UTK IRB – 3-Year Check-In for Exempt Studies and Expedited Studies not Requiring Annual Continuing Review.

Basic Study Information

IRB Number: UTK IRB —

Study Title:

Principal Investigator:

Study Status Check-In

What is the current status of the study? (choose one option below)

- (●) The study has not been initiated
- ( ) The study is open to active enrollment
- ( ) The study is closed to enrollment; however, at least one participant is still receiving research interventions
- ( ) The study is closed to enrollment and all participants have complete research interventions; however, at least one participant is still in follow-up
- ( ) The study is closed to enrollment and all participants have completed research interventions and follow-up. The remaining research activities are limited to data analysis.

Have there been revisions since the initial approval or the last 3-year check-in?

- (●) Yes, and they have been approved by the IRB
- ( ) Yes, and they have been submitted to the IRB and are awaiting approval
- ( ) Yes, and they have not been submitted to the IRB
- ( ) No

Has anything occurred since the initial review or the last 3-year check-in that has altered the risk-benefit profile?

( ) No ( ) Yes

Enrollment Information

Please enter the total number of subjects approved by the IRB on the most recent version of the study application (under "Population" in the approved application).

Note: This appears under the Participant Population Section in the Approved Application.

Please provide the total number of participants accrued since initial approval.

Note: The total number is the total number of individuals who have EVER given consent to participate.

Please provide the total number of participants accrued since the last 3-year check-in.

Note: The total since the most recent check-in is the number who have given consent since the last check-in

Have any participants withdrawn or been terminated by the investigator from the study since the initial review or the last 3-year check-in?

◯ No ◯ Yes

If participants have withdrawn or been terminated from the study, please describe the reasons and any actions taken by the investigator.

Participant Interaction

Have any participants complained about the study since the initial review or the last 3-year check-in? ◯ No ◯ Yes

If participants have complained about the study, please describe the complaints and any actions taken by the investigator.

Note: Please include dates, the nature of the complaint, and how (if at all) the complaint was resolved.

Have any Reportable Adverse Events*, Protocol Deviations**, or Unanticipated Problems Involving Risks to Participants or Others*** Occurred since the initial review or the last 3-year check-in?

◯ No ◯ Yes

* Reportable Adverse Events: any unfavorable occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or

disease, temporally associated with the subjects participation in the research, whether or not considered related to the subject's participation in the research. A significant adverse event is an adverse event that is unexpected and substantively impacts the human subjects.

**Protocol Deviations: failure to follow federal, state, or local regulations governing human subject research, institutional policies related to human subject research, or the requirements or determinations of the IRB. – See SOP 17 for More Detail

***Unanticipated Problems Involving Risks to Participants or Others: refers to any incident, experience, outcome, or new information that is unexpected, at least possibly related to participation in the research, indicates that subjects or others are at a greater risk of harm (including physical, psychological, economic, legal or social harm) than was previously known or recognized – See SOP 16 for more detail

****If the investigator, or a member of the study team, has knowledge of any Adverse Events, Protocol Deviations, or Unanticipated Problems Involving Risks to Participants, then they must be reported to the IRB, per SOPs 16, 17, and 19.

Conflict of Interest

Has a new conflict of interest (as defined in the current University of Tennessee Conflict of Interests Policy) developed for the principal investigator or other key study personnel since the initial review or the last 3-year check-in?

◯ No ◯ Yes

Investigator Sign-Off

Please confirm your approval of the submission of this 3-year check-in by clicking the "Yes" button.

◯ No ◯ Yes