

Meeting Date \_\_\_\_\_

Protocol ID \_\_\_\_\_ PD: \_\_\_\_\_

eProtocol / SQL

Regular  8a  8b  8c (circle one)

Expedited 1-7, 9

If modification is included, complete Expedited Eligibility Checklist.

\* N/A for interviews, surveys, and behavioral interventions

Yes <input type="checkbox"/> 1. Consent Form(s) received? No <input type="checkbox"/> <input type="checkbox"/> Translation(s) N/A <input type="checkbox"/> <input type="checkbox"/> Revised HIPAA <input type="checkbox"/> Revised Assent(s)	Yes <input type="checkbox"/> 2. CTA/RRI and interventions described? No <input type="checkbox"/> N/A <input type="checkbox"/>	
Yes <input type="checkbox"/> 3. Number enrolled appropriate? Consent target OK? No <input type="checkbox"/> <input type="checkbox"/> Compared to last Continuing Review N/A <input type="checkbox"/> <input type="checkbox"/> Compared to target <input type="checkbox"/> Consent target different than protocol	Yes <input type="checkbox"/> 4. Demographic distribution OK? No <input type="checkbox"/> <input type="checkbox"/> Gender <input type="checkbox"/> Minority <input type="checkbox"/> Minors N/A <input type="checkbox"/>	
5. Other Proposed Changes to Protocol not listed in Continuing Review changes question? Describe Below		Rad- /Bio-Safety?
a		
b		
c		
d		
Yes <input type="checkbox"/> 6. All Continuing Review questions answered completely? If no, questions _____ No <input type="checkbox"/>	Yes <input type="checkbox"/> 7. MPP / Training Grant? No <input type="checkbox"/> <input type="checkbox"/> Included in eProtocol title <input type="checkbox"/> Sub-study list attached	
Yes <input type="checkbox"/> 8. Personnel/COI changes? No <input type="checkbox"/>	<input type="checkbox"/> Change in Institutional COI <input type="checkbox"/> CITI required for (names) _____ <input type="checkbox"/> Change in COI for (names) _____	
Yes <input type="checkbox"/> 9. Funding OK? No <input type="checkbox"/> N/A <input type="checkbox"/>	<input type="checkbox"/> Funding change. (New SPO# _____ Funder _____) <input type="checkbox"/> Complete grant attached, only if new Federal funding)	
Yes <input type="checkbox"/> 10. Reports attached? No <input type="checkbox"/> <input type="checkbox"/> Required by monitoring plan <input type="checkbox"/> Not required; returned to investigator	Yes <input type="checkbox"/> 11. Obligations: language for approval letter? No <input type="checkbox"/> <input type="checkbox"/> Deleted items not reviewed with this event	

**12. INFORMED CONSENT CHECKLIST** If multiple, ICF name: \_\_\_\_\_

Yes <input type="checkbox"/> 13. Identifiers OK? No <input type="checkbox"/> <input type="checkbox"/> Title <input type="checkbox"/> PD N/A <input type="checkbox"/> <input type="checkbox"/> Approval Date <input type="checkbox"/> Expiration Date <input type="checkbox"/> Page numbers <input type="checkbox"/> SHC/LPCH barcode	Yes <input type="checkbox"/> 14. Benefits: "We cannot and do not guarantee"? Any format is OK. No <input type="checkbox"/> N/A <input type="checkbox"/>	Yes <input type="checkbox"/> 15. Payment: "Payments may only be made..."? No <input type="checkbox"/> <input type="checkbox"/> SU <input type="checkbox"/> VA (old language) N/A <input type="checkbox"/>
Yes <input type="checkbox"/> *16. Compensation: "All forms..." paragraph same as last approved consent? No <input type="checkbox"/> <input type="checkbox"/> SU <input type="checkbox"/> VA N/A <input type="checkbox"/>	Yes <input type="checkbox"/> 17. Contact Info verbatim? No <input type="checkbox"/> N/A <input type="checkbox"/>	Yes <input type="checkbox"/> *18. Subjects Bill of Rights? No <input type="checkbox"/> <input type="checkbox"/> missing; was in previous N/A <input type="checkbox"/> "11 <sup>th</sup> bullet"
Yes <input type="checkbox"/> 19. Protocol changes appear in consent form as appropriate? No <input type="checkbox"/> <input type="checkbox"/> Specify reference letter from question 7 _____ N/A <input type="checkbox"/>	Yes <input type="checkbox"/> 20. Found "lost wages" No <input type="checkbox"/> N/A <input type="checkbox"/>	

21. Other Consent Form changes not already listed in Continuing Review changes or otherwise inappropriate? Describe Below

a	
b	
c	

Yes <input type="checkbox"/> 22. Signature OK? No <input type="checkbox"/> <input type="checkbox"/> Participant N/A <input type="checkbox"/> <input type="checkbox"/> *POC (if Bill of Rights) <input type="checkbox"/> Short Form witness line <input type="checkbox"/> SU LAR <input type="checkbox"/> VA LAR <input type="checkbox"/> VA SSN <input type="checkbox"/> VA witness <input type="checkbox"/> VA initials each page deleted	Yes <input type="checkbox"/> 23. HIPAA OK? No <input type="checkbox"/> <input type="checkbox"/> Font 14 pt <input type="checkbox"/> Title (any OK) N/A <input type="checkbox"/> <input type="checkbox"/> Expiration beyond next renewal <input type="checkbox"/> PHI recipients <input type="checkbox"/> Separate signature & date <input type="checkbox"/> Consent font visibly different (embedded only) <input type="checkbox"/> Meeting date (after 9/07) <input type="checkbox"/> SU LAR <input type="checkbox"/> VA LAR <input type="checkbox"/> VA health benefits clause <input type="checkbox"/> VA SSN & line for printed name	Yes <input type="checkbox"/> 24. Children? No <input type="checkbox"/> <input type="checkbox"/> Parental consent box on ICF or separate consent for children <input type="checkbox"/> 404/405 (51/52) 2 signature lines <input type="checkbox"/> 406/407 (53/54) 2 signature lines and parent-unavailable boxes <input type="checkbox"/> Assent: meeting date <input type="checkbox"/> Assent: no approval or expiration dates <input type="checkbox"/> Assent not required <input type="checkbox"/> Everything's OK
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Signed \_\_\_\_\_

Date \_\_\_\_\_