

Attachment D
Informed Consent Form

Approved

Form

OMB NO. _____

Exp. Date _____

Informed Consent Form

HUMAN SMOKING BEHAVIOR STUDY INFORMED CONSENT FORM

Prospective Research Subject: Read this consent form carefully and ask as many questions as you like before you decide whether you want to participate in this research study. You are free to ask questions at any time before, during, or after your participation in this research.

Project Information

Project Title: Human Smoking Behavior	Project Number: XXX
Site IRB Number: IRB00000284	Sponsor: National Center for Chronic Disease Prevention and Health Promotion and National Center for Environmental Health, Centers for Disease Control and Prevention
Battelle Project Lead Deon M. Harvey, PhD	Organization: Battelle Centers for Public Health Research and Evaluation
Location: Baltimore, MD	Phone: 410-823-8226

1. PURPOSE OF THIS RESEARCH STUDY

You are being asked to participate in a research study to look at how people smoke different brands of cigarette. You qualify for this study because you are an established smoker who smokes the brand of cigarettes we want to research. This study will look at the way you smoke your brand of cigarette. This study will also look at nicotine and cancer-causing chemicals from cigarette smoke that appear in your urine, and saliva, and carbon monoxide in your breath.

Everyone in the study will smoke their own brand of cigarettes. Everyone will also come to two laboratory clinic visits in a row. If you are a woman and there is any chance that you may be pregnant, you cannot be in this study. Approximately 360 people will participate in the study. The study is sponsored by the U.S. 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.

2. PROCEDURES

If you participate in this study, you will visit the laboratory clinic two days in a row. The first time will be in the morning. The second time will be in the afternoon. At each visit, you should come to the laboratory clinic feeling like you “really want” a cigarette.

First Visit. At the first visit, you will be asked questions to make sure you are still eligible for the study. If you are still eligible, you will provide a urine sample. The sample will be sent to a laboratory at the CDC to find out what chemicals from cigarette smoke are in your urine. You will also be given a small piece of cotton to place in your mouth until it is soaked with your saliva. You will put this cotton into a special container. You will be given another piece of cotton for another saliva specimen. The two saliva specimens will also be sent to the CDC to determine the levels of chemicals from cigarette smoke you have in your saliva.

You will 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. You will then wash the glow-in-the-dark lipstick off your lips and wash the vitamin solution off of your fingers using a mild soap.

You will put on a special vest. Three stick-on patches will be attached to your skin to pick up your heart beat and send a record of it to the vest. The vest also contains special bands to measure your breathing while you are smoking. Information from the vest will be recorded by a computer.

Next, you will take in a deep breath. You will hold it for 15-20 seconds and then blow into a machine. This machine measures the amount of carbon monoxide in your breath. After, you will smoke one of your own cigarettes using a special cigarette holder. When we spoke to you on the phone, we asked you to bring 4 cigarette butts of your current brand that you smoked at home. Like the lipstick and vitamin painting, these butts will help determine how you hold your cigarette when you smoke. Depending on the way you hold your cigarette, we may put a small piece of tape on it before you smoke. We will then put the cigarette in the special holder. You will smoke one cigarette through the special holder. The cigarette holder will be hooked up to a computer that measures how you smoke your cigarettes. 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 protect your privacy. They will be stored in a locked cabinet, and only 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.

You will come back to the laboratory clinic the next day in the afternoon. You will bring all the butts that you collected with you.

[FOR WOMEN ONLY] We will use a few small drops of your urine sample to test for pregnancy. The test we perform is a standard test like the ones that you buy at a pharmacy. If you receive a positive pregnancy test, we will instruct you to go to your health care provider for another test and healthcare advice. This test needs confirmation to be read accurately. For this study, however, you would no longer be eligible to participate. We will compensate you as if you were completing the first visit, provide you with brief counseling and information on the risks of smoking while pregnant, and assist with a referral if you need one.

Second Afternoon Visit. You will return to the laboratory clinic and will bring all the butts you collected since your first morning visit. Again, you will provide a urine specimen to be sent to the CDC. You will be given a small piece of cotton to place in your mouth until it is soaked with your saliva. After you put the cotton into a special container, you will be given another piece of cotton for another saliva specimen.

You will blow into the machine to determine the amount of carbon monoxide in your breath. You will again have some glow-in-the-dark lipstick applied to your lips, and some vitamin solution painted on your fingers. You will then wash the glow-in-the-dark lipstick off your lips and wash the vitamin solution off of your fingers using a mild soap.

If we taped your cigarette at the first visit, we will tape it again. 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. Your smoking will be recorded on video tape.

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

3. POSSIBLE RISKS OR DISCOMFORT

The risks of being in this study are the same risks that you take every day with regular smoking.

Keeping the laboratory clinic appointments on schedule will be very important. This may be inconvenient. We will do everything possible to work with your schedule.

Collecting all of your cigarette butts between visits may require you to change some habits. We will need you to collect each butt in the individual containers that we give you. You will also need to record the time that you smoked each cigarette. It will be important to not throw any butts away. It will also be important to not put butts out by dipping them in anything wet. If you think these changes will be too inconvenient, you should not participate in this study.

There is always a concern about safeguarding your privacy. To safeguard your privacy, we will give you a number that will be used to label all your information and samples, including the video tape of your smoking. Your personal information, such as your name and contact information, and the video tape of your smoking, will be kept in a locked file.

We will tell you about any new information discovered during the study that may affect your willingness to continue in the study.

