Chesapeake IRB
Human Connection >>> Technology Driven

PROTOCOL APPROVAL WITH MODIFICATION

DATE: 2 Dec 2016

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

PROTOCOL: F.D.A. Center for Tobacco Products - W3 CC, Multicultural Campaign Wave 3: Focus group study of youth reactions to creative advertising concepts designed to prevent tobacco use (Pro00019800)

APPROVAL DATE: 1 Dec 2016

EXPIRATION DATE: 1 Dec 2017

IRB APPROVED DOCUMENTATION:

Protocol Version:

- Protocol (Version Not Dated)

Consent Form:

- PARTICIPANT ASSENT FORM AGES 12 – 17 (Chesapeake IRB Approved Version 1 Dec 2016)
- PARENTAL / GUARDIAN CONSENT FORM (Chesapeake IRB Approved Version 1 Dec 2016)
- PARENTAL / GUARDIAN CONSENT VERBAL SCRIPT (Chesapeake IRB Approved Version 1 Dec 2016)
- PARENTAL / GUARDIAN CONSENT FORM Opt out form (Chesapeake IRB Approved Version 1 Dec 2016)

Recruitment Material:

- INFORMATIONAL PACKET (PARENTAL CONSENT) (Not Dated)
- INFORMATIONAL PACKET (PARENTAL OPT-OUT) (Not Dated)
- Parent Contact Form (For Consent Only) (Not Dated)
- School Recruitment Principal Email (Not Dated)
- Screener (Not Dated)
- Screener Script (Not Dated)
- Study Overview (Not Dated)

Other Material:

- Instructions for Research Team (Not Dated)
- Check-In Survey (Not Dated)
- Moderator Guide (Not Dated)
- Creative Concept Survey (Not Dated)
- Addendum A – Creative Concept Stimuli (Not Dated)
- APPROVED PARTICIPANT LIST (Not Dated)

Association for the Accreditation of Human Research Protection Programs, Inc. Full Accreditation
6940 Columbia Gateway Drive, Suite 110, Columbia, MD 21046 | 410 884 2900 | chesapeakeirb.com

- CHECK OUT FORM (Not Dated)
- Document Submitted As: Student Reminder Notes (Not Dated)

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

- **Revisions to the Consent Forms**
- **Revisions to the Screener to add elements of consent and grant waiver documentation of consent for its use in recruitment**

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 granted waiver of parental consent for subjects aged 13 to 17 and a waiver of documentation of consent for subjects age 12.

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 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 by accessing CIRBI™ (www.cirbi.net). Log on to your CIRBI homepage ("My Home") and select the "Reference Materials" tab for IRB requirements and guidance. A copy of the most recent IRB roster is also available under "Reference Materials".

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

Full Accreditation
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RESCUE

Carolyn Stalgaitis <carolyn@rescueagency.com>

IRB Message Re: F.D.A. Center for Tobacco Products - W3 CC

1 message

cirbi@chesapeakeirb.com <cirbi@chesapeakeirb.com> Tue, Dec 6, 2016 at 3:38 PM
Reply-To: cirbi@chesapeakeirb.com
To: dana@rescuescg.com, rgauvin@rescueagency.com, anjana@rescueagency.com, carolyn@rescuescg.com

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CIRBI Link:	Pro00019800
Protocol:	F.D.A. Center for Tobacco Products - W3 CC
From:	Chesapeake IRB
Attachment(s):	There are no items to display

Hello Carolyn
As a follow up to our call earlier. 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. All revisions to the consent forms and recruitment 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 / aredmond@chesapeakeirb.com

Please click on the CIRBI link Pro00019800 and use the **Contact IRB** to respond to the message.

Template:PRO_A_Contact Client