**U.S. Food and Drug Administration**
**Center for Tobacco Products**
**Nicotine Education Project**

**OMB Control Number 0910-0810**

**SUPPORTING STATEMENT A**

## A. Justification

### 1. Circumstances Making the Collection of Information Necessary

The Tobacco Control Act (Pub. L. 111-31) amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to grant the U.S. Food and Drug Administration (FDA) authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors. FDA is considering a potential product standard that would lower nicotine levels in combustible cigarettes to minimally or nonaddictive levels. Therefore, FDA needs formative research support to understand how best to educate the public to minimize the risks of this potential product standard. Our research will identify key nicotine misperceptions among youth and young adults, including harms of nicotine, and examine how nicotine misperceptions and health concerns vary by product type (cigarettes, vapes, and nicotine replacement therapies (NRTs) and other characteristics.

### 2. Purpose and Use of the Information Collection

The Food and Drug Administration's (FDA's) Center for Tobacco Products (CTP) contracted with RTI to conduct an online survey of 2,004 youth and young adults (ages 15-24) to gain insight on gaps in youth and young adults' knowledge of the harms of nicotine and how the perceived risks of nicotine vary by product type (cigarettes, cigars, vapes).

Information gathered will not be used for the purpose of substantially informing influential policy decisions. The information gathered is also not intended to yield results that are statistically projectable, nationally representative, or precise estimates of population parameters.

The purpose of the research is to gain insight on gaps in youth and young adults' knowledge of the harms of nicotine and how the perceived risks and benefits of nicotine vary by product type (cigarettes, vapes, and NRT). In addition, we aim to assess youth and young adults' awareness and relative harm/addictiveness perceptions of synthetic nicotine and the extent to which nicotine-related knowledge, attitudes, and behaviors vary by age and tobacco use history.

Specifically, survey questions will be designed to answer the following research questions:

- What are sociodemographic and tobacco use characteristics of youth/young adults with different levels of knowledge about nicotine?
- Do health concerns of nicotine vary by nicotine source (all nicotine, cigarettes, vapes, and NRT)?

- Do perceived absolute harms of nicotine vary by nicotine source (nicotine on its own, cigarettes, vapes, and NRT)?
- Do general nicotine knowledge, attitudes, and behaviors (KABs) vary by age and tobacco uptake?
- Do health concerns of nicotine vary by age and tobacco uptake?
- Do perceived absolute harms of nicotine vary by age and tobacco uptake?
- What are the perceived relative harms of synthetic vs. derived nicotine?

**3. Use of Improved Information Technology and Burden Reduction**

Because this is a web-based study, 100% of the respondents will submit the information in an electronic format. Web-based surveys reduce respondent burden, minimize possible administration errors, and expedite the timeliness of data processing. Furthermore, web-based surveys are less intrusive and less costly compared with face-to-face interviews and mail and telephone surveys. Because there is no interviewer present, participant responses to a web-based survey are less prone to social desirability bias.

**4. Efforts to Identify Duplication and Use of Similar Information**

There is no duplicative collection of this information. No comparable data have been collected by any other entities. We carefully reviewed the literature and existing data sets to determine whether any of them are sufficiently similar or could be modified to address FDA's need for information on gaps in youth and young adults' knowledge of the harms of nicotine and how the perceived risks and benefits of nicotine vary by product type. We concluded that the existing literature and existing data sources do not include the measures needed by FDA.

**5. Impact on Small Businesses or Other Small Entities**

No small businesses will be involved in this collection of information.

**6. Consequences of Collecting the Information Less Frequently**

This is a one-time data collection. The collection of information will provide important data needed for FDA to create an education initiative designed to support a nicotine product standard being considered by the FDA. Failure to collect these data could reduce effectiveness of the FDA's messaging, and therefore reduce the benefit of the messages for youth and young adults in the United States.

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

This information collection fully complies with 5 CFR 1320.5(d)(2). No special circumstances are associated with this information collection that would be inconsistent with the regulation.

