United States Food and Drug Administration
Center for Tobacco Products
Survey of Risk Factors of Lithium-Ion Batteries used in ENDS

Supporting Statement: Summary

- The goal of this project is to survey current adult users of electronic nicotine delivery systems (ENDS) to better the products, user characteristics, circumstances, and outcomes associated with incidents of overheating, fire, and explosion (O/F/E) related to the use of lithium-ion batteries in ENDS.
- The study will be conducted using a web-based survey that is self-administered on personal computers and mobile devices. The study will use an online survey to target approximately 6,100 adults aged 21 and older who have used ENDS on at least 1 of the past 30 days.
- The survey will take approximately 16 minutes to complete.
- Results of the survey will help CTP better understand perceptions and prevalence of O/F/E among adult ENDS users and inform how best to protect ENDS users against O/F/E incidents.

- **REQUESTED APPROVAL DATE: [TBD]**

Study Materials (attached):

Participant Consent & Invitation

- Appendix A: Email Prompt
- Appendix C: Participant Consent Form

Data Collection Instruments:

- Appendix B: Screener
- Appendix D: Questionnaire

Additional Materials:

- Appendix E: IRB Approval Letter
- Appendix F: FDA IRB Determination

United States Food and Drug Administration

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Survey of Risk Factors of Lithium-Ion Batteries used in ENDS
OMB Control No. 0910-0810

Generic IC SUPPORTING STATEMENT PART A

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection is in support of the U.S. Food and Drug Administration's (FDA, us or we) Center for Tobacco Products (CTP) efforts to enhance FDA's understanding of electronic nicotine delivery systems (ENDS) users perceptions of their likelihood of experiencing overheating, fire, and explosion (O/F/E) incidents related to the use of lithium-ion batteries in ENDS. As the use of ENDS has increased in recent years, there has been an increase in the number of O/F/E incidents related to the use of lithium-ion batteries in ENDS. The combination of an ENDS and a lithium-ion battery poses a significant hazard due to the proximity to the face and body which can lead to life-threatening injuries.

FDA needs additional information on ENDS-related O/F/E incidents. Many incidents are not reported to FDA's Safety Reporting Portal. For example, a study using data from the Consumer Product Safety Commission's National Electronic Injury Surveillance System identified more ENDS-related explosion and burn injuries than were reported to FDA from 2009 to 2015 (Rossheim et al., 2019). Additionally, incidents may go unreported due to a lack of injury or less severe injury. Similarly, the ENDS-related O/F/E incidents reported to FDA frequently lack sufficient information to identify risk factors or determine causes.

In addition to enhancing FDA's understanding of ENDS' users' perceptions of their likelihood of experiencing O/F/E and beliefs about associated risk factors, we are also interested in estimates on the prevalence of O/F/E incidents and potentially identify practices and products that may increase the risk of O/F/E incidents. Understanding perceptions of O/F/E incidents and the prevalence of O/F/E incidents among ENDS users can help FDA gather data to understand how best to protect ENDS users against O/F/E incidents. This project's results will not provide support for any potential future policy or rulemaking.

2. Purpose and Use of the Information Collection

In support of FDA's efforts to understand the causes of ENDS-related O/F/E incidents and identify ways in which FDA may decrease the frequency of ENDS-related O/F/E incidents, CTP will conduct a study to explore causes and experiences of O/F/E. To better understand causes and experiences of O/F/E, this project has four objectives:

- Objective 1: Estimate the prevalence of use of devices, batteries, and other materials (e.g., chargers) that may increase the risk of O/F/E incidents.
- Objective 2: Estimate the prevalence of ENDS and battery practices among current ENDS users that may increase the risk of O/F/E incidents.

- Objective 3: Assess ENDS users' perceptions of their likelihood of experiencing O/F/E incidents and beliefs about associated risk behaviors.
- Objective 4: Estimate the prevalence of O/F/E incidents and evaluate the contextual details of any O/F/E incidents experienced by participants to identify potential causes.

