Tulane University Human Research Protection Program
International Research Guidance Document

The Tulane University IRB is responsible for ensuring that human research conducted outside the US conforms to the same ethical and regulatory standards to which research conducted in the US is held. International human research must be conducted in accordance with applicable Tulane University HRPP Policies for the conduct and review of human research, including informed consent and the use of vulnerable populations.

Tulane University researchers who will be conducting research abroad should keep in mind the following important tips:

- **YOU MUST OBTAIN INSTITUTIONAL REVIEW BOARD (IRB) APPROVAL BEFORE YOUR STUDY CAN BEGIN.**

  Whether you are a Tulane University faculty member, staff, or student, your human subjects’ research study must be approved by the IRB before it can be implemented.

  *We suggest you apply to the IRB at least two months before you leave to ensure adequate time for review and approval before leave the country. Bring your IRB approval letter with you on your trip.*

- **DEMONSTRATE CULTURAL UNDERSTANDING AND SENSITIVITY.**

  In preparing your research project, consider that you may encounter cultural barriers. For example, obtaining signed consent from human subjects may not be culturally acceptable in the country where you will be obtaining your research. Your application and protocol should describe any anticipated cultural sensitivities in conducting your research and how you intend to overcome those barriers. Special consideration is needed for: local laws, customs, political factors and sensitivities, licensing for special equipment (e.g., video and voice recordings), language (including whether you will need a translator), and the literacy level of your subjects.

- **UNDERSTAND THE RESEARCH ETHICS AND GUIDELINES FOR THE HOST COUNTRY.**

  In addition to Tulane University approval, you will need to obtain approval from a Local IRB/Ethics Committee, or research permits from the country in which you will be conducting research. This process can take several months or more. This approval must be on file with the IRB before IRB approval is granted. Please refer to *The International Compilation of Human Research Protections* from the Office of Human Research Protections. This document is a listing of the laws, regulations, and guidelines that govern human subjects research in many countries around the world:

  [http://www.hhs.gov/ohrp/international/intlcompilation/intlcompilation.html](http://www.hhs.gov/ohrp/international/intlcompilation/intlcompilation.html)
In addition to Local IRB/Ethics Committee approval, researchers will also require approvals from the actual site where the research is occurring. For example, if conducting human subjects research at a school in Peru, you will need permission from the local country IRB/Ethics Board and from the school(s) taking part in the research. The IRB(s) will determine what approvals are necessary and sufficient for conducting the research.

- **IF POSSIBLE, PLEASE CONTACT THE HRPO/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, it is discovered that some aspects of your research study must be modified for whatever reason, please notify the HRPO/IRB office immediately (504-988-2665 or irbmain@tulane.edu). The HRPO/IRB will do its best to quickly respond to your modification request with further instructions and guidance. Please wait to hear back from the IRB before making any changes to your protocol unless the participant would be at risk.

*Student Researchers: Remember to keep your advisor in the loop as well!! Before leaving the country, develop a communication plan with your advisor so that he/she can continue to oversee the research.*

**INTERNATIONAL RESEARCH AT TULANE UNIVERSITY:**

If any aspect of your research involves international activities (i.e., travel outside of the US, the import or export of items into or out of the US or the involvement of foreign nationals), then the International Projects Preliminary Questionnaire (IPPQ) must be completed. This form is available at:

http://tulane.edu/asvpr/ora/upload/IPPQuestionnaire.pdf

This form does NOT need to be submitted to the IRB.

**TULANE HRPP POLICY:**

Please consult Section 17 of the HRPP Policies regarding Collaborative Research and Off-Site Research at:

http://tulane.edu/asvpr/irb/sops.cfm

**ADDITIONAL REFERENCES:**

http://www.hhs.gov/ohrp/international/

http://bioethics.od.nih.gov/internationalrecthics.html