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)