PROTOCOL APPROVAL WITH MODIFICATIONS

DATE: 7 Jun 2019

TO: Dana Wagner, Ph.D.

PROTOCOL: F.D.A. Center for Tobacco Products - 17352 - AI/AN BCC, Developing Brand and Creative Concepts Designed to Prevent AI/AN Youth Tobacco Use (Pro00033326)

APPROVAL DATE: 28 May 2019

IRB APPROVED DOCUMENTATION:

Protocol Version(s):

- Submitted as "AIAN BCC Protocol 2019"

Consent Form(s):

- Assent Form (Advarra IRB Approved Version 28 May 2019)
- Guardian Opt-Out Form (Advarra IRB Approved Version 28 May 2019)
- Guardian Informed Consent Form (Advarra IRB Approved 28 May 2019)
- Guardian Verbal Consent Script (Advarra IRB Approved 28 May 2019)

Recruitment Material:

- Screener (Not Dated)
- RECRUITMENT MATERIALS (Not Dated)

Other Material:

- Creative Addendum (Not Dated)
- APPROVED PARTICIPANT LIST (Not Dated)
- CHECK-OUT FORMS (Not Dated)
- CREATIVE CONCEPT SURVEY (Not Dated)
- BRAND TEST SURVEY (Version A)
- BRAND TEST SURVEY (Version B)
- Check-In Survey (Not Dated)
- INFORMATION PACKET MATERIALS (Not Dated)
- Moderator Guide (Not Dated)
- Funding Documentation (Not Dated)

The IRB approved the above referenced protocol and your site with the modifications listed below on 28 May 2019:

- **Revisions to the Consent Forms**

If you wish to have the IRB reconsider the imposed modifications, you may follow the procedures outlined below:

1. Submit supporting documentation that addresses the IRB's concerns.
2. Provide a written justification for relief of any IRB imposed condition.

The IRB reviewed the project in accordance with 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."*

Waiver of parental consent is approved. Obtaining documented parental consent is permitted from 1 parent, as determined appropriate by the study investigator.

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

If there are any changes to the IRB approved material, IRB approval will be needed prior to use. This includes changes in relative size and type of font in the material to be viewed by potential subjects.

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.

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 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.

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RESCUE

Marisa Greenberg <mgreenberg@rescueagency.com>

Pro0003326

1 message

Amy Redmond <Amy.Redmond@advarra.com> Wed, Jun 12, 2019 at 6:37 PM
To: "mgreenberg@rescueagency.com" <mgreenberg@rescueagency.com>

To clarify the IRB approval for the above referenced submission.

The IRB Approval with Modifications Notice (Dated 28 May 2019) for the F.D.A. Center for Tobacco Products 17352 study states the PI/site was approved to conduct this study with the modifications as listed on the notice. The bullet point references modifications made by the IRB to the consent/assent documents. All revisions to the consent/assent documents per the notice are incorporated in the approved material released with the notice. There is no further action needed from Rescue Agency unless additional changes are made to the consent/assent documents.

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