

SUPPORTING STATEMENT: PART A

2019 Electronic Nicotine Delivery Systems Formative Data Collection to Inform Experimenter and Established User Definitions

Supporting Statement: Summary

- The goals of this project are 1) to assess youth use and correlates of Electronic Nicotine Delivery Systems (ENDS); and 2) using measures of ENDS use, construct and then test which experimental use definitions are most optimal in discriminating between experimental and more established ENDS user groups on key attitudinal and behavioral constructs. Findings from these analyses will be used to inform FDA CTP health communication strategies.
- Participants will be recruited via an online panel and enrolled via a screener survey. Participants who qualify for study inclusion will complete the questionnaire online using their own device. The assent and screener will take no more than two minutes to complete, and the questionnaire will take no more than 18 minutes for participants to complete.
- A total of 1,600 youth who are 13-17 years old and who have ever used an ENDS product will be enrolled. Youth must be ages 13-17 to participate in order to comply with Children's Online Privacy Protection Act (COPPA) regulations.
- The resulting data will be analyzed using conventional tabulation techniques for quantitative data. The study questions collect information about respondents' ENDS use and its social context, measures of tobacco dependence, KABs, advertising and counter-marketing exposure, a sensation-seeking scale, measures of other tobacco product use, and demographics.
- **REQUESTED APPROVAL DATE: March 29, 2019**

Data Collection Instruments

- Attachment A: Study Screener
- Attachment B: Study Questionnaire

Participant Assent/Consent Forms

- Attachment C: Recruitment Email
- Attachment D: Parental Permission Form
- Attachment E: Youth Assent Form

Additional Materials

- Attachment F: RTI IRB Approval Letter

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A. Justification

1. Circumstances Making the Collection of Information Necessary

Introduction

On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act (FSPTCA) (Public Law 111-31) was signed into law. The FSPTCA granted the U.S. Food and Drug Administration (FDA) important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. Part of the FDA's responsibility is to inform the public on health-related issues.

FDA CTP develops and executes health communication campaigns to educate youth about the dangers of tobacco use. Most of CTP's tobacco-related health communication campaigns are framed as prevention campaigns targeted toward individuals who are either susceptible to or have experimented with tobacco products, including Electronic Nicotine Delivery Systems (ENDS) such as e-cigarettes. To inform message development and ad campaign targeting, CTP is interested in examining definitions that distinguish ENDS experimenters from more established users. Currently, CTP does not have an established definition of youth ENDS experimentation, and previous literature has not yet validated or developed a gold standard definition. Thus, there is a need to examine different approaches for characterizing ENDS experimentation and differentiating experimental from more established ENDS use.

A previous secondary analysis conducted for FDA (RTI International 2018) used available items from the Population Assessment of Tobacco and Health (PATH) survey to construct various categorizations of ENDS experimentation. These experimenters were compared to more established users in terms of Knowledge, Attitudes, and Beliefs (KABs) related to ENDS and general tobacco. However, these analyses were limited by small sample sizes for the established user groups in some definitions, questions not incorporating recent ENDS brands and forms of products that are popular among youth, and limited KABs included on the PATH survey. Different items beyond those on existing surveys may be needed to better understand what distinguishes experimenters from more established ENDS users.

The current study will leverage a data collection among U.S. youth who have ever used ENDS products, to assess tobacco-related KABs, social context of ENDS use, tobacco dependence, tobacco-related advertising and countermarketing exposure, and use and correlates of various tobacco products. Questions to be asked were developed collaboratively by CTP and RTI and include measures examined in the earlier PATH analysis as well as more recent measures from the literature. Analyses will build on the

analysis conducted for the earlier report, using measures of use to construct and then test which experimental use definitions are most optimal in discriminating between experimental and more established ENDS user groups on key attitudinal and behavioral constructs. Results from these analyses will help CTP identify and characterize their target audiences to inform communication strategies.

2. Purpose and Use of the Information Collection

In support of FDA's efforts to inform the public on tobacco-related health issues, CTP will conduct a study to explore youth use and correlates of ENDS use to develop a working definition for youth ENDS experimentation as contrasted with established users. Parents of youth aged 13-17 will be recruited using a national online panel of adults and youth managed by market research firm Lightspeed. The respondent universe for this study is up to 1,600 youth aged 13-17 who have ever used an ENDS device such as an e-cigarette. Participants will be recruited online and will complete an online screener survey to determine eligibility to participate in the study.

For the information collection, the panel vendor Lightspeed will send email invitations to the target audiences using their market research database panel. Adolescents (aged 13-17) will be invited to participate through an email invitation to an adult panel member who has indicated in their panel profile that they have a child in the eligible age range. Parents or guardians will be asked to provide permission before allowing their child to participate. Once a child of a panel member enters the secure web site, they will be presented with a brief introduction informing the participant of the confidential and voluntary nature of the study and will be asked to provide assent to participate. Next, participants will complete a brief screener to determine eligibility based on the study inclusion criteria (i.e. is aged 13-17 and has ever used an ENDS device such as an e-cigarette).

