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| The purpose of this worksheet is to provide support for IRB staff and Committee members reviewing research that will be conducted outside of the United States. This worksheet only applies to research procedures conducted outside the US. This worksheet is to be used. It does not need to be completed or retained. |
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| 1. Research Procedures to be Conducted Outside the US (Check all that apply) |
| Online data collection Data/specimen analysis  In-person interaction In-person intervention |
| 1. Risk Level of Procedures Conducted Outside the US (Check one) |
| Minimal risk  Greater than minimal risk |
| 1. Local Context Information  N/A, go to Section 5 (This box should be checked when no in-person interactions or interventions will occur outside of the US) |
| When there will be in-person interactions or interventions at a site outside the US, the reviewer has materials necessary about the local research context through: **(Select all that apply)**  Written materials such as (1) previous consultations; (2) information from the Department of State website; (3) information from the OHRP Compilation of Human Research Standards; (4) information provided by research team.  Consultants with expertise in the local context where the research is being conducted.  Personal knowledge of the local research context.  Approval from a local ethics committee.  Approval from a local authority. |
| 1. Local Context Considerations  N/A, go to Section 5 (This box should be checked when no in-person interactions or interventions will occur outside of the US which are greater than minimal risk) |
| When there will be in-person interactions or interventions that involve greater than minimal risk at a site outside the US, the reviewer has obtained information about the following local research context considerations: **(All must be checked)**  The types of subject populations likely to be involved;  Applicable law;  Local culture and norms related to the research, the research procedures, subject matter being researched, and informed consent (if applicable),  Method for protection of privacy of subjects;  Method for maintenance of confidentiality of data;  Language(s) understood by prospective subjects and methods for effectively communicating with them;  Method for minimizing the possibility of coercion or undue influence in seeking consent (if applicable);  Safeguards to protect the rights and welfare of vulnerable subjects; and  Approval has been obtained from a local ethics committee. |
| 1. Local Context Determination (All must be checked) |
| The research appears to be acceptable in terms of institutional commitments, regulations, applicable law and standards of professional conduct and practice. |
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