IRB Appendix O - Research in International Settings

Rev. February 2019

Complete this form when conducting research in locations outside the United States. Provide information about the local context in which the research will be conducted.

Procedures:

- Determine if local research and/or ethics reviews are also required. If so, attach a copy of the approval/review.
- Provide local letters of support from host or participating organizations, if applicable.

For a list of regulations, laws, and guidelines pertaining to international human subjects research for selected countries, see International Compilation of Human Research Protections.

Principal Investigator:

Protocol Short Title:

1. Describe the international site(s). Provide location, name of local contact or investigator, and local contact information, as applicable.

2. Describe any cultural, political, religious, or other local influences that may affect conduct of the proposed research and how these will be addressed (e.g., issues posing potential threats, requiring changes in recruitment methods, etc.). ☐ N/A

3. Describe any local exceptions to the required consent process and how these will be addressed (e.g., a request from outsiders to sign documents would be treated with suspicion based on customs, previous history, etc.). ☐ N/A

4. List the language(s) in which the research will be conducted. Indicate whether a member of the research team is fluent in the language of the potential participants. If not, describe the provisions in place to provide translation services throughout the duration of the study.

5. Will children be enrolled in the study?

◯ Yes
◯ No

If Yes **-->** Describe any local exceptions regarding the requirements for adult permission and child assent and how these will be addressed.

6. If compensation is being offered, describe its appropriateness for the setting.

☐ N/A

7. Explain any benefits to the local community that will remain with the community once the research is complete.

8. Describe the researchers' training/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

9. Provide the name, title, and contact information (including email addresses) for two individuals who are ***not affiliated*** with the research (or researchers) who are knowledgeable about the location and population who could serve as a consultant(s) regarding the proposed research. ***Note: It is not required that these individuals reside or work in the research location.***

10. Describe communication and oversight plans between the IRB and the researchers(s) who will be on-site. ***Note: Consider how issues will be handled that might be relevant to the protection of participants (e.g., unanticipated problems, complaints, noncompliance, etc.).***

11. Describe procedures for data storage in the local setting and for transfer of data to URI.

12. Will the research involve medical procedures and/or treatment?

- ◯ Yes
- ◯ No

If **Yes** **-->** Indicate if any planned research procedures are considered to be standard of care in the country or location.

If **Yes** **-->** Describe provisions for emergency treatment that are available in the location.