**Principal Investigator:**

**Study Title:**

*The IRB Review of International Research form must be completed and attached to your IRB application, when “Yes” is answered to question 4.5 in Section 4. Methods.*

**Research conducted by Syracuse University investigators falls under University purview and guidelines even when conducted elsewhere. Research projects must have been approved by the local equivalent of an IRB *before* they can receive final approval from the Syracuse University IRB. When there is no equivalent board or group, investigators must rely on local experts of community leaders to provide approval. The SU IRB requires documentation of this “local approval” before final approval for your research is granted.**

1. **Describe what qualifications, relevant coursework, past experience, or training the researcher(s) has to justify his/her international research capabilities.**

1. **In each of the items below (a-e), describe the context of cultural norms and local laws, specifically, how they differ from U.S. culture. In your description include any cultural sensitivities required to conduct this study.**
	1. **Research autonomy of individuals or groups (Who has the authority to decide if an individual participates in research? For example, in some cultures it may be a tribal leader, a community or religious leader, or a woman’s husband.):**

* 1. **Consent procedures (Some or all requirements for written consent may be waived due to cultural norms or conditions requiring such a waiver. For example, in societies that do not use written language or the collections of signatures is improper.):**

* 1. **Recruitment techniques (What are the appropriate recruitment techniques in this culture? Through community/tribal leaders or word of mouth, as opposed to electronic recruitment or telephone calls.):**

* 1. **Age of majority or the age at which one is no longer considered a minor (i.e. The age of 18 in New York State):**

* 1. **Requirement of parental consent :**

1. **Describe how the researcher has obtained 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. In addition, the researcher must remain in compliance with U.S. regulations as well as local requirements.**

*Consider current events and attach additional documentation if necessary.*

**While Syracuse University cannot impose our standards for written documentation of consent on other cultures, we do not relax our standards for ethical conduct of research or for a meaningful consent process. The IRB understands in some instances it may be appropriate to waive some or all requirements for written consent due to cultural norms or conditions requiring such a waiver (see 2.b. above).**

1. **Describe how special attention will be given to local customs and to local cultural and religious norms in creating your consent documents or in proposing alternative consent formats. Provide copies of translated documents.**

1. **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.**

1. **Explain provisions for culturally appropriate recruitment and consent accommodations such as, translations or involvement of native language speakers.**

1. **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.**

1. **Provide information about the ethics committee (IRB equivalent), or where there is no equivalent board or group, the local experts or community leaders in the host country that will review the research project. Provide documentation of this “local approval”.**

1. **Describe any aspects of the cultural, political, or economic climate in the host country that might increase the risks for participants. Include the steps you will take to minimize these risks.**

1. **How will you communicate with the SU IRB while you are conducting the research in the event that your protocol requires changes (amendments) or there are reportable events?**

1. **If the researcher is a student, how will the student communicate with the advisor during the conduct of the research? How will the advisor oversee the research?**