OMB #: XXXX-XXXX

Expiration Date: XX/XX/XXXX

ATTACHMENT 3: INITIAL REVIEW LOCAL CONTEXT WORKSHEET

Please complete a copy of this worksheet for each relying institution. This form should be completed by the Site Principal Investigator (PI)/Lead Investigator with the local context representative. The local context representative is typically an individual with knowledge of the **INSTITUTIONAL** *human research protection program and its policies as well as state and local law. Answers pertain to the implementation of the protocol named below at your institution.*

Date of Submission: _____ (DD/MM/YY)

Site PI/Lead Investigator	
Protocol Title	
Protocol #	
Institution Relying on NIH for IRB Review (signatory institution):	
Local Context Representative	
Title of Local Context Representative	
Attestation by Site PI/Lead Investigator	I attest to the accuracy of the responses provided and to having confirmed these with the Local Context Representative listed above. _____ _____ Site PI/Lead Investigator signature Date

SUBJECT SELECTION

1. Does the selection and recruitment process for this protocol comply with local laws and your institutional policies?
   - ☐ Yes
   - ☐ No *(If no, please attach an explanation to this form.)*

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

3. Is there anything else the NIH IRB should know about the anticipated study population 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 this protocol. 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 of the relying institution as research subjects.

   Please describe: _____

5. Will non-English speakers be enrolled?
   - ☐ Yes
   - ☐ No *(If no, please attach an explanation to this form.)*

INFORMED CONSENT PROCESS

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

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

8. 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: _____
     _____

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

COMPENSATION

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

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

PRIVACY AND CONFIDENTIALITY

12. 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.)*

13. 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.)*

14. 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

COMMUNITY DESCRIPTORS

15. Given the nature of this particular research study, are there any additional factors particular to this study site or the community (community attitudes, ethnic diversity, language, etc.) that may contribute to the acceptability of this research in your area?
    ☐ Yes *(If so, please attach an explanation to this form.)*
    ☐ No

16. Does the community have a positive attitude toward the conduct of research?
    ☐ Yes
    ☐ No *(If no, please attach an explanation to this form.)*

STATE AND LOCAL LAW

17. 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.)*

18. 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, an attachment can be added.)*

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

20. 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.

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

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

ADDITIONAL INFORMATION

23. Describe your institution's process to receive and address concerns from study participants and others about the conduct of the research. *If applicable, an attachment may be added.*

24. a. Describe how the relying institution gathers and evaluates the PI and research staff for financial conflicts of interest (COI). (*If applicable, an attachment may be added.)*

    b. Confirm that the applicable COI policy has, and will be, followed for the protocol in question, during the entire time period (initial review, continuing review, amendments) that the NIH IRB will be the IRB of record.
    ☐ Yes
    ☐ No (*Individuals not in compliance with local COI requirements may not participate in the protocol being reviewed by the NIH)*

25. Please describe your institution's requirements for human subjects protections training for PIs and other staff engaged in research.

    a. Confirm that the investigators involved in the research are in compliance with local training requirements.
    ☐ Yes
    ☐ No *(If so, please attach an explanation to this form.)*

26. Provide the boilerplate language that is specific to your institution. This is standard language required by your institution that is added to the research-specific text of an informed consent document, such as: birth control language, coverage of research injury, required phone numbers for the PI or study representative, and a person unaffiliated with the study who can answer general study questions, etc. (*If applicable, an attachment may be added.)*

27. Provide the institutional letterhead used for the informed consent document. (*If applicable, an attachment may be added.)*

28. Provide any other institutional requirements for informed consent documents. For example, if the relying institution has identified a conflict of interest, does the relying institution's management plan require a change in the informed consent document? *(If applicable, an attachment may be added.)*

29. Is there anything else the NIH IRB should know about the institution's local context or institutional policies?
    - ☐ Yes
    - ☐ No

30. Confirm that the institution has the adequate training, experience, facilities and resources to conduct the proposed research procedures. (*If applicable, an attachment may be added.)*
    - ☐ Yes
    - ☐ No

31. Add any additional comments that will help the NIH IRB in its review process: (*If applicable, an attachment may be added.)*