4. OWNERSHIP AND DOCUMENTATION OF YOUR URINE AND SALIVA SPECIMENS, AND YOUR COLLECTED CIGARETTE BUTTS

The urine and saliva samples will be sent to CDC for testing. The cigarette butts will also be sent to CDC for testing. The samples will be the property of CDC. The samples will be labeled only with your study ID number in order to protect your privacy. These samples will only be used for this study and will be destroyed after CDC analyzes them.

POSSIBLE BENEFITS

Participation in the study is not expected to benefit you directly. As you may know, smoking causes lung cancer, heart disease, emphysema and may complicate pregnancy. Quitting smoking now greatly reduces serious risks to your health.

We will give you your carbon monoxide levels immediately. The study results will be available when published by CDC. We will discuss how to quit smoking. We will provide you with this information if you are interested. If you want to quit smoking at any time during this study, we will give you information about how to quit. We can also give you a list of local organizations that provide services to help you quit.

However, the decision to use these services is yours. You do not need to consider quitting to be a participant in this study.

5. FINANCIAL CONSIDERATIONS

You will be paid for your time and effort. You will be paid \$30 for completing your first laboratory clinic session. This includes \$10 for a brief eligibility questionnaire, carbon monoxide measurements and smoking one of your own cigarettes using the special holder; \$10 for providing saliva and urine specimens; and \$10 for being on time for your scheduled appointment. You will be paid \$50 for completing your second laboratory clinic visit. This includes \$10 for carbon monoxide measurements and smoking one of your own cigarettes using the special holder; \$10 for submitting saliva and urine specimens; \$20 for collecting your cigarette butts; and \$10 for being on time for your scheduled appointment. The maximum payment for completing this study is \$80.

Activity	Total
Complete Visit 1	\$10
Visit 1 Eligibility Screener	
Smoking through the machine	
Carbon Monoxide Measurements	
Bringing in 4 smoked butts	
Urine and Saliva Specimens	\$10
Keeping Appointment on Time	\$10
TOTAL VISIT 1	\$30
Complete Visit 2	\$10
Smoking through the machine	
Carbon Monoxide Measurements	
Urine and Saliva Specimens	\$10
Butt Collection	\$20
Keeping Appointment on Time	\$10
TOTAL VISIT 2	\$50
TOTAL	\$80

We will also give you a pack of your regular cigarettes. We ask that you only smoke your regular cigarettes and save all your smoked butts in the special containers.

Other than the cost of your transportation to the laboratory clinic, no additional cost to you is expected. If you have difficulty with transportation to the laboratory clinic, we will provide you with a bus token.

6. AVAILABLE TREATMENT ALTERNATIVES

This is not a study that involves any treatments, so this section is not applicable to this study.

7. AVAILABLE MEDICAL TREATMENT FOR ADVERSE EXPERIENCES

This study involves minimal risk. Adverse experiences are not likely.

8. CONFIDENTIALITY

Your identity in this study will be treated in a confidential manner. CDC does not plan to share identifiable data unless compelled by law. The results of the study may be published for scientific purposes but will not give your name or include information that will identify you.

However, any records or data obtained as a result of your participation in this study may be inspected by the sponsor, or by the Battelle or CDC Institutional Review Board. (These are the groups that make sure human subjects are protected.)

All of your information and all of the samples that you provide will be identified only by a number. The file that links your name and contact information with the number will be kept in a locked file that will be accessible to a very limited number of study personnel.

9. TERMINATION OF RESEARCH STUDY

You are free to choose whether or not to be in this study. You can choose to discontinue the study at any time.

In addition, your participation in the study may be terminated by the investigator without your consent under the following circumstances:

- o You are unable or unwilling to follow the study protocol. This includes smoking only your regular cigarettes, collecting your cigarette butts, and keeping your laboratory clinic appointments.
- o The sponsor of the study decides to cancel before your participation is complete.

10. AVAILABLE SOURCES OF INFORMATION

- o Any further questions you have about this study will be answered by the Battelle Project Lead:
Name: Dr. Deon Harvey
Phone Number: 410-372-2742
- o Any further questions you have about this study may also be answered by the Laboratory Manager:
Name: Ms. Daniela Rennie
Phone Number: 410-823-8226 (1-866-264-0012)

o Any questions you may have about your rights as a research subject will be answered by:

Name: Margaret Pennybacker

Phone Number: 1-877-810-9530 x500

o In case of a research-related emergency, call: 911

Day Emergency Number: 410-823-8226 (1-866-264-0012)

Night Emergency Number: 911

11. AUTHORIZATION

I have read and understand this consent form. I volunteer to participate in this research study. I understand that I will receive a copy of this form. I voluntarily choose to participate. I understand that my consent does not take away any legal rights in the case of negligence or other legal fault of anyone who is involved in this study. I further understand that nothing in this consent form is intended to replace any applicable Federal, state, or local laws.

Participant Name: _____

Participant Signature: _____

Date: _____

Project Lead Signature: _____

Date: _____

Signature of Person Obtaining Consent: _____

Date: _____

FEMALE VOLUNTEERS ONLY

I understand the risks of smoking tobacco while pregnant. To the best of my knowledge, I (am / am not) currently pregnant. I understand that I will be given a pregnancy test at the beginning of the study. A positive result will disqualify me from participating, but I will receive payment for attending the first visit.

Participant Name: _____

Participant Signature: _____

Date: _____

Project Lead Signature: _____

Date: _____

Signature of Person Obtaining Consent: _____

Date: _____

