

PROTOCOL APPROVAL WITH MODIFICATION

DATE: 8 Dec 2017

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

PROTOCOL: F.D.A. Center for Tobacco Products - 14913 - FE W3 CT, Multicultural Campaign: Wave 3 Online Quantitative Study of Reactions to Rough-Cut Advertising Designed to Prevent Multicultural Youth Tobacco Use (Pro00023377)

APPROVAL DATE: 6 Dec 2017

EXPIRATION DATE: 6 Dec 2018

IRB APPROVED DOCUMENTATION:

- Protocol Version(s):**
- Protocol (Version: 12.1.2017)
- Consent Form(s):**
- PARENT / GUARDIAN CONSENT Opt-Out Form (Chesapeake IRB Approved Version 6 Dec 2017)
 - PARTICIPANT ASSENT/CONSENT FORM (Chesapeake IRB Approved Version 6 Dec 2017)
- Recruitment Material:**
- Screener (Not Dated)
 - Social Media Advertisements (Addendum A)
- Other Material:**
- Video Ad Stimuli (Addendum B)
 - Parent & Participant Electronic Communications (Not Dated)
 - Questionnaire (Not Dated)
 - Funding Documentation (HHSF223201750007A)

The IRB approved the above referenced protocol and your site with the modifications listed below:

- **Revisions to the Consent Form(s)**
- **Revision to the informed consent process: A Waiver of Documentation of Consent is granted for the use of the Screener for Recruitment Purposes only.**

The IRB also approved a Waiver of Documentation of Consent for Subjects and with a Waiver of Parental Consent.

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.”*

The above referenced recruitment material is available on your CIRBI workspace under the “IRB Issued Documents” tab.

Please submit a final formatted copy of all recruitment material approved in script format only (e.g. television or radio script in .mp3, .wav, or .wmf format). The final format must be in the format potential subjects will see and hear.

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.

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

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





Carolyn Stalgaitis <carolyn@rescueagency.com>

IRB Message Re: F.D.A. Center for Tobacco Products - 14913 - FE W3 CT

1 message

cirbi@chesapeakeirb.com <cirbi@chesapeakeirb.com>

Wed, Dec 13, 2017 at 4:45 PM

Reply-To: cirbi@chesapeakeirb.com

To: dana@rescuescg.com, anjana@rescueagency.com, carolyn@rescuescg.com

CIRBI Link: [Pro00023377](#)

Submission: F.D.A. Center for Tobacco Products - 14913 - FE W3 CT

Protocol Title: Multicultural Campaign: Wave 3 Online Quantitative Study of Reactions to Rough-Cut Advertising Designed to Prevent Multicultural Youth Tobacco Use

From: Chesapeake IRB

Attachment(s): There are no items to display

Please note, the IRB approval with modification notice states that your PI has been approved (to conduct this study) with the modifications listed on the notice. These are modifications made by the IRB to the consent documents. All revisions to the consent documents per the approval notice are incorporated in the approved material released with the approval notice. There is no further action needed with the IRB unless additional changes are made. Let me know if you have any questions. Thanks

Kind Regards,
Amy Redmond
[443-283-1622](tel:443-283-1622) / aredmond@chesapeakeirb.com

Please click on the CIRBI link [Pro00023377](#) and use the **Contact IRB** to respond to the message.

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