

UNIVERSITY OF SOUTH CAROLINA

CONSENT TO BE A RESEARCH SUBJECT

Evaluation of cigarette package inserts for enhanced communication with smokers

KEY INFORMATION ABOUT THIS RESEARCH STUDY:

You are invited to volunteer for a research study conducted by Dr. Jim Thrasher in the Department of Health Promotion, Education & Behavior, at the University of South Carolina. The University of South Carolina, Department of Health Promotion Education & Behavior and the National Institutes of Health are sponsoring this research study. The purpose of this study is to evaluate smokers' perceptions and behaviors using a smartphone over a two-week period. You are being asked to participate in this study because you are adult smoker who smokes at least 10 cigarettes per day. This study is being done at the University of South Carolina and Cornell University and will involve approximately 380 volunteers.

The purpose of this study is to understand what smokers think and how they behave over a two-week period. Participants will be given a smartphone and use it to indicate every cigarette they smoke. About 4 times a day, they will be asked to respond to a 2-3 minute survey after they smoke. Also, each evening, they will respond to a 1-2 minute survey. Aside from any inconvenience from these short surveys, we do not expect participation will result in any risks or discomforts from participation. The main benefit of the study will be to increase understanding of ways to help smokers quit.

This form explains what you will be asked to do, if you decide to participate in this study. Please read it carefully and feel free to ask questions before you make a decision about participating.

PROCEDURES:

If you agree to participate in this study, you will do the following:

1. A study orientation at USC lasting between 1 hour to 1 hour and 30 minutes.
Activities will include:
 - a. A non-invasive breath test where you breathe into a tube that measures the carbon monoxide in your breath to indicates the amount you smoke. This will help confirm your eligibility for the study.
 - b. A brief survey about your background, smoking behaviors, and opinions about smoking. This information will be kept confidential and will not include any personal information that would allow anyone from outside the research team to link the responses to you.
 - c. Orientation to the smartphone app, including how to use it to fill out cigarette logs and complete the brief questionnaires
 - d. Receive a 2 week supply of cigarettes, as determined by the amount you normally smoke.

2. Follow the study protocol for the 14 consecutive days after your orientation.
 - a. Smoke only the cigarettes provided to you, unless you run out of these cigarettes. A 2-week supply of cigarettes will be provided, with the quantity determined by the amount you normally smoke. Although we will remove the cellophane from the packs, we will not touch the cigarettes.
 - b. During each day of the study, use the smartphone application to indicate each time you smoke a cigarette.
 - c. Approximately 4 times a day, you will be prompted to take a 2-3 minute survey after you indicate you are smoking. You will NOT be asked to do this after every time you smoke a cigarette. These surveys will ask about your smoking session, including what is going on around you.
 - d. At the end of each day of the study, use the smartphone application to answer a brief 1-2 minute survey.
 - e. At the end of each day, you should fully charge the smartphone
3. When the 14 days are complete, you will return to USC's campus for a meeting with a member of the study team lasting between 1 hour to 1 hour and 30 minutes. During this meeting, you will return the smartphone, conduct a brief complete a follow-up survey, and receive a \$150 Visa gift card as a token of appreciation for your participation.

DURATION:

Participation in the study involves 2 visits to USC over a period of 2 weeks. Each study visit will last between 1 hour to 1 hour and 30 minutes.

RISKS/DISCOMFORTS:

We expect little to no risk for you from participating in this study. Our surveys will ask you a few details about your thoughts about smoking and about what is going on around you during smoking sessions. We will provide you with a 2 week supply of cigarettes, but prior research indicates that this is unlikely to cause you to smoke more than you would normally smoke. All data that we collect will be associated with a unique identification number that we give you when you start the study. All data you give us will be stored on a secured database or uploaded automatically to secured, cloud storage server. Researchers will download the data from the database and server for analysis. This downloaded data will be stored on password-protected computers and will not include any personal identifiers, such as your name.

BENEFITS:

Taking part in this study is not likely to benefit you personally. However, this research may help researchers understand strategies to promote smoking cessation.

COSTS:

There will be no costs to you for participating in this study other than possible costs related to transportation to and from the research site.

PAYMENT TO PARTICIPANTS:

You will be paid \$150 for participating in this research study, as well as a 2 week supply of your preferred brand of cigarettes. If you do not complete the study, you will not receive the \$150, but you can keep the 2-week supply of cigarettes.

CONFIDENTIALITY OF RECORDS:

Information that is obtained in connection with this study will remain confidential. Any information disclosed would be with your express written permission. Study information will be securely online databases, servers, and on password-protected computers.. Results of this research study may be published or presented at seminars; however, the report(s) or presentation(s) will not include your name or other identifying information about you.

