

**ATTACHMENT 4: CONTINUING REVIEW LOCAL CONTEXT**

*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	<p>I attest to the accuracy of the responses provided and to having confirmed these with the Local Context Representative listed above.-</p> <p>_____</p> <p>Site Principal/Lead Investigator signature      Date</p>

**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.)