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

The following individuals inside the agency have been consulted on the design of the study, instrument development, or intra-agency coordination of information collection efforts:

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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.

The following individuals outside of the agency have been consulted on questionnaire development.

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## 9. Explanation of Any Payment or Gift to Respondents

As a token of appreciation, participants recruited through social media who complete and submit the full survey will receive a $5 gift card, which reflects the burden of spending an estimated average time of 15 minutes taking the survey. There is no token of appreciation for completing the screener.

The token of appreciation allows us to treat participants justly and with respect by acknowledging competing demands for their time and the effort they spend participating. A token of appreciation is necessary to minimize non-response bias, complete data collection goals in a timely manner, reduce overall burden, and reduce costs.

. Offering incentives for participation in the survey also contributes to information quality by enhancing the performance of the recruitment activities. The recruitment strategy relies on the effective placement and reach of the advertisements used to recruit participants of the target populations into the study. This placement and reach on social media platforms are determined by the platforms' systems for targeting the populations necessary for participation in the study. These systems price and place advertisements using an "auction" system, setting prices and prioritizing advertisement placement based in-part on the rate that potential participants engage with the advertisements. Due to the way these advertisement systems function, increasing potential participant engagement with the advertisements results in increased reach of subsequent advertisements among the target populations. Featuring an offer for a token of appreciation in recruitment advertisements greatly enhances engagement with the advertisements such that it is necessary for the advertisement strategy to successfully recruit the required sample size of the study target population

## 10. Assurance of Confidentiality Provided to Respondents

OMB Control Number 0910-0810 is covered under a Privacy Impact Assessment that has been approved by the Department of Health and Human Services (PIA Unique Identifier: P-9008729-198376). Concern for privacy and protection of respondents' rights will play a central role in the study implementation, storage and handling of data, and data analysis and reporting. The Institutional Review Board (IRB) of RTI International, the research organization contracted to manage data collection reviewed and approved the protocols for the survey. CTP's Research Involving Human Subjects Committee (RIHSC) also conducted a courtesy review before submission to RTI IRB. The primary concern of IRB is protecting respondents' rights, one of which is maintaining the privacy of respondent information.

As part of this study, RTI International (RTI), the contractor acting on behalf of FDA, is collecting and maintaining personally identifiable information (PII) about participants who complete the online screener and the online survey. The only PII RTI will collect are email address and birth date, but this information will be stored separately from each other as noted below. RTI will not collect any protected health information, defined as "personally identifiable information" that relates to a person's health, medical treatment or payment, and which was obtained from a "covered entity" (health care provider, health plan, or healthcare clearinghouse), as defined by HIPAA (Health Insurance Portability and Accountability Act) regulations[1]. Online survey data will be collected one time only; there will be no future contact with participants after they complete the online survey.

Privacy for survey respondents will be ensured in a number of ways:

- Survey data will be downloaded from Qualtrics (which requires a password) and stored in databases only on RTI's secure shared drive. After the database is cleaned and incentives are distributed, the databases will be deleted from our Qualtrics account and remain only on RTI's secure shared drive.
- Qualtrics will use a unique alphanumeric ID for each survey participant. Email addresses (for the purpose of distributing incentives) will be collected through a separate Qualtrics form. Only RTI maintains a link between alphanumeric IDs, personally identifying information, and survey responses. RTI will use this information for the purposes of fraud detection and distributing incentives, and the link between personally identifying email addresses and survey responses will be broken once the study is complete and incentives have been distributed. Identifiable information will not be collected with survey data. A separate form will collect email address (for incentive processing only) so that it is not linked to participant data. Only RTI maintains a link between code numbers and personally identifying email address; FDA will not receive data containing the link between code numbers and email addresses. RTI will process the incentives by sharing only the provided email addresses via a password-protected Excel document with the vendor Creative Group Inc. The consent document states that email address provided will only be used for the purpose of sending the incentive and will not be otherwise sold or shared. Creative Group Inc. will never have access to survey data.

