

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

OMB Control Number 0910-0810

GEN IC SUPPORTING STATEMENT B

B. Statistical Methods

1. Respondent Universe and Sampling Methods

The respondent universe for this study are Hispanic-identifying youth (ages 13-17) and young adults (ages 18-24) 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.)

Eligibility to participate in the online survey will be based on the following criteria:

1. Respondent consented to study (young adults 18-24). Parent/guardian did not opt out their children 13-17 from the study and youth assented to participation.
2. Age: Youth ages 13 to 17 will qualify for this online study to comply with the Children’s Online Privacy Protection Rule (COPPA) regulations (16 CFR Part 312). Young adults will be ages 18-24.
3. Hispanic/Latino ethnicity.
4. Electronic Nicotine Delivery Systems (ENDS) Use Status (see Table 1):
 - a. *Inclusion Criteria:*
 - i. **Susceptible Non-Trier:** Respondents who respond that they have never used ENDS in their lifetime but answer with an affirmative response to the ENDS susceptibility questions (i.e., did not answer “Definitely not” to all three questions) *and* who answered anything other than “Not at all curious” to the ENDS curiosity questions will be assigned to the Susceptible Non-Trier category.
 - ii. **Experimenter:** Respondents who indicate in the Screener that they have ever tried ENDS and have either used in the past 30 days or are susceptible based on the susceptibility criteria outlined in Table 1 will be assigned to the Experimenter segment (which is comprised of both Current Users and Susceptible Past Experimenters).
 - b. *Exclusion Criteria:*
 - i. Respondents who respond that they have never used ENDS in their lifetime and respond, “Definitely not,” to all three questions assessing susceptibility to tobacco use will be defined as “Non-Susceptible Non-Triers” and will be excluded from participation in the Questionnaire.
 - ii. Respondents who indicate they have used ENDS in their lifetime but have not reported use in the last 30 days and are not susceptible to ENDS use (based on the susceptibility scale) will be excluded from the study (these are defined as “Non-Susceptible Past Experimenters”).

Table 1: ENDS Use Risk Groups for Inclusion in the Online Survey

Participant Type	Definition																				
<p>SUSCEPTIBLE NON-TRIERS</p>	<p>(A) The next questions are about vaping products or vapes. You may also know them as e-cigarettes. They can contain nicotine and/or flavors. Some common brands are JUUL, Puff Bar, Blu, Sourin, and Vuse. Please do <u>NOT</u> include vaping marijuana/THC/CBD when answering this question. Have you ever tried vaping, even one time? [Must select 2. No]</p> <p>1. Yes → Move to (B) 2. No → Skip to (C)</p> <p>(C) Please do <u>NOT</u> include vaping marijuana/THC/CBD when answering these questions. Thinking about the future... [Must select options 1-3 for at least one of the following:]</p> <table border="1" data-bbox="500 653 1344 1052"> <thead> <tr> <th></th> <th>1. Definitel y Yes</th> <th>2. Probabl y Yes</th> <th>3. Probably Not</th> <th>4. Definitel y Not</th> </tr> </thead> <tbody> <tr> <td>Do you think that you will vape soon?</td> <td><input type="checkbox"/>₁</td> <td><input type="checkbox"/>₂</td> <td><input type="checkbox"/>₃</td> <td><input type="checkbox"/>₄</td> </tr> <tr> <td>Do you think you will vape at any time in the next year?</td> <td><input type="checkbox"/>₁</td> <td><input type="checkbox"/>₂</td> <td><input type="checkbox"/>₃</td> <td><input type="checkbox"/>₄</td> </tr> <tr> <td>If one of your best friends were to offer you a vape, would you use it?</td> <td><input type="checkbox"/>₁</td> <td><input type="checkbox"/>₂</td> <td><input type="checkbox"/>₃</td> <td><input type="checkbox"/>₄</td> </tr> </tbody> </table> <p>ALL RESPONDENTS MOVE TO (D)</p> <p>AND</p> <p>(D) Are you curious about vaping nicotine? [Must select options 1-3]</p> <p>1. Definitely yes 2. Probably yes 3. Probably not 4. Definitely not</p>		1. Definitel y Yes	2. Probabl y Yes	3. Probably Not	4. Definitel y Not	Do you think that you will vape soon?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	Do you think you will vape at any time in the next year?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	If one of your best friends were to offer you a vape , would you use it?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄
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<p>EXPERIMENTERS: CURRENT USERS</p>	<p>(A) The next questions are about vaping products or vapes. You may also know them as e-cigarettes. They can contain nicotine and/or flavors. Some common brands are JUUL, Puff Bar, Blu, Sourin and Vuse. Please do <u>NOT</u> include vaping marijuana/THC/CBD when answering this question. Have you ever tried vaping, even one time? [Must select 1. Yes]</p> <p>1. Yes → Move to (B) 2. No → Skip to (C)</p> <p>(B) During the past 30 days, on how many days did you vape? Please do <u>NOT</u> include vaping marijuana/THC/CBD when answering this question. _____ [Must be >0] _____ [0-30 Days]</p>																				
<p>EXPERIMENTERS: SUSCEPTIBLE PAST EXPERIMENTERS</p>	<p>(A) The next questions are about vaping products or vapes. You may also know them as e-cigarettes. They can contain nicotine and/or flavors. Some common brands are JUUL, Puff Bar, Blu, Sourin and Vuse. Please do <u>NOT</u> include vaping marijuana/THC/CBD when answering this question. Have you ever tried vaping, even one time?</p>																				

