Initial Review Local Context Worksheet

Your site is participating in a study where Texas A&M University-Kingsville IRB serve as the IRB of record. When relying on the TAMUK IRB, relying institutions must provide the following information to assist TAMUK IRB review:

- The requirements of any applicable state or local laws, regulations, institutional policies, standards, or other local factors, including local site ancillary reviews, relevant to the research that would affect the conduct or approval of the research at your institution.
- Site-specific consent information for this study incorporated into the TAMUK Consent Template.

Please review the approved protocol and the approved consent form and complete the local context questionnaire below. Provide any locally required consent form language to the approved consent form and explain additions below. **Please note that any additions to the approved TAMUK Informed Consent document must be approved through approval of the reliance agreement before they are utilized in the study.**

We strongly recommend that the local context questionnaire be completed as a collaborative effort with your IRB to ensure all necessary information is provided.

For questions about completing this local context questionnaire, you can contact the TAMUK IRB at tamuk.irb@tamuk.edu

TAMUK PI:	
TAMUK protocol number:	
Study Title:	
TAMUK approval date:	

Institution Relying on TAMUK for IRB Review (signatory institution):	
Local Context Representative/IRB contact	
Title of Local Context Representative/IRB contact	
Attestation by Local Context Representative/IRB contact	I attest to the accuracy of the responses provided. _____ _____ Local Context Representative Signature Date

1. ORGANIZATION INFORMATION

1.1. Please provide the legal name of the organization:

1.2. Provide any other names the site is known by or any affiliations, such as a university or hospital.

1.3. Please provide the organization's Federal Wide Assurance (FWA):

1.4. Has the site's FWA (federal wide assurance) been extended to nonfederally funded research?

- ☐ Yes
- ☐ No

1.5. If the site is within a network or system, do any sites have a separate FWA?

- ☐ Yes
- ☐ No

1.6. Please list sites within network that have a separate FWA.

1.7. Are there any investigations, audits, or findings (e.g., OHRP, FDA, or local audits) over the past three years that would be relevant to the conduct of new human subjects research proposed at the site?

- ☐ Yes
- ☐ No

1.8. If "Yes," please explain any investigations, audits or findings that may be relevant.

1.9. Does the institution have a post approval monitoring program or other regulatory oversight for ongoing research?

☐ Yes
☐ No

1.10. Does the post approval monitoring program or other regulatory oversight monitor studies that have been deferred to an external IRB?

☐ Yes
☐ No

1.11. Please provide a link (URL) to the post approval monitoring program/regulatory oversight information or paste information here.

1.12. Please confirm that the institution has adequate facilities and resources to conduct the proposed research procedures. (*If applicable, an attachment maybe added.)*

☐ Yes
☐ No

2. LOCAL CONTEXT – ALL SITES

2.1 Participating sites are responsible for reviewing the protocol and determining whether a conflict of interest exists in accordance with the participating site's institutional policies. It is the relying site's responsibility to manage or eliminate anyconflict.

Does the Principal Investigator or any member of the study team have a (potential) financial conflict of interest which could affect or be affected by this research?

☐ Yes. These conflicts have been disclosed and a Management Plan implemented in accordance with local institutional policy. *Please provide a summary of the conflict and a copy of the management plan requirements (or asummary of the management plan requirements) and any language that shouldbe incorporated into the site's consent form.*

☐ No. This institution does not have a mechanism to review potential conflicts of interest. The site will need to rely on the Reviewing site to perform this function.

2.2 Please confirm that the investigators and personnel engaged in the research are in compliance with human subjects protections training requirements at your institution. This would include GCP training for NIH funded clinical trials.

- ☐ Yes
- ☐ No *(please attach an explanation to this form)*

2.3 Please confirm that the institution has adequate education, expertise andexperience to conduct the proposed research procedures. (*If applicable, an attachment may be added)*

- ☐ Yes
- ☐ No *(please attach an explanation to this form)*

2.4 Are the privacy and confidentiality provisions of the protocol consistent with the resources and practices available at your institution?

- ☐ Yes
- ☐ No *(If no, please attach an explanation to this form)*

2.5 Are the privacy and confidentiality provisions of the protocol consistent with local laws, institutional policies, and HIPAA (if applicable)?

- ☐ Yes
- ☐ No *(If no, please attach an explanation to this form)*

2.6 Are there any other sections of the protocol which are inconsistent with local laws or your institution's policies?

- ☐ Yes *(If so, please attach an explanation to this form.)*
- ☐ No

2.7 Are there any state and local laws that are relevant for the human subjects research proposed at this site? (If applicable, an attachment can be added.)

