

Quantitative Study of Tobacco Facts Designed to Inform Youth Tobacco Prevention Messaging 0910-0810

Supporting Statement: Summary

- The goal of this project is to measure youth's perceptions of various tobacco-related facts and the effectiveness of these facts among youth aged 13 to 17 who have either experimented with smoking (i.e., have reported smoking fewer than 100 cigarettes in lifetime) or are at risk of initiating smoking (e.g., would smoke if a friend offered them a cigarette).
- The study will be conducted using web-based surveys that are self-administered on personal computers. The study will use an online survey to target approximately 1,500 youth who are 13-17 years old, and who have experimented with cigarettes or who are at risk of experimenting with cigarettes. The study will take approximately 20 minutes to complete per participant.
- The outcome of the survey will be an understanding of teen's receptivity to various tobacco-related facts. Understanding teen perceptions of these facts can help refine tobacco-related messaging for future tobacco prevention campaigns.
- The resulting data will be analyzed using conventional tabulation techniques. The study questions collect information about respondents' reactions to tobacco-related facts, and also include basic demographic and tobacco use information in order to understand whether and how these factors may influence individuals' responses to these facts.

Consent Forms

- Attachment A: Invitation and Parental Permission Form
- Attachment B: Invitation and Youth Assent Form

Data Collection Instruments

- Attachment C: Screener
- Attachment D: Survey
- Attachment E: Facts to be Tested

Quantitative Study of Tobacco Facts Designed to Inform Youth Tobacco Prevention Messaging

0910-0810

Supporting Statement: Part A

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

On June 22, 2009, the Food and Drug Administration (FDA) was granted new authority to regulate the manufacture, marketing, and distribution of tobacco products and educate the public about the dangers of tobacco use. Under the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (P.L. 111-31), FDA is responsible for protecting the public health and reducing tobacco use among minors. Section 1003(d)(2)(D) of the Food, Drug and Cosmetic Act (21 U.S.C. Section 393(d)(2)(D)) and Sections 2, 3, 105, 201, 204, 904, and 908 of the Tobacco Control Act support the development and implementation of FDA public education campaigns related to tobacco use. Accordingly, FDA will implement multi-strategy youth-targeted public education campaigns to reduce the public health burden of tobacco that will consist of general market paid media campaigns, geo-targeted campaigns to reach specific target audiences, community outreach activities, and a comprehensive social media effort.

Tobacco use is the leading preventable cause of disease, disability, and death in the United States. More than 480,000 deaths are caused by tobacco use each year in the United States (USDHHS, 2014). Each day, more than 2,600 youth in the United States try their first cigarette, and nearly 600 youth become daily smokers (NSDUH, 2014). The FDA Center for Tobacco Products (CTP) was created to carry out the authorities granted under the 2009 Tobacco Control Act, to educate the public about the dangers of tobacco use and serve as a public health resource for tobacco and health information.

Through CTP, FDA researches, develops, and distributes information about tobacco and health to the public, professionals, various branches of government, and other interested groups nationwide using a wide array of formats and media channels. FDA will implement youth tobacco prevention campaigns, which are currently under development and will include evidence-based paid media advertising that highlights the negative health consequences of tobacco use. The objective of the proposed data collection is to measure the effectiveness of tobacco-related facts among youth aged 13 to 17 who have either experimented with smoking or are at risk of experimenting with smoking.

This study is designed to measure youth's perceptions of various tobacco-related facts. The study will be conducted using web-based surveys that are self-administered on personal computers. The study will use an online survey to target approximately 1,500 youth who are

13-17 years old, and who have experimented with cigarettes or who are at risk of experimenting with cigarettes. This study will aim to learn about youth's opinions of tobacco-related facts. This survey will ask participants to rate approximately 10 randomly selected facts about tobacco and then answer questions about their knowledge, attitudes and beliefs about these facts.

Participants will be recruited through an existing GfK panel of adults with children ages 13-17 who have been prescreened for their willingness for their child to participate in online surveys. Adult panelists will receive an initial email invitation from GfK that indicates their child has been invited to participate in a new survey (Attachment A). If the parent determines that they would like their child to participate in this particular survey, they will be asked to provide parental permission and an email address for the child. An introductory email will then be sent to the youth inviting them to participate in the study and requesting their assent (Attachment B). If the youth gives their assent, they will be redirected to the online screener (Attachment C). If they qualify to participate in the study, they will begin the survey (Attachment D).

