

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

TITLE OF INFORMATION COLLECTION:

Consumer Comprehension of Displays of Harmful and Potentially Harmful Constituents (HPHCs) in Tobacco Products; OMB Control Number 0910-0796.

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. Statement of need:

The Food and Drug Administration's (FDA's) Center for Tobacco Products (CTP) is seeking OMB approval under generic clearance 0910-0796 to conduct a series of 50 individual in-depth interviews (IDIs) with adults and youth (14 to 17 years old) to gather information about different ways of presenting harmful and potentially harmful constituent (HPHC) information.

In the past, FDA conducted preliminary research including focus groups and an experimental study which tested a prototype of a list of HPHCs in tobacco. This research found significant gaps in consumer understanding of tobacco constituents and their health effects. Further, it was concluded that the prototype tested did not present HPHC information in a manner that was understandable and not misleading as required by the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act).

FDA plans to leverage its first phase of HPHC research in a new phase of research to gain insight on consumer comprehension of and preferences regarding presentation of information about HPHCs in tobacco products and tobacco smoke. This study will inform the Agency's efforts to make publicly available a list of HPHCs in a way that is understandable and not misleading as required by the Tobacco Control Act.

2. Intended use of information:

Section 904(d)(1) of the Tobacco Control Act states "the Secretary shall publish in a format that is understandable and not misleading to a lay person, and place on public display (in a manner determined by the Secretary) the list [of harmful and potentially harmful constituents] established under subsection (e)." Information obtained through this qualitative study will inform the best way to convey HPHC information that is understandable and not misleading to a layperson. Interview participants will be asked to answer questions regarding different ways of presenting HPHC information.

The study will consist of a series of IDIs with adults and youth. IDIs will be designed to answer the following questions:

- What do adults and youth know and what do they perceive about HPHCs in tobacco products?
- How and in what formats do adults and youth prefer to receive information regarding HPHCs?
- How do adults and youth understand and perceive the information about HPHCs provided in sample formats?

3. Description of respondents:

Fifty (50) IDIs will be conducted with adults and youth (14 to 17 years old) representing a diverse population. To ensure that 50 IDIs are completed, recruitment facilities will recruit 65 potential participants who are adult cigarette users, adult smokeless tobacco users, adult former cigarette or smokeless tobacco users, youth cigarette and/or smokeless tobacco users, or youth who are susceptible to using tobacco products. Approximately 400 adults and youth will be screened to obtain a final sample size of 50.

The IDIs are tentatively scheduled to be conducted in Pensacola, FL, Birmingham, AL, and San Diego, CA. These locations were chosen to maximize geographic distribution while ensuring that research would be conducted in markets with high rates of tobacco use.

4. Date(s) to be conducted:

Recruitment is expected to begin 2 weeks after final OMB/IRB approvals and data collection is expected to last for 6 weeks.

5. How the information is being collected:

A professional interviewer with experience conducting IDIs with adults and youth will collect the information. The interviewer will engage participants in a series of questions using a semi-structured interview guide; encourage participants to respond openly and spontaneously; and, with participants' permission, audio-record and video stream participants' answers and reactions to those answers. For each interview, a research assistant will take notes from an observation suite. Data will be collected in market research facilities. Each participants' participation will last up to 90 minutes.

Youth will be required to bring a signed *Parent Permission Form* with them to the facility in order to participate. Upon arrival to the facility, youth will be asked to read and sign a *Youth Assent Form* while adults will be asked to read and sign a *Consent Form* (30 minutes). During the interview, the interviewer will provide a brief study introduction. Next, participants will be asked questions to assess knowledge and perceptions of chemicals in tobacco products (10 minutes). Then, participants will be asked questions to determine their preferences in the display of HPHC information (20 minutes). Finally, participants will be asked to give feedback on several sample formats of HPHC displays (30 minutes). The interviewer will end the interview and assist participants with collecting their incentives.

6. Confidentiality of respondents:

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

Researchers will inform youth in the assent form, parents in the parent permission form, and adult participants in the consent form that the information they provide during the recruitment screening process and during the interviews will only be viewed by the researchers. Additionally, the 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 reports delivered to the agency. All data received by FDA will remain in a secured area or on a password-protected computer. No data

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 \$40 for adult participants and \$20 for youth participants (with an additional \$20 incentive paid to parents/guardians who bring the youth to the interviews). Because participants often have competing demands for their time, incentives are used to encourage participation in research. The use of incentives treats participants justly and with respect by recognizing and acknowledging the effort they expend to participate. In this particular research, we are asking participants to provide thought-intensive, open-ended feedback that requires a high level of engagement.

8. Questions of a sensitive nature:

Some studies require the inclusion of people who match selected characteristics of the target audience that FDA is trying to reach. This may require asking questions about race/ethnicity, education, health behaviors, and/or health status on the initial screening questionnaire used for recruiting. Potential participants are informed that this is being done to make sure that FDA speaks with the kinds of people for whom its messages are intended. Respondents will be 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 preventing premature mortality from heart disease and oral and respiratory cancers, and may involve asking questions about (or discussing) how one perceives his/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, while not as personal as those about sexual behavior or religious beliefs, for instance, still 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.

FDA tobacco communications may also be concerned with tobacco use by youth before they start. It is important to understand perceptions about smoking from youth who use tobacco or who are susceptible to use because their opinions are valuable in informing campaign or materials development. To identify youth who have used tobacco, researchers need to ask questions about current tobacco use. FDA acknowledges such questions are potentially sensitive because tobacco use among youth under 18 years of age is illegal in some states and selling tobacco to minors is illegal in all states.

Raw data that include sensitive information (e.g., screening questionnaires, youth or parent contact information) 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 interview 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. For this interview study, all participants will be initially contacted by telephone, and over-recruiting will be done to compensate for non-respondents (i.e., no shows).

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

Youth Screener and Assent | estimated participation time: 10 minutes

Adult Screener and Consent | estimated participation time: 10 minutes

Parental Permission Form | estimated participation time: 5 minutes

On site consent/assent (including early arrival) | estimated participation time: 30 minutes

Individual Interview | estimated participation time: 60 minutes

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Screened Potential Participants			
Screening Questionnaire and Assent/Consent	400	10	67
Parental Opt-Out or Consent	28	5	2
On site consent/assent (including early arrival)	50	30	25
Individual Interview		60	50
	Total		144

REQUESTED APPROVAL DATE: 12/22/2016

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