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| **This form is to be uploaded as an attachment to your Ideate application.** |

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| **When to use this form:** If you are a researcher travelling internationally to conduct any of your research activities that may include (but are not limited to) data collection and analysis, interaction with human subjects, access to identifiable health information of human subjects. These projects require the local equivalent of an IRB/ethics committee review and approval prior to initiation of any study activities.  |

1. **PROTOCOL INFORMATION**

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| **1A. Principal Investigator:**       |
| **1B. Protocol Number:**       |
| **1C. Project Title:**       |

1. **RESEARCH ACTIVITIES**

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| **2A. Where is the research being conducted?**       |
| **2B. Are there any aspects of the cultural, political, or economic climate in the country where the research will be conducted that might increase the risks for participation?** [ ]  Yes [ ]  No**If yes, describe these risks:**      **Describe what steps the researchers will take to minimize these risks:**       |
| **2C. Was the researcher invited into the community?** [ ]  Yes [ ]  No**If no, describe how the researcher will have culturally appropriate access to the community:**       |
| **2D. Will research subjects be compensated for their participation?** [ ]  Yes [ ]  No**If yes, answer the following:** **In what form will the currency be provided?**      **What is the conversion to US dollars?**       |
| **2E. Will the researchers consult with the research subjects before study findings are presented or published?** [ ]  Yes [ ]  No**If yes, please describe:**       |
| **2F. Will any identifiable health information be brought back or transferred to the United States during or after the research study is completed?** [ ]  Yes [ ]  No**If yes, please describe and outline how HIPAA requirements for PHI will be managed:**       |

1. **INTERNATIONAL IRB EQUIVALENTS**

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| **3A. Is there an ethics committee or other IRB equivalent that requires review of research in the country where research is being conducted?** [ ]  Yes [ ]  No(Note: OHRP compiles a list of international human research standards that can be viewed [here](https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html).)**If yes, attach documentation of approval.** [ ]  Documentation Attached**Please provide a translated copy of this approval if it is not in English.** |
| **3B. Provide contact information for the local IRB equivalent.**      |
| **3C. Are there any other regulatory agencies or organizations that require review prior to human subjects’ research, such as drug companies, community leaders, stakeholders, etc.?** [ ]  Yes [ ]  No**If yes, attach documentation of approval.** [ ]  Documentation Attached**Please provide a translated copy of this approval if it is not in English.** |

1. **RESEARCH PERSONNEL**

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| **4A. Describe qualifications the researcher has in relevant coursework, past experience, and/or training to justify their international research capabilities:**       |
| **4B. Describe the PI’s ongoing oversight of the research activities conducted internationally:**      |
| **4C. Describe how the researchers collecting data internationally will communicate with the IRB in the event the project requires changes or there are reportable events:**      |
| **4D. Identify a local contact who is fluent in the local language and name this person here:**     **This information is to also be placed in the informed consent document(s).** [ ]  Information Included |