OMB Control No. 0910-0697
Expiration date: 12/31/2023

U.S. Food and Drug Administration (FDA)
Center for Tobacco Products (CTP)
Safety Reporting Portal Audience Study: Discussion Group Consent Form
Tobacco Product Users/Concerned Citizens

Please read this form carefully. You can ask as many questions as you want by emailing the recruiter, Cynthia Cross, at cynthia@hagensinclair.com or the research project lead, Liz Gall, at lgall@iqsolutions.com. If there is any information you do not understand, researchers will be happy to explain it to you. **You must electronically sign, date, and return this form to Hagen/Sinclair before you can take part in the discussion group. Please email this form to us within 24 hours of your session at cynthia@hagensinclair.com.**

Why is this discussion group being conducted?

- The goal of this study is to help us understand the needs of tobacco product users and others (e.g., friends, family members) who may be affected by a problem with a tobacco product. FDA's Center for Tobacco Products wants to know how its system for reporting tobacco problems, the Safety Reporting Portal, can be improved.

What will happen?

- We will send you a link to a copy of the Safety Reporting Portal. Before the start of your discussion group, we would like you to follow the instructions to start a tobacco product report. You do not need to fully complete the report or submit it, just explore the survey questions.
- The discussion groups will take place in English. Your discussion group will last about 60 minutes. Discussion groups will be held virtually using an online platform (Zoom) that will allow the moderator and discussion group participants to see and hear each other, like a secure video conference. We would like you to feel comfortable sharing your video with us, but it is not required. You can turn your camera off during the discussion.
- Only your first name will be used during the discussion. We also ask that you do not identify yourself with anything other than your first name, and do not share any information that could break privacy.
- You will be in a group of up to four other people. A total of six discussion groups and 30 interviews will be held for this study. The study team will keep all conversations private within each group and interview session.

- The discussion group will be audio-recorded and transcribed. No names or other identifying information will appear in the transcript or on any discussion group materials. Instead, you will be assigned a unique identifier. If you do not want to be audio-recorded, you cannot take part in this study.
- The study team will summarize everyone's thoughts in a final report. The report will not have your name or other information that identifies you. The study team will share the report with FDA. Anonymous data from this study may be published in professional journals or presented at scientific conferences, but you will not be identified or linked to the results.

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- You should seek a quiet and private space to minimize the risk of other people listening to your conversation during the discussion group.
- No computer system is 100 percent secure, so there is some risk that your information could be part of a data breach. We will do our best to protect against this unauthorized access to private information by keeping information password-protected, enabling two-factor authentication on all staff devices, limiting access to ONLY the people who need it, and using services like ZoomGov that have enhanced security and privacy protections.
- There is a chance that some of the questions may make you uncomfortable or may ask something you don't feel comfortable sharing in a group setting. You can always choose not to answer any question during the discussion.
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- We have obtained a Certificate of Confidentiality from the Federal Government. This helps protect your privacy by allowing us to refuse to release your name or other information outside of the research study, even by a court order. The Certificate of Confidentiality will not be used to prevent disclosures to local authorities of child abuse or neglect, or harm to self or others. The Certificate does not prevent you or a member of your family from releasing data about yourself or your involvement in this study.
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Do I have to take part in this interview?

- 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. If you choose not to take part in the interview, or if you start and then stop early, you will not face any penalty or loss of benefits to which you are otherwise entitled. (You may not be eligible for the incentive if you choose not to take part in the interview.)

- You do not have to answer any questions that you do not want to. You will be paid even if you do not answer all questions or choose to leave the interview before it ends.

Who will have access to the audio recording or my identity?

- Only the study team will have access to the audio recording. The audio files will be stored on a password-protected computer. We will only use the audio files to make accurate notes of the interview (transcription).

- The audio recordings will be deleted immediately after transcription, and any study information, including transcriptions and signed consent forms, will be destroyed after the completion of the study. It will be destroyed by permanently deleting electronic files.

- Some members of the team will take notes during the interview. Interviews will not be video recorded.

- You can choose which name to use in Zoom (the moderator can help you with this) and whether you wish to share your video.

- Your information will be kept as private as possible according to all local, state, and federal laws. Regulatory agencies, including FDA and Salus Institutional Review Board (IRB) may also have access to study records for monitoring purposes (such as confirming

we have consent forms from everyone in the study), but your name and information will not be used in any way that someone outside of the study team could identify you.

- We have obtained a Certificate of Confidentiality from the Federal Government. This helps protect your privacy by allowing us to refuse to release your name or other information outside of the research study, even by a court order. The Certificate of Confidentiality will not be used to prevent disclosures to local authorities of child abuse or neglect, or harm to self or others. The Certificate does not prevent you or a member of your family from releasing data about yourself or your involvement in this study.
- The study team will not link your identity, including your name, to your responses. When we spoke to you about the study, we asked for your name and phone number. We will use this information to schedule the interview and to provide the token of appreciation, but we will not connect this information to your responses. This means that your answers will not be connected to your name or contact information. No one will know what answers you gave us. The study 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 after study completion.

Whom do I contact if I have questions?

- If you have any questions about this interview, would like to offer feedback, or feel that you may have been harmed by participating in the study, you should contact the research lead, Liz Gall, at lgall@iqsolutions.com or the recruiter, Cynthia Cross, at cynthia@hagensinclair.com.
- If you have any questions about your rights as a research participant, you may contact Salus IRB at 1-800-472-3241, or by email at subject@salusirb.com. The study reference number for Salus is 23053. Salus IRB is a group of people who performs independent review of research to protect the rights and welfare of research participants.
- Please keep a copy of this form for your records. If you would like an additional blank copy of this form, send an email to lgall@iqsolutions.com.

Consent

- Your written consent indicates that you have read the information about this study and agree to take part. By providing electronic consent to participate in this study, you do not give up any of your legal rights.
- Do you agree to take part in this interview and be audio-recorded?

☐ **Yes, I agree to participate in this study and to be audio-recorded. I have read and had time to consider all of the information above. My questions have been answered and I have no further questions. By checking this box and typing my name on the signature line below, I am electronically signing this consent form.**

☐ **No, I do not agree to participate in this study. I have read and had time to consider all of the information above. My questions have been answered and I have no further questions.**

_____ _____

Participant Consent Signature Date