The study will be conducted using a web-based survey that is self-administered on personal computers or mobile devices. The study will include approximately 6,100 adults aged 21 and older who have used ENDS on at least 1 of the past 30 days. Participants will be recruited from the online survey vendor, Dynata. Given the absence of nationally representative data, the true prevalence of O/F/E experiences among current ENDS users is unknown and can only be estimated based on existing data about injury reports. Researchers have estimated 1,022 emergency room visits from ENDS burn injuries in 2016 (Consumer Product Safety Commission, 2022). The sales rate of ENDS was estimated to be 1500 units per 100,000 per month in 2016, equating to roughly 570,000 total ENDS sales in 2016 in the US (Wang et al., 2018). Based on this estimation, at least 1 in 570 ENDS products (0.2%) is expected to cause a field failure (i.e., overheating, fire, or explosion incidents). At least 12 serious incidents are needed in order to conduct a qualitative analysis of the incidents (Hennink & Kaiser, 2022). Given the estimated failure rate of ENDS and that we anticipate that current ENDS users will have purchased at least 1 ENDS product in the past year, the goal sample of 6,100 ENDS users is needed for the survey in order to include at least 12 ENDS users who have experienced serious O/F/E.

Potential participants will receive a generic email (Attachment A) notifying them there are new studies available in their panel portal and prompting them to log in; the email is not an invitation to any particular study. Once in the portal, there will be a link directing them to the online screener (Attachment B). The screener will ask whether they are willing to answer a few questions to determine eligibility. Upon screener completion, participants will be immediately notified if they qualify. If they qualify to participate in the study, their consent will be requested (Attachment C). If they consent, they will be automatically directed to an online survey (Attachment D).

The one-time online survey includes questions assessing characteristics of their most frequently used ENDS device, ENDS purchasing behaviors, ENDS use behaviors, believes of risk behaviors associated with O/F/E/s, perceptions of O/F/Es, details of any O/F/E incidents experienced (if relevant), consequences of any O/F/E incidents experienced (if relevant), measures of other tobacco product use, and demographics.

We anticipate data collection to take place over four to six weeks. Analyses will examine sample characteristics, prevalence of use of ENDS device types, prevalence of engaging in practices that increase or decrease the risk of experiencing O/F/E incidents, prevalence and contextual details of O/F/E incidents, and demographic and behavioral correlates of having experienced O/F/E.

3. Use of Improved Information Technology and Burden Reduction

This study will rely on electronic web-based survey data collection. 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. Finally, this technology permits respondents to complete the survey questions in private. Because there is no interviewer present, participant responses to a web-based survey are less prone to social desirability bias. Providing the respondent with a methodology that improves privacy reduces the potential for

experiencing embarrassment or stigmatization when reporting on tobacco use behaviors and enhances response validity and response rates.

4. Efforts to Identify Duplication and Use of Similar Information

There is no duplicative collection of this information.

In order to ensure no duplication of efforts, we have reviewed existing survey instruments and data sets (for example, the Population Assessment of Tobacco and Health [PATH] and National Health Interview Survey [HINTS]) to determine whether any of them are sufficiently similar or could be modified to address FDA's need for information on causes and prevalence of ENDS-related O/F/E incidents. These existing survey instruments and data sets do not include data about O/F/E.

FDA maintains a public portal that allows individuals to self-report O/F/E incidents, but these data are not comparable because submissions to the portal are initiated by the individual who has already experienced an O/F/E. Thus, there is no opportunity to estimate prevalence of O/F/E experiences and no representation of ENDS users who have not experienced O/F/E. In addition, the portal does not contain the full set of questions that are necessary for addressing our research questions. For example, there are no items that ask ENDS users to estimate their likelihood of experiencing O/F/E (Objective 3 of this study).

5. Impact on Small Businesses or Other Small Entities

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

6. Consequences of Collecting the Information Less Frequently

This is a one-time survey, ensuring that the participant burden is as low as possible. Without the information collection requested for this evaluation study, it would be difficult for FDA to understand the causes of and risk factors for ENDS-related O/F/E incidents. Failure to collect these data could reduce FDA's ability to identify ways in which FDA may decrease the frequency of ENDS-related O/F/E incidents in order to protect the public health.

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).

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:

Name

Azieb Kidanu
Office of Science
Center for Tobacco Products
Food and Drug Administration
11785 Beltsville Drive
Beltsville, MD 20705

Phone: (301) 796-1248
E-mail: azieb.kidanu@fda.hhs.gov

Chelsea McKinney
Office of Science
Center for Tobacco Products
Food and Drug Administration
11785 Beltsville Drive
Beltsville, MD 20705
E-mail: chelsea.mckinney@fda.hhs.gov

Alexander Persoskie
Office of Science
Center for Tobacco Products
Food and Drug Administration
11785 Beltsville Drive
Beltsville, MD 20705
Phone: (240) 402-6864
E-mail: alexander.persoskie@fda.hhs.gov

