UWG Institutional Review Board
ORSP Office – 316 Ingram Library
1601 Maple Street
Carrollton, GA 30118
Phone: 678/839-6119 / irb@westga.edu

IRB Review of International Research

When conducting international research, additional review and documentation are required from both the international site and the UWG IRB. We recommend you start the process early and request a consultation with the IRB while planning your project. While UWG does not impose our standards on other cultures, we do not relax our standards for ethical conduct in research. When research is conducted outside the United States, investigators must comply both with the U.S. regulations and with the local policies and regulations governing the international research sites. This is true whether the researchers are traveling to the foreign location or conducting their research remotely.

The Office of Human Research Protections (OHRP) publishes the International Compilation of Human Research Standards, a listing of over 1,000 laws, regulations, and guidelines on human subjects protections in over 100 countries and several international organizations. Researchers should check this document to determine the countries applicable laws, regulations and guidelines on Human Subjects Research.

Depending on the nature of the proposed research and the location, researchers should take the following steps:

1. Determine if a local IRB or comparable review body exists. If a local IRB has jurisdiction over the site, you may be required to use them (such as the IRB for a collaborating investigator or a ministry for the country in question).

   The local ethics committee may be referred to as an Institutional Review Board (IRB), an Independent Ethics Committee (IEC), an Ethical Review Board (ERB), or Research Ethics Board (REB). Investigators are required to obtain IRB approval for research done internationally from the UWG IRB and also from the local IRB/Ethics Committee within the country in which they will be doing their research, if one exists. Please visit the International Compilation of Human Research Standards for assistance with countries' laws, regulations, and guidelines.

2. Even if local IRB approval is not required, a local IRB still may be the most appropriate source for local context and guidance. If a local body does not exist or is not available to review the proposed research, review can be obtained from an appropriate consultant, such as an in-country expert with direct knowledge of the local context or a community

leader. This can be submitted to the UWG IRB to verify that the study has been reviewed, is compliant with local laws, and is sensitive to norms and rules in the local context. This is generally appropriate for research that is considered to be minimal risk, or where the possibility of harm or discomfort is not anticipated to be greater than that encountered in everyday life.

Review Documentation Required for Minimal Risk Studies

Based on local requirements, please submit one of the following:

- A Letter of approval from an Ethics Committee. This must:
  - Reference the title of the study displayed in the IRB application
  - Clearly state the planned research was reviewed and approved
  - Have the date of completion
  - Be provided on the official letterhead of the signatory
  - If the document is not in English, an English translation should be provided.
- Documentation that the local regulations do not require a local ethics review. This could take multiple forms, including:
  - Direct references to the local regulations that state ethics review is not required, OR
  - Documentation from a regulatory official indicating that the study does not require local review, in the form of an Acknowledgement of Unregulated Research Activities (PDF) letter. This must:
    - Be provided on the official letterhead of the signatory
    - Have the date of completion
    - Clearly state the planned research does not require local regulatory oversight
    - Confirm the Regulatory Official understands the intent of the research and activities to be performed
    - Reference the title of the study displayed in the IRB application
    - If the document is not in English, an English translation should be provided.
  - Documentation from a local expert or community leader verifying that local regulations do not require an ethics review or do not speak to this issue and noting that this person has reviewed the proposed research and finds it acceptable regarding the laws, rules, norms, customs, and values of the local site. This should take the form of a Memo of Cultural Appropriateness (PDF) authored by an individual completely independent of the study who is highly knowledgeable about the culture in the region where the research will be conducted. This document must be specific to the proposed research. Blanket statements about research within a particular country or culture are not sufficient. This memo must:
    - Reference the title of the study displayed in the IRB application

  - Describe the expertise of the individual preparing the letter to address the local cultural and social norms
  - Confirm they understand the intent of the research and activities to be performed
  - Confirm the planned study does not conflict with local and cultural norms
  - Document is dated
  - If the document is not in English, an English translation should be provided.

If the culture of the research location is suitably similar to the United States, this requirement may be waived if the PI provides what the IRB deems to be sufficient reasoning.