We anticipate data collection to take approximately 3 months. The outcome of the survey will be an understanding of teens' receptivity to various tobacco-related facts. Understanding teen perceptions of tobacco facts can help refine tobacco-related messaging for future tobacco prevention campaigns.

2. Purpose and Use of the Information

The information obtained from the proposed data collection activities is collected from youth ages 13-17 in American households, and will be used to inform FDA, prevention practitioners, and researchers about youth's receptivity to tobacco-related facts. While not exhaustive, the list below illustrates a range of purposes and uses for the proposed information collection:

- Understand what type of tobacco-related facts youth perceive as most effective to prevent smoking.
- Inform FDA, policy makers, and other stakeholders on the impact of potential campaign messages.
- Inform future programs that may be designed for similar purposes.

To achieve these goals, data collection will consist of a survey dissemination to 1,500 teens ages 13-17, 750 who have experimented with smoking and 750 who are at risk of initiating smoking. The survey dissemination will occur over a 3-month period. Youth will not be re-contacted in this study.

All tracking surveys will be conducted by RTI International using a 'participant panel' supplied by GfK. GfK has a nationwide online panel, known as KnowledgePanel®. KnowledgePanel is a nationality representative panel because they use a probability-based sampling methodology which ensures the highest level of accuracy and representativeness available on the web. Their panel is composed of adults in the United States with children

ages 13-17 who have been prescreened for their willingness for their child to participate in online surveys. Adult panelists will receive an initial email invitation from GfK that indicates their child has been invited to participate in a new survey (Attachment A). If the parent determines that they would like their child to participate in this particular survey, they will be asked to provide parental permission and an email address for the child. An introductory email will then be sent to the youth inviting them to participate in the study and requesting their assent (Attachment B). If the youth gives their assent, they will be redirected to the online screener (Attachment C). If they qualify to participate in the study, they will begin the survey (Attachment D) where they will be asked basic demographic information as well as be shown approximately 10 tobacco-related facts.

3. Use of Information Technology and Burden Reduction

This study will rely on web-based survey data collection on receptivity to tobacco-related facts among youth ages 13-17 who have either experimented with smoking or are at risk of initiating smoking. Using an anonymous survey allows the respondent to be more candid with their responses. This allows for more accurate data because respondents provide more honest responses than other types of research methodology, especially since it is clear that the answers will remain confidential. In addition, using a survey will allow for more participants to respond in a cost-effective and timely manner. The self-administered, web-based survey permits greater expediency with respect to data processing and analysis (e.g., a number of back-end processing steps, including coding and data entry). Data are transmitted electronically at the end of the day, rather than by mail. These efficiencies save time due to the speed of data transmission, as well as receipt in a format suitable for analysis. Finally, as noted above, this technology permits respondents to complete the interview in privacy. Providing the respondent with a methodology that improves privacy makes reporting of potentially embarrassing or stigmatizing behaviors (e.g., tobacco use) less threatening and enhances response validity and response rates.

4. Efforts to Identify Duplication and Use of Similar Information

FDA's youth tobacco prevention campaign efforts are relatively new, and therefore it is important to develop messages which will have the largest impact on reducing tobacco use among at-risk youth.

To date, there has been no in-depth testing of youth reactions to different types of tobacco facts, and therefore there are limited data sources that can help identify the most effective tobacco use prevention campaign messages. In order to ensure no duplication of efforts, we have reviewed existing data sets to determine whether any of them are sufficiently similar or could be modified to address FDA's need for information on the tobacco use prevention campaign messages with respect to reducing youth tobacco initiation.

FDA collaborates with other federal government agencies that sponsor or endorse health communication projects, such as the Centers for Disease Control and Prevention, Office on Smoking and Health (CDC/OSH), the Substance Abuse and Mental Health Services Administration (SAMHSA) and the National Institutes of Health – National Cancer Institute

(NIH/NCI). These affiliations serve as information channels, help prevent redundancy, and promote use of consistent measures of effectiveness. Coordination activities include:

- Review of proposed messages for advertisements;
- Review of questionnaires for testing purposes;
- Sharing data; and
- Standardizing survey tools where at all possible.

FDA will share the findings from this collection of information with these agencies. CDC and FDA are developing complementary but distinct communication campaigns to educate the public about the harmful effects of tobacco products. Staff members in FDA's Health Communication and Education unit work closely with staff in OSH's Health Communications Branch. Regularly scheduled conference calls are held to review plans, discuss campaign coordination and share research findings of mutual interest. Staff members in FDA's Health Communication and Education unit are thus working closely with staff in OSH's Health Communications Branch, ASPA, ASPE, and other HHS OPDIVS as appropriate. It was determined that message testing proposed in this GenIC does not duplicate CDC/OSH efforts.

