

Cover page for Parental Consent Form

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Grant number: R01DA047356

Grant Title: Impact of Nicotine Reduction on Adolescent Cigarette Use, Alternative Tobacco Use, and
Harm From Tobacco

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BROWN UNIVERSITY
PARENTAL CONSENT FOR RESEARCH PARTICIPATION

Impact of nicotine reduction on adolescent cigarette use, alternative tobacco use, and harm from tobacco

Version 10, 9.28.20

KEY INFORMATION:

Your child is invited to take part in a Brown University research study. Participation is voluntary.

- PURPOSE: To look at the effect of different levels of nicotine in cigarettes on teen smoking behavior.
- PROCEDURES: We will ask your child to come to our lab a total of 4 times (including today) to complete two virtual check-ins via Zoom and complete several questionnaires each day on their smartphone for 5 weeks. Your child will also be asked to switch from using their usual brand cigarette to using a study cigarette that we will provide to them. They will be asked for a breath sample, urine sample, and pregnancy test, if able to get pregnant. Your child will also be asked to complete a questionnaire about their experiences related to COVID-19.
- TIME INVOLVED: Your child will be in this study for 5 weeks and completing the surveys will take up to 10-15 minutes per day. Lab visits will take between 45 minutes and 2 hours. Virtual check-ins will take up to 40 minutes.
- COMPENSATION: Your child will receive up to \$523 for their time and effort, depending on how many surveys they respond to, cigarettes they return, and lab/virtual visits they complete.
- RISKS: Some of the questions may be about drug use or mental health, but your child is free not to answer any questions they do not wish to answer. Your child may also experience nicotine withdrawal, but the study does not restrict their use of other nicotine-containing products that aren't cigarettes. If able to get pregnant and become pregnant during the study, your child may experience emotional distress and may be in need of a medical professional.
- BENEFITS: There are no direct benefits to your child from participating in this research study.

1. Researchers:

Questions about the study should be directed to Dr. Rachel Cassidy at 401-863-6621 or Dr. Suzanne Colby at 401-863-6655. Questions about the rights of a research participant should be directed to the Human Research Protections Program at 401-863-3050.

2. What is this study about?

This study is investigating the effects of different levels of nicotine in cigarettes on teen tobacco use, health, attitudes, mood and other outcomes. **This study is not going to ask your child to quit smoking, or help your child quit smoking.** Your child is being invited to take part in this research study because he or she is a teen smoker.

3. What will my child be asked to do?

If you agree to your child's participation, your child will be asked to attend a total of six individual sessions. The first session has two parts: screening and (if your child is eligible based on the screening), the Baseline 1 [BL1] assessment will be completed on the same day. Your child will be



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asked to attend five more sessions. There will be seven days in between each session. We call these sessions: Baseline 2 (BL2, a lab visit), Week 1 (W1, a virtual check-in session), Week 2 (W2, a lab visit), Week 3 (W3, a virtual check-in session), and Week 4 (W4, a lab visit). This study can be completed in five weeks. Lab sessions will occur in our research lab. Virtual check-in sessions will be conducted remotely via Zoom.



On each day of the study, starting tomorrow, your child will receive notifications throughout the day from the app [PiLR Health] that will ask him or her to conduct a short survey in the app. The surveys will ask your child about the cigarettes he or she smoked, any other tobacco products that he or she used, and questions about how your child is feeling and what he or she is doing. Your child will also be asked to complete surveys in the app several times each day. We will show your child how to download the app onto his or her phone and how to complete the surveys in the app if he or she is eligible. If your child does not have a phone, we can lend him or her a phone to use during the study. Your child will do several types of surveys on their phone during the first two weeks and the last week of the study. During weeks 3 and 4, your child will only need to complete one survey on their phone per day.

If you consent to your child's participation, they will be scheduled for an in-person screening session. At that session, after we have explained the study to your child we will then take a breath sample that shows how much they've been smoking recently. We will also ask your child some questions, and he or she will complete some questionnaires, including about his or her history of smoking. Your child may also be asked to provide a urine sample so we can check to see how much nicotine is in his or her system.

