

**SECTION I: INFORMATION**

Principal Investigator:		Report Date:	
Site Under Review:		Protocol ID #:	
Protocol Title:			
Local Context Representative:			

The research study named above is being conducted in a location other than the United States. U.S. federal rules governing the oversight of human subjects research do not apply at the intended research site (as it is research outside of the U.S.). Therefore, in order to provide appropriate oversight, the Teachers College Institutional Review Board (TC IRB) is seeking information about the laws, regulations, and customs that prevail at the intended site of the research.

You have been identified as someone who may have local knowledge (“Local Context Reviewer”) that could support TC IRB to understand the relevant research context, and therefore to provide appropriate guidance and protection for the human subjects who will be involved in this research. You are either (1) representing the local ethics committee; (2) a local ethics expert; (3) a local collaborator (who may also be Co-investigator on the project); (4) a local research staff member (affiliated with a study site); and/or (5) an expert in the study field (even if not a research staff member on the project).

We thank you for your willingness to share your understanding and knowledge of the study site or local context. Please carefully review the information about Conflicts of Interest and the Confidentiality Agreement below. If you agree to proceed, please answer the questions in this form.

SECTION II: INTERNATIONAL RESEARCH PERFORMANCE SITE ASSESSMENT SUPPLEMENT

The Teachers College Institutional Review Board (TC IRB) invites you to provide a review of local context factors that could have a bearing on the research activity named above. Before completing the following Local Context Review form, please take a few moments to determine whether you have a conflict of interest with the above referenced research study.

The TC IRB “Conflict of Interest” policy requires disclosure of any financial interests, relationship, affiliation, or any other circumstance that is, or might be reasonably perceived as, a conflict of interest on the part of the consulting Local Context Reviewer.

Conflict of Interest Statement:

With the above referenced study, do you have a conflict of interest?

- ☐ Yes
☐ No

If Yes, please describe the conflict of interest below and contact the IRB Office at IRB@tc.edu or (212-678-4105) to arrange for a different Local Context Reviewer:

SECTION III: CONFIDENTIALITY PLEDGE

BY COMPLETING THIS FORM, you are agreeing to this pledge of confidentiality as the Local Context Reviewer. Please read these statements carefully.

In consideration of my access to records and information related to leading a human subjects protection review of the referenced research study at my site (or within my local context):

- I agree to protect the privacy and confidentiality of all materials as it pertains to human subjects in research.
- I will not disseminate, disclose, or in any way circulate beyond reasonably necessary (and with permission) any information provided by TC IRB as part of the local context review process, or if applicable, information discussed at a proposed meeting.
- I understand and acknowledge that the dissemination of personally identifiable information in a public context is strictly prohibited.

SECTION IV: LOCAL CONTEXT QUESTIONS

To assist the TC IRB review of the-referenced research study, please respond to the following questions related to the local research context. Documents describing the planned research activities are available for your reference as the Local Context Reviewer.

Participant Selection and Recruitment:

Section 3 of the attached Application for Review describes the selection and recruitment of participants for this research study. Based on the information provided:

1. Are the selection and recruitment procedures outlined in section 3 consistent with local laws, local institutional policies, and local practices or customs?

☐ Yes
☐ No
2. Will this study be reviewed by a local ethics committee at the intended research site, that is familiar with the laws and ethical codes that might apply to the country or locale in which the research is being conducted?

☐ No
☒ Yes → Please describe this local ethics committee and the review process

3. Please describe, to the best of your knowledge and ability, the local laws, regulations, and customs that TC IRB should consider in its review of the study being conducted at the study site.

If you answered “no” to the previous questions or have additional comments about local laws or institutional policies relating to participant selection and recruitment, please explain:

SECTION V: CONSENTING PROCESS AND PARTICIPANT COMPENSATION

Sections 4 and 5 of the Local Context Reviewer form describes the consenting process and compensation for participants. Based on the information provided:

1. Is the consent *process* outlined in sections 4 and 5 consistent with local laws and customs, and/or with the consent policies of local institutions?
☐ Yes
☐ No
2. Are the consent *documents* (and/or waiver of consent or documented consent) consistent with local laws and customs, and/or with the consent policies of local institutions?
☐ Yes
☐ No
3. Is the *participant compensation* that is proposed for this research study consistent with local laws and customs, and/or with the policies of local institutions?
☐ Yes
☐ No

4. Do you find the consent process, documents, and proposed compensation acceptable given the context of the locale where the research will be conducted?

☐ Yes

☐ No

If you answered “no” to any of these questions, or if you have any additional comments about local laws, customs, or institutional policies relating to participant consent and compensation, please explain:

SECTION V: PRIVACY AND CONFIDENTIALITY

Section 7 of the Application for Review describes provisions for privacy and confidentiality. Based on the information provided:

1. Are the responses provided in section 7 consistent with the resources and practices that are typical for the planned locale of this research?

☐ Yes

☐ No

2. Are the provisions for privacy and confidentiality consistent with local laws and customs, and/or with the policies of local institutions?

☐ Yes

☐ No

3. Do you find the provisions for privacy and confidentiality acceptable given the context of the locale where the research will be conducted?

☐ Yes

☐ No

If you answered “no” to any of these questions, or if you have any additional comments about local laws, customs, or institutional policies relating to privacy and confidentiality, please explain:

OTHER CONSIDERATIONS

1. Are there any other sections of the Application for Review that are *not* consistent with local laws and customs, and/or with the consent policies of local institutions?

☐ No

☐ Yes → explain: _____

2. Have there been any recent events in the local community that may have created specific attitudes, either positive or negative, towards human subjects research?

☐ No

☐ Yes → explain: _____

3. Given the nature of this particular research study, are there any additional factors (community attitudes, ethnic diversity, language, etc.) that may contribute to the acceptability of this research in your area?

☐ No

☐ Yes → explain: _____

4. Please add any additional comments that will help the Teachers College IRB in its review process:

Local Context Reviewer Name:

Title:

Date:

Signature: