**International/Transnational Research**

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| **PI Name:**  | **Date:**  |
| Title:  |

**Note: PIs conducting research at international sites are expected to provide the same level of participant protections as they would locally.**

1. **International Setting**
	1. **Where is the research to be conducted?**

* 1. **Describe the cultural norms with respect to research, individual autonomy, consent, age of majority, etc. in this setting:**

* 1. **Are there privacy/confidentiality concerns unique to the country/region?** **[ ]  Yes** **[ ]  No**

**If yes, describe.**

1. **Consent**
	1. **Describe how consent will be obtained from participants/surrogates/legally authorized representatives:**

**Note #1:** If children will be included in the study, please complete a “Request for Inclusion of Children” form ( <https://research.nd.edu/our-services/resource-library/> )

**Note #2:** Any request for a waiver of the requirements for informed consent must include completion of a “Request for Waiver of Consent” form ( <https://research.nd.edu/our-services/resource-library/> )

* 1. **Describe how you or other investigators will ensure that participants understand the nature of the research (i.e., procedures, risks, potential benefits, privacy, confidentiality, etc.):**

* 1. **Describe the steps that will be taken to ensure that potential participants understand that participation is voluntary and, if they choose to participate, that they can stop at any time without penalty or loss of benefits they are entitled to receive:**

* 1. **If consent forms are to be used with persons not fluent in written English, describe how translations will be obtained and your plans for use of interpreters?**

**Note:** All translated consent forms, assent forms, recruitment materials must be submitted to the IRB. It is acceptable to wait until the English version is approved and then add the translated consent form as a response to conditions for approval or as an amendment. Any request for a waiver of the requirements for documentation of informed consent must include completion of a “Request for Waiver of Consent Documentation” form (<https://research.nd.edu/our-services/resource-library/> )

1. **Language**
	1. **What is the primary language(s) in the region(s) where the research will be conducted?**

* 1. **Will you, as principal investigator, be interacting directly with participants?** **[ ]  Yes** **[ ]  No**
	2. **Are you fluent in the primary language of the subjects? [ ]  Yes [ ]  No**

**If “No”, describe the steps that will be taken to ensure that you are able to communicate with participants (e.g., research team members are fluent in the local language, will be working with a local collaborator who is fluent in the local language):**

1. **Expertise and Consultation**
	1. **What, as principal investigator, are your qualifications to conduct research in this setting (Include your or, if applicable, your faculty advisor’s knowledge of local customs, culture, laws and experience with the type of research described for the study)?**

* 1. **Will you be collaborating with local persons (e.g., researchers, universities, community leaders, etc.)? [ ]  Yes [ ]  No**

**If “Yes”, describe:**

* 1. **Will this research be reviewed by a local, regional or national IRB or ethics committee? [ ]  Yes [ ]  No**

**If “Yes”, provide contact information for the ethics committee and describe how you will communicate and coordinate with the committee:**

**How will you handle and report complaints, non-compliance and unanticipated problems?**

**If “No”, do you have local/regional/national permission/certification to conduct research in the country?**

**[ ]  Yes** **[ ]  No**

**If “Yes”, describe (and upload a copy of the approval letter):**

**If “No”, explain (i.e., how do you know you have approval/permission to be there):**

1. **Export Control**
	1. **Will this research be conducted in a country under embargo or sanctions with regard to export control? [ ]  Yes [ ]  No**

**Consult with the Notre Dame OIT Office at** [**http://oithelp.nd.edu/information-security/stay-secure/traveling-securely**](http://oithelp.nd.edu/information-security/stay-secure/traveling-securely) **on how to ensure that the data collection tools (e.g. laptops, ipads, notebooks, smart phones and the technology they contain) are secure and for recommendations on how to reduce the risks associated with traveling with these devices, namely loss, seizure, or tampering. Also, look for information on whether you are permitted to bring the tools into the country(ies) that you will visiting.**