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	<p data-bbox="500 243 738 275">[Must select 1. Yes]</p> <p data-bbox="690 310 1081 386">1. Yes → Move to (B) 2. No → Skip to (C)</p> <p data-bbox="500 422 1390 527">(B) During the past 30 days, on how many days did you vape? Please do <u>NOT</u> include vaping marijuana/THC/CBD when answering this question. _____ [Must =0] _____ [0-30 Days]</p> <p data-bbox="500 562 1356 625">C) Please do <u>NOT</u> include vaping marijuana/THC/CBD when answering these questions. Thinking about the future...</p> <p data-bbox="500 625 1177 657">[Must select options 1-3 for at least one of the following:]</p> <table border="1" data-bbox="500 657 1341 1056"> <thead> <tr> <th data-bbox="500 657 834 768"></th> <th data-bbox="834 657 959 768">1. Definitel y Yes</th> <th data-bbox="959 657 1081 768">2. Probabl y Yes</th> <th data-bbox="1081 657 1211 768">3. Probabl y Not</th> <th data-bbox="1211 657 1341 768">4. Definitel y Not</th> </tr> </thead> <tbody> <tr> <td data-bbox="500 768 834 842">Do you think that you will vape soon?</td> <td data-bbox="834 768 959 842"><input type="checkbox"/>₁</td> <td data-bbox="959 768 1081 842"><input type="checkbox"/>₂</td> <td data-bbox="1081 768 1211 842"><input type="checkbox"/>₃</td> <td data-bbox="1211 768 1341 842"><input type="checkbox"/>₄</td> </tr> <tr> <td data-bbox="500 842 834 953">Do you think you will vape at any time in the next year?</td> <td data-bbox="834 842 959 953"><input type="checkbox"/>₁</td> <td data-bbox="959 842 1081 953"><input type="checkbox"/>₂</td> <td data-bbox="1081 842 1211 953"><input type="checkbox"/>₃</td> <td data-bbox="1211 842 1341 953"><input type="checkbox"/>₄</td> </tr> <tr> <td data-bbox="500 953 834 1056">If one of your best friends were to offer you a vape, would you use it?</td> <td data-bbox="834 953 959 1056"><input type="checkbox"/>₁</td> <td data-bbox="959 953 1081 1056"><input type="checkbox"/>₂</td> <td data-bbox="1081 953 1211 1056"><input type="checkbox"/>₃</td> <td data-bbox="1211 953 1341 1056"><input type="checkbox"/>₄</td> </tr> </tbody> </table>		1. Definitel y Yes	2. Probabl y Yes	3. Probabl y Not	4. Definitel y Not	Do you think that you will vape soon?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	Do you think you will vape at any time in the next year?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	If one of your best friends were to offer you a vape , would you use it?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄
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The screener will include questions assessing race, gender identity, sexual orientation, state of residence and acculturation level (a measure based on preferred language and participant/parent nativity).

The study will use convenience samples rather than probability samples. We do not intend to generate nationally representative results or precise estimates of population parameters from the study; generating a representative sample of the size necessary for this study (e.g., using random digital dialing or a similar method) would be cost prohibitive. Additionally, it is not necessary as gathering surveillance estimates is not a goal of the study.

2. Procedures for the Collection of Information

This section provides an overview of the study procedures, provides information on the degree of accuracy required for the study, and discusses the estimation procedures.

