**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 the investigators will ensure that participants understand the nature of the research**

* 1. **Describe the steps that will be taken to ensure that potential participants understand that participation is voluntary**

* 1. **If consent forms are to be used with persons not fluent in written English, how will translations be obtained?**

**Note:** All translated consent forms, assent forms, recruitment materials must be submitted to the IRB. 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. **Are the investigators who will be interacting with participants fluent in the primary language of the subjects?  Yes  No**

**If no, describe the steps that will be taken to ensure that participants and investigators are able to communicate with each other:**

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

* 1. **Will the investigator 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 IRB or ethics committee?  Yes  No**

**If yes, describe how you will communicate and coordinate with the committee:**

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

**Please provide the contact information for the local IRB or ethics committee:**

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

**Yes**  **No**

**If yes, describe.**

**If no, explain.**

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.**