
ATTACHMENT I: PARENTAL OPT-OUT FORM

**TITLE OF INFORMATION COLLECTION: HISPANIC/LATINO YOUTH AND YOUNG ADULT
TOBACCO USE ONLINE SURVEY STUDY**

FDA Project Lead: Emily Sanders, M.P.H.

Food and Drug Administration (FDA)

Center for Tobacco Products (CTP)

Principal Investigator: Everly Macario, Sc.D., M.S., Ed.M.

Telephone: 224.244.3965

Address: IQ Solutions, Inc., 11300 Rockville Pike, # 901, Rockville, MD 20852

PARENTAL OPT OUT FORM

Dear Parent:

Your [INSERT CHILD'S AGE]-year-old child is within the target age range to participate in a study conducted by IQ Solutions, Inc. on behalf of the U.S. Food and Drug Administration (FDA). The study will ask youth, ages 13-17, and young adults, ages 18 to 24, to complete an online questionnaire about their perceptions of vaping and tobacco product use. Your child's answers will help inform messaging for future public health campaigns. It will take about 15 minutes for your child to complete the questionnaire.

Please review the study information on this form.

If you **are willing** to refer your child aged 13-17 to participate, please **forward this study link [study link]** to your child. If your child chooses to take the questionnaire, they must first complete and sign an assent/consent form before they are directed to the questionnaire. This assent/consent form will appear first, before the questionnaire, at the study link.

If you **are not willing** to refer your child aged 13-17 to participate, no further action is required. Please **do not** forward your child the study link.

Should you wish to see a copy of the questionnaire, please contact the Principal Investigator, Dr. Everly Macario, at emacario@iqsolutions.com or 224-244-3965.

If you do not want your child to continue participating once they have already begun the questionnaire, please contact the Principal Investigator and we will remove your child's responses from the analysis.

Please read this carefully. If there is any information you do not understand, researchers will be happy to explain it to you. You may ask questions by contacting the Principal Investigator, Dr. Everly Macario, at emacario@iqsolutions.com or 224-244-3965.

Note: All references to “you” hereafter signifies “your child.”

Overview of Study

- You can take part in this research study because you are either 13-17 years old or 18-24 years old. This consent form goes over this study. You may keep this form.
- You may ask the research team questions about the study at any time. They will give answers.

Who sponsors this study?

- IQ Solutions is a contractor running this study. The study is funded by the Food and Drug Administration (FDA), but the FDA will not conduct this research.
- The mission of the FDA is to promote and protect public health. In conducting this study, the FDA does not intend to sell tobacco, nor promote, condone, normalize, or encourage its use. The survey in this study is not intended to promote, directly or indirectly, other behaviors that may be a gateway to subsequent risky behaviors, such as illegal drug use and smoking.

Why is this survey being conducted?

- The aim of this study, which will be an online survey, is to help us understand youth’s and young adults’ perspectives on vaping and tobacco product use. There will be a total of up to 2,600 participants in this portion of the study.

What will happen?

- After you agree to take part, you will complete a questionnaire that will take approximately 15 minutes to complete.
- The questionnaire is available in both English and Spanish.
- We may keep information you provided from both the screener survey and the full study questionnaire.
- The research team will summarize everyone’s responses in a final report. The report will not have your name or other information that identifies you. The research team will share the report with the FDA. Anonymous data from this study may be published in professional journals or at scientific conferences, but you will not be identified or linked to the results.

What are the risks?

- It is possible that you may feel uncomfortable answering the questions on the questionnaire. If any of the questions do upset you, you can choose not to answer them. You can stop filling out the questionnaire. Information you share will not be shared with anyone outside of the research team.
- There is also a potential risk of a breach of confidentiality. However, all reasonable steps will be taken to protect your privacy.
- This research is covered by a special protection (called a Certificate of Confidentiality) from the FDA. This special protection makes sure that staff involved in this project protects your privacy. This means that project staff generally cannot provide your name, or any other information that could identify you, to anyone who is not connected with the project. Project staff cannot share this information in court or during other legal proceedings, unless you agree, even if there is a court order for the information. However, in other settings, project staff may share study information that could identify you if:
 - You actively agree that project staff can share information;
 - The study information is used for other scientific research, as allowed by law;

- o The FDA, which is paying for the study, needs information to check how their research money is being spent; or
- o A law requires sharing information (for example, when project staff must report to FDA or if project staff hears threats of harm to others or reports of child abuse).

The Certificate of Confidentiality does not prevent you from sharing any personal information or information about your involvement in this study with others if you choose to. For example, you can share that you are taking part in this project.

- The research team may have to share your private information with federal, state, or local authorities if the information is about something that puts you or someone else in imminent danger, may lead to bodily harm, or creates a public health risk, such as child abuse, self-harm, infectious diseases, or other similar topics.
- Researchers may also contact you in the unlikely case that there is a breach of confidentiality, for example, because of hacking. In the unlikely event that the study data are hacked, we will tell you within 5 business days of discovery. We will try our best to maintain the privacy of data collected during the study by using standard online data safeguards.

What are the benefits?

- There is no direct benefit to you for being in this study. However, your thoughts and opinions may help others as they may inform health education and promotion messages, resources, and/or campaigns. The alternative is to not participate in the study.

Will I be paid?

- If you complete the questionnaire, you will receive points awarded through your affiliated research panel no later than 2 weeks after participation in the survey. These points will be equivalent to a value of \$10. There is no cost to you for taking part in this study. However, internet access or data usage costs may apply.

Do I have to take part in this survey?

- This study is completely voluntary. You do not have to take part, and you can stop at any time. You can agree to participate now and still change your mind later. You can choose not to take part in the study, or you can start and then stop early, without penalty or loss of benefits to which you are otherwise entitled. You do not have to answer any questions that you do not want to. You will receive points even if you do not answer all questions, as long as you submit the questionnaire.

Who will have access to my identity?

- Your information will be kept as confidential as possible according to all local, state, and federal laws. The Institutional Review Board (IRB) – a team of reviewers that makes sure the rights and welfare of research participants are protected – may also have access to study records for *monitoring* purposes, but your name and information will *not* be used in any way that someone outside of the research team could identify you.

The research team does *not* have access to your name and contact information and the answers you provide cannot be connected to this information. No one will know what answers you gave us. The research team will keep your personal information as private as possible to the extent allowed by law. All study data will be stored in a password-secured network. All personal information will be destroyed 3 years after the study is over. It will be destroyed by permanently deleting electronic files.

Whom do I contact if I have questions?

If you have any questions about this survey, would like to offer input, or if you feel that you may have been harmed by participating in the study, you should contact the Principal Investigator, Dr. Everly Macario at emacario@iqsolutions.com or 224-244-3965.

If you have questions about your rights as a research participant, or if you have questions, concerns or complaints about the research, please feel free to contact the IRB for this study, Ethical & Independent Review Services (E&I), at (800) 472-3241 or subject@eandireview.com. You may also contact E&I IRB if the research staff cannot be reached or if you wish to talk to someone other than Dr. Macario and the research staff. Please reference E&I study number 22095.

- Please feel free to print or save a copy of this form for your records.

To learn more about tobacco prevention, visit: <https://therealcost.betobaccofree.hhs.gov/vapes>.

If you or anyone you know is interested in quitting tobacco products, you can find more information at: <https://smokefree.gov>.

Paperwork Reduction Act Statement: An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The public reporting burden for this information collection has been estimated to average 2 minutes per response to read, review, and complete this **Parental Opt Out Form**. Send comments regarding this burden estimate or any other aspects of this information collection, including suggestions for reducing burden, to PRASupport@fda.hhs.gov.