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| The purpose of this worksheet is to provide support for IRB review of international research. |
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| 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 subjects, 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/subject advocate |
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| 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) |
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| 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 |
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| 1. Research Team Expertise / Resources

Research conducted internationally may require specific expertise, skills, experience, and resources. The following should be considered, when appropriate: |
| [ ]  | 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](http://global.umn.edu/travel/approval/#who-tab)) approval. |
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| 1. Additional Considerations

The following are additional considerations that may be relevant to the research 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 Worksheet, HRP-335 Data and Safety Monitoring) |