

JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH
ORAL PARENT PERMISSION SCRIPT

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

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IRB No.: IRB00011404

PI Version Date: 5/August 1, 2022

[Greeting]. I am [Data Collector Name] from [Johns Hopkins]. I am calling because your child [Name] indicated they were interested in participating in a study we are conducting in partnership with the U.S. Food and Drug Administration's Center For Tobacco Products. This study is about tobacco education messages, and we are recruiting youth age 13-17 to learn more about how to create more effective messages about the harms of tobacco. May I tell you a bit about the study? [If yes, continue...]

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- 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 are partnering with the U.S. Food and Drug Administration's (FDA) Center for Tobacco Products to conduct this study. We are asking you to permit your child to join our work/research study because your child might be eligible for our study. You do not have to give permission, it is your choice. There will be no penalty to you or your child if you decide not to permit your child to join.
- We will also ask your child if they wish to join the study. We must have your permission and your child's assent to enroll your child in the study.
- If your child also agrees, we will ask your child to attend a study visit at our office on Johns Hopkins East Baltimore campus. **If your child is between 13-15 years old, they will have to bring someone over the age of 18 with them to this study visit, otherwise they will not be allowed to participate in the study.** We will look at the ID of this person to verify they are over 18. If your child does not come to their study visit, we will contact you at the number you provide us. This study visit will take about 90 minutes. The study visit will take place at a time you choose when school is not in session, such as after school hours or weekends.
- During this study visit, we will ask your child to complete a three-part survey. Part one asks questions about your child's demographic characteristics, tobacco use behaviors, and the tobacco use behaviors

of people your child knows; part two asks questions about tobacco education videos that we will show your child – there will be four videos and we will ask your child to answer questions about each one; part three asks question about your child’s personality. We will also ask your child to complete two activities on the computer.

- We will also ask to place 3 monitors on their fingers, four monitors on their face, special glasses, and wear a headband with additional monitors. These monitors measure blood flow in the brain, how facial muscles move, sweat on the fingertips, heartbeat, and where your child is looking while they watch tobacco education and prevention messages.
- All of the study procedures are non-invasive and commonly done. Your child may feel uncomfortable having the monitors or tape placed on their skin and head. Putting the monitors on will not hurt. The monitors on the band may be uncomfortable. If the monitors or band are uncomfortable, we can adjust them so your child is more comfortable. The monitors on your child’s face and 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 child’s skin may irritate their skin. If any of the monitors or glasses are uncomfortable, your child can let us know and we will adjust them. Some of the questions we ask your child may make them uncomfortable. We will ask about their tobacco use, their feelings about tobacco products, their feelings about the messages, and their characteristics. Your child can skip any questions they want or take time thinking about their responses. We will keep their answers private. Your child may also find participating in the study boring.
- Due to the COVID-19 pandemic, there is the risk of contracting COVID-19. We will ask you and your child to wear a mask to help mitigate this risk. We will provide a mask if you or your child do not have one, or for you to place over a personal mask. Masks should only be removed to complete study procedures. Study staff will instruct your child on when he or she is permitted to remove their mask. We will contact you the day before the study visit to complete a symptom check. We will also complete a symptom check and temperature check when you arrive for the study visit. If your child or the person accompanying them to the study visit exhibit any symptoms or have a temperature over 100.3, we will reschedule the study visit.
- 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 your child provides us, and that we record about your child through the monitors, will be stored on a computer. There is a risk that someone outside the study will see this information. We will do our best to keep your child’s information safe by not recording any information that will allow someone to identify your child, such as their name. When we share your child’s information with other researchers, we will ask them to use the same protections. They will also not receive any identifiable information about you or your child.
- We will not share any of your child’s data with you. During your child’s study visit, we will ask you (or the adult accompanying your child) to wait in a waiting area in the study room.

- Your child will be compensated with a \$50 gift card upon completion of their study visit.
- To participate in this study, your child, or the adult accompanying children aged 13-15, 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 reimburse for these costs.
- Your child's study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your child's 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 child's information if we learn of possible harm to your child or others, or if your child needs medical help.
- Disclosures that you make yourself about your child's study information are not protected.
- Your child will not benefit directly from participating, 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.
- Do you have any questions? [Probe to assess the participant's understanding.]
- Will you allow your child to join the study?
 - [If yes] [Schedule study visit]
 - What would be the best way to contact you about your child's study visit? [Obtain parent's contact information]. Thank you. We will contact you to remind you about their study visit. We will also contact you if your child does not attend their study visit.
- You may contact Dr. Meghan Moran at 443-937-3260 or mmoran22@jhu.edu 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 child's rights as a study participant. Contact the IRB if you feel you or your child have not been treated fairly or if you have other concerns. The IRB contact information is:
Telephone: <<410-955-3193>> Toll Free: <<1-888-262-3242>>
E-mail: <<jhsph.irboffice@jhu.edu>>
- Would you like me to send you a copy of the information we just discussed?
 - [If yes] What would be the best way for me to send you the information? [Obtain contact information to send copy of this document (Parental Permission)]