Those respondents who are determined to be eligible to participate will complete a one-time online survey with questions assessing ENDS use and its social context, measures of tobacco dependence, KABs, advertising and counter-marketing exposure, a sensation-seeking scale, measures of other tobacco product use, and demographics. The study does not include any experimental components. Analyses will build on the analysis conducted for the earlier report, using more comprehensive measures of ENDS use to construct and then test which definitions are most optimal in discriminating between experimental and more established ENDS user groups on key attitudinal and behavioral constructs.

3. Use of Improved Information Technology and Burden Reduction

The use of electronic screener and questionnaire surveys offers a number of benefits. First, computerized administration permits the instrument designer to incorporate into the instruments routings that might be overly complex or not possible using a paper-based survey. For example, screener surveys can be programmed to implement skip patterns based on a respondent's previous answers. Interviewer and respondent errors caused by faulty implementation of skip instructions are virtually eliminated. Second, electronic administration increases the consistency of the data. The electronic screener and questionnaire can be programmed to identify inconsistent responses and attempt to resolve them through respondent prompts. This approach reduces the need for most manual and machine editing, thus saving time and money. In addition, it is likely that

respondent-resolved inconsistencies will result in data that are more accurate than when inconsistencies are resolved using editing rules. Third, electronic data collection permits greater expediency with respect to data processing and analysis (e.g., a number of back-end processing steps, including coding and data entry, will be minimized). These efficiencies save time due to the speed of data transmission, as well as receipt in a format suitable for analysis. Finally, this technology permits respondents to complete the instruments 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.

This study will recruit youth through a national online panel of adults managed by Lightspeed, which has a proven and demonstrated ability to orchestrate and support the sampling plan specifications of these studies. During recruitment for this study, participants will complete the screener electronically on their own device such as a mobile phone, tablet, or computer. This allows for more accurate data collection because respondents provide more honest responses, since it is clear that the answers will remain private.

This study, which relies on electronic data collection to provide accurate records of questionnaire completion, will reduce burden by increasing participation rates, thereby reducing the number of participants needed to complete the screener in order to achieve the desired sample size.

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. A previous secondary analysis conducted for FDA (RTI International 2018) used available items from the PATH survey to construct various categorizations of ENDS experimentation. However, these analyses were limited by small sample sizes for the established user groups in some definitions, questions not incorporating recent ENDS brand and technological development, and limited KABs included on the PATH survey. Therefore, we have determined that the proposed information collection does not duplicate previous efforts.

5. Impact on Small Businesses or Other Small Entities

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

6. Consequences of Collecting the Information Less Frequently

There are no legal obstacles to reduce the participant burden. 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, it would be difficult to understand how best to differentiate ENDS experimenters from more established users to inform audience targeting for FDA's media campaigns. Failure to collect this data could

reduce effectiveness of the FDA's message targeting, and therefore reduce the benefit of the campaigns.

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

This information collection fully complies with 5 CFR 1320.5(d)(2). There are no special circumstances 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 survey development and data collection implementation:

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The following individuals outside of the agency have been consulted on survey development and data collection implementation:

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9. Explanation of Any Incentive or Gift to Respondents

As is customary with online surveys conducted via panel sampling, panelists are invited by the panel management company to respond to the survey opportunity incentivized with award points (called “Lifepoints”) that are accrued and redeemable with the panel company for cash or other rewards. Lightspeed panelists will receive 100 Lifepoints (approximately \$2), for their child’s completion of a survey. A participant must be eligible to participate (per the screener) and submit the questionnaire to receive the token of appreciation.

Numerous empirical studies have shown that a token of appreciation can significantly increase response rates in cross-sectional surveys and reduce attrition in longitudinal surveys (e.g., Abreu & Winters, 1999; Castiglioni, Pforr, & Krieger, 2008; Shettle & Mooney, 1999; Singer, 2002). The use of a modest incentive is expected to enhance survey response rates without biasing responses. An incentive must be high enough to address competing demands for participants’ time and to equalize the burden placed on participants with respect to their time and cost of participation. An inadequate incentive may also result in a significantly more difficult and lengthy recruitment process and/or increases in the number of participants who agree to participate and then drop out early. An inadequate incentive may thus result in a more costly and lengthy period of data collection by increasing recruitment and other associated data collection costs.

