Principal Investigator: Reviewer: Date:
CHA-IRB- Amendment #:
Study Title:

Expedited Amendment Review Form

☐ The amendment is a minor change to previously approved research; it is eligible for expedited review according to 45 CFR 46.110(b)/21 CFR 56.110 (either or both of the following applies: (1) some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk, (2) minor changes in previously approved research during the period for which approval is authorized.
Category ( ). REVIEWER: Specify category 1 and/or 2) and document rationale below.
☐ The proposed amendment is to be reviewed by the **convened IRB**. The amendment is greater than minimal risk, or it is not a minor change (e.g., procedures involving increased risk or discomfort are added). Please document rationale below.

☐ Re-consent of currently enrolled active subjects is required.

☐ Re-consent of currently enrolled active subjects is *not required* or not applicable.

Review Comments
☐ Amendment approved as submitted. Version date or number of protocol approved: _____ Version date or number of ICF approved:_____☐ N/A ☐ Follow up/clarification required from Principal Investigator; detailed below. ☐ Findings (e.g., consent waiver, minors): Comments/Notes:

I have reviewed this Expedited Amendment Review request by expedited procedures and, unless noted differently above, confirm:

- I do not have a potential conflict of interest with this study.
- This modification is minimal risk (45 CFR 46.102(j)) (45 CFR 46.102(i) of the pre-2018 requirements) and qualifies for expedited review (45 CFR 46.110).
- I have reviewed the COI disclosure forms for the study team or have received confirmation from ____ that no member of the study team has a COI.
- The risks to subjects are minimized by: (1) Using procedures that are consistent with sound research design and which do not unnecessarily expose participants to risk; (2) when appropriate, using procedures already being performed on the participants for diagnostic or treatment purposes. (45 CFR 46.111(a)(1))
- Risks to subjects are reasonable in relation to anticipated benefits, if any, to the participants and the importance of the knowledge that may reasonably be expected to result (45 CFR 46.111(a)(2)).
- Selection of subjects is equitable (45 CFR 46.111(a)(3)).
- Informed consent will be sought and documented or waived (45 CFR 46.111(a)(4), 45 CFR 46.111(a)(5)), 45 CFR 46.116, 117, as applicable).
- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects (45 CFR 46.111(a)(6)).
- When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data (45 CFR 46.111(a)(7)).
- Appropriate safeguards are included to protect subjects likely to be vulnerable to coercion or undue influence (45 CFR 46.111(b)).
- When the research involves pregnant women, fetuses, or neonates; prisoners; or children, the research satisfies the additional requirements for IRB approval under DHHS regulations at 45 CFR 46 subpart B, C, or D, respectively.

Date of modification approval:
Approval valid until:

Signature Date