[1] https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html

- The resulting de-identified dataset will not include any email addresses or any other identifying information. Each respondent will be known only by a unique alphanumeric ID variable.
- Respondents cannot back up in the survey to view previous responses. For example, if a youth were to exit the survey, the parent could not view previously entered responses. During survey testing, the test links will always include the ability to back up, but this will not be possible in the actual survey that participants complete. RTI will confirm this after testing and before survey launch.
- When data collection is complete, the deidentified data file will be transmitted from RTI to FDA via a website with an SSL certificate applied. The data file, which contains no PII, will be stored by RTI and FDA on a restricted-access folder on a shared network drive, and only authorized project members will have access. RTI will store data for 5 years before deletion.

This study is funded by the FDA, a Department of Health and Human Services supported agency, and is covered by a Certificate of Confidentiality (CoC). Section 2012 of the 21st Century Cures Act includes significant amendments, to the previous statutory authority for such protections, to enhance privacy protections for individuals who are the subjects of federally funded research, under subsection 301(d) of the Public Health Service Act (42 U.S.C. 241). Specifically, the amended authority requires the FDA to issue a CoC to investigators or institutions engaged in research funded by the Federal government to protect the privacy of individuals who are subjects of this research. RTI will notify participants in the assent/consent form of the protections that the Certificate provides.

## 11. Justification for Sensitive Questions

Most questions asked will not be of a sensitive nature. However, it will be necessary to ask some questions that may be considered of a sensitive nature to assess specific health behaviors, such as tobacco use and knowledge about the potential negative health consequences of tobacco products. Asking such questions is critical to the objectives to this information collection, namely: gain insight on gaps in youth and young adults' knowledge of the harms of nicotine and how the perceived risks of nicotine vary by product type.

Some questions about tobacco use are potentially sensitive because tobacco use among adolescents under age 18 is illegal in a few states, and sales to individuals under age 21 are illegal nationwide. These questions are essential to the objectives of this information collection because participants' risk perceptions of nicotine are influenced by whether or not the participant uses tobacco products. Questions concerning lifestyle (e.g., tobacco use) and demographic information, such as race and ethnicity, could be considered sensitive but not highly sensitive. These questions are essential to the objectives of this information collection because they are necessary for measuring the characteristics identified in the stated research question: What are sociodemographic and tobacco use characteristics of youth/young adults with different levels of knowledge about nicotine? To address any concerns about inadvertent disclosure of sensitive information, respondents will be fully informed of the applicable privacy safeguards. The assent/consent form will apprise respondents that the topic of tobacco use 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 participate and that if they choose to participate, they need not answer any question on the survey (aside from required screening questions) that makes them feel uncomfortable or that they simply do not wish to answer.
- The web survey is entirely self-administered to maximize respondent privacy without the need to verbalize responses.
- Participants will be provided with a specific toll-free phone number for the RTI Office of Research Protection and the RTI Principal Investigator to contact in case they have a question or concern about the sensitive issue.

## 12. Estimates of Annualized Burden Hours and Costs

### 12a. *Annualized Hour Burden Estimate*

Information will be collected through a self-administered, online screener and survey of 2,004 youth and young adults (ages 15-24), with a target of 1,336 young adult completes and 668 youth completes. Approximately 8,040 (2,680 youth and 5,360 young adult) respondents will complete a screener to determine eligibility for participation in the study, estimated to take approximately 5 minutes per response, for a total of 669 hours for screening activities. We estimate that 2,004 (668 youth and 1,336 young adult) respondents will complete the informed consent at 2.5 minutes per response, for a total of 84 hours. Finally, we estimate that 2,004 (668 youth and 1,336 young adult) respondents will complete the survey at 15 minutes per response, for a total of 501 hours for completion of both youth and young adult respondents. This data collection will take place one time in 2022. Thus, the annualized response burden is estimated at 1,254 hours. Table 1 provides details about how this estimate was calculated.

