Winthrop University
Institutional Review Board
IRB Guidelines on International Research and Research with Non-English Speaking Participants

Research with Non-English Speaking Participants

Translations

Researchers should submit to the IRB copies of all materials in English. To reduce the burden on translations, once the IRB approves the documents, these documents (surveys, questionnaires, recruitment materials and informed consent) should be translated to the languages involved in the research. Translated documents and translation certification letters should be presented to the IRB as a *modification of the initial protocol*.

Please note that the IRB recommends that informed consent with illiterate subjects is observed by an impartial witness and audio recorded. Interpreters and translators might not serve as witnesses.

Interpreters and translators:

Must read, speak, and write the native language and English.

An interpreter should available to answer participant's questions at any stage of the study.

Family members of the participant cannot act as interpreters or translators.

The following can serve as interpreters or translators in research with human subjects:

a) Fluent study team member.
b) Non-certified translator who is not part of the team.
c) Certified translator who is not part of the team.
d) Bilingual individual who is not part of the team.
e) Bilingual clinical staff who is not part of the team.
f) Medical interpreter who is not part of the team.

Please note:

- If using a translator for oral interviews, the translator must sign a certificate of confidentiality.
- It must be clearly stated in the protocol whether a translator is just providing translation services or if he/she in a full participant in the research team.

International Research

When research is conducted in other country, investigators must comply with both the US regulations AND with the local policies and regulations governing the international research sites. It is recommended that the researcher enlist local collaborators that can assist in obtaining ethics reviews and permissions to conduct research at that international site. This collaboration should be detailed in the IRB protocol.

The IRB protocol should include:

1) Detailed information about how members of the research team are prepared for research in the host country, including language/communication and cultural awareness.
2) A letter of support from a local organization or community leader, or an explanation of how the researcher will ensure they are invited into the local community if there are no formal organizations with which they will work.
3) Statement of Cultural Appropriateness (authored by an independent entity from the research team who is highly familiar with the cultural norms of the research site.)
4) One of the following: references about the local regulations that state ethics review is not required OR statement acknowledging unregulated research activities. If there is a local ethics review the IRB protocol should include a letter from the ethics committee.

Please refer to the information on foreign research regulations:
https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html

The protocol should also state the steps that the research team takes to protect electronic devices with participant data from loss or theft, and show that the researchers are familiar with export customs laws governing computing devices and data. Also, researchers should include steps that they will take to prevent exposure of data obtained under the promise of confidentiality (eg. use Blackboard Content instead of public shared file locations).