

JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH  
ASSENT FORM

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

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Hello. I am [Data Collector Name] from the Johns Hopkins Bloomberg School of Public Health and would like to talk to you about the Tobacco Messaging Study.

- **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 want to tell you about a research study we are doing in partnership with the U.S. Food and Drug Administration's Center for Tobacco Products. Research allows us to collect information from people to help us answer questions about health. We would like to find out more about how people respond to tobacco education messages to learn more about how to create more effective messages about the harms of tobacco.
- You are being asked to join the study because you are 13-17 years old and can offer opinions about cigarettes or e-cigarettes. As I mentioned, we are working to learn about how people respond to messages designed to educate about and prevent tobacco use among youth. We hope to include about 50 other adolescents like you in this study.
- You do not have to participate, it is your choice. No one will be mad at you if you decide not to join the study. You can ask me questions about what I'm saying at any time.
- If you agree to join this study, you will be asked:
  - To come to one study visit that takes about 90 minutes
  - Allow me to use rubbing alcohol and cleaning creams on 2 spots on your face
  - Allow me to use water to wipe off three of your fingers
  - Allow me to place monitors to your body to measure how it reacts while you watch the messages, including:

- Sticky foam monitors on 2 fingers [show EDA electrodes]
- A plastic clip on 1 finger [show PPG electrodes]
- Small plastic monitors on your face, using tape to keep them attached [show EMG electrodes]
- A band with monitors on your head [show fNIRS band]
- Special glasses on your face [show eye-tracker]
- Sit quietly while looking at the blank computer screen, or with your eyes closed, for three minutes.
- Complete two activities on the computer.
- Watch four video messages about tobacco use
- Complete a three-part survey: 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.
- Allow me to remove the monitors
- All of the study procedures are non-invasive and commonly done.
- You may find watching the video messages about tobacco and answer the survey questions boring. You may find the three minute waiting period before viewing the messages to be boring.
- You may feel uncomfortable having the monitors or tape placed on your skin and on your head. Putting the monitors on will not hurt. The monitors on the band may be uncomfortable. If the monitors on the band are uncomfortable, we can adjust them so that they are more comfortable. 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. It is unlikely, but the alcohol or cream we use to clean your skin may irritate your skin. If any of the monitors or glasses are uncomfortable, let me know and I will adjust them.
- Some of the questions we will ask may make you uncomfortable. We will ask about your tobacco use, your feelings about tobacco products, your feelings about the messages, and about your characteristics. You may skip any questions you want or take time thinking about your responses. You may stop at any time. We will keep your answers private and will not share them with your parent/guardian.
- 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.
- The information you provide us, and that we record about you through the monitors, will be stored on a computer. 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 information that will allow someone to identify 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.

- 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.
- This study will not help you, but we hope to learn things that will help the government to make messages about tobacco that keep young people from using tobacco and getting sick from it.
- You do not have to join this study. It is up to you. You can say okay now, and you can change your mind later. All you have to do is tell us. No one will be mad at you if you change your mind.
- You will receive a \$50 Visa gift card when you finish the study. If you are 13-15 years old, the adult who accompanies you will also receive a \$25 Visa gift card to reimburse for the cost of transportation to the study site. If you are 16-17 years old, you will receive the \$25 gift card.
- Do you have any questions?
- Would you like to join the study?