

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"/> If Federal funding: Is complete grant attached? | |
| Yes <input type="checkbox"/> 10. Reports attached? <input type="checkbox"/> <i>Sponsor-Investigator</i> : Annual Report to FDA No <input type="checkbox"/> <input type="checkbox"/> Not required; returned to investigator <input type="checkbox"/> Required by monitoring plan | 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"/> N/A <input type="checkbox"/> <input type="checkbox"/> SU <input type="checkbox"/> VA (old language) |
| Yes <input type="checkbox"/> *16. Compensation: "All forms..." paragraph same as last approved consent? No <input type="checkbox"/> N/A <input type="checkbox"/> <input type="checkbox"/> SU <input type="checkbox"/> VA | 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 th 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 witness <input type="checkbox"/> VA initials each page deleted <input type="checkbox"/> VA SSN 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 (50.51/50.52) - two signature lines <input type="checkbox"/> 406/407 (50.53/54) - two signature lines and checkboxes <input type="checkbox"/> Assent: no approval/expiration dates <input type="checkbox"/> Assent not required <input type="checkbox"/> Everything's OK |

Signed _____

Date _____