Points of contact for this coordination are:

CDC: Diane Beistle, Chief, Health Communication Branch, Phone: (770) 488-5066, Email: zgv1@cdc.gov

CDC: Deesha Patel, Health Communication Specialist, Health Communication Branch, Phone: (770) 488-8503, Email: wnm2@cdc.gov

NCI: Erik Augustson, Program Director, Tobacco Control Research Branch, Phone: (240) 276-6774, Email: augustse@mail.nih.gov

NCI: Yvonne Hunt, Program Director, Tobacco Control Research Branch, Phone: (240) 276-6975, Email: huntym@mail.nih.gov

5. Impact on Small Businesses or Other Small Entities

Respondents in this study will be members of the general public, specific subpopulations or specific professions, not business entities. No impact on small businesses or other small entities is anticipated.

6. Consequence of Collecting the Information Less Frequently

Respondents to this collection of information will answer only once to ensure the participant burden is as low as possible. Without the information collection requested for this evaluation study, it would be difficult to determine the most effective messages to use in upcoming tobacco prevention campaigns. Failure to collect these data could reduce effectiveness of the

FDA's messaging, and therefore reduce the benefit of the messages for youth in the United States.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information that require the data collection to be conducted in a manner inconsistent with 5 CFR 1320.5(d)(2). The message testing activities fully comply with the guidelines in 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency

Not applicable.

9. Explanation of Any Payment or Gift to Respondents

The survey will be disseminated using an existing adult GfK participant panel with children ages 13-17 who have been prescreened for their willingness for their child to participate in online surveys. Adult panelists will receive an initial email invitation from GfK that indicates their child has been invited to participate in a new survey (Attachment A). If the parent determines that they would like their child to participate in this particular survey, they will be asked to provide parental permission and an email address for the child. An introductory email will then be sent to the youth inviting them to participate in the study and requesting their assent (Attachment B). If the youth gives their assent, they will be redirected to the online screener (Attachment C). If they qualify to participate in the study, they will begin the survey (Attachment D) where they will be asked basic demographic information as well as be shown approximately 10 tobacco-related facts.

Incentives will be received as non-monetary 'points' through the parent's GfK account. Points can later be redeemed by the parent on behalf of their child. These points can be redeemed by the parent through GfK's system for goods or gift cards. The approximate value of the points is \$5 per survey. We estimate that the survey will take 20 minutes to complete. The incentives are intended to recognize the time burden placed on participants, encourage their cooperation, and convey appreciation for contributing to this important study and are similar to incentives that are offered for most surveys of this type. Numerous empirical studies have shown that incentives can significantly increase response rates in cross-sectional surveys and reduce attrition in longitudinal surveys (e.g., Abreu & Winters, 1999; Castiglioni, Pforr, & Krieger, 2008; Jäckle & Lynn, 2008; Shettle & Mooney, 1999; Singer, 2002).

The use of modest incentives is expected to enhance survey response rates without biasing responses. A smaller incentive would not appear sufficiently attractive to participants. We also believe that the incentives will result in higher data validity as participants will become more engaged in the survey process. The specific amount of the proposed incentive is based on a GfK incentive equation for the time burden per participant which results in a recommended incentive amount.

Table 1. Incentive Type and Amount

Type of Incentive	Participant	Amount/Value
Youth survey	All panel members	~ \$5 / survey (points equivalent)

10. Assurance of Confidentiality Provided to Respondents

RTI's Institutional Review Board (IRB) will review and approve the protocols and consent forms for the outcome evaluation survey prior to any respondent contact. The IRB's primary concern is protecting respondents' rights, one of which is maintaining the privacy of respondent information to the fullest extent of the law.

Overview of Data Collection System

All information will be collected electronically through a self-administered survey instrument hosted in a secure, online, web-based data collection system. Respondents will be recruited through an existing GfK web-based panel system, and screened for eligibility and interest prior to administration of the main information collection instrument. All respondents will be ages 13 to 17 who have either experimented with smoking or are at risk of initiating smoking, and they will have parental permission to participate in the study prior to responding to any study questions. Each respondent will give basic demographic information and then give their opinions of approximately 10 tobacco-related facts. The respondent will participate at the time of his or her choosing. There is no website content directed at children younger than 13 years of age. RTI will not have direct contact with participants nor will RTI have access to any personal identifying information about the panelists.