Review Documentation Required for Greater than Minimal Risk Studies

Studies that are designated as greater than minimal risk require a formal ethics review within the country where the research will be conducted. Not all countries have an ethics review committee; if the country in question does not, this may be addressed by a different, appropriate governmental entity. Researchers must submit:

- A Letter of Approval from an Ethics Committee, including:
  - Reference the title of the study displayed in the IRB application
  - Clearly state the planned research was reviewed and approved
  - Document is dated
  - Provided on the official letterhead of the signatory

Guidance on Timelines for Submitting UWG IRB Applications

Minimal Risk applications should be submitted a minimum of 2 months prior to investigator approval deadlines. Submission 3 months prior is highly encouraged.

For Greater Than Minimal Risk applications, the location and topic of the research may require the UWG IRB to employ a foreign consultant with the appropriate expertise to assist in the ethical review. Locating and enlisting the assistance of consultants may make the review process take significantly longer.

Do not make any specific travel plans or purchase plane tickets until you have received all foreign and domestic approvals. There is no guarantee of IRB approval by a given deadline. **The IRB expects researchers to obtain IRB approval before a study begins**

As you plan international research, please keep the following in mind:

The IRB expects researchers to demonstrate cultural understanding and sensitivity. The IRB protocol should describe any anticipated cultural sensitivities related to conducting research and how the researcher(s) intends to overcome those barriers. The researcher(s) should be familiar with local customs, culture, and religious norms in the country where the study will be conducted. This may include cultural differences in signing consent forms, recruiting participants, or cultural barriers to fieldwork.

Both the U.S. and host country standards for protecting human participants must be respected through the IRB review process and the conduct of the research. Where the two sets of standards present a conflict, the research must meet the higher standard. For example, with all due respect and sensitivity for local customs, minors who are treated as adults in their own country will be treated as minors for the purpose of protection in research. However, the definition of who may provide 'parental permission' to participate may appropriately be adjusted based on cultural norms. It is possible that grandparents or even tribal leaders may be the cultural head of household and may ethically serve as the designated guardian for a minor participating in research. That said, the cultural norms in question must be identified in the research protocol and the exception to policy anticipated.

The IRB expects researchers to demonstrate knowledge of data laws. While not specifically under the IRB's domain, there are some restrictions on bringing identifiable data into/out of some countries. The EU, for example, has laws surrounding what kind of identifiable information can be taken out of Europe and brought to the US (this applies to electronic data that will be housed on a US server as well). Data export laws may also affect your research in countries with which the US has embargoes or trade restrictions, such as Iran. This knowledge should be expressed in the IRB application. If you plan to conduct research in a country under embargo, sanctions, or heightened risk and are uncertain how export control may apply, contact Export Control at ITAR@westga.edu to determine if additional action is required or if the activity may proceed before submitting your application to the UWG IRB.

What information should be included in the IRB application?

In your IRB submission, it is important that you tell us what you know about the country where the study is being conducted. The IRB relies on the information you provide to help assess whether the rights protections are in place for subjects. Your IRB protocol should describe relevant local context information, any anticipated cultural sensitivities of conducting your research and how you intend to overcome those barriers. This should include, but is not limited to, the following:

Demographics of the research site, including:

- Cities, regions, countries where research will be conducted

- Economic status of the country/community
- Literacy rate of the potential subject population
- Languages and dialects of the potential subject population

Research rationale and justification, including:

- Scientific/ethical justification for conducting the research in an international setting
- Relevance of the research to the area's health, economic, educational, or other needs
- Distribution of risks and current and future benefits

Cultural, religious, or societal beliefs/norms and/or environmental factors that may impact the research, including:

- Current events or socio-political environment in the country that may impact research conduct or alter the risks or benefits to subjects
- Societal and cultural beliefs in the country that may impact research conduct or alter the risks or benefits to subjects
- The role of women and children in the society, including their autonomy and legal capacity to make decisions

The consent process with cultural norms and sensitives in mind. The IRB will consider alternative consent form formats or methods if culturally appropriate. In some instances, it may be appropriate for the IRB to waive some or all requirements for written consent in favor of a verbal consent for cultural, religious, or literacy reasons. Research proposals for which this may be reasonable should include explanations of cultural norms or conditions requiring such as waiver (e.g. societies where no written language is used, or societies where signatures represent the surrender of spirit or soul to the researcher). Additionally, the consent form should be submitted in both the local language of the host country and in English. Please clearly label each form for the IRB. The application should also indicate who conducted the translation of the forms and provide a letter certifying the translations are correct. In cases of minimal risk research, it can be acceptable for a member of the research team who is a native speaker to provide the translation. The IRB application should note the qualifications of the person who conducted the translation.

