

Attachment B
Computer-Assisted Telephone Interviewing Instrument

Form

Approved

OMB NO. _____

Exp. Date _____

Computer-Assisted Telephone Interviewing Instrument

Upon receiving a call for the study, the staff member will open the computerized tracking system and select the study screener icon. Once the first question is answered, the tracking system will automatically assign an ID number to the caller even before eligibility is discerned as a means of determining call volume. The staff member will then read the following introduction script.

Thank you for your interest in our cigarette study. My name is _____. As you know we are currently screening people for our study on behalf of the Centers for Disease Control and Prevention (CDC). The information is being collected under section 301 of the Public Health Service Act. This Act gives federal health agencies, such as CDC, broad authority to do many public health activities, including this type of research. Participation is voluntary. You do not have to answer any questions that make you feel uncomfortable. You can stop participating or answering questions at any time without penalty.

The study would involve your coming to our smoking research laboratory clinic 2 days in a row for about 1 hour each time. The first visit needs to be in the morning and the second visit needs to be in the afternoon, and you should come to the laboratory clinic feeling like you “really want” a cigarette. At each visit you will answer some questions and give urine, saliva and breath samples. You will smoke one of your own cigarettes through our smoking machine while wearing a special vest to measure your breathing. In addition, you will have some glow-in-the-dark lipstick applied to your lips and vitamin solution applied to your fingers to see how you hold your cigarette. Before we discuss the study further, I would like to ask you a few questions to see if you qualify for the study. It should take about 5 minutes, and everything you say will be treated in a confidential manner. Do you have time for this now or any questions?

Public reporting burden of this collection of information is estimated to average 5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. 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. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-XXXX)

The following screening questions will then be asked.

QUESTION	REPNSE				ELIGIBLE RESPONSE
How did you find out about this study	Newspaper	Poster or Flyer	Friend	Other	N/A
How old are you?	Age: _____				≥18 years
Please tell me which of these best describes your race and ethnic group:	White, Non-Hispanic	African American, Non-Hispanic	American Indian or Alaskan Native		White (non-Hispanic) or African American (non-Hispanic) or Hispanic; dependent upon cell availability
	White, Hispanic	African American, Hispanic	Asian or Pacific Islander		
	Something else (SPECIFY) _____				
Could you please specify your gender?	Male	Female			Dependent upon cell availability
How many years have you been smoking?					2 or more years
Do you regularly smoke cigarettes? By regularly, we mean daily or almost daily.	Yes	No			Yes
On a typical day, how many cigarettes do you smoke?	_ cigarettes	White: min ≥ 4 max ≤ 44 Black: min ≥ 1 max ≤ 34 Hispanic: min ≥ 1 max ≤ 30			Based on ethnicity
What brand of cigarettes do you currently smoke?	Brand: _____				Dependent upon cell availability
Is your current brand a “light”, “ultralight”, “full-flavored non-menthol”, or a “full-flavored menthol cigarette”?	LIGHT ULTRALIGHT FULL-FLAVORED MENTHOL FULL-FAVORED NON-MENTHOL				Dependent upon cell availability
How long have you been smoking your current brand?	≥ 3 months	< 3 months			≥ 3 months
Have you switched from a “full-flavored” brand to a “light” or “ultralight” brand in the past 9 months?	Yes	No			No
Do you use other tobacco products, such as chewing tobacco or nicotine gum?	Yes	No			No
Could you come to the lab 2 days in a row, in the morning the 1st day and the afternoon the 2nd day, and stay for about 1 hr each	Yes	No			Yes

time?					
Have you had any problems with bronchitis in the last three months?	Yes	No			No
Have you had any problems with pneumonia in the last three months?	Yes	No			No
Have you had any heart or lung problems in the last three months?	Yes	No			No
Have you ever been told by a healthcare professional that you have/had asthma?	Yes	No			No
Have you ever been told by a healthcare professional that you have/had emphysema?	Yes	No			No
Have you ever been told by a healthcare professional that you have/had other lung problems?	Yes	No			No
Have you ever been medically diagnosed with cancer?	Yes	No			No
Have you ever had a medically-diagnosed pre-cancerous lesion?	Yes	No			No
WOMEN: Are you pregnant, breastfeeding or trying to become pregnant?	Yes	No			No

If the response inputted into the tracking system makes the caller INELIGIBLE, a pop-up window will appear with the following message:

The entry just made will make the respondent ineligible. Should this respondent be considered ineligible? Select 'Yes' to continue processing the respondent as ineligible or 'No' to enter the correct choice for the question.

