here on pages 2 and 3).

(3) Researchers must provide plans for additional in-country oversight and contacts. Depending on risk levels, student researchers may be required to recruit a faculty member from an institution in-country to supervise obtaining proper approvals and to be available to consult by phone during data collection. IRB Applications must include how language differences will be handled, how local customs and culture might impact recruitment, consent, and data collection, and for student research, how the UD faculty advisor will oversee the project from the U.S.

(4) Student research in foreign countries will only be permitted if the study is determined by the IRB to be minimal risk (i.e., eligible for expedited review by the IRB). This restriction may be lifted after a period of time where international research studies have proven to be amenable to IRB oversight. **Please contact the IRB@udayton.edu for additional information regarding risk determinations.** It is best to make this contact BEFORE designing your research.

PLEASE NOTE It is critical that you work with the IRB throughout the process of planning your international research project. Please e-mail the IRB@udayton.edu as soon as you determine an interest in international data collection.

Additional Information for International Human Research

(Form adapted from University of Minnesota)

This form should be included with your IRB application. *PLEASE NOTE* It is critical that you work with the IRB throughout the process of planning your international research project. Please e-mail the IRB@udayton.edu as soon as you determine an interest in international data collection.

Research conducted by University of Dayton investigators falls under University oversight and guidelines even when conducted elsewhere. Research projects must have been approved by the local equivalent of an IRB in the foreign country before they can receive final approval from the University of Dayton IRB. When there is no equivalent board or group, investigators must rely on local experts or community leaders to provide approval. The IRB requires documentation of this "local approval" before it gives its approval. The best resource for such information is the DHHS International Compilation of Human Research Standards, found at: <http://www.hhs.gov/ohrp/international/intlcompilation/intlcompilation.html>.

- 1. Describe qualifications the researcher has in relevant coursework, past experience, or training to justify his/her international research capabilities.**

- 2. Provide a description of the context of cultural norms or local laws and differences with U.S. culture with respect to research autonomy of individuals, or groups, consent procedures, recruitment techniques, age of majority, if parental consent is required, etc. Include an explanation of what cultural sensitivities will be required to conduct this study.**

Consider current events (Attach additional documentation if necessary):

- 3. Explain the researcher's ability to speak, read, or write the language of the potential participants. Describe the primary language(s) spoken in the community. Explain provisions for culturally appropriate recruitment and consent accommodations such as, translations or involvement of native language speakers.**

- 4. Describe if the researcher has the knowledge or expertise of the local or state or national laws that may have an impact on this research. The researcher must understand cultural or community attitudes to appreciate laws, regulations, or norms and remain in compliance with U.S. regulations for the research as well as local requirements.**

Consider current events (Attach documentation if necessary):

- 5. Describe if the researcher was invited into the community. If yes, then provide documentation of the collaboration. If not, describe how the researcher will have culturally appropriate access to the community.**

6. Provide information about the ethics committee (IRB equivalent) or other regulatory entity requiring review of the research in the host country that will review the protocol/project. Provide contact information for the local entity. If this research is US federally funded, additional documentation and inter-institutional agreements will be needed. (contact the IRB office for assistance):

7. Describe any aspects of the cultural, political or economic climate in the country where the research will be conducted which might increase the risks for participants. Describe the steps you will take to minimize these risks:

8. Describe how you will communicate with the IRB while you are conducting the research in the event that the project requires changes or there are reportable events.

9. If the researcher is a student, describe how the student will communicate with the advisor during the conduct of the research, how the advisor will oversee the research, and who will be the on-site faculty mentor equivalent (i.e., a faculty member from a university in the country).

10. As separate attachments, please provide both translations of consent documents.

PLEASE NOTE It is critical that you work with the IRB throughout the process of planning your international research project. Please e-mail the IRB@udayton.edu as soon as you determine an interest in international data collection so we can assist you in developing your application. For more information and guidance on how to help the IRB review your project efficiently, go to: <https://www.udayton.edu/research/compliance/irb/index.php>.