FDA recognizes that “[p]aying research subjects in exchange for their participation is a common and, in general, acceptable practice” in a recent guidance document (FDA, 2018). The population of respondents needed to complete the data collection represents a special population for whom incentives are necessary to recruit. Among youth aged 13-17, approximately 24% report having ever used ENDS products (NYTS, 2017). Thus, respondents needed for this study represent a minority of the general population. In addition, identifying adolescent ENDS ever users is difficult as use of tobacco products is illegal in a few states for those under age 18 and sales to adolescents under age 18 is illegal in nearly every state. Additionally, previous research has shown that recruiting and retaining adolescents into studies about tobacco use is challenging (Diviak et al., 2006; McCormick et al., 1999). We believe that utilizing 100 Lifepoints (approximately \$2), as

a token of appreciation in the current study will reduce overall burden by increasing participation rates, thereby reducing the number of participants needed to complete the screener in order to achieve the required sample size.

10. Privacy Impact Assessment Information

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. This study has been reviewed and approved by the Institutional Review Board (IRB) of RTI International, the research organization contracted to manage data collection, as well as FDA's IRB. 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.

Security for respondents will be assured in a number of ways:

- Lightspeed will invite adolescent children of adult panel participants to participate in the study through an email invitation (with links to the screener) to their parents asking for their consent to have their child participate, which is fully compliant with the Children's Online Privacy Protection Act's (COPPA) revised standards. Lightspeed will invite adult panel participants directly through an email invitation (with links to the screener). Each respondent will be known only by a unique alphanumeric variable.
- Participants will log onto Lightspeed's secure server using a link provided by Lightspeed. RTI will receive no personally identifiable information (PII) about participants.
- Respondents will be informed before they encounter the first questionnaire item that their data will be kept private consistent with laws governing privacy.
- Respondents will be required to provide their assent to freely participate before they encounter the questionnaire.
- Respondents will have the option to decline to respond to any item in the questionnaire for any reason.
- Redirect links embedded in the questionnaire will direct adolescents back to Lightspeed to report having completed the questionnaire and receive non-monetary compensation. All those who handle or analyze data will be required to adhere to the standard data security policies of RTI.
- After data collection is complete, screener and questionnaire data will be merged together and aggregated for analysis.

Data Management

All data collection activities will be conducted in full compliance with FDA regulations to maintain the privacy of data obtained from respondents and to protect the rights and welfare of human research subjects as contained in their regulations.

To ensure data security, all RTI project staff are required to adhere to strict standards and to sign a nondisclosure agreement as a condition of employment on this project. RTI maintains restricted access to all data preparation areas (i.e., receipt, coding). All data files on multi-user systems will be under the control of a database manager, with access

limited to project staff on a “need-to-know” basis only. No respondent identifiers will be contained in reports to FDA, and results will only be presented in aggregate form.

Implementation of data security systems and processes will occur as part of the study data collection. Data security provisions will involve the following:

- All data collection activities will be conducted in full compliance with FDA regulations to maintain the privacy of data obtained from respondents and to protect the rights and welfare of human research subjects as provided in its regulations. Respondents will receive information about privacy protections as part of the informed consent process.
- All project employees will sign a non-disclosure agreement.
- All data are secured on Lightspeed’s database servers that only reside on private, backend servers that are behind layered firewall architecture. Data are never stored on a public network or outside the data tier. Relational database management systems (RDBMS) access is strictly controlled and limited to only a few authorized users whose access is limited to the minimum necessary to accomplish administrative tasks. Web and application servers communicate with the RDBMS only via a private network segment with a multi-layer firewall architecture in place. Access control is provided to secure data directories. All client specific data are stored in restricted access data directories controlled by access control lists.
- All data transmission will be encrypted as the responses will be on a Web site with an SSL certificate applied. Data will be passed through a firewall at RTI and then collected and stored on a protected network share on the RTI network. Only authorized RTI project staff members will have access to the data on the secure network.

RTI and Lightspeed will follow the Standard of Good Practice (SoGP, <https://www.securityforum.org/tool/the-isf-standard-good-practice-information-security-2018/>) security practices which emphasize security management, safe business application protocol, safe computer installations, network fidelity, awareness of systems development requirements, and safety of the end-user environment. Following these guidelines, the monitoring of data and sensitive information will take place following the SoGP security practices such as limiting access to information and data encryption. Members of the CTP research team will receive de-identified data that will be in an encrypted format when it is transmitted. This data transfer will occur via an encrypted and secure broadband connection.

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 tobacco use. Potentially sensitive questions include questions A1-A9, C1, C4, G1, G2, and G3 (See Attachment B for a full list of questionnaire items). These questions are essential to the objectives of this information collection. Questions assessing demographic characteristics, such as race and ethnicity,

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:

- The screener and questionnaire are entirely self-administered and maximize respondent privacy without the need to verbalize responses.
- Participants will be provided with contact information for the Principal Investigator of this study and for RTI’s IRB if they have any questions or concerns about this study or about their rights as study participants.

