IRB Study Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PI NaME: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

short stUDY tITLE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ aUDIT dATE/aUDITOR: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

## INFORMED CONSENT (IC) DOCUMENTATION

(To be used when a subject signature is required for participation as determined by the IRB application)

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| Subject # | IC Present and Signed & Dated by Adult Subject/LAR? | If subject did not provide consent for self, did the appropriate LAR(s) sign? | Rationale for LAR consent, LAR identification process & attempts to contact, and reasons for unavailability documented? | Date Signed by Subject/LAR | IC Version Signed | POC signature and date present on IC? | POC was IRB-approved as study personnel (with appropriate role) at this time? | IC was the appropriate version (based on IRB approval date)? | IC Process documented? *(minimum: IC provided in advance & reviewed with subject, opportunity for questions, consent obtained prior to study procedures & copy given to keep)* | If IC was revised, was subject re-consented / notified in manner & timeframe approved by IRB? | Comments |
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IRB Study Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PI NaME: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

short stUDY tITLE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ aUDIT dATE/aUDITOR: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

## ASSENT (AST) DOCUMENTATION

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| Subject # | If AST signature was not required (per IRB application), was verbal assent obtained? *(Best practice would include documenting the verbal assent process in the study records)* | If AST signature was required, is AST present and signed by Minor/ILCC? | Date Signed by Minor/ILCC?  *(note: Minor/ILCC subjects are not required to date their signatures themselves)* | Was AST obtained (and signature obtained, if applicable) prior to Study Procedures? | AST Version Signed | AST was the appropriate version (based on IRB approval date)? | Was AST signature obtained on correct document (IC vs AST) as per IRB application? | If Minor reached age of majority, was self-consent obtained prior to continuation of study procedures? | If ILCC gained capacity, was self-consent obtained prior to continuation of study procedures? | Comments |
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IRB Study Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PI NaME: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

short stUDY tITLE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ aUDIT dATE/aUDITOR: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

## AUTHORIZATION

(To be used when a written authorization, i.e., subject/LAR signature, is required for participation)

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| Subject # | Auth Present and Signed by Adult Subject/LAR and dated? | If subject did not provide authorization for self, did the appropriate LAR(s) sign? | Date Signed by Subject/LAR | Was the Auth signed (and received, if applicable) prior to study procedures? | Auth Version Signed | Auth was the correct version (based on IRB approval date)? | Auth is complete? (including subject address?) | For stand-alone authorization, did subject/LAR indicate any access restrictions that would prohibit participation? | Auth Process documented? (minimum: signed copy given) | If Minor reached age of majority, was self-authorization obtained prior to continuation of study procedures? | If ILCC gained capacity, was self-authorization obtained prior to continuation of study procedures? | Comments |
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