PROTOCOL APPROVAL WITH MODIFICATIONS

DATE:	13 Oct 2023
TO:	Anna MacMonegle
PROTOCOL:	RTI International - Monthly Implementation Assessment Study (MIA) (Pro00073709)
APPROVAL DATE:	29 Sep 2023

IRB APPROVED DOCUMENTATION:

Protocol Version(s):

- Protocol (Version 7-6-2023)

Consent Form(s):

- Main Informed Consent Form (Advarra IRB Approved Version 10 Oct 2023)
- Assent Form 12-AOM (Advarra IRB Approved Version 10 Oct 2023)
- Parent Guardian Informed Consent Form (Advarra IRB Approved Version 10 Oct 2023)

Recruitment Material:

- Attachment 3 Screener Invitation Email (Version 7-10-2023)
- Questionnaire, Attachment 1: Parent Screener to Determine Youth Eligibility (Version 7-10-2023)
- Attachment 4 Knowledge Panel Recruitment Procedures (Version 7-10-2023)

Other Material:

- Attachment 8: Reminder Email Notifications to Parents (Version 7-10-2023)
- Attachment 9: Reminder Email Notifications to Participants (Version 7-10-2023)
- Questionnaire, Attachment 2b: Monthly Implementation Assessment Instrument (CIGS) (Version 7-10-2023)
- Questionnaire, Attachment 2a: Monthly Implementation Assessment Instrument (ENDS) (Version 7-10-2023)

The IRB approved the above referenced protocol and your site with the modifications listed below on 29 Sep 2023:

- **Revisions to the Informed Consent Forms**
- **Revisions to the Assent Form**
- **Revisions to the Reminder Email Notifications to Parents Material**

- **Revisions to the Reminder Email Notifications to Participants Material**

The IRB granted a waiver of documentation of consent/assent for this study.

On 10 Oct 2023, the IRB reviewed and approved additional edits to the Informed Consent and Assent Forms.

The above referenced recruitment/subject material is available on your Advarra CIRBI Platform workspace under the "IRB Issued Documents" tab.

The IRB reviewed the project in accordance with the 45 CFR Part 46, Subpart D Federal Regulations which provide for additional protections for children as research subjects.

The IRB determined that the research study meets the criteria found in the risk category described as follows:

- 45 CFR 46.404: *"Research not involving greater than minimal risk." The IRB has granted a waiver of parental permission for minors ages 12 to Age of Majority.*

Assent from participants is required for ages 12 to Age of Majority.

There is no expiration date for this study, and it is not subject to requirements for continuing review under the revised Common Rule (2018 Requirements). However, a termination report must be submitted upon termination of the study.

If the study is in an FDA 30-day wait period, subjects **may not** be consented or screened, as consent would be required before study-specific screening activities may begin. However, some initial activities related to determining a potential subject's interest in the upcoming study may occur. Such activities should be limited to recruitment efforts to inform potential subjects, or a community that a study may soon begin on a given condition. However, screening subjects to determine eligibility would not be acceptable until the IND is in effect.

Audio/visual recruitment or subject material approved in script format only must be submitted in final format for the IRB to review what potential subjects will see or hear. The IRB does not review the content found in embedded links or QR codes, therefore this content must be submitted for review and approval separately, prior to use.

If you wish to appeal the IRB's determinations and/or imposed modifications, please submit supporting documentation to address the IRB's concerns by creating an Appeal Modification in CIRBI.

Approved investigators and sites are required to submit to Advarra for review, and await a response, prior to implementing any amendments or changes in the protocol; informed consents; advertisements or recruitment materials ("study-related materials"); investigators; or sites (primary and additional).

Approved investigators and sites are required to notify Advarra of the following reportable events, including, but not limited to unanticipated problems involving risks to subjects or others; unanticipated adverse device effects; protocol violations that may affect the subjects' rights, safety, or well-being and/or the completeness, accuracy and reliability of the study data; subject death; suspension of enrollment; or termination of the study.

Compliance Statement/REB Attestation (Applicable for research conducted in Canada):

The IRB attests that this submission has been approved by an IRB whose membership complies with the requirements defined in Health Canada regulations, ICH GCP guidelines, FDA regulations at 21 CFR part 56, and HHS regulations at 45 CFR part 46. The IRB carries out its functions in accordance with FDA regulations at 21

CFR parts 50, 56, 312, and 812; HHS regulations at 45 CFR part 46, subparts A-E; good clinical practices; Health Canada regulations; and the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, as appropriate to the research.

Advarra IRB is registered with OHRP and FDA under IRB#00000971.

Please review the IRB Handbook located in the "Reference Materials" section of the Advarra CIRBI™ Platform (www.cirbi.net). A copy of the most recent IRB roster is also available.

Thank you for selecting Advarra IRB to provide oversight for your research project.

Sincerely,

Luke Gelinas, PhD
Executive Board Chair