**Table 1. Estimated Annual Reporting Burden**

| Type of Respondent | Activity | Number of Respondents | Number of Responses per Respondent | Total Responses | Average Burden per Response | Total Hours |
|---|---|---|---|---|---|---|
| **Screening** | | | | | | |
| Youth aged 15–17 | Youth Recruiting and Screening | 2,680 | 1 | 2,680 | 5 minutes (0.0833 hours) | **223** |
| Young Adult aged 18-24 | Young Adult Recruiting and Screening | 5,360 | 1 | 5,360 | 5 minutes (0.0833 hours) | **446** |
| Total Screener Hours | | | | | | **669** |
| **Informed Consent** | | | | | | |
| Youth aged 15–17 | Youth Assent | 668 | 1 | 668 | 2.5 minutes (0.0416 hours) | **28** |
| Young Adult aged 18-24 | Young Adult Consent | 1,336 | 1 | 1,336 | 2.5 minutes (0.0416 hours) | **56** |
| Total Informed Consent Hours | | | | | | **84** |
| **Survey** | | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| Youth aged 15–17 | Online Survey | 668 | 1 | 668 | 15 minutes (0.25 hours) | **167** |
| Young Adult aged 18-24 | Online Survey | 1,336 | 1 | 1,336 | 15 minutes (0.25 hours) | **334** |
| Total Survey Hours | | | | | | **501** |
| **Total Combined Hours** | | | | | | **1,254** |

### 12b. *Annualized Cost Burden Estimate*

The estimated value of respondents' time for participating in the information collection is $19,892.62. This value was calculated by multiplying the burden hours for young adults (18+) and youth (15 to 17) by the 2020 mean hourly wage as reported by the U.S. Department of Labor, Bureau of Labor Statistics ($20.17) and the federal hourly minimum wage ($7.25), respectively. The annualized cost burden estimate is summarized in Table 2.

**Table 2. Estimated Annualized Cost**

| Type of Respondent | Total Burden Hours | Hourly Wage Rate | Total Respondent Costs |
|---|---|---|---|
| Total Youth (15–17) | 418 | $7.25 | $3,030.50 |
| Total Young Adults (18-24) | 836 | $20.17 | $16,862.12 |
| **Total** | **1,254** | | **$19,892.62** |

## 13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

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

## 14. Annualized Cost to the Federal Government

The total estimated cost to the Federal Government for this study is $120,342.42 as shown in Table 3[2]. Contractor costs attributable to this information collection are $92,398.02. This includes costs to program the survey, draw the sample, and collect the data. Other contractor activities outside this data collection estimate include coordination with FDA to develop the instrument and deliver the final data set and reporting deliverables.

**Table 3. Itemized Cost to the Federal Government**

| Government Personnel | Time Commitment | Average Annual Salary | Total |
|---|---|---|---|
| GS-13 | 20% | $103,690 | $20,738 |
| GS-15 | 5% | $144,128 | $7,206.40 |
| Total Salary Costs | | | $27,944.40 |
| Contractor Costs | | | $92,398.02 |
| **Total** | | | **$120,342.42** |

[2] https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/

## 15. Explanation for Program Changes or Adjustments

This is a new data collection.

## 16. Plans for Tabulation and Publication and Project Time Schedule

The project schedule is shown in Table 4. Future development and research activities are dependent on the timely completion of the present study.

**Table 4. Project Schedule**

| Project Activity | Approximate Date |
|---|---|
| Data Collection | April 2022 |
| Data Delivery | June 2022 |
| Draft Reporting Deliverables | September 2022 |
| Final Reporting Deliverables | October 2022 |

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

FDA is not requesting an exemption for display of the OMB expiration date and is also not seeking OMB approval to exclude the expiration date for this information collection. The OMB approval and expiration date will be displayed on the relevant materials associated with the study.

## 18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.