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PROTOCOL APPROVAL WITH MODIFICATIONS

DATE:	30 Sep 2022
TO:	Matt Eggers, MPH
PROTOCOL:	Food and Drug Administration (FDA) - Pro00065519, Copy Testing of Tobacco Prevention and Cessation Advertisements Research Study (Umbrella Study) (Pro00065519)
APPROVAL DATE:	25 Aug 2022

IRB APPROVED DOCUMENTATION:

Protocol Version(s):

- Protocol (Not Dated)

Consent Form(s):

- Parent/Legal Guardian Informed Consent Form (Advarra IRB Approved Version 13 Sep 2022)
- Assent Form (Advarra IRB Approved Version 13 Sep 2022)

Recruitment Material:

- Questionnaire, Screener (Not Dated)
- Questionnaire, Survey Instrument (Not Dated)
- Internet, Appendix E: Sample Social Media Ads (Not Dated)
- Social Media Ads Video Script (Not Dated)
- Internet, Produced Social Media Ad (Dated 09282022)

The IRB approved the above referenced protocol and your site with the modifications listed below on 25 Aug 2022:

- **Revisions to the Parent/Legal Guardian Informed Consent Form**
- **Revisions to the Assent Form**
- **Revisions to the Appendix E Sample Social Media Ads**

On 13 Sep 2022, the IRB reviewed and approved additional revisions to the Informed Consent and Assent Forms.

On 28 Sep 2022, the IRB reviewed and approved revisions to the Sample Social Media Ads and the Social Media Ads Video Script.

The IRB granted a Waiver of Documentation of Consent/Assent for this study.

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

The IRB reviewed the project in accordance with the 21 CFR Part 50, Subpart D Federal Regulations and/or 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:

- 21 CFR 50.51 / 45 CFR 46.404: *"Research not involving greater than minimal risk." Permission of one parent is required.*

The IRB granted a Waiver of Parental Permission for the Direct Youth Recruitment only.

Assent is required for subjects ages 13 – 17.

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 this 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.

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.

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.