

ATTACHMENT 4: CONTINUING REVIEW LOCAL CONTEXT WORKSHEET

This form should be completed by the Site PI. 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)

Principal Investigator	
Protocol Title	
Protocol #	
Institution Relying on NIH for IRB Review (signatory institution)	
Local Context Representative:	

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 23-30 on the Initial Review Local Context Worksheet)

- No change
- Changed (If changed, please attach an explanation to this form.)