U.S. Food and Drug Administration
Hispanic/Latino Youth and Young Adult Tobacco Use Online Survey Study

OMB Control Number 0910-0810

GENERIC IC SUPPORTING STATEMENT A

A. Justification

1. Circumstances Making the Collection of Information Necessary

This study aims to examine risk and protective factors for tobacco product use to better understand and segment subpopulations at higher risk of Electronic Nicotine Delivery Systems (ENDS) use. Specifically, millions of Hispanic youth and young adults in the U.S. are at elevated risk of morbidity and mortality related to tobacco use.[1] Moreover Hispanic youth are more likely to be curious about and/or initiate tobacco use with e-cigarettes compared to non-Hispanic peers. The Food and Drug Administration's (FDA's) Center for Tobacco Products (CTP) is conducting theory-based foundational research with Hispanic youth ages 13 to 17 (hereafter referred to as youth) and young adults ages 18 to 24 (hereafter referred to as young adults) guided by the following overarching research question: "Who among Hispanic youth and young adults is most at risk for tobacco product use (with a focus on electronic nicotine delivery systems or ENDS)?" We would like to better understand the demographic, psychographic, and sociocultural determinants of tobacco and ENDS use and identify segments of the Hispanic population most at risk. The research proposed will contribute to a more nuanced understanding of this audience to inform targeted outreach of CTP's tobacco prevention communication strategy and messaging.

2. Purpose and Use of the Information Collection

CTP contracted with IQ Solutions (IQS) to conduct an online survey of 2,600 Hispanic youth and young participants (ages 13-24) from the 48 contiguous U.S. states, Alaska, Hawaii, and the District of Columbia (those residing in Puerto Rico are *not* eligible for this study). The objectives of this task are to: 1) Gain insights into the population of Hispanic youth/young adults in the United States who are Susceptible Non-Triers and Experimenters of ENDS products as well as dual or poly tobacco users; 2) Examine risk and protective factors for ENDS use across different segments of the Hispanic population; and 3) Explore how intersections between Hispanic identity and key demographics affect risk/susceptibility and use of ENDS and other tobacco products.

To achieve these objectives, we will conduct an online survey designed to address the following overarching research questions:

- How does tobacco use and susceptibility among Hispanic youth and young adults differ by key demographics, including age, gender and acculturation level?

[1] IQ Solutions Team (2021, April). Hispanic/Latino Youth and Young Adults' Tobacco Use: Foundational Research. Rockville, MD. Prepared for the U.S. Food and Drug Administration, Center for Tobacco Products.

- How do tobacco risk and protective factors for ENDS use vary by key demographics including age, gender, and acculturation level?
- How does identification as Hispanic intersect with other characteristics (e.g., acculturation, gender, sexual orientation) to influence tobacco susceptibility, experimentation, and initiation?
- How might Hispanic youth and young adults be segmented by ENDS susceptibility for more effective message targeting?

Ultimately this data collection will inform CTP's understanding of the Hispanic youth and young adults who may be at higher risk of ENDS and other tobacco use. The results of this study will be informative to CTPs efforts to develop communication strategies and messaging targeting demographic groups at high risk of tobacco use.

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 needs. 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

The collection of information will provide important data needed for FDA to develop more targeted messaging to address the needs of the largest minority group in the US. Failure to collect these data could reduce effectiveness of the FDA's tobacco prevention 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

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

A token of appreciation for participation will be specified by the panel vendors and will include non-monetary "points" redeemable for gift cards or goods as a thank you for the respondent's time. This token of appreciation is equivalent to the monetary value of $10. Respondents who are eligible to participate in the study and submit their responses to the survey will receive a token of appreciation. Respondents who choose to skip one or more questions will still receive the token of appreciation. If a respondent does not qualify or meet all of the eligibility criteria, or does not submit their survey responses, they will not receive the token of appreciation.

To receive tokens of appreciation, respondents will be automatically directed through the online research panels' interfaces and can redeem their token of appreciation. Respondents will not be in direct contact with IQS about their tokens of appreciation and FDA researchers will never have access to or be provided any identifiable data.

Hispanic/Latino youth and young adults are traditionally underrepresented in research and therefore harder to recruit. People of low SES, non-White racial, and Latino ethnic groups are less likely to be recruited into research studies as non-Hispanic White participants with

middle SES (Wendler et al., 2006[2]). Despite comprising 18.7% of the U.S. population (according to the 2020 Census), Hispanic participants are consistently underrepresented in large research studies (Flores 2021; Duma 2018; FDA 2017[3]). One reason for this may be because compared to White participants, a higher percentage of Hispanic/Latino participants are lower socioeconomic status which in turn means they may be unable to take time off work for research study participation (Garcia 2017[4]). Indeed, compared to White adults in the U.S., Hispanic adults receive less income at the same education levels, have markedly less wealth at equivalent income levels, and have less purchasing power due higher costs of goods and services in the residential environments where they are disproportionately located (Williams, Mohammed et al. 2010[5]). A token of appreciation treats these traditionally underrepresented participants justly and with respect by recognizing and acknowledging the additional effort they expend to participate (Gelinas, 2018).