Finally, as with all information collected, these data will be summarized in aggregate with all identifiers removed.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

An estimated one-time reporting burden for this collection is 1,191 hours (Exhibit 1). This includes the time burden associated with the parent permission, youth assent and screener, and youth questionnaire completion.

To obtain a final sample of 1,600 youth enrolled participants, we estimate that we will need to obtain parental permission from up to 8,888 parents and screen up to 6,222 youth.

Based on previous experience, we estimate that parental permission will take no more than 1 minute per participant, parent recruitment email will take no more than 1 minute per participant, and the youth assent and screener will take no more than 4 minutes per participant. Questionnaire completion will take an estimated 18 minutes for participants

Exhibit 1. Estimated Annual Reporting Burden

Type of Respondent	Activity	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Hours
Parent	Parent permission	8,888	1	8,888	0.0166 (1 min)	148
Parent	Parent recruitment email	8,888	1	8,888	.0166 (1 min)	148
Youth	Youth assent and screener	6,222	1	6,222	0.06666 (4 min)	415
Youth	Youth questionnaire completion	1,600	1	1,600	0.30 (18 min)	480

Total Annualized Hours	1,191
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12b. Annualized Cost Burden Estimate

Respondents participate on a 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 studies of similar length and content among youth.

To calculate this cost, an hourly wage of \$7.25 was used for youth and \$27.56 for parents. These prices represent the federal minimum wage and average hourly wages for US youth and adults, respectively, according to the U.S. Department of Labor (DOL) Bureau of Labor Statistics. There are no direct costs to respondents associated with participation in this study. Thus, assuming an average hourly wage of \$7.25 for youth and \$27.56 for parents, the estimated cost to participants will be \$14,644.75. The estimated value of respondents' time for participating is summarized in Exhibit 2.

Exhibit 2. Estimated Annual Cost

Type of Respondent	Activity	Annual Burden Hours	Hourly Wage Rate	Total Cost
Parent	Parent permission	148	\$27.56	\$4,078.88
Parent	Parent recruitment email	148	\$27.56	\$4,078.88
Youth	Youth assent and screener	415	\$7.25	\$3,008.75
Youth	Youth questionnaire completion	480	\$7.25	\$3,480.00
Total				\$14,644.75

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

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

14. Annualized Cost to the Federal Government

This information collection is funded through a contract with RTI. The total estimated costs attributable to this data collection are \$391,570.50 (Exhibit 3). There are additional contract-funded activities occurring before and after this data collection that include project planning and data analysis. Other activities outside this data collection include coordination with FDA, data collection plan development, instrument development, reporting, IRB, and progress reporting and project management. This information collection will occur in 2019.

Exhibit 3. Itemized Cost to the Federal Government

Government Personnel	Time Commitment	Average Annual Salary	Total
GS-13	5%	\$ 96,970	\$4,848.50
GS-13	10%	\$ 96,970	\$9,697
		Total Salary Costs	\$14,545.50
		Contract Cost	\$377,025.00
		Total	\$391,570.50

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Analyses will descriptively examine youth ENDS use and its social context, measures of tobacco dependence, KABs, advertising and counter-marketing exposure, a sensation-seeking scale, measures of other tobacco product use, and demographics. Measures of ENDS use will also be used to construct and then test which experimental use definitions are most optimal in discriminating between experimental and more established ENDS user groups on key attitudinal and behavioral constructs. Findings from these analyses will be used to inform FDA CTP health communication strategies.

Reporting

The reporting and dissemination mechanism will consist of two primary components: 1) a comprehensive report summarizing findings from this information collection, and 2) a manuscript or conference presentation summarizing findings. The key events and reports to be prepared are listed in Exhibit 4.

Exhibit 4. Project Schedule

Project Activity	Date
Survey	April 2019
Data analysis	April – June 2019
Presentation of findings	July 2019 (Approximate)

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

Not applicable. All data collection instruments will display the expiration date for OMB approval of the information collection.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

Not applicable. There are no exceptions to the certification statement.

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).

Diviak KR et al. (2006). Recruitment and retention of adolescents in a smoking trajectory study: Who participates and lessons learned. *Subst Use Misuse*. 41: 175–182;

McCormick LK et al. (1999). Recruiting adolescents into qualitative tobacco research studies: experiences and lessons learned. *J Sch Health*. 69: 95–99.

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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.

U.S. Food and Drug Administration (FDA), “Payment and Reimbursement to Research Subjects - Information Sheet” (Jan. 25, 2018). This information sheet may be accessed at <https://www.fda.gov/RegulatoryInformation/Guidances/ucm126429.htm>.