RESEARCH CONSENT FORM

Basic Information

Title of Project: Online Tobacco Study

NCT05838378

IRB Number: H-43316

Sponsor: National Institutes of Health, National Cancer Institute

Principal Investigator: Jennifer Cornacchione Ross
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715 Albany St., Boston, MA, 02118

Study Phone Number: 617-358-1905

Overview

We are asking you to be in a research study. A research study is an organized way of collecting information about scientific questions. This form will tell you what you should expect if you agree to be in the study. There are programs in place to make sure that investigators fulfill their obligations listed in this form.

It is your decision whether or not to join the study. We are asking you to be in this study because you previously reported that you have smoked cigarillos. We are interested what you think about tobacco products and cigarillo flavors. We are doing the research to understand what people think about tobacco products. If you agree, you will complete a survey every week for 4 weeks. You will be in the study for 4 weeks if you decide to stay for the whole study. You will find more information about what will happen in this study later in this form.

There is minimal risk to you for completing the survey. You are not expected to personally benefit from this survey, but the results may help others in the future.

Purpose

The goal of the survey is to understand what young adults think about some tobacco products. After you complete the final survey, or at the end of your participation in the study, we will provide additional information about the purpose of our study.

What Will Happen in This Research Study

You will complete a survey every week for 4 weeks. The first survey will take about 15 minutes to complete. The surveys during weeks 2 and 3 will take about 8 minutes to complete. The week 4 survey will take about 15 minutes. You will receive a notification each week containing the link to the survey. We will ask you questions about you, your tobacco use, and you will participate in an image-sorting task of cigarillo packages that have different flavors. You will be one of approximately 900 subjects aged 21+ who will be asked to be in the study.

Risks and Discomforts
There is minimal risk to you completing this study.

There is a risk to the confidentiality of your survey responses. We take special efforts to protect your responses, but there is a small chance of a data breach. The ways we will protect your privacy and confidentiality are described in a separate section later in this form.

Potential Benefits
You will receive no direct benefit from being in this study. However, answering questions about your tobacco use might make you think about your tobacco use and stopping. The primary goal of this research is to collect information about the scientific questions asked in this study. Your being in this study may help the investigators learn more about what people think about tobacco products.

Costs
There are no costs to you for being in this research study.

Payment
After you complete the study, you will receive a payment from your panel provider within 1 week of the Week 4 survey closing. For this study, participants who complete all 4 weekly surveys will receive an $8 credit.

Confidentiality
We will not record your name or any information that shows your identity. You will not be signing this form. You will be assigned a randomly generated identification number for purposes of study management. The personal information you provide directly to your survey panel (such as your email address) will not be linked to study data. You will complete the survey on Qualtrics software, which will host your data. The data will not be shared with your panel provider or any person outside of the study team. All electronic data will be password protected. No reference to any individual participant will appear in reports, presentations, or publications that may arise from the study. Participant demographics (age, race, ethnicity, gender only) will be entered into a National Institutes of Health database, which only the study PI and NIH staff have access to; the data are used for reporting purposes to track study progress and will not be used in any way.

This study is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health. All studies funded by the National Institutes of Health that involve identifiable information are covered by a CoC**.** The CoC provides how we can share research information. Because we have a CoC, we cannot give out research information that may identify you to anyone that is not involved in the research. Even if someone tries to get your information in connection with a legal proceeding, we cannot give it to them. The CoC does not prevent you from sharing your own research information.

We will share research data where we have removed anything that we think would show your identity. There still may be a small chance that someone could figure out that the information is about you. Such sharing includes:

- Publishing results in a medical book or journal.
- Adding results to a Federal government database.

BMC and BU Medical Campus IRB
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- Using research data in future studies, done by us or by other scientists

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Subject's Rights

By consenting to be in this study you do not waive any of your legal rights. Consenting means that you have been given information about this study and that you agree to participate in the study.

If you do not agree to be in this study or if at any time you withdraw from this study you will not suffer any penalty or lose any benefits to which you are entitled. Your participation is completely up to you. You will only be paid for the study activities that you complete before withdrawing.

Questions

The investigator or a member of the research team will try to answer all of your questions. If you have questions or concerns at any time, contact the Principal Investigator, Jennifer Cornacchione Ross, at jjross@bu.edu.

You may also call 617-358-5372 or email medirb@bu.edu. You will be talking to someone at the Boston Medical Center and Boston University Medical Campus IRB. The IRB is a group that helps monitor research. You should call or email the IRB if you want to find out about your rights as a research subject. You should also call or email if you want to talk to someone who is not part of the study about your questions, concerns, or problems.

By agreeing to be in this research, you are indicating that you have read this form, that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study.

Selecting "Yes" below and clicking "Next" indicates that:
- you have read the above information
- you voluntarily agree to participate

Do you wish to participate in this research study?
☐ Yes
☐ No