The research team's experience and engagement with the host country, including:

- Involvement of organizations, community leaders, or experts in engaging the subject population or conducting the research
- Description of the research team's knowledge of or experience in the host country as well as their qualifications for performing research in this location (e.g. coursework, training, experience, etc.)
- Your ability to speak, read, and write the language of potential participants. If needed, provisions for research assistants or translators should be explained.
- Description of if you were invited into the community to conduct research. If not, description of how you will have culturally appropriate access to the community.

- If applicable, describe collaboration with local researchers, university, etc.

Any proposed compensation (payment, gifts, incentives, etc.) for subjects. Researchers should be mindful that compensation is intended to reflect participants' time, effort, and costs without unduly influencing decisions to participate in the research. Compensation in international contexts should take the local economic context into account and provide information including:

- Specific description of the compensation (payment, gifts, incentives, etc.)
- Value both in U.S. and local currency
- Local household income information (e.g. how much an average household earns in a month or a year in U.S. and local currency), to the extent that this information is available in the country in question
- When compensation will be given during the study (the payment schedule)
- To whom compensation will be given
- Whether the compensation could pose undue influence on the subject's decision to participate.

Data storage at all stages of the project. Note where the data will be stored while you are collecting it in the host country, while you are traveling back to the US and once you arrive here.

If the proposed research will be conducted by a student, describe how the PI will oversee the student researcher during the course of the project.

What language(s) should documents be submitted in?

All documentation, including ethics reviews, site permissions, and memos of cultural appropriateness, must first be submitted in English. Once conditional approval is obtained, the PI must submit translations of all pertinent documentation into the local language of the host country. This includes, but may not be limited to, recruitment materials, informed consent/assent documentation, and information sheets. Local contact information should be provided for participants to contact about research related questions.

When are site permissions required?

When research is conducted at any site other than UWG or UWG facilities, an authorized individual from the proposed research site must provide written permission that the research can be conducted. This requirement may be waived if the local ethics approval affords access to the site, if research will be conducted in a truly public location, or if the research is conducted remotely. A Site Permission Letter (PDF) from authorized individual must:

- Reference the title of the study displayed in the IRB application

- Confirm the authorized individual understands the intent of the research and activities to be performed
- Include a statement permitting the research to be conducted at that site
- Include signatures and date of completion

If obtaining written site permission is not culturally appropriate due to low literacy rates or cultural norms, this justification should be provided to the IRB with the application. Similarly, if you are unable to obtain written site permission prior to travelling to the international site due to technological barriers, please explain this in the application.

Do researchers need a local collaborator?

It is important to do your homework early and, whenever possible, enlist a local collaborator to help you address that site's requirements. Such a collaborator can assist in identifying who to contact and what is required to obtain ethics reviews and permissions to conduct research at that international site. Based upon study location and risk level, the IRB may require a local site collaborator. Investigators are strongly encouraged to collaborate with an individual or organization with expertise in the region.

What if a study is Federally funded?

The OHRP International Program works to ensure that human subjects outside of the United States who participate in research projects conducted or funded by HHS receive an equal level of protection as research participants inside the United States. Research studies supported by US Federal funds are required to undergo foreign IRB review by an Ethics committee that holds a Federal Wide Assurance (FWA). Federally funded research studies can search the OHRP "Database for Registered IORGs and IRBs, Approved FWAs and for Documents Received by OHRP in the Last 60 days" to locate foreign IRBs that hold an FWA:

- Choose the "FWAs" tab
- Press the "Advanced Search" link
- Select the appropriate country & Search

Non-federally funded studies can use this same search to locate and contact a foreign ethics committee/IRB. There is a single version of the FWA and the Terms of Assurance for U.S. and non-U.S. institutions. For additional information see here.

Please contact the IRB while abroad if you encounter any problems or need to change your IRB-approved protocol. If you find that upon arrival in the host country, some aspects of your research study must be modified for whatever reason, please notify the IRB office immediately. The IRB will do its best to quickly respond to your notification with further instructions and guidance. Please wait to hear back from the IRB before making any changes to your protocol!