CTP has previously used this $10 token approach in a study with similar participants (youth ages 13-17 who had experimented with ENDS use or at-risk of ENDS use) and study design; that study had a diverse sample and timely data collection (OMB control number 0910-0810). In that study, the response rate was about 19% (1,660 completed out of 8,837 screened). This past data show that this is a difficult population to recruit and enroll, and an incentive rate lower than $10 would severely negatively impact the response rate, costing the government additional time and money. Other CTP studies have used similar tokens of appreciation for surveys of similar length and with similar target populations (e.g., Monthly Monitoring Study, OMB control number 0910-0810).

A reasonable token of appreciation is standard practice for research and is suggested by organizations that set the standards for conducting ethical industry-led research among human subjects (Code of Ethics and Standards for Market Research and Data Analytics, 2021).[6]

10. <u>Assurance of Confidentiality Provided to Respondents</u>

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 IQS International, the research organization contracted to manage data collection has reviewed and approved the protocols for the survey. FDA's Research Involving Human Subjects Committee (RIHSC) conducted a courtesy review before submission to IQS

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[2] Wendler D, Kington R, Madans J, Van Wye G, Christ-Schmidt H, Pratt LA, Emanuel E. Are racial and ethnic minorities less willing to participate in health research? *PLoS Medicine.* 2006;3:201–210.

[3] Flores LE, Frontera WR, Andrasik MP, et al. Assessment of the Inclusion of Racial/Ethnic Minority, Female, and Older Individuals in Vaccine Clinical Trials. *JAMA Netw Open.* 2021;4(2):e2037640. doi:10.1001/jamanetworkopen.2020.37640

Duma N, Aguilera JV, Paludo J et al. representation of Minorities and Women in Oncology Clinical Trials: Review of the Past 14 Years. DOI: 10.1200/JOP.2017.025288 *Journal of Oncology Practice* 14, no. 1 (January 01, 2018) e1-e10.

FDA. 2017 Drug Trials Snapshots: Summary Report. https://www.fda.gov/media/112373/download

[4] García AA, Zuñiga JA, Lagon C. A Personal Touch: The Most Important Strategy for Recruiting Latino Research Participants. J Transcult Nurs. 2017 Jul;28(4):342-347. doi: 10.1177/1043659616644958. Epub 2016 Apr 25. PMID: 27114390; PMCID: PMC5079844.

[5] Williams DR, Mohammed SA, et al. Race, socioeconomic status, and health: Complexities, ongoing challenges, and research opportunities. *Annals of the New York Academy of Sciences.* 2010;1186(1):69–101.

[6] Insights Association. (2021). Code of Standards and Ethics for Market Research and Data Analytics. https://www.insightsassociation.org/sites/default/files/misc_files/ia_code_revised_november_2021_finalv2.pdf

IRB; RIHSC determined that FDA is not engaged in the research. The primary concern of IRB is protecting respondents' rights, one of which is maintaining the privacy of respondent information. OMB Control Number 0910-0810 is covered underneath a Privacy Impact Assessment that has been approved by the Department of Health and Human Services (PIA Unique Identifier: P-9008729-198376).

Privacy for survey respondents will be ensured in several ways:

- Each respondent will be known to FDA and IQS only by a unique alphanumeric ID variable provided by the panel provider. That ID variable is specific to the study. Although partner survey vendors maintain databases of names and e-mail addresses of potential participants as part of their normal operations, neither FDA nor IQS will receive or request this information from the panel vendor.
- The screener requests date of birth and zip code, which is considered PII. The screener data file that will be shared with FDA will not contain any PII.
- The panel vendor(s) will invite young adult panelists (18-24) via e-mail (See attachment L) directly to participant in the survey. After screening, eligible participants will be directed to the informed consent form prior to proceeding to the main survey.

