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PARTICIPANTS**

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Approval date:

Approved consent version No.:

**JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH**

**ORAL CONSENT SCRIPT FOR STUDIES WITH ADULT PARTICIPANTS**

**Study Title: Assessing Physiological, Neural and Self-Reported Response to Tobacco Education Messages**

**Principal Investigator: Meghan Moran, PhD**

**IRB No.: IRB00011404**

**PI Version Date: 5/August 1, 2022**

Hello. I am [Data Collector Name] from Johns Hopkins Bloomberg School of Public and would like to talk to you about the Tobacco Messaging Study to understand how people respond to tobacco education messages. This study is sponsored by the US Food & Drug Administration. We want to know your thoughts about the messages, and also want to see how your body and brain react to the messages to learn more about how to create more effective messages about the harms of tobacco.

Paperwork Reduction Act Statement: According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is XXXX. The time required to complete this information collection 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. Send comments regarding this burden estimate or any other aspects of this collection of information, including suggestions for reducing burden to [PRASTAFF@fda.hhs.gov](mailto:PRASTAFF@fda.hhs.gov).

We ask you to join our work/research study because

- You are 18-24 years old and the questions you answered in the screener qualified you for the study

We asked you questions on a survey to find out if you were eligible for this study before scheduling this appointment. You do not have to join this study, it is your choice.

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If you say you want to participate, the study visit will take between 90 mins. I will ask you to take a survey that has 3 parts. Part one asks questions about your demographic characteristics, tobacco use behaviors, and the tobacco use behaviors of people you know; part two asks questions about tobacco education videos that we will show you – there will be four videos and we will ask you to answer questions about each one; part three asks question about your personality. Before you begin the survey, I will put monitors on your head to measure blood flow in your brain, apply three monitors to your fingers to measure sweat production and your heart rate, apply 4 monitors on your face to measure how the muscles there move, and put on glasses to measure where you are looking. I will first ask you to let me place this band [show fNIRS band] on your head. I will ask you to let me clean 3 spots on your face and 2 fingers with alcohol and cream. I will then place monitors, which are adhesive foam stickers, on your face and fingers [show monitors]. I may use tape to help hold the monitor wires in place and keep them out of your face. I will also place a plastic clip on your finger [show clip]. I will then ask you to put these glasses on [show eye-tracking glasses]. I will ask you to sit quietly while looking at the blank computer screen, or with your eyes closed, for three minutes. I will also ask you to complete two activities on the computer. You may then begin the survey. Once you have finished the survey, I will remove the equipment from you. This should take about 90 minutes.

All of the study procedures are non-invasive and commonly done. You may find that the band is uncomfortable. If this happens, we will try to adjust the band to a more comfortable position. You may feel uncomfortable having monitors or tape placed on your skin. It is unlikely, but there is a chance the alcohol and cream used to cleanse your skin or the monitors and tape may irritate your skin. If the monitors, clip or glasses are uncomfortable, let me know and I will adjust them. The monitors on your face and your fingers use tape to stay on. Taking this tape off may hurt about as much as taking off a band-aid. Most people do not say this is painful. You may find looking at tobacco messages and completing the questionnaire boring. You may find the period before viewing the ads to be boring. You may be uncomfortable answering questions about yourself, your tobacco use, or your sexual orientation. You do not have to answer all the questions in the survey and you may stop at any time. The information you provide us, and that we record about you through the band, monitors and the clip on your finger, and glasses will be stored electronically. There is a risk that someone outside the study will see your information. We will do our best to keep your information safe by not recording any identifiable information about you, such as your name. When we share your information with other researchers, we will ask them to use the same protections. They will also not receive any identifiable information about you.

Due to the COVID-19 pandemic, there is the risk of contracting COVID-19. We have asked you to wear a mask to help mitigate this risk, and we have set up the study space to facilitate physical distancing. Study personnel are also mitigating this risk by wearing masks and gloves, and disinfecting study equipment after each study visit. If after this study visit, you learn that you are COVID-19 positive, we ask that you immediately contact study staff by email at TobaccoMessageStudy@jhu.edu or by phone or text message at 410-635-0535.

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Your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

We will use the data we collect to answer our questions about how people respond to tobacco education messages. The information we collect may be used to help the development of future tobacco education messages. These messages may help people learn about tobacco. We will let the community know about the results of the study.

- You will receive a \$50 Visa gift card for your participation when you finish the study. You may incur costs associated with traveling to the study such as parking fees or public transportation fare. An additional \$25 gift card will be provided to account for these costs.

Do you have any questions? You may contact Meghan Moran at 410-614-6872 about your questions or problems with this work.

Call or contact the **Johns Hopkins Bloomberg School of Public Health IRB Office** if you have questions about your rights as a study participant. Contact the IRB if you feel you have not been treated fairly or if you have other concerns. The IRB contact information is:

Address: Johns Hopkins Bloomberg School of Public Health  
615 N. Wolfe Street, Suite E1100, Baltimore, MD 21205

Telephone: 410-955-3193 Toll Free: 1-888-262-3242

E-mail: [jhsph.irboffice@jhu.edu](mailto:jhsph.irboffice@jhu.edu)

Would you like to join the study?

[if yes] May I begin?

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