

ATTACHMENT 3B: CONSENT FOR SMARTPHONE APPLICATION-BASED SURVEYS

1 Consent Form: Point of Sale Intervention for Tobacco Evaluation (POSITeV)

Form Approved
OMB No. 0910-0851
Exp. Date 04/30/2021
RIHSC No. 17-082CTP

Thank you for completing the Point of Sale Intervention for Tobacco Evaluation (POSITeV) questionnaire. When you completed the questionnaire, you said that you own a smartphone. We are inviting you to participate in a smartphone application-based component of our study. This new approach to research uses your phone's technology to determine how often you go to stores that sell tobacco products. When analyzed together with the survey responses that you already provided, information from this app will help the FDA to collect information about advertisements adults have seen and their attitudes towards smoking and programs that help smokers who want to quit.

If you choose to download the smartphone application (or app), it will use your phone's location services to record the time, date, and your location whenever you go into and exit these kinds of stores. This technology only works when your location services are activated. As a result, we hope that you will keep location services activated as much as possible.

The app will also ask you to complete a short questionnaire (5 minutes or less) [IF WAVE = 2 FILL: two times; IF WAVE = 3 FILL: once over the next several months. After you complete [IF WAVE = 2 FILL: each questionnaire; IF WAVE = 3 FILL: the questionnaire] with the app, you will receive a \$5 electronic gift card that can be redeemed from an online vendor. You will receive an e-mail containing instructions on how to redeem your gift card. The app will not interact with, obtain information from, or transmit information to any of the other apps installed on the phone. Although the app will access location data from the phone, no location data will be logged except data for the mapped convenience stores. The data obtained from the app will not be used for any purpose except for analysis.

The app was developed by a company that develops apps to research health and behavior. If you choose to participate, the interviewer will give you the instructions to download the app onto your phone now. Afterwards, you will not need to do anything else with the app except answer [IF WAVE = 2 FILL: two brief questionnaires; IF WAVE = 3 FILL: one brief questionnaire] over the next several months when prompted by the app to do so. However, you may be prompted to approve and/or download any updates that we create to make the app work better.

Types of Questions

The app-based [IF WAVE = 2 FILL: questionnaires ask; IF WAVE = 3 FILL: questionnaire asks] about the types of ads you've seen, your tobacco use, intention to quit smoking, and tobacco purchasing behaviors.

Voluntary Participation

Your participation in this study is completely voluntary. If you refuse to participate in this portion of the evaluation, you can still participate in the other parts of the study (a total of 4 online or in-person questionnaires over 24 months). You can decide not to answer any or all questions asked by the app or delete the app from your phone at any time. We simply ask that you contact us when you do so. You can stop the app-based questionnaire at any time,

however, you will only receive the \$5 token of appreciation if you complete the questionnaire.

Risks

There are no physical risks to you from participating in this component of the study. Some questions in the app-based questionnaire may be personal and might make you mildly uncomfortable. Wait until you are in a safe place to complete the questionnaires when prompted to do so. Please do not complete the questionnaires when driving, operating machinery, or performing other tasks that could put you or other people in danger. All of the information we collect from the app will be kept private and only used for research. We cannot guarantee the privacy of all of your information when it is communicated electronically, but we are making every possible effort to keep your information private.

Benefits

There are no direct benefits to you from answering our questions. However, you will be contributing to important research.

Costs

There is no cost to download the app. However, data collected by the app will count towards any data usage limits included in your phone plan. The app attempts to send data once a day. It uses cellular data only when you are not connected to a WiFi network. Before downloading the app, we recommend that you make sure that you have a data plan on your phone. You will be responsible for the costs of your phone bill including any data usage for the app. We estimate that the app may use about 50MB (megabytes) of data per month. In 2017, most data plans ranged from 500MB of data per month to unlimited data. Charges for going over your data limit vary greatly by phone carrier but may range from \$0 to \$30 each time you go over. You may be charged this amount more than once. The app may also affect the battery life of your phone.

Confidentiality

We ask you for your e-mail address and phone number so that we can remind you to complete the [IF WAVE = 2 FILL: brief questionnaires; IF WAVE = 3 FILL: brief questionnaire]. You will also use a username that we provide you to sign into the app. We also ask for your e-mail address to provide you with a \$5 electronic gift card in appreciation for your time. The application will not collect information from other apps in your phone. The app will not record any information about what you do in stores. Your survey answers and your location data will be recorded by the app and stored on the app vendor's secure server. Your name will be kept private. Your answers will be labeled with a special number instead of your name. This makes it so only research staff will know these are your answers. Your specific answers to the survey questions will not be shared outside of the app vendor's or RTI's research teams. Instead, the information you provide will be combined with answers of many others and reported in a summary form. All of your answers will be kept private. We may send your data over the internet. It is not completely safe to send data through the Internet but we are doing everything we can to protect your data. All staff involved in this research are committed to keeping your information private. At the end of the study, we will ask you to delete the app so that it no longer collects information from you. Once RTI receives your information from the app, the app vendor will delete all information about you on their servers. If you withdraw from the study, we will ask you to delete the app, but some copies of your visits to convenience stores that sell tobacco may not be able to be destroyed or deleted.

Questions

If you have any questions about the study, you may call the project assistance line toll-free at 1-800-957-6457 between 9 am and 5 pm, Eastern Time, Monday through Friday or email us at fdastudy@rti.org. If you have any questions about your rights as a study participant,

you may call RTI's Office of Research Protection at 1-866-214-2043 (a toll-free number). This research study was reviewed and approved by RTI International's Institutional Review Board (IRB), a committee that evaluates research that involves human participants.

You will be given a copy of this consent form to keep.

Do you agree to participate in the app-based portion of the study?

- 1 Yes GO TO APP_INSTRUCTIONS1
- 2 No GO TO APP_REFUSAL