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

Erik Crankshaw
RTI International
3040 Cornwallis Road
Research Triangle Park, NC 27709
Phone: 919-316-3809
E-mail: ecrankshaw@rti.org

Matt Eggers
RTI International
3040 Cornwallis Road
Research Triangle Park, NC 27709
Phone: 919-541-6683
E-mail: meggers@rti.org

Laura Baum
RTI International
2987 Clairmont Road NE
Atlanta, GA 30329-4434
Phone: 770-234-5017
E-mail: lbaum@rti.org

9. Explanation of Any Payment or Gift to Respondents

As is customary with online surveys conducted via panel sampling, panelists receive tokens of appreciation from the panel company for completing the survey. Dynata panelists will receive nonmonetary points valued at approximately $3.00-$4.00 for completion of the survey. Dynata determines the number of points based on survey length. To receive a token of appreciation, a participant must be eligible to participate (per the screener), submit the questionnaire to receive the token of appreciation, and not be a "speeder" (defined by Dynata defined by Dynata as a survey completion time that is 30% or lower of the median length of survey).

This token of appreciation is warranted as we aim to recruit harder-to-reach populations, including young adults and ENDS users that have experienced an O/F/E incident. According to the 2020 National Health Interview Survey (NHIS), an estimated 3.7% of adults aged 18 and older are current users (Cornelius et al, 2022). By age group, the prevalence of current ENDS use is highest among those aged 18-24 and decreases with increasing age (e.g., 9.4% for those aged 18-24; 5.2% for those aged 25-44; 2.2% for those aged 45-64; and 0.6% for those aged 65 and older) (Cornelius et al, 2022). These national estimates provide evidence that young adults aged 18 to 24 (the includes the target audience for our research) are more likely to be ENDS users than adults aged 25 and older; therefore, it is essential that we can successfully recruit this population to meet the goals of this study. Young adults are considered harder-to-reach due to survey fatigue. They are often overwhelmed by the number of surveys they encounter in daily life, and thus, are not as motivated to participate in research (Kalberg, 2015). Tokens of appreciation help improve recruitment and response rates of online surveys in this population (Cantrell et al., 2018). Additionally, we seek to include participants who have experienced serious and less serious O/F/E incidents to better understand the practices and products that increase risk of an O/F/E incident. Though available evidence from public safety surveillance indicates that O/F/E incidents are underreported (Rudy & Durmowicz, 2016), preliminary estimates suggest that less than 1% of ENDS users experience serious incidents (Consumer Product Safety Commission, 2022). The token of appreciation offered in this study reflects the unique nature of a sample that will likely be difficult to identify and recruit within the ENDS user population. Finally, the token of appreciation treats participants justly and with respect by recognizing and acknowledging the effort they expend to participate (Gelinas et al., 2018). When applied in a reasonable manner, tokens of appreciation are not an unjust inducement—they are an approach that acknowledges participants for their participation (Halpern et al., 2004).

FDA recognizes that "paying research subjects in exchange for their participation is a common and, in general, acceptable practice" in a guidance document (FDA, 2018). In this research, we are asking participants to respond to close-ended and open-ended questions and provide thought-intensive, open-ended responses on their O/F/E experiences and ENDS use, which requires a high level of engagement. The use of a token of appreciation is provided as a thank you for the participants' time and the effort they expend to participate. We believe that utilizing a point award that is valued at approximately $3.00-$4.00 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. Assurance of Confidentiality Provided to Respondents

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 web-based panel and screened for eligibility prior to administration of the main information collection instrument. Participants will be adults aged 21 or older who report using ENDS on one or more of the past 30 days. Each respondent will respond to items assessing characteristics of their most frequently used ENDS device, ENDS purchasing behaviors, ENDS use behaviors, believes of risk behaviors associated with O/F/E/s, perceptions of O/F/Es, details of any O/F/E incidents experienced, consequences of any O/F/E incidents experienced, measures of other tobacco product use, and basic demographic information. FDA will not have direct contact with participants, nor will FDA 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 from adults aged 21 and older who are current ENDS users (i.e., have used ENDS on at least 1 of the past 30 days) through the web-based panel vendor, Dynata. Dynata will host the screener, consent, and survey. Dynata will send RTI the dataset using a secure and password-protected online portal (e.g., ftp site). The password will be sent in a separate email from the link to the online portal. RTI will analyze this data to describe sample characteristics, the prevalence of use of ENDS devices and related materials that may increase the risk of O/F/E, the frequency of practices that may increase the risk of O/F/E, perceptions of O/F/E incidents, the prevalence of O/F/E, and the key contextual factors of O/F/E incidents. RTI will share the results of the analysis in the form of a report and manuscript. RTI will also send a copy of the dataset to FDA using a secure and password-protected online portal (e.g., ftp site).