2a. Study Procedures

Objectives and Research Questions

The objectives of the Hispanic/Latino Youth and Young Adult Tobacco Use Online Survey Study are to:

- Gain insights into the population of Hispanic youth/adults in the United States who are Susceptible Non-Triers and Experimenters of ENDS products as well as dual or poly tobacco users.
- Examine risk and protective factors for ENDS use across different segments of the Hispanic population.
- Explore how intersections between Hispanic identity and key demographics affect risk/susceptibility and use of ENDS and other tobacco products.

These objectives are guided by the following overarching research questions:

- **RQ1:** How does tobacco use and susceptibility among Hispanic youth and young adults differ by key demographics, including age, gender and acculturation level?
- **RQ2:** How do tobacco risk and protective factors for ENDS use vary by key demographics including age, gender, and acculturation level?
- **RQ3:** How does identification as Hispanic intersect with other characteristics (e.g., acculturation, gender, sexual orientation) to influence tobacco susceptibility, experimentation and initiation?
- **RQ4:** How might Hispanic youth and young adults be segmented by ENDS susceptibility for more effective message targeting?

Study Design and Protocol

To address the objectives and research questions above, we will conduct an online survey among up to 2,600 Hispanic youth (aged 13-17) and young adults (aged 18-24) recruited from a national online panel provider that specializes in recruiting Hispanic/Latino participants.

The study will include an online screener and questionnaire. Both will be available in both English and Spanish. Respondents can choose their preferred language and will have the option to change language preferences if desired.

Participants will be recruited by an online survey vendor(s) that manages a national online panel of adults and pre-registered, double opt-in youth (aged 13-17). Interested participants will be asked to complete a screener that will collect the following information:

- a. Demographic information: age, race/ethnicity, country of origin/national background, languages spoken with family, gender, sexual orientation, state, birthplace, parents' birthplace.
- b. Self-reported ever-use and past 30-day use of ENDS.
- c. Battery of questions to determine susceptibility to and curiosity about ENDS use.
- d. Self-reported ever-use of and number of cigarettes used in the past 30 days.
- e. Perceived family financial security measure.¹
- f. Zip code (to confirm respondents are within the United States; post-hoc analyses may be conducted to understand potential regional variations).

¹ Hammond, M. A., Khurana, A., & Stormshak, E. A. (2021). Adolescent measures of family socioeconomic status: Reliability, validity, and effects on substance use behaviors in adolescence and young adulthood. *Preventive medicine reports*, 21, 101317. <https://doi.org/10.1016/j.pmedr.2021.101317>

- g. IP Address (collected automatically to reduce fraudulent activity and verify respondent country of origin/national background).

To access the screener, respondents will click on a link to a survey hosted on a Qualtrics account owned and managed by IQS. To prevent collection of unnecessary data from ineligible respondents, all respondents who take the screener will be notified upon completion if they qualified or did not qualify. Respondents who are eligible to progress to the survey will be directed to complete a consent or assent form prior to accessing the survey. No identifying information collected via the screener (e.g. birth date or zip code) will be retained or included in analyses.

Eligible participants who consent or assent to participation will then be directed to the questionnaire which will include the following measures:

1. Self-reported tobacco ever use, current use and susceptibility including use of ENDS/vapes, cigarettes, hookah, cigarillos and blunts
2. Assessment of tobacco and marijuana use in the home.
3. Smoking identity.
4. Harm and addiction perceptions.
5. Social norms.
6. Hispanic identity.
7. Hispanic community connection.
8. Familism.
9. Discrimination experiences.
10. Mental health.
11. Religious activity.
12. Sensation seeking.
13. Peer influence.
14. Skin color.
15. Frequency of media use (television, YouTube, streaming radio, social media, gaming).
16. Additional demographic information (e.g., grade, education level, employment status, geographic type [urban, suburban, rural]). Note: Grade will only be asked of those 13-17.
17. Education level and employment status will only be asked of respondents 18-24.

Recruitment and survey administration

Participants will be recruited by an online survey vendor(s) that manages a national online panel of adults and pre-registered, double opt-in youth (aged 13-17). All aspects of data collection (screener, consent, and survey administration) will be hosted by IQS, regardless of the panel through which the participant was recruited.

Adult panelists (ages 18-24) and adult panelists with children ages 13-17 along with youth aged 13-17 who are pre-registered, double opt-in members (i.e., both the parent/guardian and child have pre-consented to participate in surveys sent to them) will be contacted directly by the recruitment vendor and invited to take the screener to see if they are eligible to participate. This invitation will be either delivered via email or a message delivered to the respondent's inbox on the panel website. The invitation will contain the approximate length of the survey and

the token of appreciation offered for completion.