If able to become pregnant: Smoking during pregnancy can lead to miscarriage, preterm delivery, stillbirth, birth defects, and other problems. To avoid these risks, it is important that your child not be pregnant during this study. For that reason, your child will be tested for pregnancy at this and every in-person lab visit. If your child tests positive for pregnancy, we will provide your child with a referral to a doctor and/or encourage your child to seek medical attention from your current primary care physician, if applicable. Your child will also be provided with local pregnancy resources. Your child will not be able to be in the study if they are pregnant, and if they becomes pregnant during the study, they will have to withdraw from the study. If your child is ineligible due to pregnancy at the screening visit, they will still be paid \$25.



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Your child will be asked to switch from his or her usual cigarettes to research cigarettes for four weeks. During each of his or her next two in-person study visits, your child will receive research cigarettes for the following two weeks. Your child will be asked to smoke only those cigarettes and none of his or her usual brand or any other brand of cigarettes. However, your child may choose to use other tobacco products during this time, such as e-cigarettes and little cigars.

We will ask your child to keep track of all research cigarettes and to bring back any empty packs, unopened packs, and unsmoked cigarettes to the lab. Your child must not share research cigarettes with anyone else. They are only for your child. Your child will receive a payment for bringing in his or her unsmoked cigarettes and/or unopened packs of up to \$5 per week, for a total possible amount of \$20.

Your child will be randomly assigned to one of two study conditions. Random assignment is a procedure similar to flipping a coin. Your child has an equal chance of being in one condition or the other. If your child is assigned to one condition, he or she will be trying cigarettes that contain a different amount of nicotine than what is found in most brands. If your child is assigned to the other condition, he or she will be trying cigarettes that have levels of nicotine that are similar to cigarettes available in stores. Your child will not be told the nicotine content of his or her study cigarettes until after the study has been completed.

During lab sessions, your child will be asked to complete questionnaires on the computer about any recent health changes, recent use of tobacco products, alcohol and marijuana, and about how he or she is feeling. At the BL2 and W2 sessions, we will also ask your child to smoke one research cigarette in the lab, and to complete questionnaires about how he or she feels before and after smoking. Your child will also be asked to give a breath sample before and after smoking, to measure how much smoke he or she is exposed to from the cigarette. We will also ask your child to rate the cigarette after smoking it (e.g., how much he or she likes the taste, etc.) and to complete some questionnaires that measure your child's preference for the research cigarette compared to other tobacco products. These lab sessions will take about an hour and a half to two hours to complete.

At the BL2 and W4 sessions, your child will also be asked to give a urine sample, which we will have tested to tell us how much nicotine and other toxicants related to tobacco use he or she has in his or her system. During these two sessions, your child will also be asked to blow into a device that measures lung function.

At virtual check-in sessions (W1 and W3), we will ask about recent changes in your child's health, and ask your child about recent use of tobacco products, alcohol, and marijuana.

During session W4, the final session, we will collect any remaining research cigarettes from your child. He or she will answer some final questions anonymously on his or her experience in the study, and we will schedule a phone call for 30 days from then so we can check in on your child and his or her recent smoking. If your child feels comfortable, we will also ask to participate in an open-ended audio interview regarding the COVID-19 pandemic where you can share how this pandemic has affected your child. This audio interview is optional and will be recorded on a device that is stored in a locked drawer that only research personnel has access to. The audio file will be transferred from the device and onto a secure sever that only the research staff has access to and deleted from the device. There will be no personal identifying information obtained in this



interview (i.e., you will be referred to as your participant ID number and not your first or last name).

It is very important for your child to attend his or her appointments for this study. Throughout the study, if your child reschedules his or her sessions more than 3 times for any reason, he or she may be withdrawn from the study.

The study can be completed in five weeks. The daily surveys will take about 90 seconds per survey to complete each day. Each in-person lab session will vary in length but will not take more than two hours.

