IRB Protocol #: _____ Expiration Date: _____

Principal Investigator: _____ Potential expedite: ◯ Yes ◯ No

Primary Contact: _____

Please address the following issues.

(to see how these issues were determined, please see the following pages for the IRB staff pre-review checklist)

Pre-Review Checklist for Continuing Reviews

SECTION I

1. Did the PI disclose an outside interest in the "Submit to IRB" activity in the CR form?

◯ No ◯ yes → if yes, document for IRB reviewer. If any action is needed, note in "Issues."

2. If the study is funded by a grant, has the grant progress report been submitted?

◯ N/A ◯ Yes, submitted ◯ Yes, but progress report is not needed because: _____ ◯ No, progress report is needed (note in Issues)

3. Are all listed personnel in compliance with the BSD training policy?
https://biologicalsciences.uchicago.edu/sites/biologicalsciences/files/2019-06/PITrainingPolicy.pdf

◯ Yes ◯ No, the following personnel are not in compliance *(note in Issues)*: _____

4. Is the study FDA-regulated? ◯ Yes ◯ No ◯ Unclear (document any necessary action in Issues)

SECTION II: ENROLLMENT

5. What is the current status of enrollment? Are research activities ongoing?

◯ Open to enrollment
◯ Temporarily halted
◯ Unclear – see Issues
◯ Waiver of consent – still enrolling (skip to question 6)
◯ Waiver of consent – closed (skip to question 6)
◯ Permanently closed to enrollment (skip to question 6)

If still open to enrollment or temporarily halted:

A. Do the current consent/authorization form(s) comply with current policies and regulatory requirements?

◯ Yes ◯ No, non compliant with policy (note in Issues) ◯ No, regulatory element missing (note in Issues)

B. Has any outside financial interest been disclosed in the consent form?

◯ N/A (no COI has been disclosed) ◯ No, see Issues ◯ Yes, the following were described _____

C. Do any advertisements meet the policy requirements?

◯ N/A (no ads) ◯ Yes, no issues with current ads ◯ No, ad(s) require revision (see Issues)

D. Do the current surveys/questionnaires meet IRB standards?

◯ N/A (no surveys) ◯ yes, no issues ◯ No, note in Issues

6. Number approved to enroll ____

Has this number been exceeded? ◯ No ◯ Yes, see note in Issues or explain here why no action is needed: _____

7. Does enrollment align with previously reported numbers?

◯ N/A, no enrollment to date or this is the first CR ◯ Yes, no action needed ◯ No, see Issues

8. Are children an approved study population?

- ◯ No, and no children have been enrolled
- ◯ No, and children have been enrolled (see note in Issues)
- ◯ Yes (go to question 7.A)

A. Is re-consent at age 18 a protocol requirement? ◯ No ◯ Yes

B. If yes, has this been done for some/all kids? Note any issues.

SECTION III: PROGRESS TO DATE

9. Have monitoring reports been provided?

- ☐ N/A, no monitoring
- ☐ Yes, internal monitoring report provided
- ☐ Yes, external DSMB or equivalent report provided
- ☐ No, monitoring committee has not met to date
- ☐ No, explain here or note in Issues section

10. Was a summary of safety events and deviations provided?

- ◯ N/A, no intervention on study
- ◯ Yes, appropriate reporting was provided
- ◯ Yes, but reporting appears incomplete (see Issues)
- ◯ No, additional information is needed (see Issues)

11. Were appropriate literature searches provided?

◯ Yes ◯ No, see Issues ◯ N/A. Explain here why this is N/A:

12. Were results reported?

- ◯ Yes, no action needed
- ◯ Yes, but see Issues
- ◯ N/A (explain as needed)
- ◯ No, and see Issues

13. If the study was approved with stipulations, were those addressed?

◯ N/A, there were no stipulations ◯ Yes, no comments ◯ No, see Issues

14. Have there been unanticipated problems (UPs) reported since the last review?

◯ N/A ◯ Yes, describe and/or note any issues:

15. Have there been any amendments since last review?

- ◯ N/A
- ◯ Yes, but only personnel changes
- ◯ Yes, and there are no outstanding issues
- ◯ Yes, and issues are noted above (examples include consent form modifications that may affect CR, amendment reported enrollment as closed but CR says it is open, etc.)