**UNC IRB INITIAL REVIEW LOCAL CONTEXT WORKSHEET**

Please complete a copy of this worksheet. The study team at the relying institution (aka “Site”) may collaborate with the institution’s local context representative to complete the form, but the form should be signed by the relying institution’s 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.

Relying institutions with questions about completing this form may contact the UNC IRB at IRBreliance@unc.edu.

* **Study Title:** Click or tap here to enter text.
* **UNC IRB Study #**: Click or tap here to enter text.
* **Institution Relying UNC is relying on for IRB Review (Signatory Institution)**: Click or tap here to enter text.
* **Site Principal Investigator**: Click or tap here to enter text.
* **Local Context Representative/IRB contact (Name, Title, email):** Click or tap here to enter text.
* **I attest to the accuracy of the responses provided**: (Local Context Representative/IRB Contact to sign)

1. **RELYING INSTITUTION INFORMATION** (all institutions need to complete)

	1. **Please provide the full legal name of the organization:**

 Click or tap here to enter text.

1.2 **Provide any other names the site is known by or any affiliation, such as a university or** **hospital**:

 Click or tap here to enter text.

1.3 **Please provide the organization’s Federal Wide Assurance (FWA) Number**:

 Click or tap here to enter text.

1.4 [ ]  Yes [ ]  No **Has the site's FWA (federal wide assurance) been extended to non**-**federally funded research** (i.e. has the institution “checked the box” on their FWA)?

1.5 [ ]  Yes [ ]  No **If the site is within a network or system, do any sites have a separate FWA**?

1.6 **Please list sites within network that have a separate FWA**:

 Click or tap here to enter text.

1.7 [ ]  Yes\* [ ]  No **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?**

\*If “Yes,” please explain any investigations, audits or findings that may be relevant:

 Click or tap here to enter text.

1.8 [ ]  Yes\* [ ]  No **Does the institution have a post approval monitoring program or other regulatory oversight for ongoing research?**

**\***If yes, does the post approval monitoring program or other regulatory oversight monitor studies that have been deferred to an external IRB?

Click or tap here to enter text.

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

 Click or tap here to enter text.

1.9 [ ]  Yes [ ]  No **Please confirm that the institution has adequate facilities and resources to conduct the proposed research procedures. (If applicable, an attachment may be added.)**

1. **LOCAL CONTEXT– ALL SITES MUST COMPLETE THIS SECTION**

Participating sites are responsible for reviewing the protocol and determining whether the UNC-approved study conflicts with or does not address state laws or institutional policies at the Relying Institution. It is also the relying site’s responsibility to manage or eliminate any conflict of interest or report management plans to the UNC IRB.

2.1 **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.

2.2 [ ]  Yes [ ]  No\* **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.**

\*If ‘No’ please explain:

Click or tap here to enter text.

2.3 [ ]  Yes [ ]  No\* **Please confirm that the relying institution’s investigators have the adequate education, expertise and experience to conduct the proposed research procedures.** (If applicable, an attachment may be added)

\* If ‘No’ please explain:

Click or tap here to enter text.

2.4 [ ]  Yes [ ]  No\* **Are the UNC approved privacy and confidentiality provisions consistent with the resources and practices available at your institution?**

\*If ‘No’ please explain:

 Click or tap here to enter text.

2.5 [ ]  Yes [ ]  No\* **Are the UNC approved privacy and confidentiality provisions consistent with local laws, institutional policies, and HIPAA (if applicable)?**

\*If ‘No’ please explain:

 Click or tap here to enter text.

2.6 [ ]  Yes [ ]  No\* **Are the UNC approved data use and security provisions consistent with your institutional policies/requirements?**

 \*If ‘No’ please explain:

 Click or tap here to enter text.

2.7 [ ]  Yes\* [ ]  No **Are there any other sections of the UNC-approved protocol which are inconsistent with local laws or your institution’s policies?**

\*If ‘Yes’ please explain:

 Click or tap here to enter text.

2.8 [ ]  Yes [ ]  No\* **Are there any state and/or local laws that are relevant for the human subjects research proposed at this site?** (If applicable, an attachment can be added):

Click or tap here to enter text.

2.9 [ ]  Yes [ ]  No\* [ ]  N/a\* **Please confirm that all site-specific ancillary reviews have been**  **completed (e.g. Pharmacy, Radiation safety, etc.)**

\*If ‘No’ or ‘N/a’ please explain:

 Click or tap here to enter text.

