

**FDA DOCUMENTATION FOR THE GENERIC CLEARANCE FOR THE COLLECTION OF
QUALITATIVE DATA ON TOBACCO PRODUCTS AND COMMUNICATIONS (0910-0796)**

TITLE OF INFORMATION COLLECTION: Qualitative Study of Perceptions and Knowledge of Visually Depicted Health Conditions

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. Statement of need:

The Food and Drug Administration's (FDA) Center for Tobacco Products (CTP) is seeking OMB approval under generic clearance 0910-0796 to conduct in-depth interviews ($n=54$) with youth ages 12-17 who are susceptible to smoking, young adult smokers ages 18-24, and adult smokers ages 25-60. The research will be fielded to assess participants' understanding of cigarette graphic health warning (GHW) images designed to increase knowledge and correct misperceptions about the negative health consequences of cigarette smoking.

2. Intended use of information:

Information obtained through this study will inform the development of new cigarette GHW labels designed to increase knowledge and correct misperceptions of the negative health consequences of cigarette smoking. Study participants will view draft images depicting a range of negative health consequences and answer questions regarding image comprehension, relevance, and believability. The results will be used to identify the most promising images as well as indicate areas for further refinement.

3. Description of respondents:

The study will consist of fifty-four (54) participants, including eighteen (18) non-smoking youth ages 12-17 who are open to smoking, eighteen (18) young adult smokers ages 18-24, and eighteen (18) adult smokers ages 25 to 60. Eighteen (18) of the fifty-four (54) participants will be Spanish-reading. Study participants will be otherwise diverse in race/ethnicity and gender. Up to one thousand (1,300) potential participants will be screened to obtain the desired sample size of fifty-four (54) total participants.

4. Date(s) to be conducted:

Data collection is projected to occur two (2) weeks after final OMB approval is received, and will last for approximately four (4) months.

5. How the information is being collected:

The information will be collected through fifty-four (54) in-depth interviews led by either an English- or Spanish-speaking professional interviewer in private meeting rooms or research facilities. The interviewer will ask each participant a series of questions using a semi-structured interview guide and encourage participants to respond openly and spontaneously. Each interview will last up to sixty (60) minutes. Individual interviews with English-speaking participants will be live streamed to allow FDA staff to remotely monitor the sessions. All interviews will be audio-recorded to aid in data analysis.

GHW Image In-Depth Interviews: 60 minutes

After the participant check-in process (5 min.) is completed, the interviewer will obtain the participant's consent for audio recording and live streaming, read a brief statement describing the research purpose and the interview process, and ask the participant a few introductory questions (10 min.). The participant will then be shown up to twelve (12) draft

images depicting negative health consequences of cigarette smoking in random order. After each image is shown, the interviewer will ask the participant a series of questions to obtain feedback on image comprehension, relevance, and believability (35 min.). At the conclusion of the interview, the participant will be asked to briefly review twelve (12) additional images at the same time for comparison and feedback (5 min.). Finally, the interviewer will end the interview and assist the participant with collecting his or her incentive (5 min.).

6. Confidentiality of respondents:

All data will be collected with an assurance that the participant's responses will remain private to the extent allowable by law.

Researchers will inform participants in the consent form that the information they provide in the screener for recruitment will only be viewed by the researchers. Additionally, interview questions will not ask participants to provide identifying information as part of their responses, and no identifying information will be included in the data files delivered by contractors to the agency.

Identifying information will not be included in the report delivered to the agency. All data received by the FDA will remain in a secured area or on a password-protected computer. No transcripts or analysis will contain identifying information.

Neither the contractor nor subcontractors associated with this study will share personal information regarding research participants with any third party without the participants' permission, unless it is required by law to protect their rights or to comply with judicial proceedings, a court order, or another legal process.

7. Amount and justification for any proposed incentive:

The amount of the incentive as a token of appreciation is \$75 for adult participants, \$40 for youth participants, and \$25 for the parents of youth participants who bring them to the interviews. The incentives will be in the form of a gift card. FDA will be asking respondents to provide thought-intensive, open-ended feedback on concept images that require a high level of engagement. Additionally, FDA requires participation from specialized populations that meet specific criteria including English speaking/reading youth who are susceptible to smoking (less than 30% of the youth population), English speaking/reading current young adult and adult smokers (less than 18% of the adult population), Spanish primary language speaking/reading smoking youth who are susceptible to smoke and/or who smoke, and Spanish primary language speaking/reading young adult and adult smokers. Based on feedback from local research facilities, low incentive rates can cause difficulties in recruiting participants from these subsets, resulting in an insufficient number of participants to successfully complete this study. Low incentive rates can also impact the ability to procure a suitable research facility as some facilities have declined to participate in prior studies due to insufficient incentives for recruitment.

8. Questions of a sensitive nature:

Some studies require the inclusion of people who match selected characteristics of the target audience that the FDA is trying to reach. This may require asking questions about race/ethnicity, income, education, and health behaviors on the initial screening questionnaire used for recruiting. Potential participants are informed that this is being done to make sure that the FDA speaks with the kinds of people for whom its messages are intended. Respondents are assured that the information is voluntary and will be treated as private to the extent allowable by law. All information on race/ethnicity will fully comply with the standards of OMB Statistical Policy Directive No. 15, October 1997

(<http://www.whitehouse.gov/omb/fedreg/1997standards.html>).

FDA tobacco use communications may be concerned with the prevention of premature mortality from heart disease and oral and respiratory cancers, and some projects may involve asking questions about (or discussing) how one perceives his or her own personal risk for serious illness. This information is needed to gain a better understanding of the target audience so that the messages, strategies, and materials designed will be appropriate and sensitive. Questions of this nature require some sensitivity in how they are worded and approached. Participants are informed prior to actual participation about the nature of the activity and the voluntary nature of their participation.

Raw data that include sensitive information (e.g., screening questionnaires) are not retained once the data have been extracted and aggregated. The information never becomes part of a system of records containing permanent identifiers that can be used for retrieval.

9. Description of statistical methods:

This research relies on qualitative methods to collect data. This research is not intended to yield results that are statistically projectable, nationally representative, or precise estimates of population parameters.

BURDEN HOUR COMPUTATION *Number of respondents (X) estimated response or participation time in minutes (/60) = annual burden hours:*

Type / Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Screened Potential Participants			
<i>Screening Questionnaire</i>			
Adult	700	5	58
Youth	300	5	25
Parent	300	5	25
<i>Consent</i>			
Consent (36 Adults & 18 Parents)	54	5	4.5
Assent (18 Youth)	18	5	1.5
Subtotal			114
Interview Participants			
Interview Discussion	54	60	54
Total			168

REQUESTED APPROVAL DATE: 9/18/2015

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OMB No. 0910-0796
Exp. 6/30/18

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FDA CENTER: Center for Tobacco Products (FDA/CTP)