International Research
VU Human Research Protections Program Guidance

If you are conducting research involving data and/or study populations located outside of the United States, you must provide adequate protections to your study participants, and follow appropriate local regulatory requirements, policies, and cultural norms. Below are some considerations for international research when submitting studies to the VU IRB for review.

Timeline: Submit your research in a timely manner. Since there may be a requirement for a local ethics committee review, translated materials, and/or a need for local permissions, researchers must account for this in their timeline when submitting to the VU HRPP. Researchers should also build in time for the VU HRPP review and approval process, particularly those that require review by the Convened IRB.

Host Country Local Ethics Committee (LEC) Reviews: The researcher is responsible for identifying and securing host country LEC reviews and approvals prior to beginning their human subjects research, whenever applicable.

International Research Consultant Review: The international research consultant review is conducted by an individual who has competence in local norms, regulations, policies, and the sociopolitical climate where the research is occurring and can attest to the research risks/benefits. This individual may not have any conflicts of interest (personal, financial, and/or professional interests that may affect the objective assessment of the research). If no formal LEC review and approval is required, the VU HRPP may request researchers to have a completed International Research Consultant Review Form included with their submission to the VU HRPP. The requirement to submit the International Research Consultant Form varies by review level.

- *Exempt*: The VU HRPP may request the form upon the review of the submission at their discretion.
- *Expedited*: The form is required.
- *Greater Than Minimal Risk*: The form is required.

Note that international research consultant review is expected for country or region-specific research, and not needed for global studies, such as online surveys open to

participants world-wide.

Site Permissions: Beyond a formal host country LEC review and approval, entities may require researchers to obtain local site permission(s) to obtain data or conduct human research at a particular location. It is important for researchers to identify these and obtain them before beginning their research. For example, a local nonprofit community organization may require a site permission to be obtained by the researcher for recruitment from their organization and use of their office space for research purposes.

Data Privacy Laws: Countries have varying data privacy laws, such as the European Union's General Data Protection Regulation (GDPR) or the Personal Information Protection Law (PIPL) of the People's Republic of China. The best way to ensure compliance with these local laws is to work with a local collaborator. If a data use agreement (DUA) is necessary, the researcher must obtain these accordingly. When possible, de-identify data and/or encrypt before transferring it to the United States. For inquiries about data privacy laws, contact the VU Office of the General Counsel.

Translated Materials: For non-English speaking study populations or study populations with limited English-proficiency, participant facing translated materials should be submitted to the VU HRPP. An explanation of the appropriate consent methods and whether an interpreter will be utilized should also be clearly explained in the submission to the VU HRPP.

- Minimal Risk Research: A translator attestation statement is required (e.g., "*I attest the research study materials translated from _____ to_____ are accurate and complete to the best of my knowledge.*"). A translator must speak, read, and write the native language and English proficiently.

- Greater than Minimal Risk Research: Certified back translations are required.

Risks: The VU HRPP must have a clear understanding of the research risks for participants and how those risks will be minimized. For instance, this can include social, political, legal, emotional/psychological, economic/financial, professional/reputational, or physical risks. This information must be conveyed in the submission to the VU HRPP by the researcher. In some cases, this will additionally be addressed through the international research consultant review. The review level of an international research study (i.e., exempt, expedited, or greater than minimal risk) that is submitted to the VU HRPP will be officially determined by the VU HRPP.

Benefits: Benefits to the participants, science, and society should be clearly explained in the submission to the VU HRPP. This will assist the VU HRPP to make an appropriate risks and benefits assessment for the international research study.

Location: Researchers should disclose the site(s) and geographic location of the research in their submission to the VU HRPP.

Ethical Considerations: Researchers should keep the following examples of ethical considerations in mind when designing and conducting an international research study:

- appropriate recruitment and consent methods
- protecting vulnerable study populations
- implementing adequate privacy and confidentiality practices
- understanding language proficiencies of participants
- respecting cultural norms
- accounting for safety of research participants
- understanding sociopolitical and legal contexts as it relates to the research
- minimizing group harms
- providing appropriate research participation compensation, if offered
- legal age for who is considered an adult in the host country
- data and specimen use/security/transportation/sharing/reporting across international borders

Please contact the VU HRPP office at irb@vanderbilt.edu for additional questions about international research.