



# VANDERBILT UNIVERSITY

## VU Human Research Protections Program International Research Consultant Form

### What is the Local Context Consultant Review Form?

This form applies to international research. The *International Research Consultant Form* intends to provide the VU HRPP with sufficient information regarding risks and benefits of the research occurring outside of the United States.

### Who should complete this form?

The form must be completed by an individual who has competence in local cultural norms, regulations, policies, and/or the sociopolitical conditions where human subjects research is occurring and can attest to the research risks/benefits. It is recommended that the international research consultant not be on the study team.

### When should this form be submitted?

*[The expectation to submit this form varies by review level: The form is required for expedited and greater than minimal risk research. For exempt research, the VU HRPP may request the form upon the review of the submission at their discretion.]*

If there is no formal Local Ethics Committee (LEC) review and approval required in the country(ies) where your study is occurring, please submit this completed form to the research team. The research team must submit the completed form in VERA (VU HRPP's electronic system) with your IRB submission.

## GENERAL INFORMATION

### Principal Investigator & Study Information

Principal Investigator Name	
Study Title	
Country(ies) Where Research is Occurring	

### International Research Consultant Information

Name	
Email	
Phone Number	
Why are you qualified to be an international research consultant for this research study?	
Conflict of Interest (COI)	Yes
<i>[Personal, financial, and/or professional interests that may affect the objective assessment of this research.]</i>	No
	If yes, stop here and identify an international consultant without a conflict of interest.

## LOCAL CONTEXT CONSULTANT REVIEW

Please provide a response to each item, and if applicable, include recommendations for the researcher in your response.

QUESTION	LOCAL CONTEXT CONSULTANT RESPONSE
<p><b>Q1. Recruitment:</b> Is the recruitment process for research participants is adequate, fair, and equitable?</p>	<p>Yes</p> <p>No</p> <p>If no, please explain here.</p>
<p><b>Q2. Recruitment:</b> Is the risk of coercion or undue influence for research participants adequately minimized?</p>	<p>Yes</p> <p>No</p> <p>If no, please explain here.</p>
<p><b>Q3. Language(s):</b> Will language(s) other than English be applicable to this research?</p>	<p>Yes</p> <p>No</p> <p>If yes, please list out the local languages here.</p> <ul style="list-style-type: none"> <li>▪</li> <li>▪</li> <li>▪</li> </ul>
<p><b>Q4. Consent:</b> Is the consent <i>process</i> appropriate for the research participants (e.g., method, how it's being obtained, etc.)? If consent is waived, is this appropriate?</p>	<p>Yes</p> <p>No</p> <p>Please explain here.</p>
<p><b>Q5. Consent:</b> Please explain whether or not the consent <i>materials</i> are appropriate for the research study population(s) (e.g., literacy, participant comprehension, cultural relevance, translated materials, etc.).</p>	
<p><b>Q6. Study Population:</b> What is the legal age for an adult in the host country(ies) local jurisdiction where research is occurring? (important for consent/assent purposes)</p>	
<p><b>Q7. Risks &amp; Benefits:</b> Are the risks of the research reasonable in relation to the benefits of the research?</p>	<p>Yes</p> <p>No</p> <p>If no, please explain here.</p>
<p><b>Q8. Risks - Vulnerability of Study Population(s):</b> Are any of the research study population(s) vulnerable to risks from this research (e.g., coercion/undue influence, due to location or sociopolitical</p>	<p>Yes</p> <p>No</p> <p>If yes, please explain here.</p>

conditions, unable to read or write, diminished capacity to consent, physical or psychological/emotional risks, reputational harm, etc.)?	
<b>Q9. Risks - Privacy &amp; Confidentiality:</b> Are the provisions outlined adequate for protecting research participant privacy and confidentiality?	Yes No If no, please explain here.
<b>Q10. Minimizing Risks:</b> Are the risks adequately minimized in this research? If not, what recommendations can be offered to the research team to enhance minimization of research-related risks?	Yes No Please explain here.
<b>Q11. Compensation/Incentives:</b> If compensation/incentives are offered for research participants, are they appropriate to local standards?	Yes No N/A If no, please explain here.
<b>Q12. Local Oversight of Research:</b> Has the researcher adequately accounted for all of the appropriate local/national permissions/oversight/privacy laws for this research in the country(ies) where the research is occurring?	Yes No Please explain here.
<b>Additional Comments.</b>	

\_\_\_\_\_  
Signature of International Research Consultant

\_\_\_\_\_  
Date