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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) |