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 as part of this project. As part of panel development and maintenance, Dynata maintains databases with identifiable information about respondents. However, this information will not be shared with RTI or FDA.

Overview of Voluntary Participation

Before initiating the online screener, potential participants will be advised of the nature of the survey, the length of time it will require, and that participation is voluntary. They will also be asked if they are willing to answer questions to determine their eligibility. If eligible, they will read and provide affirmative consent to an online informed consent form. 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 will have the option to decline to respond to most items in the screener (with the exception of those required to determine eligibility, such as age and ENDS use) and all items in the survey for any reason and may drop out of the data collection at any time. These procedures conform to ethical practices for collecting data from human participants.

Overview of Data Security

Each respondent will be known to FDA and RTI only by a unique alphanumeric ID variable provided by Dynata. That ID variable is specific to the study. The online survey will not include or request any PII, so the resulting data file has no PII. No PII will be linked to the survey data. All data will be reported in manuscripts and reports in the aggregate only. Although Dynata maintains databases of names and email addresses of potential participants as part of their normal operations,

that PII is stored separately from survey responses. Neither FDA nor RTI will receive or request this information or any other PII from Dynata.

During data collection, all data will be stored on password-protected databases to which only panel employees working on this project have access. At Dynata, personal data is encrypted in transit and at rest and is only accessible to those whose job requires it. Dynata will not use the data it collects through the screener or survey to update panelists' profiles. The panel will keep the data in non-aggregate form for at least six months after data collection has been completed, and then the data will be deleted from the password-protected databases. When data collection is complete, the data file will be transmitted from Dynata to RTI via a website with an SSL certificate applied. The data file, which contains no PII, will be stored by RTI on a restricted-access folder on a shared network drive that only authorized RTI project members have access to. All data maintained by RTI will be maintained in a secure manner in accordance with RTI standard policies and procedures. All RTI computers are password protected. RTI will send the deidentified dataset to FDA using a secure and password-protected online portal (e.g., ftp site). The password will not be sent in the same email as link to the online portal. FDA will limit access to this portion of the share drive by limiting the personnel with access to this share drive to appropriate project staff.

RTI will store data for up to five years before deletion. FDA will store data for up to five years in a restricted-access folder on a shared network drive that only project staff can access. All FDA computers are password protected.

The RTI IRB has approved this study, including its procedures to protect the privacy of participants.

11. <u>Justification for Sensitive Questions</u>

The majority of questions asked will not be of a sensitive nature. Questions about messages concerning lifestyle (e.g., current ENDS use) and some demographic information, such as race, ethnicity, and perceived economic stability, could be considered sensitive, but not highly sensitive. These questions are necessary to assess the diversity of the sample. 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 phone number for the project director and the RTI Office of Research Protection should they have any questions or concerns about the study or their rights as a study participant.
- Along with the extensive and increasing body of literature showing tobacco use disparities among LGBTQ+ populations, the White House issued the Executive Order on Advancing Equality for Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex Individuals which includes obligations for federal agencies to collect SOGI data. The order states that,

"advancing equity and full inclusion for LGBTQI+ individuals requires that the Federal Government use evidence and data to measure and address the disparities that LGBTQI+ individuals, families, and households face." It also states that federal agencies must "describe disparities faced by LGBTQI+ individuals that could be better understood through Federal statistics and data collection" (White House, 2022).

- Furthermore, data from a nationally representative survey of adults in the US demonstrates that ENDS use was almost twice as high among lesbian, gay, and bisexual participants compared to their heterosexual counterparts (8.9% vs. 4.8%; p <0.0001) (Emory et al., 2016). Transgender participants from the same study also reported substantially higher past 30-day ENDS use than cisgender adults (21.3% vs. 5.0%; $p \leq 0.003$) and also demonstrated substantially higher odds of ENDS use (OR=5.15; 95% CI=3.36, 7.88) (Buchting et al., 2017). Including survey items on sexual orientation and gender identity is necessary to identify how ENDS use may differ by SOGI and estimate how often LGBTQ+ may experience O/F/E.

