OMB #: XXXX-XXXX

 Expiration Date: XX/XX/XXXX

# ATTACHMENT 4: CONTINUING 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 and by 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. The topics listed below reflect those asked on the Initial Review Local Context Worksheet that was previously submitted for the protocol named below. Indicate for each topic whether or not there are changes from the information previously provided. If there are changes, please describe. Attachments in support of changes may be added.*

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 Principal/Lead Investigator signature Date |

**SUBJECT SELECTION** (Questions 1-3 on the Initial Review Local Context Worksheet)

[ ]  No change

[ ]  Changed (If changed, please attach an explanation to this form.)

**VULNERABLE POPULATIONS** (Questions 4-5 on the Initial Review Local Context Worksheet)

[ ]  No change

[ ]  Changed (If changed, please attach an explanation to this form.)

**INFORMED CONSENT PROCESS** (Questions 6-9 on the Initial Review Local Context Worksheet)

[ ]  No change

[ ]  Changed (If changed, please attach an explanation to this form.)

**COMPENSATION** (Questions 10-11 on the Initial Review Local Context Worksheet)

[ ]  No change

[ ]  Changed (If changed, please attach an explanation to this form.)

**PRIVACY AND CONFIDENTIALITY** (Questions 12-14 on the Initial Review Local Context Worksheet)

[ ]  No change

[ ]  Changed (If changed, please attach an explanation to this form.)

**COMMUNITY DESCRIPTORS** (Questions 15-16 on the Initial Review Local Context Worksheet)

[ ]  No change

[ ]  Changed (If changed, please attach an explanation to this form.)

**STATE AND LOCAL LAW** (Questions 17-22 on the Initial Review Local Context Worksheet)

[ ]  No change

[ ]  Changed (If changed, please attach an explanation to this form.)

**ADDITIONAL INFORMATION** (Questions 23-31 on the Initial Review Local Context Worksheet)

[ ]  No change

[ ]  Changed (If changed, please attach an explanation to this form.)

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-xxxx). Do not return the completed form to this address.