This pop-up window will enable staff to correct their entries should a mistake be made. If the entry is correct and the participant is ineligible, a pop-up window with the following message will appear:

Those are all the questions I have. Based on your responses, you are not eligible for our study. Thank you for your time.

Staff members will be instructed to not reveal the reason for ineligibility:

Based to the answers you gave, you are not eligible for this study. However, we will have studies in the future for which you may be eligible. Please call back in a couple of months

to see if you're eligible for a different study. With your verbal permission, we can record your name and number and call you for future studies.

If the caller is interested in leaving their name and number, this information will be recorded in the database for future studies along with the staff member's name who received the verbal permission for contact.

The tracking system is not designed to automatically assess eligibility based on data cells but will generate reports showing the number of participants in each cell. These reports will be used by staff to determine whether or not the study has available space for callers based on their gender, race and cigarette brand. If participants are eligible in all aspects, except that their cell is full (ELIGIBLE), staff members will inform the caller that they cannot be enrolled in the study. Staff members will then ask permission to record the caller's name and phone number in the database along with a message noting that verbal permission has been obtained to contact the caller should a space become available for this study, or should future studies for which they may be interested in become available.

If callers are ELIGIBLE and their cell is open, the following script will be read:

Those are all the questions I have. The answers you just gave indicate that you are eligible for the study.

Let me now tell you a little more about the study and, if you are interested afterwards, I will schedule you to come to the lab.

The purpose of this research study is to study how people smoke cigarettes and to compare people who smoke one type of cigarette to others who smoke another type of cigarette. Participation is voluntary. You do not have to answer any questions that make you feel uncomfortable. You can stop participating or answering questions at any time without penalty.

If you take part in the study, you will come to the laboratory clinic 2 times, with each visit about 30 hours apart. This means that you will come to your first visit in the morning and your second visit will be the next day in the afternoon. You will need to make sure that you arrive for each appointment really "wanting" a cigarette and be sure to bring some of your own cigarettes with you. We also ask that you bring at least 4 cigarette butts of your own brand that you have smoked at home to your first appointment. We will send you baggies in which to collect these butts. Bring these baggies with you for your first visit.

At the first visit, we will ask you questions to confirm your eligibility for the study; you will blow into a machine for a breath carbon monoxide test; and you will give saliva and urine samples. You will then have some glow-in-the-dark lipstick applied to your lips, and some vitamin solution painted on your fingers. The lipstick and vitamin solution will be used to find out what parts of the cigarette you usually cover with your lips and your

fingers. Afterwards, you will wash the glow-in-the-dark lipstick off your lips and wash the vitamin solution off your fingers using a mild soap. Next, you will put on a special vest. Three stick-on patches will be attached to your skin to record your heart beat and measure your breathing. After this, you will take in a deep breath, hold it for 15-20 seconds and then blow into a machine that measures the amount of carbon monoxide in your breath. Next, you will smoke one of your own cigarettes using a special cigarette holder. After you smoke the cigarette, you will blow into the machine again to see how much carbon monoxide you have in your breath.

Your smoking will be recorded on video tape. The video tapes will be labeled only with a number to safeguard your privacy. They will be stored in a locked cabinet, and only CDC and Battelle scientists involved in the study will be able to look at them.

Finally, we will show you how to collect your smoked cigarette butts for 2 days using the special containers that we will give you. You will place one butt in each small container and write down the time that you smoked it. We will also give you a pack of your own brand to smoke so that there is no chance you will run out overnight. It will be very important that you smoke only your regular brand of cigarette.

At the second visit, you will bring all the butts you collected since your first morning visit. Again, you will provide a urine and saliva specimen, and carbon monoxide in your breath will be recorded. The glow-in-the-dark lipstick and vitamin solution will be reapplied to your lips and fingers. Like at the first visit, you will smoke one of your own cigarettes through the special holder hooked up to a computer. After smoking that cigarette, you will have your breath checked for carbon monoxide. You will wear the special vest again during smoking, and your smoking will be recorded on video tape.

The total time of your participation in the study will be during a 2-day period for about 1 hour each day as well as the time it takes you to save your cigarette butts.

For your time and effort you will receive a payment after both visits and can earn \$80 if you complete the whole study. When we say completing the study, in addition to the procedures we just described, we also mean smoking only your regular brand of cigarette and collecting all of your butts between visits.

[IF CALLER IS FEMALE] Also, a few small drops of your urine will be used for a pregnancy test. If the test is positive, you will not be eligible to continue in the study, but you will be compensated for coming to the first appointment.

Are you still interested? Ok then, I would like to schedule an appointment for you to come to our laboratory clinic.

If the caller is still interested, an appointment will be scheduled and directions to the lab and instructions about the first visit will be mailed to the participant.