3 LOCAL CONTEXT – DATA COLLECTION SITES ONLY

3.1 Are there any community or cultural differences for local population of subjects that require consideration?

Subject Selection

1. Does the selection and recruitment process for this protocol comply with locallaws and your institutional policies?
   - ☐ Yes
   - ☐ No *(If no, please attach an explanation to this form.)*
   - ☐ Not applicable

2. Do you find the selection and recruitment methods in this protocol acceptablein the context of your local area?
   - ☐ Yes
   - ☐ No *(If no, please attach an explanation to this form.)*

3. Is there anything else the TAMUK IRB should know about the anticipated studypopulation at your institution?
   - ☐ Yes *(If yes, please attach an explanation to this form.)*
   - ☐ No

Vulnerable Populations

4. Check all vulnerable populations from which you intend to enroll in thisprotocol. Will there be vulnerable groups among the study population?
   - ☐ Children
   - ☐ Pregnant women, human fetuses, and neonates
   - ☐ Prisoner
   - ☐ Adults with impaired decision making capacity
   - ☐ Emancipated minors, mature minors
   - ☐ Wards of the state
   - ☐ Other special populations. An example may include enrolling employees ofthe relying institution as research subjects.

   Please describe:

5. Will non-English speakers be enrolled?
   - ☐ Yes *(if yes, please attach a description of the non-English speaking population at your site)*
   - ☐ No *(If no, please attach an explanation to this form.)*

INFORMED CONSENT PROCESS

6. When written informed consent is required for a research study, the TAMUK IRBwill approve informed consent documents for use by the site investigator. Therelying institution may customize specific sections of the documents, i.e., the sections on the availability of treatment and compensation for research- related injury, payment/reimbursement of costs incurred by subjects for participation, and site Investigator contact information. Provide the standard language for the informed consent document required by your institution. (If applicable, an attachment may be added.)

7. Does the consent/assent process for this protocol comply with local laws andyour institution's consent policies?
   - ☐ Yes
   - ☐ No *(If no, please attach an explanation to this form.)*

8. Do the consent/assent documents (and/or waiver of consent of documented consent) for this protocol comply with local laws and your institution's policiesregarding informed consent?
   - ☐ Yes
   - ☐ No *(If no, please attach an explanation to this form.)*

9. According to the protocol, who will provide consent or parental permission?
   (check all that potentially apply)

   ☐ Potential study participant
   ☐ Parent of potential pediatric study participant
   ☐ Legally Authorized Representative (LARs)
   ☐ Other: Please describe:

10. If non-English speakers will be enrolled, describe how the recruitment and informed consent process will be conducted? *(If applicable, an attachmentmay be added e.g. copy of the relevant institutional policy.)*

11. TAMUK uses a separate standalone HIPAA Authorization form. Please indicateyour institutional policy regarding HIPAA by selecting an option below:
    ☐ Standalone HIPAA Authorization form to be used at your site
    ☐ HIPAA Authorization language included in the consent form at your site

COMPENSATION

12. Will you provide compensation to participants enrolled in this protocol?
    ☐ Yes
    ☐ No *(If no, please attach an explanation to this form.)*

13. Is the participant compensation described in the protocol consistent with locallaws and your institution's policies?
    ☐ Yes
    ☐ No *(If no, please attach an explanation to this form.)*

State and Local Law

14. List the states from which you will be recruiting and provide the age of majority for each state. (*If applicable, an attachment may be added.)*

15. If consent will be provided by LARs, describe your state and local law, and corresponding institutional policy regarding LARs. Describe who may serve as an LAR according to state laws and institutional policies. (*If applicable, anattachment can be added.)*

16. If children or adults who are decisionally impaired will be enrolled, describe your state, local, and corresponding institutional policies regarding assent bychildren or adults who are unable to provide consent. (*If applicable, an attachment can be added.)*

17. If mature or emancipated minors will be enrolled, please describe the circumstances under which they will be able to provide consent to their own participation and describe any applicable state, local, and institutional policies.

18. If wards of the state or other special populations (child or adult) will be enrolled, describe any applicable state, local, or institutional policies if theyhave requirements that go beyond what is required in the corresponding subparts of 45 CFR 46. (*If applicable, an attachment can be added.)*

19. If children or elderly will be enrolled, describe your state, local, and institutional policies regarding reporting of child and/or elderly abuse? *(Ifapplicable, an attachment can be added.)*

20. What are the other state and local laws that govern the conduct of research atyour institution? (*If applicable, an attachment can be added.)*

ADDITIONAL INFORMATION

21. If applicable, please confirm that all site-specific ancillary reviews have beencompleted (e.g. Pharmacy, Radiation safety, etc.)
    - ☐ Yes
    - ☐ No *(If so, please attach an explanation to this form.)*

22. Is there anything else the TAMUK IRB should know about the institution's localcontext or institutional policies?
    - ☐ Yes
    - ☐ No

23. Add any additional comments that will help the TAMUK IRB in its review process: (*If applicable)*