

International Research

Research in foreign countries presents special concerns regarding the rights and welfare of human participants. In general, the HREB accepts the standards of the location in which the research is taking place, unless those standards violate the basic principles of ethical human participants research as defined by U. S. policy and law. Investigators must understand the context of the locality in which they are conducting their research and must communicate that understanding to the HREB in writing. In addition, the following issues apply to international human participants research:

- All human participants research in foreign countries must be reviewed using the appropriate HREB procedures depending on the nature of the research.
- Researchers must submit the appropriate HREB application, as well as the International Research Addendum.
- Researchers are responsible for knowing and following the rules and policies of any locale where they will be conducting research. Please see OHRP's compilation of Human Research Standards. (www.hhs.gov/ohrp/international/index.html)
- All materials, including consent forms, must have English language translations included with the protocol.
- In localities where English is not the primary language, all materials presented to subjects must be understandable to them. An authority in the native language must provide documentation that the translated materials adequately convey the content of the English language version presented to the HREB.
- If documentation of permission from local authorities is required, researchers are responsible for attaining and documenting this permission before approval can be granted.
- To expedite the review process, the investigator is asked to provide the name of an individual(s) who has knowledge and/or experience in conducting research in the particular location of study.
- Where research involves minimal risk to subjects, the HREB will obtain necessary information related to the research context through written materials from the investigators or others, and/or discussions with appropriate consultants.
- Where research involves greater than minimal risk to subjects, the HREB will obtain the federally required information through written materials, personal knowledge on the part of one or more HREB members, discussions with consultants in person or via electronic means, and in interchange between the HREB and elements of the local research context, etc.
- If the project involves an international institution that is “engaged in research” ① the institution must have a federal-wide assurance on file with The Office for Human Research Protections. In certain circumstances, an Institutional Review Board Authorization Agreement may be used.

Please note: Additional time is needed when reviewing international research since the HREB may need to consult with an expert in that area for local context information.

① An institution becomes “engaged” in human subject research when its employees or agents (i) intervene or interact with living individuals for research purposes; or (ii) obtain individually identifiable private information for research purposes [45CFR46.102(d), (f)]