After screening, eligible youth will be directed to complete an assent form prior to beginning the survey. Eligible young adult (18-24) panelists will complete a consent form prior to beginning the survey. Those who do not meet the eligibility criteria will be excluded from the study. In appreciation of their or their child's participation, panelists will receive non-monetary points that can be redeemed for goods, services, or cash.

2b. Degree of Accuracy Required for the Study

The estimated total sample size of up to 2,600 includes cases that may not be included in the final analysis due to incomplete responses and duplicate or fraudulent completions, which may reduce the number of valid, complete cases in the final dataset. These numbers were derived from an a priori sample size calculation using Survey Research Systems Survey Software to determine the minimum sample size needed to be representative of the U.S. Hispanic youth population. Based on 2020 estimates, there were 12.6 million Hispanic youth ages 13-24 in the United States.² Assuming a 99% confidence level and a 4% margin of error, a sample size of 1,040 is sufficient to represent the population of interest. Surveys of 15 or more questions have, on average, a completion rate of 41.94%.³ Thus, we will aim to recruit up to 2,600 Hispanic youth/young adults for the survey (to reach at least 1,040 completes). Within the minimum 1,040, we need to reach minimums for certain sub-populations for analysis. To detect significant differences at $p < 0.05$ level, with a small effect size (OR = 1.72) and 90% power, a minimum of 235 respondents is needed for each ENDS use risk group (Susceptible Non-Triers, Current Users, and Susceptible Past Experimenters).

2c. Estimation Procedures

Statistical analyses will be conducted to address the study's primary research questions. IQS will summarize descriptive statistics, such as means, standard deviations, and percentages, as well as create crosstabs to assess how demographic and other variables and survey items may be associated. Data will be stratified by age group and acculturation level, and within each stratum.

Following data delivery and cross-tabulations from IQS, CTP will conduct inferential analyses to examine associations between demographics and tobacco product use and susceptibility, respectively. Additionally, FDA CTP will create interaction terms to examine how intersections between demographic factors are associated the outcomes variables.

3. Methods to Maximize Response Rates and Deal with Nonresponse

To maximize participation, we will incorporate best practices from similar online surveys into our data collection procedures. These include:

² United States Census Bureau (2017). American Community Survey (ACS) Demographic and Housing Estimates. https://data.census.gov/cedsci/table?q=United%20States&table=DP05&tid=ACSDP1Y2017.DP05&g=0100000US&lastDisplayedRow=29&vintage=2017&layer=state&cid=DP05_0001E

³ Kasia Perzynska. How to get survey completion rate of over 80% (a real study). Survicate. 2021. <https://survicate.com/surveys/survey-completion-rate/>

- Implementing a soft launch of the online survey to 10% of selected panel members solely for the purposes of detecting and resolving any technical difficulty. There will not be any changes to the survey questions themselves following the soft launch.
- Keeping the questionnaire at a reasonable length to minimize breakoffs.
- Including a brief introduction to the study that identifies FDA as the sponsor, states the purpose of the study, and provides contact information for participants to reach the IQS Principal Investigator with any questions about the study or their rights as a study participant.
- Recruiting verified panelists. Panel vendors use an opt-in registration process whereby panelists are invited to participate and sign up through an opt-in confirmation e-mail (See Recruitment e-mail attachment). This process protects against fraudulent account registrations and ensures that panelists are actively motivated to participate in surveys. The panel vendors will panel members who appear to be eligible based on their member profile. As part of the process of registering with the survey panel, panelists provide information about a range of sociodemographic characteristics, including whether or not they have children, that can be used to target particular groups.
- To minimize nonresponse, IQS will conduct ongoing monitoring of response levels and drop-off rates and work with the panel provider to address any problems that arise throughout the course of the collection of information.

4. Test of Procedures or Methods to be Undertaken

IQS will conduct rigorous internal testing of the online survey instruments prior to fielding. The research team from IQS will review the online test version of the instrument that we will use to verify that instrument skip patterns are functioning properly, and that all survey questions are worded correctly and are in accordance with the instrument approved by IRB and OMB. Data collection will begin with a soft launch through the panel provider who will send a generic communication to a small subset of panel members and review their responses to ensure the online survey is working properly.

Based on skip pattern testing and instrument length, some items may be excluded. Survey testing will aid survey clarity (e.g., address typos and decrease confusing wording) and will ensure that all survey questions are in accordance with the instruments approved by OMB and IRB.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The following individuals inside the agency have been consulted on the design and statistical aspects of this information collection as well as plans for data analysis:

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The following individuals outside of the agency have been consulted on questionnaire development and/or will be collecting and/or analyzing data:

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