

Appendix J: International Research

1. Local Issues/Concerns

- a) *Please describe any local community/ethical concerns and laws related to the proposed research, including any special risks to subjects of this research that may arise from the local context.*

- b) *Describe any benefits that may accrue to the subjects, community, region, etc. as a result of the research.*

- c) *Are there local research and/or ethics reviews required? Any required approval should be obtained prior to submission of the ISU IRB protocol and attached to the protocol submission. See OHRP's Compilation of Human Research Standards for guidance on many countries regulations:
<http://www.hhs.gov/ohrp/international/index.html>. Note that not all countries are listed.*

- d) *Are there any travel warnings or alerts pertaining to your research activities? (For the U.S. Department of State listings, see
<http://travel.state.gov/content/passports/english/alertswarnings.html>. If so, how do you plan to mitigate the risks to you and your respondents?*

- e) *Please describe the international site(s) and provide information on local contacts or investigators. Please also include any cultural, political, religious, or other local influences that may affect conduct of the proposed research. How will these be addressed? (Example includes potential threats that require changes in*

recruitment methods, etc.). Of particular concern is the privacy and safety of the participants.

f) Please describe your experience with conducting research (or studying or residing) in the research setting, including any relationship(s) with the community from which participants will be recruited. Please also describe communication and oversight plans between the researchers who will be on-site and those at ISU.

g) Describe any special data security considerations that arise from the local context, including how data will be returned to the United States. Please include encryption procedures and the timing thereof, how and when the data will be moved out of the country, and who might intercept the data and the possible consequences thereof. Please note that many countries have strict data security provisions that may apply to your research.

2. Translation

Per federal regulations, the consent process and documents as well as study-related documents (e.g., survey instrument, medical release forms) for participants not fluent in English must be presented in a language (preferably native) understandable to them. If it is expected that participants who do not speak English will be enrolled in a study, translated documents should be made available.

*The IRB must approve non-English language versions of written or oral consent documents and all survey instruments as a condition of approval under 45 CFR 46.117(b)(2). The IRB must pay careful attention not only to the accuracy of the translation, but the level of understanding of the subject population, as well as any cultural elements specific to the population. For specific requirements, please refer to the **IRB Translation Policy and Procedures** on the REC website at rsp.illinoisstate.edu/research/human_subjects/*

If translators are to be used, they must understand and adhere to human subjects protection standards (e.g., voluntary participation, confidentiality). Depending on the role of the translation and the circumstances of the research, a translator may be considered a co-Investigator and would be required to complete human subjects research training.

a) Please list the language(s) in which the research will be conducted on the protocol and indicate whether a member of the research team is fluent in the language of the potential participants so that questions or concerns of the participants may be appropriately addressed.

3. Subject Recruitment/Informed Consent Considerations

a) Describe any alterations to the subject selection and recruitment process that are necessary due to cultural factors.

b) Describe any alterations to the required consent process that are necessary due to cultural factors (e.g., a request from outsiders to sign documents would be treated with suspicion based on customs, previous history, etc.). PIs should also be prepared to provide local contact information for participants who have questions or issues related to the project.

c) Does this research include enrollment of children in other countries?
_____ Yes _____ No

If yes, please providing the IRB with sufficient information to verify the age at which participants in such jurisdictions have the ability to consent to participation in research, including any medical treatments or procedures if applicable.

d) If compensation will be offered for participation in the research, provide an economic context that allows the IRB to determine how influential the amount would be in the local context.