OMB# 0910-0697
Exp. 12/31/2023

INFORMED CONSENT FORM

TITLE OF INFORMATION COLLECTION: FDA CTP 2021 Educational Outreach Focus Groups with Health Educators

This research is being conducted by IQ Solutions, Inc. on behalf of the U.S. Food and Drug Administration (FDA) Center for Tobacco Products (CTP). The purpose of this research is to inform FDA CTP's efforts to develop educational materials to support tobacco prevention and education efforts in middle and high schools across the United States. As a middle school or high school teacher/educator, you have been asked to participate in a virtual focus group about skills-based health education lessons targeting tobacco and vaping prevention. During the focus group, you will be asked to share your feedback on ways to develop more effective tobacco and vaping prevention and education curricula with up to five other participants and one focus group facilitator. The focus group will be conducted virtually on Zoom, will take approximately 90 minutes, and be scheduled at a day and time convenient for you. We will hold up to 18 total virtual focus groups with middle and high school educators from around the United States.

Please remember:

- Your participation in the focus group is your choice. You do not have to answer any question during the focus group discussion that you do not want to answer, and you may leave the focus group at any time without penalty.
- The risks for taking part in this study are low. We will protect the information you share and not connect your name to anything that you say in our summary report, nor will we share your personal information with anyone associated with this project or the FDA. There is a chance that another participant in your focus group could share information discussed after the focus group ends, even though we will ask everyone not to share what was discussed outside of the focus group. Only your first name will be used during the focus group check-in and discussion. Your full name will not be shared with the focus group facilitator or other participants. The summary report will not link your comments to you or include your full name. Your personal information will be destroyed upon completion of the project. What you say during the focus group will be used to improve health education and tobacco prevention resources for middle and high school students.
- This study will not benefit you directly. However, your feedback will help FDA improve tobacco prevention and education curriculum materials and resources. All middle and high school health teachers will eventually have access to these newly developed resources.
- There are no right or wrong answers. Feel free to be open and honest in your comments. No one will be able to link your identity to your responses to questions.

- We will be audio recording the focus group and taking notes to help us remember the information discussed. This information will never be made public. There will be no video recording of the focus group discussion; once the focus group discussion ends, the Zoom webcam/video feature will be disabled and there will be no video archive of the discussion.

- Project team members from IQ Solutions and the FDA may be observing the focus groups for awareness but will be in listen-only mode. Their cameras will be turned off and they will be on mute. They will not be interacting in the focus group discussion.

- You will receive a $40 Visa gift card as a token of appreciation for participating in the focus group. You will receive the gift card even if you choose to not answer some questions or choose to leave the focus group before its completion.

- All project related data will be destroyed by securely shredding documents and permanently deleting electronic information three years after completion of the study.

- This research is covered by a special protection (called a Certificate of Confidentiality) from the FDA. This special protection ensures that researchers involved in this study protect your privacy as much as possible within the law. This means researchers generally cannot provide your name, or any other information that could identify you, to anyone who is not part of the research team. Researchers cannot share this information in court or during other legal proceedings, even if there is a court order for the information. However, researchers may share study information that could identify you if:

  - You agree to share information (for example, to get medical treatment);
  - The study information is used for other scientific research, as allowed by law;
  - The FDA, which is paying for the study, needs information to check how their research money is being spent;
  - A law requires sharing information (for example, when researchers must report to FDA, or if researchers hear threats of harm to yourself or others or reports of child abuse).

- You can share any information you want to with others. For example, you can share that you are in this research study or your history of tobacco use.

If you have any questions about this research study, you may contact Dr. Everly Macario at EMacario@IQSolutions.com, principal investigator.

You must sign, date, and return this form to [insert RECRUITMENT VENDOR email address] before you can participate in the virtual focus group.

PLEASE READ THE FOLLOWING STATEMENT, AND SIGN BELOW IF YOU AGREE.

I have read the information in this consent form, all my questions have been answered adequately, and I agree to participate in the focus group.

Print your name.

Sign your name.

Write today's date.

Please return your signed form to [insert RECRUITMENT VENDOR email address].