VOLUNTARY PARTICIPATION:

Participation in this research study is voluntary. You are free not to participate, or to stop participating at any time, for any reason without negative consequences. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner. If you wish to withdraw from the study, please call or email the principal investigator listed on this form.

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study, or a study related injury, I am to contact Dr. Jim Thrasher at 803-777-4862 or email thrasher@sc.edu.

Questions about your rights as a research subject are to be directed to, Lisa Johnson, Assistant Director, Office of Research Compliance, University of South Carolina, 1600 Hampton Street, Suite 414D, Columbia, SC 29208, phone: (803) 777-6670 or email: LisaJ@mailbox.sc.edu.

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If you wish to participate, you should sign below.

Signature of Subject / Participant

Date

Signature of Qualified Person Obtaining Consent

Date

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PROCEDURES:

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Activities will include:
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 - b. A brief survey about your background, smoking behaviors, and opinions about smoking. This information will be kept confidential and will not include any personal information that would allow anyone from outside the research team to link the responses to you.
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DURATION:

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RISKS/DISCOMFORTS:

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BENEFITS:

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COSTS:

There will be no costs to you for participating in this study other than possible costs related to transportation to and from the research site.

PAYMENT TO PARTICIPANTS:

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VOLUNTARY PARTICIPATION:

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PROCEDURES:

If you agree to participate in this study, you will do the following:

1. A brief online survey and phone interview about your background, smoking behaviors, and opinions about smoking. This information will be kept confidential and will not include any personal information that would allow anyone from outside the research team to link the responses to you.
2. Receive study materials, including a 2-week supply of cigarettes and a smartphone that you will use throughout the study.
 - a. The supply of cigarettes will be determined by the amount you normally smoke.
 - b. You may pick up these materials from USC or have a team member delivers to your home.
 - c. If you choose to come to USC to pick up the materials, you will remain in your vehicle the entire time, and a staff member will drop bring the materials to you. If you do not have a vehicle, a staff member will leave the materials on a

- bench outside of our building and will watch from a safe distance as you retrieve the materials.
- d. If a team member delivers materials to your home, we will leave them in a place where you can pick it up and where we can see you pick it up from a safe distance.
3. A study orientation via video call lasting between 1 hour to 1 hour and 30 minutes.
 - a. This video call will include: Orientation to the smartphone app, including how to use it to fill out cigarette logs and complete the brief questionnaires.
 - b. This call will be held on the same day that you receive the study materials.
 4. Follow the study protocol for the 14 consecutive days after your orientation.
 - a. Smoke only the cigarettes provided to you, unless you run out of these cigarettes. A 2-week supply of cigarettes will be provided, with the quantity determined by the amount you normally smoke. Although we will remove the cellophane from the packs, we will not touch the cigarettes.
 - b. During each day of the study, use the smartphone application to indicate each time you smoke a cigarette.
 - c. Approximately 4 times a day, you will be prompted to take a 2-3 minute survey after you indicate you are smoking. You will NOT be asked to do this after every time you smoke a cigarette. These surveys will ask about your smoking session, including what is going on around you.
 - d. At the end of each day of the study, use the smartphone application to answer a brief 1-2 minute survey.
 - e. At the end of each day, you should fully charge the smartphone
 5. When the 14 days are complete, you will take a brief follow-up survey online. You will have another call with a member of the study team lasting between 1 hour to 1 hour and 30 minutes. After this meeting, you will drop off the smartphone with a member of the team at the USC campus and receive a \$150 Visa gift card as a token of appreciation for your participation.
 - a. As in the initial meeting, you can choose to drop off the materials outside of our building on USC's campus, or we will arrange to pick them up from your home and give you the gift card.

IT IS STRONGLY RECOMMENDED THAT YOU WEAR A MASK BOTH WHEN PICKING UP CIGARETTES AND WHEN DROPPING OFF THE SMARTPHONE AND RETRIEVING YOUR GIFT CARD.

DURATION:

Participation in the study lasts a period of 2 weeks. Each video call meeting at the beginning and end of the study will last between 1 hour to 1 hour and 30 minutes.

RISKS/DISCOMFORTS:

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with a unique identification number that we give you when you start the study. All data you give us will be stored on a secured database or uploaded automatically to secured, cloud storage server. Researchers will download the data from the database and server for analysis. This downloaded data will be stored on password-protected computers and will not include any personal identifiers, such as your name.

COVID-19:

Our team is taking the necessary precautions to keep both you and our team healthy. Any items handed to you, such as cigarette packs and the smartphone will only be handled by our staff while they are wearing gloves and a mask. All staff members will have been tested for COVID-19 before returning to work, and our supplies will be regularly sanitized.

BENEFITS:

Taking part in this study is not likely to benefit you personally. However, this research may help researchers understand strategies to promote smoking cessation.

COSTS:

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