

## INITIAL REVIEW LOCAL CONTEXT WORKSHEET

*Please complete a copy of this worksheet for each relying institution. This form should be completed by the local context representative/IRB contact. 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: \_\_\_\_\_ (MM/DD/YY)

Site Investigator	
Protocol Title	
UNC IRB Protocol #	
Institution Relying on UNC for IRB Review (signatory institution):	
Local Context Representative/IRB contact	
Title of Local Context Representative/IRB contact	
Attestation by Local Context Representative/IRB contact	<p>I attest to the accuracy of the responses provided.</p> <p>_____</p> <p style="text-align: center;">Local Context Representative Signature                      Date</p>

## 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 may be 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 any conflict.

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 a summary of the management plan requirements) and any language that should be 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 the adequate education, expertise and experience 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

3.2 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 local laws 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 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 UNC 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 (*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 UNC IRB will approve informed consent documents for use by the site investigator. The relying 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 and your 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 policies regarding 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 attachment may be added e.g. copy of the relevant institutional policy.)*

11. UNC uses a separate standalone HIPAA Authorization form. Please indicate your 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 local laws 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, an attachment 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 by children 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 they have 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? *(If applicable, an attachment can be added.)*

20. 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

21. If applicable, please confirm that all site-specific ancillary reviews have been completed (e.g. Pharmacy, Radiation safety, etc.)

Yes

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

22. Is there anything else the UNC IRB should know about the institution's local context or institutional policies?

Yes

No

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