

ATTACHMENT 7: QUESTIONS AND ANSWERS ABOUT THE POINT OF SALE INTERVENTION FOR TOBACCO EVALUATION (POSITEV) (FOR INTERVIEWER REFERENCE)

Why is this study being done?

The study will provide the FDA, policy makers, and researchers with important information about how public education campaigns affect adults' attitudes, beliefs, and behaviors toward tobacco. By taking part in this study, you will make a direct impact on important tobacco-related education activities.

What does the Point of Sale Intervention for Tobacco Evaluation (POSITEV) mean?

"Point of sale" refers to retail stores. We are interested in finding out what types of stores people go to, including stores that sell tobacco products.

Why should I participate?

This is an opportunity for you to contribute to important national research that will help people develop programs that help adult smokers who want to quit. To thank you for your time, you will receive \$25 at the end of the interview.

Who is sponsoring this study?

The study is sponsored by the Food and Drug Administration (FDA). The FDA chose RTI International (RTI) to carry out this research.

Who is RTI International?

RTI is a not-for-profit research organization based in North Carolina. RTI conducts research projects for the government, schools, and companies. Professional RTI interviewers in your area are conducting interviews with households that qualify to participate in the study.

How was I chosen to participate? Can someone else participate instead?

In 2018, RTI randomly selected households in 30 counties across the country. Then, RTI mailed questionnaires to and visited these households and asked questions about the households to determine if anyone qualified to participate. Next, the computer randomly selected one adult from the list of potential participants in the household. Now, for each follow-up questionnaire, we are trying to learn what has changed and what has stayed the same with our original participants. No one else can take your place!

How will I be involved?

I will ask you to read some questions on a laptop and enter your responses directly into the computer. I may also ask you some questions out loud and enter your answers into the computer myself.

How will I recognize the RTI interviewer?

The interviewer will carry an RTI identification badge with his or her picture on it.

How long will it take?

The interview will take about 30-40 minutes, on average. Interviewers can schedule visits to your household when it is easiest for you.

What happens to the information?

Each file, which is identified only by a code number, will be sent to RTI electronically within 48 hours of when the interview is completed. The answers will then be combined with all other participants' answers, coded, totaled, and analyzed. Your household might receive a telephone call from RTI to check that the interviewer followed the correct steps in completing the questionnaire with you.

How will I be reimbursed for completing the questionnaire?

We will send you a personal check in the mail once we receive your completed online questionnaire. If you prefer to complete the questionnaire in-person, the interviewer will provide you with cash at the end of the questionnaire.

What about Privacy?

All RTI staff members and interviewers have signed a Privacy Agreement guaranteeing that they will not reveal any information to anyone other than project staff who have permission to access this kind of information. All information collected as part of the study will be kept private to the fullest extent allowable by law, and nothing you tell RTI staff will be reported with your name. You may choose whether or not to participate in the study and you can refuse to answer any questions. Answers obtained during the questionnaire will be combined with those from thousands of others from around the country.

I tried to complete the survey online, but it said I am no longer eligible.

We appreciate your continued interest in the survey. Unfortunately, study participants who have moved out of the study area are no longer eligible to participate.

What is a smartphone app?

A smartphone app is a software application (or program) that runs on smartphones, which are phones that have many of the same functions as a computer. Most smartphones are sold with several apps already installed on them. Apps allow you to use your phone to access the internet, get directions, and much more.

Why does RTI want me to download an app on my smartphone?

RTI is interested in how often people go to stores that sell tobacco products. The smartphone app will tell RTI how often you have gone to these types of stores. This information will help us make our study more effective. Participation in all parts of the study is completely voluntary, and you may decide to delete the app at any time. We just ask that you notify us if you do so.

Who developed the app and how will my information be protected?

A company that conducts digital health research designed the app, which will collect a list of dates, times, and locations for stores that you have gone into that sell tobacco products. The app may ask you to complete three brief questionnaires over the course of 18 months. RTI will use your e-mail address to send you a \$5 gift card each time you complete a questionnaire. We will also ask your permission to send you e-mails and text messages when it's time to complete the next brief questionnaire. The company that designed the app will have the information about you collected by the app. The app developer uses complex security procedures to make sure no one else has access to your information. After the study is complete, the company that developed the app will delete all the information recorded by the app, and RTI will ask you to delete the app as well.

What kind of information will the app collect?

The app is triggered to record the date, time, and location whenever you go into or leave a store that sells tobacco products. The app will use the geolocation services on your smartphone to create a list of the stores that you went into that sell tobacco products and the dates and times you were there. The app will not record any information about what you did or bought while in the store. The app will also collect your answers to three brief questionnaires over a period of 18 months.

Will the app cost me anything?

The app attempts to send the information that it collects to the app developer once a day. It uses cellular data only when you are not connected to a WiFi network. We estimate that the app may use about 50MB (megabytes) of data per month. If you do not have a data plan or, if your data plan is too small, your cellular provider may charge you their standard rates for any data overage. Data overage costs vary greatly by carrier, but tend to range from \$0 to \$30, and you may be charged this amount more than once. We recommend that you confirm that you have a data plan before

downloading the app. The study is not able to cover any data use costs associated with the app. We can download the app today and you can check your data in a week or so. If it is using too much data, you can contact us to help you get rid of the app using the phone number or email address provided on the app instruction sheet.

Will the app affect my battery?

I understand battery use might be a concern. The app doesn't affect battery life as much as you think it might. Let's give it a try. If you have problems with battery life, you can contact us at the toll-free number or email address on the app instruction sheet and we can help you remove it.

Do I have to have location services turned on?

Yes, the app uses location services. We're only interested when you're at participating convenient stores. The app won't track you everywhere you go. We can download it now and you can always remove it later.

Where can I get more information about the study?

If you have other questions about this study, you can call toll-free 1-800-957-6457 between 9 am and 5 pm, Eastern Time, Monday through Friday or e-mail fdastudy@rti.org. If you have questions about your rights as a study participant, you can call toll-free: **RTI's Office of Human Research Protections** at 1-866-214-2043.