Overview of How Information will be Shared and for What Purposes

Information will be collected by GfK's KnowledgePanel; however, they will not participate in the analysis of the data. They will provide an aggregated dataset to RTI using a password-protected, encrypted file. The password will not be sent in the same email as the encrypted file. RTI will use this data to analyze respondents understanding and preferences of specific tobacco-related facts. Confounders such as demographic characteristics, state of residence, and smoking status will be controlled for during the data analysis.

Overview of the Impact the Proposed Collection will have on the Respondent's Privacy
No individually identifiable information or personal identifying information (PII) is being collected. GfK will recruit from an existing adult panel who have been pre-screened for being parents of children ages 13 to 17. Although demographic information (e.g., gender, age, and race) will be gathered, no direct personal identifiers (e.g., full name, phone number, social security number, etc.) will be collected or maintained as part of the screener (Attachment C) or survey (Attachment D). As such, because it does not exist, no directly identifying information will be transmitted to RTI, and thus, the Privacy Act does not apply. In addition, the data at the observation level is identified through use only of sample unit identifiers. Neither GfK nor RTI employees working on the project will have access to any identifying information.

Overview of Voluntary Participation

During email invitation, potential respondents will be advised of the nature of the survey, the length of time it will require, and that participation is voluntary. The parental permission form as well as the youth assent form will inform the participant that their participation is voluntary. Respondents will be assured that they will incur no penalties if they wish not to respond to the information collection as a whole or to any specific questions. Respondents on the web-based survey will have the option to decline to respond to any item in the survey for any reason and may drop out of the survey at any time. These procedures conform to ethical practices for collecting data from human participants.

Overview of Data Security

All web-based respondents will use a link to enter the survey and the GfK software will assign them a unique ID and the responses will be anonymous. No Personally Identifiable Information will be linked to the survey data. All those who handle or analyze data will be required to adhere to the standard data security policies of RTI. All data will be reported in the aggregate only. During data collection, all data will be stored on password-protected databases to which only GfK employees working on this project have access. GfK will keep the data in non-aggregate form for six months after data collection has been completed, and then the data will be deleted from the password-protected databases. All data will be sent to RTI using a password protected, encrypted file. The password will not be sent in the same email as the encrypted file. RTI will limit access to this portion of the share drive by limiting the personnel with access to this share drive to appropriate project staff.

11. Justification for Sensitive Questions

The majority of questions asked will not be of a sensitive nature. There will be no requests for a respondent's Social Security Number (SSN). However, it will be necessary to ask some questions that may be considered to be of a sensitive nature in order to assess specific health behaviors, such as cigarette smoking. These questions are essential to the objectives of this information collection. Questions about messages concerning lifestyle (e.g., current smoking behavior) and some demographic information, such as race, ethnicity, and income, could be considered sensitive, but not highly sensitive. To address any concerns about inadvertent disclosure of sensitive information, respondents will be fully informed of the applicable privacy safeguards. The informed consent protocol will apprise respondents that these topics will be covered during the survey. This study includes a number of procedures and methodological characteristics that will minimize potential negative reactions to these types of questions, including the following:

- Respondents will be informed that they need not answer any question that makes them feel uncomfortable or that they simply do not wish to answer.
- Web surveys are entirely self-administered and maximize respondent privacy without the need to verbalize responses.

- Participants will be provided with a toll-free phone number for the RTI project director and a toll-free phone number for the RTI IRB hotline should they have any questions or concerns about the study or their rights as a study participant.

Finally, as with all information collected, these data will be presented with all identifiers removed.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

An estimated one-time reporting burden for this collection will be approximately 1,746 hours (Table 2). This includes the time burden associated with the screener.

To obtain a final sample of 1,500 youth; 750 youth ages 13-17 who have experimented with smoking and 750 youth ages 13-17 who are susceptible to smoking in the future, we will need to screen approximately 6,251 potential respondents. This is because we anticipate approximately 24% of youth have experimented with smoking, and about 16% are susceptible to initiating smoking in the future (NYTS, 2014). Based on experience from previous surveys, we anticipate about 75% of screened contacted respondents will provide both parental permission and child assent to participate in the study.