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

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

An estimated one-time reporting burden for this collection will be approximately 3,876 hours (Table 1). This includes the time burden associated with the screener. To obtain a final sample of approximately 6,100 ENDS users 21 years old or older, we will need to screen approximately 61,000 potential participants. In prior national surveys conducted by RTI with the same Dynata panel, approximately 10% of adult panel members were current ENDS users; Dynata anticipates the same 10% incidence in this study. In addition, we request an additional 1,000 to account for potential overages, resulting in a total of 62,000 individuals screened.

We note that is not possible to calculate an exact participation rate or response rate because there are no study-specific invitations sent to panelists, nor is there a sample frame (because this is a non-probability panel-based sample). Thus, there is no denominator from which to calculate a participation rate or response rate. We estimated this burden based on prior experience with similar data collections and Dynata's estimate of prevalence of ENDS use in their sample

Table 1.--Estimated Annual Reporting Burden[1]

Type of Respondent/Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Screened Adult ENDS Users Screener completions	62,000	1	62,000	0.033 (2 min)	2,046
Adult ENDS User Participants Consent	6,100	1	6,100	0.033 (2 min)	201
Adult ENDS User Participants Questionnaire	6,100	1	6,100	0.267 (16 min)	1,629
Total					0

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. Dynata has conducted many tobacco-related surveys of similar length among ENDS users. We have examined diagnostic data from prior surveys and estimate that data collection for this study completion of the online survey will take 16 minutes on average. We have also allocated an additional 2 minutes for participants to give their consent to participate.

To calculate this cost, the mean hourly wage of $28.01 was used for adult participants. This cost represents the mean hourly wage for all occupations from the Department of Labor's Occupational Employment Statistics survey (May 2021 data). There are no direct costs to respondents associated with participation in this information collection. Thus, assuming an average hourly wage of $28.01 doubling this figure to account for benefits and overhead, yielding an hourly wage rate of $56.02, the estimated one-time cost to participants is $217,133.52. The estimated value of respondents' time for participating in the information collection is summarized in Table 2.

Table 2. Estimated Annual Cost

Type of Respondent	Activity	Annual Burden Hours	Hourly Wage Rate	Total Cost[1]
Adult ENDS Users	Recruiting and Screening	2,046	$ 56.02	$ 114,616.92
	Consent	201	$ 56.02	$ 11,260.02
	Questionnaire	1,629	$ 56.02	$ 91,256.58
Total		3,876		0

[1] Cost was rounded up to the next dollar.

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

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

14. Annualized Cost to the Federal Government

The total estimated cost to the Federal Government for this study is $412,740.70 as shown in Table 3. This information collection is funded through a contract $369,041 with RTI. This includes costs to program the survey, draw the sample, and collect the data. There are additional contract-funded activities occurring outside this data collection including coordination with FDA to develop the instrument, cognitive interview testing of the instrument (i.e., creating materials for and conducting 9 cognitive interviews that are separate from this data collection effort), project management, progress reporting, delivering the final data set, and producing a draft manuscript of study methodology and findings. The GS-13 government personnel oversee the scientific activities

of the research (including study development, implementation, data analysis and reporting) and ensure activities are aligned with research priorities are within the scope of work. The GS-14 personnel supervise and provide additional support to GS-13 government personnel on the project.

Table 3. Itemized Cost to the Federal Government

Government Personnel	Time Commitment	Average Annual Salary	Total
GS-13	20%	$106,823*	$21,364.6
GS-13	15%	$106,823*	$16,023.45
GS-14	5%	$126,233*	$6,311.65
		Total Salary Costs	0
		Contract Cost	$369,041
		Total	**$412,740.70**

* This reflects basis salary and wage data for the Washington DC-Metropolitan area found at www.opm.gov for GS-13 and GS-14 employees

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 examine sample characteristics, prevalence of use of ENDS device types, prevalence of engaging in practices that increase or decrease the risk of experiencing O/F/E incidents, prevalence and contextual details of O/F/E incidents, and demographic and behavioral correlates of having experienced O/F/E. Findings from these analyses will be used to inform FDA CTP strategies for protecting ENDS users against O/F/E incidents.

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 summarizing findings. The key events and reports to be prepared are listed in Table 4.

Table 4. Project Schedule (Approximate)

Project Activity	Date
Survey data collection	January 2023
Data analysis	February 2023
Report and manuscript writing and dissemination	March 2023

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

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

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

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