HRP-336 | 3/29/2024

WORKSHEET: International Research

The purpose of this worksheet is to provide support for IRB review of international research.

1. Local research context considerations.

[ ]  The research protocol should be designed to address local research context. The following should be considered, when appropriate:

[ ]  Equitable selection of participants, specifically justification for the international setting, appropriate access to the community, and relevance to the community’s needs.

[ ]  Economic prosperity, cultural or political climate of the area that may increase risks to participants.

[ ]  Influence of local officials on the population.

[ ]  Local understanding or beliefs about research and/or medical treatment.

[ ]  Local legal rights of the population, including age of majority and autonomy.

[ ]  Access to healthcare services or facilities (if applicable).

[ ]  Access to treatment or other services post-study completion (if applicable).

[ ]  Inclusion of a local, participant advocate.

1. Informed Consent

[ ]  The following should be considered, when appropriate:

[ ]  Disclosure of scientific and medical facts to individuals who may be unfamiliar with or distrustful of the concepts

[ ]  Differences in cultural and societal norms

[ ]  Differences in the role of women and children in society

[ ]  Differences in the role of family and community in the consent process

[ ]  Identification of local language(s)

[ ]  Literacy rate of the area

[ ]  Justification for use of oral consent process

[ ]  Local contact information for persons who can answer research-related questions, including local emergency contact information, if applicable

[ ]  Local contact information for persons who can answer questions about subject rights (local IRB, NGO, or ethics committee)

1. Local Approval / Oversight

[ ]  Consider whether the researcher has addressed local approvals and oversight responsibilities (when appropriate):

[ ]  Appropriate local IRB or ethics approval obtained (See the [International Compilation of Human Research Standards](https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html))

[ ]  Collaborating sites are identified and roles are described

[ ]  Procedures of including officials from the area in the monitoring of the research (if applicable)

[ ]  Describes policies and procedures aligned with local laws (including GDPR)

1. Research Team Expertise / Resources[[1]](#endnote-2)

[ ]  The following should be considered based on the specific expertise needed and the complexity of the protocol:

[ ]  Researcher is appropriately qualified based on prior experience, relevant training, and ability to conduct the research procedures in accordance with local law, customs, and U.S. requirements.

[ ]  Adequate resources are available.

[ ]  For student research, adequate oversight by a faculty PI and documentation of International Travel Risk Assessment and Advisory Committee ([ITRAAC](https://global.umn.edu/travel/approval#who-tab)) approval is provided.

1. Additional Considerations

[ ]  The following should be considered based on the protocol under review:

[ ]  Procedures for how complaints will be reported and to whom.

[ ]  Communication plan for sharing reportable new information to the IRB in areas with limited communication/technological resources.

[ ]  Procedures for data management, including transmission in and outside of the U.S.

[ ]  Adequate provisions outlined for data and safety monitoring, commensurate with the complexity, size, and nature of the research (see HRP-335 - WORKSHEET -Data and Safety Monitoring)

1. Research conducted internationally may require specific expertise, skills, experience, and resources. [↑](#endnote-ref-2)