**International Research Form**

**Submission Date:** Click or tap here to enter text.

**When to use this form:** Researchers travelling internationally to collect data are still subject to federal and University regulations and guidelines. These projects should also be reviewed and approved by the local equivalent of an ethics committee or an IRB, when possible. When there is no equivalent committee, researchers are asked to rely on local experts or community leaders to provide approval. The Northeastern University IRB may request documentation of local approval before granting IRB approval. Note:

At the end of this guidance are links to Northeastern University policy as they pertain to international travel. Please review each policy and reach out to the point of contact on each document with questions.

For guidance on conducting in research outside the United States, please refer to [HSR Guidance page](https://research.northeastern.edu/hsrp/guidance/).

**PROTOCOL INFORMATION**

|  |
| --- |
| **Principal Investigator:** Click or tap here to enter text. |
| **Student Investigator [if applicable]:** Click or tap here to enter text. |
| **IRB Number [if available]:** Click or tap here to enter text. |
| **Protocol Title:** Click or tap here to enter text. |

**Section 1. RESEARCH ACTIVITIES**

|  |
| --- |
| Where is the research being conducted? Click or tap here to enter text. |
| 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 [ ]  NoIf yes, describe these risks: Click or tap here to enter text.Describe what steps the researchers will take to minimize these risks:       |
| Was the researcher invited into the community? [ ]  Yes [ ]  NoIf no, describe how the researcher will have culturally appropriate access to the community: Click or tap here to enter text. |
| Will research participants be compensated for their participation? [ ]  Yes [ ]  NoIf yes, answer the following: In what form will the currency be provided? Click or tap here to enter text. How much is the compensation in relation to the average daily pay or household income in the country where the research will be conducted? Click or tap here to enter text.What is the conversion to USD? Click or tap here to enter text. |
| Will the researchers consult with the research participants before study findings are presented or published? [ ]  Yes [ ]  NoIf yes, please describe: Click or tap here to enter text. |

**Section 2. INTERNATIONAL IRB EQUIVALENTS**

|  |
| --- |
| 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 |
| Provide contact information for the local IRB equivalent.Click or tap here to enter text. |
| 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 [ ]  NoIf yes, attach documentation of approval. [ ]  Documentation Attached |

**Section 4. RESEARCH PERSONNEL**

|  |
| --- |
| Describe qualifications the researcher has in relevant coursework, past experience, and/or training to justify their international research capabilities and/or knowledge of the community: Click or tap here to enter text. |
| Describe the PI’s ongoing oversight of the research activities conducted internationally:Click or tap here to enter text. |
| Describe how the researchers collecting data internationally will communicate with Northeastern’s IRB in the event the project requires changes or there are reportable events:Click or tap here to enter text. |
| Identify a local contact who is fluent in the local language and provide their contact information:Click or tap here to enter text.Note: This information is to also be placed in the informed consent document(s).  |
| Has or will the study team include a consultant or collaborator with local expertise?[ ]  Yes [ ]  NoIf yes, answer the following: Who is the consultant or collaborator and what is their experience with the country/community? Click or tap here to enter text.How will they be involved in the project and/or how will they be consulted? For example, did they assist with study design or will they provide ongoing onsite oversight of the project? Outline all activities they have and/or will be involved in. Click or tap here to enter text.Based upon study location and risk level, the IRB may require a local site collaborator. |

Resources:

[Policy on Travel and Expense Reimbursement | Policies (northeastern.edu)](https://policies.northeastern.edu/policy306/)

[Policy Requiring Registration of University Travel | Policies (northeastern.edu)](https://policies.northeastern.edu/policy612/)

[Policy on Travel to High-Risk and Sanctioned Destinations | Policies (northeastern.edu)](https://policies.northeastern.edu/policy613/)

[Policy on Computers and Mobile Devices for Travel to Destinations with Heightened Cybersecurity Risk | Policies (northeastern.edu)](https://policies.northeastern.edu/policy701/)

[International Compilation of Human Research Standards | HHS.gov](https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html)