  Youth aged 13-17 who are pre-registered, double opt-in panel members (i.e., both the parent/guardian and child have pre-consented to participate in surveys sent to them) will also be contacted directly by the recruitment vendor and invited to take the screener to see if they are eligible to participate. If needed, the panel vendor(s) may also reach out directly to invite young adult panelists with children ages 13-17 via email (See Attachment L) to complete the survey via an initial generic communication.
- All parent/guardians will be provided with a Parental Opt-Out Form with clear and simple instructions for how to opt-out of participation in the research study. Parent/guardians will be informed that by providing their child access to the survey screener link, they are giving permission for their child to participate in the survey. See the Parental Opt-Out Form for email template. Parent/guardians will be asked to allow their child to complete the screener and survey in private, so they cannot see the responses. Eligible youth participants will complete an assent form and will be informed that their answers will not be shared with their parents. The Parental Opt-Out Form will also provide a telephone number and email address for the PI, who can answer any questions or respond to parental concerns about the study.
- Respondents cannot back up in the survey to view previous responses. For example, if a youth participant were to exit the survey, the parent/guardian could not view previously entered responses. During survey testing, the test links will include the ability to back up, but this will not be possible in the actual survey that participants complete.
- Respondents will access the survey through a unique link that cannot be shared with others to use because it is unique.
- The online survey is self-administered, and respondents will participate on a voluntary basis. Questions in the screener are required for determining eligibility;

however, respondents can exit the survey by closing the browser if they do not wish to answer these. All other questions are optional. The voluntary nature of the information collection is described in the online parental permission and assent forms to which participants provide online affirmative agreement.

- The panel vendors will not have access to data collected through the screener or survey as these instruments will be hosted on a platform by IQS.
- When data collection is complete, the deidentified data file will be transmitted from IQS to FDA via a website with an SSL certificate applied. The data file, which contains no PII, will be stored by IQS and FDA on a restricted-access folder on a shared network drive, and only authorized project members will have access. IQS 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. We will notify participants in the assent form (and Parental Opt-Out 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 marijuana/cannabis use. Asking such questions is critical to the objectives to this information collection.

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. One question assessing ever having vaped marijuana/cannabis may also be sensitive because youth possession of marijuana/cannabis is illegal in the U.S. These questions are essential to the objectives of this information collection.

Demographic questions such as race and ethnicity, gender identity, sexual orientation and language preference or place of birth, could be considered sensitive. The purpose of these questions is to ensure a representative respondent sample that enables subgroup comparisons to ultimately be able to tailor educational and outreach services and resources to specific segments of the Hispanic/Latino audience.

Decades of research has shown significant disparities in tobacco use by race (e.g., Harlow et al., 2019; Odani et al, 2018), gender identity (e.g., Johnson et al, 2019; Delahanty et al, 2019), and sexual orientation (e.g., Johnson et al, 2019; McCabe et al., 2018). Therefore, collecting detailed information on these demographic characteristics among our sample will allow us to measure Hispanic/Latino subgroup differences with the goal of reducing these disparities. As multiple studies of youth and young adults have reported approximately 12-15% of the sample identified as gender non-conforming/non-binary (e.g., The Human Rights Campaign 2018

LGBTQ+ Youth Report; The Trevor Project 2020 National Survey on LGBT Youth Mental Health; CTP's evaluation of This Free Life campaign), including gender non-conforming/non-binary response options is necessary to identify and assess tobacco use among this population. Gender identity questions with genderqueer/gender non-conforming/non-binary response options have been approved by OMB for ExPECTT (0910-0753) and for RESPECT (0910-0808).

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."[7] This further reinforces the need to collect SOGI data. Moreover, given that teens and young adults who are sexual or gender minorities have higher use of tobacco products compared to heterosexual and cisgender teens, it's important for us to capture both sexual and gender identity information to accurately identify our target audience for education activities and address disparities in tobacco product use among Hispanic/Latino youth and young adults.

The screener for this survey additional includes a question on Hispanic/Latino country origin. This question is modeled after the 2020 U.S. Census which includes country of origin/national background when asking about Hispanic/Latino ethnicity. We have included the OMB standard categories (Mexican/Mexican American, Chicano, Puerto Rican and Cuban) and have expanded the list to include options for Salvadoran and Cuban so that the top 5 countries of origin are represented based on the 2020 U.S. Census data. This level of detail is necessary as data shows disparities in tobacco use and susceptibility depending on Hispanic/Latino country of origin.[8] It is important for CTP to capture this information to better understand Hispanic/Latino tobacco use and prevention which is the focus of this survey. This will also help us to ensure that we have adequate representation from across national backgrounds for monitoring during fielding so that we can look at tobacco use by national background in our analysis.

Responses to these questions are needed to ensure adequate information is determined in assessing respondent eligibility. Participants may exit the screener at any time without penalty

[7] https://www.whitehouse.gov/briefing-room/presidential-actions/2022/06/15/executive-order-on-advancing-equality-for-lesbian-gay-bisexual-transgender-queer-and-intersex-individuals/

[8] Slobig Z. Latino College Health Initiative: A Study of Tobacco-Related Health Disparities In Hispanic/Latino Subpopulations. Truth Initiative; 2014:44. Accessed January 14, 2021. https://truthinitiative.org/sites/default/files/media/files/2019/03/Latino_College_Health_Initative_2014.pdf

