PROTOCOL APPROVAL WITH MODIFICATIONS

DATE:	24 Jul 2019
TO:	Dawnyea Jackson, PhD
PROTOCOL:	F.D.A. Center for Tobacco Products - 17441 - Nicotine Education Project, Nicotine Education Project: Qualitative Study to Gain Insights from Adult Current and Former Smokers to Educate the General Public about Changing Nicotine Standards (Pro00037456)
APPROVAL DATE:	24 Jul 2019
EXPIRATION DATE:	24 Jul 2020

IRB APPROVED DOCUMENTATION:

Protocol Version:
- Protocol (Not Dated)

Consent Form:
- Informed Consent Form (Advarra IRB Approved Version 24 Jul 2019)

Other Material:
- Check-In Survey (Submitted as: Appendix E2_Check-In Survey_Former Smokers_Use Nicotine_7.22.19)
- Check-In Survey (Submitted as: Appendix E1_Check-In Survey_Current Smokers_7.22.19)
- Check-In Survey (Submitted as: Appendix E3_Check-In Survey_Former Smokers_Quit All Forms of Nicotine_7.22.19)
- Nicotine Education Project – Moderator Guide (90 Min) [Not Dated]
- Screener (Not Dated)
- Participant Check Out Form (Not Dated)
- Screener Contact Sheet (Not Dated)

The IRB approved the above referenced protocol and your site with the modifications listed below on 24 Jul 2019:

- **Modifications to the Informed Consent Form**

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.

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; 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

Molly Barry <mbarry@rescueagency.com>

IRB Message Re: F.D.A. Center for Tobacco Products - 17441 - Nicotine Education Project

1 message

cirbi@advarra.com <cirbi@advarra.com> Thu, Jul 25, 2019 at 1:42 PM
Reply-To: cirbi@advarra.com
To: blong@rescueagency.com, dana@rescuescg.com, mbarry@rescueagency.com, icrowe@rescueagency.com, djackson@rescueagency.com

CIRBI Link:	Pro00037456
Submission:	F.D.A. Center for Tobacco Products - 17441 - Nicotine Education Project
Protocol Title:	Nicotine Education Project: Qualitative Study to Gain Insights from Adult Current and Former Smokers to Educate the General Public about Changing Nicotine Standards
From:	Advarra IRB
Attachment(s):	There are no items to display

The approval with modifications notice is the IRB's final approval. The revisions to the consent form(s) have been incorporaed on your behalf and no further action on your part is required. Thanks

Kind Regards,
Amy Redmond
443-283-1622 / amy.redmond@advarra.com

Please click on the CIRBI link Pro00037456 and use the **Contact IRB** to respond to the message.

Template:PRO_A_Contact Client