

OMB Amendment Explanatory Memo

To: Office of Management and the Budget (OMB)

From: FDA/CTP/OHCE

FDA Sponsor: Tesfa Alexander

Date: 1/27/2021

RE: Amendment to *Wave 3 Phase 1 Qualitative Research: General Market ("The Real Cost") At-Risk Youth Tobacco Prevention Focus Groups*; OMB Control Number 0910-0674.

Principal Investigator: David Cortés, Garfinkel FCB

Background:

The Food and Drug Administration's (FDA) Center for Tobacco Products (CTP) is seeking an amendment to the study, *Wave 3 Phase 1 Qualitative Research: General Market ("The Real Cost") At-Risk Youth Tobacco Prevention Focus Groups* under generic clearance OMB Control Number 0910-0674. The purpose of this study is to assess participants' emotional and cognitive reactions to draft strategic and creative advertising concepts designed to reduce youth tobacco use for the third wave of CTP's General Market At-Risk Youth Tobacco Prevention Campaign ("The Real Cost").

Overview of Study:

In 2014, FDA launched its first youth tobacco prevention campaign targeting at-risk youth aged 12-17 (The Real Cost). To keep the target audience engaged with the campaign, FDA is developing new advertisements, which will begin running in market in 2016. FDA will also be developing advertisements that aim to prevent e-cigarette use. In support of these efforts, the Center for Tobacco Products will conduct a qualitative research study to inform the development of appropriate messaging to prevent combustible cigarette and e-cigarette use among youth. Specifically, this study will use focus group discussions to explore the target audience's reactions to various strategic and creative advertisement concepts intended to prevent youth smoking. Approximately 36 focus groups with an average of six participants each will be conducted in various locations across the U.S. with a total sample of approximately 220 youth. The research will be conducted with youth aged 12-17 who: 1) are at risk of initiating cigarette use; 2) are at risk for initiating e-cigarette use; 3) have experimented with cigarettes, 4) have experimented with e-cigarettes, and 5) have experimented with cigarettes and e-cigarettes. Youth will be diverse in terms of race/ethnicity, gender, and geographical location.

Study Progress:

Study recruitment will begin in July 2015, pending RIHSC approval and OMB approval. Once approved, participants will be recruited, and focus groups will be held starting in August. No progress has been made since receipt of OMB approval granted prior this year.

Description of Proposed Protocol Amendments and Rationale:

This study amendment includes the following changes to the originally-approved OMB package:

1. Memo

- Increased number of focus groups from 30 to 36, resulting in an increase in sample size from 180 to 220 participants. Total increase of 120 respondents.
- Included additional subgroups of participants (i.e., added subgroups of youth who are at risk for using e-cigarettes, youth you are experimenting with e-cigarettes, and youth who are experimenting with both e-cigarettes and cigarettes).
- Updated number of groups of “experimenters” from 90 to 170 and number of groups of “at-risk youth” from 90 to 50.
- Updated study dates.
- Updated description of focus groups activities and time allocations per activity.
- Updated burden estimates to account for increase in sample size from 363 to 443 (burden estimates per participant remain the same). Total increase of 80 burden hours.

2. Screener

- Added questions about e-cigarette susceptibility and usage.
- Removed nonessential questions to account for addition of questions (eliminated questions related to: [1] the nature of the employment of family members, [2] history of market research participation, [3] history of participating in market research on the topic of tobacco, and [4] openness and creativity).
- Modified script so that study staff can assign youth to groups post-phone call and call the youth after screening to provide information on the date, time, and location of the focus group to which they will be assigned.

3. Parental Consent Form

- Simplified language to improve readability to a Flesch Kincaid grade level of 8.5 and to reduce redundancies.
- Noted that focus groups will be audio recorded and that they may be livestreamed (but not video recorded) for other members of the research team.
- Included language about the possibility of loss of privacy due to data breach.

4. Youth Assent Form

- Simplified language to improve readability to a Flesch Kincaid grade level of

7.5.

- Noted that focus groups will be audio recorded and that they may be livestreamed (but not video recorded) for other members of the research team.

5. Discussion Guide:

- Modified Creative Concept discussion guide to include e-cigarette questions.
- Modified Strategic Concept discussion guide to include e-cigarette questions and to include creative concept questions (now the Combined Strategic and Creative Concept discussion guide).
- Updated description of stimuli in instructions.
- Included closing language for wrap-up.

Documents Submitted for OMB Review (including this memo):

1. OMB Amendment Explanatory Memo [*New document*]
2. OMB Justification Memo
3. OMB Justification Memo]
4. General Market Youth Tobacco Wave 3 Screener General Market Youth Tobacco Wave 3 Parental Consent Form
5. General Market Youth Tobacco Wave 3 Youth Assent
General Market Youth Tobacco Wave 3 Discussion Guide