

## PROTOCOL APPROVAL WITH MODIFICATIONS

**DATE:** 17 May 2017

**TO:** Sarah A. Evans, Ph.D.  
Fors Marsh Group

**PROTOCOL:** Food and Drug Administration (FDA) Center for Tobacco Products -, TRC Smokeless Wave 2 Creative Concept Testing – Focus Groups and In-depth Interviews With Rural Youth (Pro00021668)

**APPROVAL DATE:** 16 May 2017

**EXPIRATION DATE:** 16 May 2018

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### IRB APPROVED DOCUMENTATION:

- Protocol Version:**
- Protocol, "TRC Smokeless Wave 2 Creative Concept Testing – Focus Groups and In-depth Interviews With Rural Youth" (Dated May 8, 2017)
- Consent Forms:**
- Focus Groups 12-17 Assent Form (Chesapeake IRB Approved Version 16 May 2017)
  - In-Home Interviews 12-17 Assent Form (Chesapeake IRB Approved Version 16 May 2017)
  - In-School Interviews 12-17 Assent Form (Chesapeake IRB Approved Version 16 May 2017)
  - Focus Groups Parent of Children Age 12 Informed Consent Form (Chesapeake IRB Approved Version 16 May 2017)
  - In-Home Interviews Parent of Children Age 12-17 Informed Consent Form (Chesapeake IRB Approved Version 16 May 2017)
  - In-School Interviews Parent of Children Age 12 Informed Consent Form (Chesapeake IRB Approved Version 16 May 2017)
  - Focus Groups Parent of Children Age 13-17 Notification Form (Chesapeake IRB Approved Version 16 May 2017)
  - In-School Interviews Parent of Children Age 13-17 Notification Form (Chesapeake IRB Approved Version 16 May 2017)
- Recruitment Material:**
- TRC Smokeless Wave 2 Creative Concept Testing, Focus Group Initial School Contact Scripts (Not Dated)
  - Focus Group High Level Overview: Upcoming Research Project (Not Dated)
  - TRC Smokeless Wave 2 Creative Concept Testing, Focus Group Screener (Not Dated)

- TRC Smokeless Wave 2 Creative Concept Testing, In-Home Interview Contact Script (Not Dated)
- TRC Smokeless Wave 2 Creative Concept Testing, Initial School Contact Scripts (Not Dated)
- In-Depth Interviews High Level Overview: Upcoming Research Project (Not Dated)
- TRC Smokeless Wave 2 Creative Concept Testing, In-depth Interview Screener (Not Dated)
- TRC Smokeless Wave 2 Creative Concept Testing, In-Home Interview Contact Notification (Not Dated)

**Other Material:**

- Creative Concept Rating Worksheet (Not Dated)
- Creative Concept Stimuli (Not Dated)
- SLT Imagery Boards (Not Dated)
- TRC Smokeless Wave 2 Creative Concept Testing, FG Concept Ranking Worksheet (Not Dated)
- TRC Smokeless Wave 2 Creative Concept Testing, FG Concept Rating Worksheet (Not Dated)
- TRC Smokeless Wave 2 Creative Concept Testing, Focus Group Discussion Guide (Not Dated)
- TRC Smokeless Wave 2 Creative Concept Testing, Pre-Session Activity (Not Dated)
- TRC Smokeless Wave 2 Creative Concept Testing, In-Depth Interview, Activity (Not Dated)
- TRC Smokeless Wave 2 Creative Concept Testing, In-Depth Interview Discussion Guide (Not Dated)

The IRB approved the above referenced protocol and your site with the modifications listed below on 16 May 2017:

- **Modifications to the Consent Forms**
- **Revision to the Informed Consent Process: A Waiver of Documentation of Consent for the collection of personal information for recruitment purposes has been granted for the Focus Group Screener and the In-depth Interview Screener**

**The IRB also granted a Waiver of Parental Consent for the Parental Notification Forms.**

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 for 12 year old participants and in schools where the Principal requires parental permission for all other participants.*

The above referenced recruitment material is available on your CIRBI workspace 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.

Please review the IRB Handbook by accessing CIRBI™ ([www.cirbi.net](http://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.