4. Will my child be paid?

Your child will be paid for completing each of the sessions as follows: \$25 for Screening/BL1; \$50 for BL2; \$15 each for W1 and W3, \$50 each for W2 and W4. Your child will be paid up to \$5.00 for every day that he or she interacts with the phone app, during weeks 1,2 and 5; and up to \$2 for completing one phone survey per day during weeks 3 and 4. Your child will also be eligible to earn up to \$40 in random bonuses if they interact with the app, for a maximum total of \$173. A bonus payment of \$50 will be paid if your child completes 80% or more of the surveys on the phone app. A completion bonus of \$75 will be given if your child attends all 4 lab sessions. A maximum of \$20 possible compensation is available for returned cigarettes and packs (up to \$5 per week). The total amount that your child can earn for participating in the study, if he or she completes all sessions and app surveys, is \$523.

Payments for each of the sessions will be made at the end of each session. Bonuses will be paid at the end of the study. All study payments will be made on a ClinCard. This pre-paid card works like a bank debit card. Your child will receive further information about how to use this card. If you or your child decide to withdraw from the study before your child completes it, we will add the money to your child's ClinCard for the number of sessions and daily app surveys that he or she completed before stopping. If your child decides to quit smoking during the study, he or she may still be paid for any remaining study procedures that he or she completes.

We will pay for your child's transportation expenses to in-person lab sessions as follows: If your child drives to the study, parking in the garage at our research building will be paid for by the study. If your child prefers to take a bus, bus tickets will be provided at each visit. We can also pay if your child takes Uber to appointments if he or she sends us the receipt from his or her phone. If none of these options works for your child, we can arrange for a taxi bring him or her to the study and back; when your child schedules his or her appointment, the study staff will also schedule a taxi.

Completion of the surveys using the app will incur normal data and texting rates from the phone service provider that the study does not specifically compensate for.

5. What are the risks?

Discomfort from nicotine withdrawal: Your child may experience nicotine withdrawal symptoms during this study. Symptoms can include irritability, frustration, anxiety, sadness, craving to smoke, difficulty concentrating, muscle pain, fatigue or difficulty sleeping, and increased hunger. These feelings can be uncomfortable, but they are normal, temporary, and are usually mild.



Discomfort from interview procedures: We will ask your child questions about whether he or she is experiencing psychological symptoms and about your child's background and smoking/drug use history. Answering these questions could cause your child some minor discomfort. However, the questions we ask are commonly used in research and clinical practice and your child will not be required to answer any question he or she is not comfortable answering. All answers to these questions will be kept confidential.

Risks related to smoking cigarettes: All cigarettes are bad for a person's health and can lead to heart disease, lung diseases, cancer, and death. However, exposure to smoke and nicotine in this project is not significantly more than what your child is exposed to on a daily basis. Your child does not have to smoke more than he or she normally would. The study cigarettes do not provide any less risk than your child's usual brand cigarette. Only those teenagers who smoke cigarettes daily, and have smoked this much for 6 months or longer, will be allowed to participate. Because some of the cigarettes in the study may have less nicotine in them, your child may use other nicotine-containing products in response. The type of product your child chooses to use may result in increased risk, while others may reduce risk relative to cigarette use. Nicotine is an addictive chemical. All products containing nicotine can become addictive and lead to longer-term use in the future. Symptoms of too much nicotine include headache, dizziness, shakiness, nausea, vomiting or diarrhea, weakness, and fast heartbeat.

Potential Discomfort Related to Electronic Cigarette Use: The FDA has not regulated electronic cigarettes to date and electronic cigarettes have not been fully studied. We currently don't know all risks of electronic cigarettes when used as intended, how much potentially harmful chemicals are being inhaled during use, or whether there are any benefits associated with using these products. The studies to date indicate that electronic cigarettes are likely less harmful than regular cigarettes. The most common discomfort from electronic cigarettes is that some people find the vapor irritating. The most frequently reported discomforts are mouth irritation, throat irritation, and dry cough. Other possible effects may include: nausea, sore throat, or headache. No serious health effects have been clearly due to electronic cigarettes in any study. When used as intended, serious risks related to electronic cigarettes are rare but it is important to use the electronic cigarette and e-liquid provided by the study as intended and to not alter the device or e-liquid. It is important to follow all the study instructions regarding the electronic cigarette and e-liquid, since there have been cases of serious injury, including burns and explosions. The FDA has become aware that some people have experienced seizures, with most reports involving teens or young adult users. Seizure activity is a known potential side effect of nicotine toxicity. There are no known interactions of electronic cigarettes with any medications.

