**International Research Guidelines:**

**Conducting Human Subject Research Outside of the United States**

Conducting research in an international setting poses unique challenges. The information below provides guidance to TCU faculty and students engaging in human subject research in foreign countries.

TCU faculty and students conducting human subject research must obtain IRB approval from the TCU IRB before beginning any research activities at an international site.

Each country has different cultures and values, and it is crucial to understand the local context. As a result, the TCU IRB expects you to acknowledge and understand the following:

* **You must obtain IRB approval before your study can begin**. Whether you are faculty member, staff or student, your research study must be approved by the IRB before it can begin. To avoid confusion, make sure you have the IRB’s approval before you leave the country. As additional review and documentation may be needed, the application timeline can be lengthy. It is advised to start the process early and expect delays.
* **Demonstrate cultural understanding and sensitivity**. Your IRB protocol should describe any anticipated cultural sensitivities of conducting your research and how your intent to overcome those barriers. The researcher should be familiar with local customs, culture and religious norms in the country where the study will be conducted. Is the typical process of signing an informed consent document culturally acceptable for your study? How should recruitment be done? Are there other cultural barriers you might encounter once you arrive? The IRB will consider alternative consent form formats or methods if culturally appropriate.
* **Understand the research ethics guidelines of the host country**. Investigators will be required to obtain IRB approval for research done internationally from the TCU IRB and also from the local IRB/Ethics Committee within the country in which they will be doing their research. This approval must be on file with the IRB prior to IRB approval being granted. The IRB strongly recommends you clearly understand the host country’s requirements for reviewing and approving human subject research Some countries have clear ethical guidelines that must be met for conducting domestic and/or international research. Other countries will not have a formal process but might rely on another neighboring countries to assist with the review. Where there is no equivalent board or group, researchers must rely on local experts or community leaders to provide approval. If the researcher has difficulty determining the existence of an IRB/Ethic Committee in the foreign country, they should contact the IRB.
* **Know the data laws**. While not specifically under the IRB’s domain, you should know what that 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 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.

What information should be in your IRB protocol/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 assess whether the right protections are in place for participants. In addition to the usually required information submitted for review to the IRB, the following points should be addressed.

* 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 of conducting your research and how your intent to overcome those barriers. This should include, but not limited to the following:

1. Cities, regions countries where research will be conducted
2. Scientific/ethical Justification for conducting the research in an international setting
3. Economic status of the country/community
4. Current events or socio-political environment in the country that may impact research conduct or alter the risk or benefits to participants
5. Societal and cultural beliefs in the country that may impact research conduct or alter the risk or benefits to participants.
6. The role of women and children in the society, including their autonomy and legal capacity to make decisions.
7. Literacy rate of the potential subject population
8. Languages and dialects of the potential participant population
9. Involvement of organizations, community leaders, or experts in engaging the participant population or conducting the research
10. Description of the research’s knowledge of or experience in the host country
11. Relevance of the research to the area’s health, economic, educations, or other needs
12. Distributions of risk and current and future benefits
13. Detail any proposed remuneration (payment, gifts, incentives, etc.) for subjects including:

* Specific description of the remuneration (payment, gifts, incentives, etc.)
* Value both in US and local currency
* Local household income information (e.g. how much an average household earns in a month or a year in US and local currency
* When remuneration will be given during the study (the payment schedule)
* To whom remuneration will be given
* Whether the remunerations could pose undue influence or on the participant’s decision to participate.
  + Approval letter from the local IRB/Ethics Committee within the country where research will be conducted. equivalent board or group, researchers should provide an explanation of such and should consult with local experts or community leaders to provide an approval letter that the research as proposed meets local standards.
  + 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.
  + Local contact information for participants to contact about research related questions.
  + Recruitment materials to be used in both the local language of the host country and in English.
  + Describe how you will keep your data secure at all stages: while you are collecting it in the host country, while you are traveling back to the US and once you arrive here.

**Additional Resources**

* The Office of Human Research Protections (OHRP) publishes the [International Compilation of Human Research Standards](http://www.hhs.gov/ohrp/international/index.html), 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 Researcher.
* The Office of Human Research Protection (OHRP) has issued a[Listing of 27 Social-Behavioral Research Standards](http://www.hhs.gov/ohrp/international/social-behavioral-research-standards/index.html). This includes laws, guidelines, and regulations applicable to social-behavioral research around the world.