Kaplan RC, Bangdiala SI, Barnhart JM, et al. Smoking among US Hispanic/Latino adults: The Hispanic Community Health Study/Study of Latinos. Am J Prev Med. 2014;46(5):496-506. doi:10.1016/j.amepre.2014.01.014

Parrinello CM, Isasi CR, Xue X, et al. Risk of cigarette smoking initiation during Adolescence among US-Born and non-US-born Hispanics/Latinos: The Hispanic Community Health Study/Study of Latinos. Am J Public Health. 2015;105(6):1230-1236. doi:10.2105/AJPH.2014.302155

Bandiera FC, Arguelles W, Gellman M, et al. Cigarette smoking and depressive symptoms among Hispanic/Latino adults: Results from the Hispanic Community Health Study/Study of Latinos (hchs/Sol). Nicotine Tob Res. 2015;17(6):727-734. doi:10.1093/ntr/ntu209

should they not wish to answer a question or longer wish to participate. The question regarding respondent's birthplace will have a "Prefer not to answer" option. If respondents are uncomfortable with any of the questions, they can terminate screening at any time without penalty. The survey includes potentially sensitive questions about smoking identity, mental health, and discrimination experiences. These questions will help us understand our respondents' backgrounds and the stressors that may put them at risk for tobacco product use.

To address any concerns about inadvertent disclosure of sensitive information, respondents will be fully informed of the applicable privacy safeguards. 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 do not need participate and that if they choose to participate, they do not need 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 telephone number and email address for the IQS 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*

Table 1. Estimated Annual Reporting Burden

Type of Respondent	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (Hours)	Total Hours
Parent of Youth—Generic invitation, [Recruitment E-mail, Parental Opt Out Form]	1,000	1	1,000	0.05 (3 minutes)	50
Youth—Screener	750	1	750	0.05 (3 minutes)	38
Youth—Assent [Participant Consent/Assent Form]	750	1	750	0.07 (4 minutes)	53

Youth—Survey	400	1	400	0.25 (15 minutes)	100
Young Adult – Recruitment E-mail	4,000	1	4,000	0.017 (1 minute)	68
Young Adult—Screener	4,000	1	4,000	0.05 (3 minutes)	200
Young Adult—Consent	4,000	1	4,000	0.07 (4 minutes)	280
Young Adult—Survey	2,200	1	2,200	0.25 (15 minutes)	550
Total Burden Hours					**1,339**

Information will be collected through a self-administered, online screener and survey among youth (ages 13-17) and young adults (ages 18-24), with a target of 2,600 completes. Approximately 1,000 parents will review a generic invitation/permission form estimated to take approximately 3 minutes per response, for a total of 50 hours. After receiving parental consent to participate in the study, approximately 750 youth will complete an assent form and screener to determine eligibility for participation in the study, estimated to take approximately 2 and 3 minutes per response, respectively, for a total of 91 hours for assent and screening activities. Approximately 4,000 young adults will receive an email invitation (estimated to take 1 minute to review) and complete the consent form and screener to determine eligibility for participation in the study, estimated to take approximately 2 and 3 minutes, respectively, for a total of 548 hours for consent and screening activities. We estimate that 400 youth and 2,200 young adults for a total of 2,600 respondents will complete the survey at an average of 15 minutes per response, for a total of 650 hours. This data collection will take place in 2023. The annualized response burden is estimated at 1,339 hours. Table 1 provides details about how this estimate was calculated.

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

To estimate the annualized cost burden, the mean hourly wage of $7.25 was used for youth and $28.01 was used for parents and adult participants. The youth price represents the minimum wage, and the young adult costs represent the mean hourly wage for other occupation earnings from the U.S. Department of Labor Bureau of Labor Statistics (May 2021 data). There are no direct costs to respondents associated with participation in this information collection. Thus, assuming an average hourly wage of $7.25 and $28.01 (youth and adult), and doubling this to account for benefits and overhead, yielding an hourly wage rate of $14.50 for youth and $56.02 for young adults, the estimated one-time cost to participants is $ 67,080.46. The estimated value of respondents' time for participating in the information collection is summarized in Table 2.

Table 2. Estimated Annualized Cost

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Parent	50	$56.02	$2,801
Youth (13–17)	191	$14.50	$2,769.50
Young Adults (18-24)	1,098	$56.02	$61,509.96
Total	**1,339**		**0**

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 $180,687.20 as shown in Table 3 below. Contractor costs attributable to this information collection are $149,321. 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%	$121,065	$24,213.00
GS-14	5%	$143,064	$7,153.20
Total Salary Costs			$31,366.20
Contractor Costs			$149,321.00
Total			**$180,687.20**

15. Explanation for Program Changes or Adjustments

This is a new individual generic 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

Activity	Approximate Date
Data Collection	July 2023
Draft Reporting Deliverables	August 2023
Final Reporting Deliverables	September 2023

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.