2.10 [ ]  Yes\* [ ]  No **Is there anything else the UNC IRB should know about the institution’s local context or institutional policies?**

\*If ‘Yes’ please provide details:

 Click or tap here to enter text.

1. **LOCAL CONTEXT – ONLY THE SITES THAT ARE ENROLLING THEIR OWN PARTICIPANTS SHOULD COMPLETE SECTION**

This section covers any information that will affect UNC review for the Relying Institution regarding subject selection and the informed consent process. Note that UNC requests that you provide any institutionally required language or and/or considerations that will affect site-specific, participant facing documents. When written informed consent is required for a research study, the UNC IRB will approve site-specific recruitment materials and 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.

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

 Click or tap here to enter text.

3.2 [ ]  Yes [ ]  No\* [ ]  Not applicable **Does the selection and recruitment process for this study comply with local laws and your institutional policies?**

\*If ‘No’ please explain:

 Click or tap here to enter text.

3.3 [ ]  Yes [ ]  No\* **Do you find the selection and recruitment methods in this study acceptable in the context of your local area?**

\*If ‘No’ please explain or provide site-specific plans that may differ from the UNC study team:

 Click or tap here to enter text.

3.4 [ ]  Yes\* [ ]  No **Is there anything else the UNC IRB should know about the anticipated study population at your institution?**

\*If ‘Yes’ please explain:

 Click or tap here to enter text.

3.5 **Check all vulnerable populations from which you intend to enroll in this protocol**:

[ ]  Not Applicable
[ ]  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: Click or tap here to enter text.

3.6 [ ]  Yes\* [ ]  No\* **Will non-English speakers be enrolled?**

\*If ‘Yes’ please describe the non-English speaking population at your site:

Click or tap here to enter text.

\* If ‘No’ please provide an explanation why:

 Click or tap here to enter text.

3.7 **Provide any standard language for the informed consent document required by your institution.** (If applicable, an attachment may be added. This includes subject injury language, study activities, confidentiality language, participant protections, etc.)

 Click or tap here to enter text.

3.8 [ ]  Yes [ ]  No\* **Does the consent/assent process for this study comply with local laws and your institution’s consent policies?**

\*If ‘No’ please explain:

 Click or tap here to enter text.

3.9 [ ]  Yes [ ]  No\* **Do the consent/assent documents (and/or waiver of documentation of consent ) for this study comply with local laws and your institution’s policies regarding informed consent?**

\* If ‘No’ please explain:

 Click or tap here to enter text.

3.10 **At your site 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: Click or tap here to enter text.

3.11 **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.)

 Click or tap here to enter text.

3.12 **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

3.13 [ ] Yes [ ] No\* **Will you provide compensation to participants enrolled in this protocol?**

\*If ‘No’ please explain:

 Click or tap here to enter text.

3.14 [ ]  Yes [ ]  No\* **Is the participant compensation described in the study consistent with local laws and your institution’s policies?**

\*If ‘No’ please explain: Click or tap here to enter text.

3.15 [ ]  Yes\* [ ]  No **Will this site be requesting that UNC grant a limited HIPAA waiver for recruitment and eligibility?**

\*If ‘Yes’ please provide a response to the following prompts:

3.15.1 Under this limited waiver, you are allowed to access and use only the minimum amount of PHI necessary to review eligibility criteria and contact potential subjects. List the data you are planning to collect for this purpose. Be specific (e.g., date of birth, diagnosis of hypertension, A1C.).

 Click or tap here to enter text.

3.15.2 Describe how confidentiality/privacy will be protected prior to ascertaining the patient’s willingness to participate.

 Click or tap here to enter text.

3.15.3 Describe when and how you will destroy PHI for individuals who participate or for individuals decline participation. If retention of PHI is required for the research, you will need to obtain authorization from the subjects. Note: identifiers should be destroyed when their purpose is fulfilled, such as at the conclusion of screening.

 Click or tap here to enter text.

3.15.4 Please explain how screening could not be practicably conducted without the waiver.

Click or tap here to enter text.

3.15.5 Explain why it would not be possible to conduct the screening without the use of PHI.

 Click or tap here to enter text.

3.16 **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.)

 Click or tap here to enter text.

3.17 **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.)

 Click or tap here to enter text.

3.18 **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.)

Click or tap here to enter text.

3.19 **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**. (If applicable, an attachment can be added.)

 Click or tap here to enter text.

3.20 **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.)

 Click or tap here to enter text.

3.21 **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.)

 Click or tap here to enter text.

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

 Click or tap here to enter text.

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

 Click or tap here to enter text.