PROTOCOL APPROVAL WITH MODIFICATIONS

DATE: 17 May 2018

TO: Dana Wagner, Ph.D.
Rescue Social Change Group

PROTOCOL: F.D.A. Center for Tobacco Products - 15543 - Strat Concepts Research, Developing Strategic Concepts Designed to Prevent AI/AN Youth Tobacco Use (Pro00024887)

APPROVAL DATE: 16 May 2018

EXPIRATION DATE: 16 May 2019

IRB APPROVED DOCUMENTATION:

Protocol Version:

- Protocol (Not Dated)

Consent Forms:

- Parent Guardian Permission Form (Advarra IRB Approved Version 16 May 2018)
- Assent Form 12-17 Year Olds (Advarra IRB Approved Version 16 May 2018)
- Parental Permission Verbal Script (Advarra IRB Approved Version 16 May 2018)

Recruitment Material:

- Discussion Group Overview (Not Dated)
- Screener Script (Not Dated)
- Screener (Not Dated)
- List of Federally Recognized Tribes in the Lower 48 States (Not Dated)

Other Material:

- Moderator Guide (Not Dated)
- Document Submitted As: Att 06 Individual Picture Sort Deck.pdf
- Picture Sort Form (Not Dated)
- Check-In Survey (Not Dated)
- Document Submitted As: Att 09 ID Projection.pdf
- Video Stimuli - Addendum A (Not Dated)
- CHECK OUT FORM - YOUTH (Not Dated)
- CHECK OUT FORM - ADULTS (Not Dated)
- APPROVED PARTICIPANT LIST (Not Dated)
- Grant Document (Not Dated)

The IRB approved the above referenced protocol and your site with the modifications listed below on 16 May 2018:

- **Modifications to the Parent Guardian Permission Form**
- **Modifications to the Assent Form 12-17 Year Olds**
- **Modifications to the Parental Permission Verbal Script**
- **Modification to the Informed Consent Process: A Waiver of Documentation of Consent is granted for the use of the Screener Script and Screener for Recruitment Purposes only.**

In addition, the IRB granted a waiver of consent for 14-17 year old's parent/guardian, but opt-out consent is allowed. Also, the IRB determined all minor participants must provide assent and consent from the parent/guardian of 12-13 year olds must be provided.

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 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." Permission of one parent is required.*

The above referenced recruitment 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.

If the study is expected to last beyond the approval period, you must request and receive re-approval prior to the expiration date noted above. A report to the Board on the status of this study is due prior to the expiration date or at the time the study closes, whichever is earlier. It is recommended that you submit status reports at least 4 weeks prior to your expiration date to avoid any additional fees or lapses in approval.

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; 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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Columbia, MD 21046

RESCUE

Samantha Jacobs <sjacobs@rescueagency.com>

Pro00024887 Clarifying Language and IAA

Rebecca Fisher <Rebecca.Fisher@advarra.com> Wed, May 30, 2018 at 11:16 AM
To: Samantha Jacobs <sjacobs@rescueagency.com>

Hi Samantha,

Please see below:

The IRB Approval with Modifications Notice (Dated 17 May 2018) for the F.D.A. Center for Tobacco Products 15543 study states the PI/site was approved to conduct this study with the modifications as listed on the notice. The first three bullet points reference 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 Social Change Group unless additional changes are made to the consent/assent documents.

In addition, per our conversation yesterday, you can reach out to cpg@advarra.com regarding IRB Authorization Agreements.

Please let me know if you need anything further.

Thanks,

ADVARRA

Rebecca (Reba) A. Fisher, B.A., CIP| Manager, Client Services
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From: Samantha Jacobs <sjacobs@rescueagency.com>
Sent: Wednesday, May 30, 2018 10:53 AM
To: Rebecca Fisher <Rebecca.Fisher@advarra.com>
Subject: Fwd: Pro00024887 Clarifying Language and IAA

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