What are the benefits?

There are no immediate benefits from participating in the study. Your child will have the chance to learn more about the effects of smoking. Also, your child will help us learn more about how nicotine in cigarettes affects teen smoking.

6. How will my child's information be protected?

Participation in this study and information gathered from the study will be kept confidential to the extent allowable by law. All information that your child gives us will be identified only by a code number, not your child's name. Your child's answers and test results are confidential and will not be shared with you, or anyone else who is not involved in conducting, overseeing, or monitoring the



research. There are two exceptions to this. The first is if your child reports any plans to hurt himself or herself, or anyone else. The second is if your child reports any physical or sexual abuse of him/herself, other minors, or elderly people. If your child reports these things, then we are ordered by law to report them to the proper agency, to help keep your child and other people safe. Also, if your child reports plans to harm himself or herself, we will share that information with our medical provider, who will talk with your child about it, to help keep him or her safe.

Participation in this study may require a sign-in or download for using Zoom and will require that your child has internet access or access to WiFi. Your child should schedule their interviews with appropriate times to ensure privacy.

In addition to the investigators listed on the first page of this consent form and their research staff, organizations that oversee this research may ask to review information we collect that may identify you. These organizations include the Brown University Research Protections Program and the National Institute on Drug Abuse. The findings of the study may be published but individual participants will not be identified.

Additionally, authorized representatives from any governmental agency that regulates the study may also have access to your child's identifiable information. Agencies include the Food and Drug Administration (FDA), the U.S. Department of Health and Human Services (DHHS) and Office for Human Research Protections (OHRP).

A description of this trial will be available on <http://www.ClinicalTrials.gov> as required by U.S. Law. This website will not include information that can identify your child. At most, the website will include a summary of the results. You and your child can search this Website at any time.

Certificate of Confidentiality

To help us protect your child's privacy, we have received a Certificate of Confidentiality from the National Institutes of Health. We can use this certificate to legally refuse to provide information about your child, even if there is a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings.

The Certificate cannot be used to refuse to provide information to the U.S. Government or the Federal Food and Drug Administration (FDA). The U.S. Government or the FDA can require us to provide information so that they can audit or evaluate this federally funded research project. You and your child should understand that a Certificate of Confidentiality does not prevent you or your child from voluntarily releasing information about your child's involvement in the research. If an insurer, employer or other person obtains your written consent to receive research information, then we may not use the Certificate to withhold that information. The Certificate of Confidentiality will not be used to prevent us from contacting state or local authorities if your child reports child or elder abuse, or plans to hurt himself/herself or others.

The medical monitors of this study may decide to withdraw you from the study if they feel it is necessary to protect your health.

7. What if my child wants to stop participating?

Your child does not have to be in this study if you do not want them to be, or if he or she does not want to. Even if you decide to consent to let your child be in this study and he or she assents to



participate, you can change your mind and withdraw them, or they can stop participating at any time. We will keep the data and specimens we collected from your child prior to your withdrawal.

If you do not consent to your child's participation or if your child leaves the study, your child's current or future relationship with Brown University will not be affected.

8. Who can I talk to if I have questions about this study?

Please ask any questions you have now. You can email us at ProjectSiren@brown.edu with any general study questions, or call Jasmine at 401-863-6645 [jasminette_dilorenzo@brown.edu].

Any further questions about the study should be directed to Dr. Rachel Cassidy at 401-863-6621 (Rachel_cassidy@brown.edu) or Dr. Suzanne Colby at 401-863-6655 (Suzanne_Colby@brown.edu).

9. Who can I talk to if I have questions about my child's rights as a participant?

If you have questions about your child's rights as a research participant, you can contact Brown University's Human Research Protection Program at 401-863-3050 or email them at IRB@Brown.edu.

10. Consent to Participate

Your signature below shows that you have read and understood the information in this document, and you agree that your child can volunteer as a research participant for this study. You will be offered a copy of this form.

Parent's Signature and Date /

PRINTED NAME

Research Staff Signature and Date /

PRINTED NAME