# Series 701 International Research

## The Institutional Review Board from Series 701 of International Research

USU requires all human subjects research performed in an international setting to provide equivalent levels of protection that would be required for participants in the United States, while simultaneously complying with local laws and taking into account any cultural context. Research funded by a US federal agency research must follow the regulations of that agency.

Research that occurs outside the United States will be reviewed using, at a minimum, Expedited review procedures, except in the case of a project that meets U.S. exemption standards and has received ethics review in the location(s) where the research will be conducted. To qualify for exemption, the local review process must occur prior to submission of a protocol to the USU IRB. During the USU IRB review process, consultants with ample appropriate expertise in rules, laws, and customs of the country where the proposed research will take place may be invited to assist the IRB members and staff in conducting the review.

### I. Local Review

The PI is responsible for obtaining any official governmental permission or substantive equivalent in order to conduct research in a jurisdiction that requires such permissions or approvals. In some cases, local oversight bodies may require the study team to pay administrative fees to obtain approval. The PI and research team are responsible for following all regulations and requirements for obtaining approval from the governmental bodies. USU IRB may provide a preliminary approval letter to the PI should the governmental body require one for research to be approved in the country where research is to take place.

The PI is also responsible for obtaining local ethics review, whenever possible. If no local review is possible, the PI should reach out to institutions in countries and regions where research will take place and connect the USU IRB with experts in the field who can provide a local context review or be available to answer USU IRB questions regarding the appropriateness of its review in the local context. If this cannot be completed, the USU IRB will seek out a suitable reviewer for support in understanding and implementing the requirements of the local context. Researchers should be aware that this adds substantial time to the review process, particular where the work is in developing jurisdictions where extra care should be extended to ensure a culturally appropriate review process.

### II. Communication with Participants

All communications with participants should take place in a language that is understandable to the participant population targeted for inclusion in the research. Prior to approval of a protocol, recruitment and informed consent documentation must be provided in the languages in which they will be utilized. It is the responsibility of the research team to secure appropriately translated information, where applicable. Researchers are strongly encouraged to ensure that their informed consent processes and documentation are responsive to the cultural context where research will occur. Local guides, translators, and adding members of the research team for their language abilities are all suggested means to ensure this can be accomplished. For written materials, certified translations, translations by USU Languages faculty, or uncertified translations by knowledgeable individuals accompanied by a back translation are all recommended. Research projects which do not have adequate resources to ensure productive and understandable communication between the research team and local research participants cannot be approved.

### III. Reporting

All USU, sponsor, and U.S. reporting requirements remain in effect for research carried out in non-U.S. jurisdictions. In the case of research carried out where the dominant languages are not English and Spanish, the research team must be

prepared to facilitate communication between the IRB and any parties that may need to be contacted in the local context to manage the event that requires reporting. In many cases, the research team must be prepared to report concerns, problems, or complaints to the USU IRB on behalf of the participants (or their communities), given potential difficulties for participants at a distance to connect with the USU IRB.