Table 2.—Estimated Annual Reporting Burden¹

Type of Respondent	Activity	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Hours ¹
Screened Potential Participants						
General population	Invitation and Parental Permission	6,251	1	6,251	0.08	500
Youth aged 13 to 17	Invitation and Youth Assent / Youth Screening	4,688	1	4,688	0.16	750
Youth Participants						
Youth aged 13 to 17	Youth ages 13 to 17 in the United States, who are at risk of initiating smoking	750	1	750	0.33	248
	Youth ages 13 to 17 in the United States, who have experimented with smoking	750	1	750	0.33	248
	Total:	1,500				496
Total Annualized Hours						1,746

¹The total number of respondents is 6,251; for this study 1,500 represent the total number of participants.

12b. Annualized Cost Burden Estimate

Respondents participate on a purely voluntary basis and, therefore, are subject to no direct costs other than time to participate. There are also no start-up or maintenance costs. RTI has conducted many smoking-related surveys of similar length among youth. We have examined diagnostic data from prior surveys and estimate that data collection for this study will take approximately 20 minutes per respondent. We have also allocated a few minutes time for parents to give their permission for their child to participate and for youth to give their assent to participate.

To calculate this cost, the mean hourly wage of \$7.25 was used for youth and \$22.33 was used for parents. The youth price represents the minimum wage, and the parental costs represent the Department of Labor estimated mean for state, local, and private industry earnings. There are no direct costs to respondents associated with participation in this information collection. Thus, assuming an average hourly wage of \$7.25 and \$22.33 (youth and parent), the estimated one-year annualized cost to participants will be \$17,480. The estimated value of respondents' time for participating in the information collection is summarized in Exhibit 3.

Table 3. Estimated Annual Cost

Type of Respondent	Activity	Annual Burden Hours	Hourly Wage Rate	Total Cost
Screened Potential Participants	Invitation and Parental Permission Form (Parent)	500	\$ 22.33	\$ 11,165
	Youth Screening Questionnaire (Youth)	750	\$ 7.25	\$ 5,438
Youth Participants	Youth ages 13-17	496	\$ 7.25	\$ 3,596
Total		1,746		\$ 20,199

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no capital, start-up, operating, or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

Table 4. Itemized Cost to the Federal Government

Government Personnel	Time Commitment	Average Annual Salary	Total
GS-12	5%	\$77,490	\$3,874
GS-13	10%	\$92,145	\$9,215
		Total Salary Costs	\$13,089
		Contract Cost	\$93,000
		Total	\$106,089

15. Explanation for Program Changes or Adjustments

This is a new collection of information.

16. Plans for Tabulation and Publication and Project Time Schedule

The analysis will examine overall levels of perceived effectiveness and rating of tobacco-related facts that were tested. Summary statistics will be analyzed for each tobacco-related message for groups such as all youth, at-risk youth, youth who have experimented with smoking as well as for various demographic categories (e.g. age, gender, race/ethnicity). All analyses will be estimated with sampling weights that adjust for non-response and sample design. Findings from these analyses will be used to inform FDA CTP health communication strategies.

Reporting

The reporting and dissemination mechanism will consist of three primary components: (1) summary statistics (in the form of PowerPoint presentations and other briefings) on youth perceptions and preference of tobacco related facts, and (2) a comprehensive evaluation report summarizing findings from this information collection. The key events and reports to be prepared are listed in Exhibit 5.

Table 5. Project Schedule

Project Activity	Date
Survey	March 2016 to April 2016 (Approximate)
Data Analysis	May 2016 to June 2016 (Approximate)
Report Writing and Dissemination	July 2016 to November 2016 (Approximate)

17. Reason(s) Display of OMB Expiration Date is Inappropriate

We are not requesting an exemption to this requirement. The OMB expiration date will be displayed.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

These information collection activities involve no exception to the Certification for Paperwork Reduction Act Submissions.

References

Abreu, D. A., & Winters, F. (1999). Using monetary incentives to reduce attrition in the survey of income and program participation. *Proceedings of the Survey Research Methods Section* (pp. 533-538).

Castiglioni, L., Pforr, K., & Krieger, U. (2008, December). The effect of incentives on response rates and panel attrition: Results of a controlled experiment. *Survey Research Methods* (Vol. 2, No. 3, pp. 151-158).

Jäckle, A., & Lynn, P. (2008). Offre de primes d'encouragement aux répondants dans une enquête par panel multimodes: effets cumulatifs sur la non-réponse et le biais. *Techniques d'enquête*, 34(1), 115-130.

Singer, E. (2002). The use of incentives to reduce nonresponse in household surveys. *Survey Nonresponse*, 51, 163-177.

Shettle, C., & Mooney, G. (1999). Monetary incentives in US government surveys. *Journal of Official Statistics*, 15(2), 231.