Name _____

Date_____

Effects of Nicotine Content in Cigarettes and
E-Cigarette Characteristics on Smoking in Adolescents

Brown University
CONSENT FORM

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SOURCE OF SUPPORT: National Institute on Drug Abuse

KEY INFORMATION:

You are invited to take part in a Brown University research study. Your participation is voluntary.

- PURPOSE: The study is about the effects of different nicotine levels in cigarettes, different nicotine levels in vaping devices, and different flavors in vaping devices in adolescents between the ages of 15 to 20. This research may help the Food and Drug Administration (FDA) figure out how to regulate tobacco products in the future to improve public health.
- PROCEDURES: You will be asked to answer questions about your health, smoking, and mood. You will also try the study cigarettes and vaping device and answer questions about them. In each of the study sessions you will make a series of 10 choices. Choices will be for either 2 puffs of the research cigarette, 2 puffs of the vaping device, or no puffs at all.
- TIME INVOLVED: The study will take about 12 hours of your time over 6 sessions. Sessions will be from 2 to 7 days apart. It will take about 2 to 4 weeks to complete it.
- COMPENSATION: You will receive $570 for your time if you complete all 6 visits.
- RISKS: Answering personal questions could make you feel uncomfortable; the blood pressure cuff might be a little uncomfortable; all cigarette smoking is harmful; vaping devices contain harmful chemicals; nicotine is an addictive chemical; you may feel discomfort from not smoking on the days of your lab visits.
- BENEFITS: There are no immediate benefits from participating in the study.

1. THE PROJECT

Why is this research being done?

You are invited to participate in a Brown University research study about teenagers' use of cigarettes and electronic cigarettes (also called e-cigarettes or vaping devices). We are studying how different types of cigarettes and vaping devices affect teenagers' responses to these products. This study will examine the effects of:

- Different nicotine levels in cigarettes,
- Different nicotine levels in vaping devices, and
- Different flavors in vaping devices

This research may help the Food and Drug Administration (FDA) figure out how to regulate tobacco products in the future, to improve public health. This is not a treatment program for smoking. If you would like to quit smoking, we can provide you with information about where to get help quitting smoking.

Tobacco use causes many diseases and can also cause death. One way to reduce harm from cigarettes is to lower the amount of nicotine in them. This could make cigarettes less addictive. And it could help people cut down on their smoking. It could even help people quit smoking completely.

Another thing that might lower how much people smoke is if vaping devices are available as an alternative to smoking. Vaping devices can have different flavors and different amounts of nicotine in them. The flavors and nicotine content in vaping devices might affect how much teen smokers use vaping devices, and how much they smoke cigarettes.

Who is being asked to take part in this research study?

You are being asked to be in this research study because you are a teen smoker who is not currently seeking treatment for quitting smoking. Participants must be between the ages of 15 to 20 years old and healthy. If you are female, you cannot be pregnant or breastfeeding. Up to 150 teen smokers may be asked to participate.

Study Cigarettes

We have gotten our study cigarettes from the National Institutes on Drug Abuse. These cigarettes are made in the same way as usual brand cigarettes, except some of them contain tobacco that was grown (genetically modified) to have lower levels of nicotine in it.

The FDA has reviewed this protocol. Use of the study cigarettes will be carefully supervised in the research laboratory. Study cigarettes may not be taken home or used outside the research laboratory.

Study Vaping Device and e-Liquids

The study vaping device and e-liquids we will use are commercially available. In other words, they can be purchased online or in stores. In the research laboratory, you will be given a vaping device to use during the study. You will have several different flavors to choose from during the study. Use of the vaping device will be carefully supervised in the research laboratory. Study vaping devices may not be taken home or used outside the research laboratory.

2. WHAT WILL BE DONE

Overall Study Design

Estimated Timeline (may vary)	In person sessions	Study Cigarette Tested	Study Vaping Device Tested
Day 0	Screening and Baseline Assessments	No	No
Day 3	Lab Session 1	Yes	(Practice)
Day 6	Lab Session 2	Yes	Yes
Day 9	Lab Session 3	Yes	Yes
Day 12	Lab Session 4	Yes	Yes
Day 15	Lab Session 5	Yes	Yes

You will complete 6 sessions. Sessions will take about 2 hours each. Sessions will be from 2 to 7 days apart. The total time you will be in the study is about 2 to 4 weeks, depending on the number of days in between your sessions.

Screening Visit Procedures

Signing this form does not mean that you will be able to take part in this study. You will complete screening tests to help the study team decide if you are eligible to be in this study. If you agree to the screening, you will be asked to do several things:

1) If you are female, we will ask you for a sample of your urine to do a pregnancy test. If the test shows that you are pregnant, you will not be able to be in the study.

2) You will be asked to blow into a small machine that will tell us how much you have been smoking. If the test shows you are not a regular smoker, we will test your urine for nicotine. If this test also shows you are not a regular smoker, you will not be able to be in the study.

3) If the tests show that you are a regular smoker, then we will measure your blood pressure and your heart rate. Also, we will ask you about your current mood and how you are feeling. We will ask about your past and current smoking, vaping, and other tobacco use. We will also ask about your attitudes and beliefs about tobacco use, and about recent use of other substances. We will ask about your medical history and any medications you are taking.

After these activities, we will make an initial decision about whether you can be in the study. If we find you are not eligible for the study, you will still be paid $35 for completing the screening visit.

If your screening visit indicates that you may be eligible for the study, you will stay and complete a set of questionnaires. We will ask more questions about your past and current smoking and vaping. We will ask you to provide us with a saliva sample and a urine sample while you are in the lab, which we will test for levels of nicotine that are in cigarettes.

We will give your medical history to one of our study's medical providers to review. He or she will decide if it is appropriate for you to sample the study products (i.e. study cigarettes and vaping device) in the laboratory. If the study medical provider does not think you should sample the study products, the research assistant will contact you before your first Lab Session Visit to cancel your appointment. You will receive $70 for completing this screening/baseline session, even if you are not eligible for the study or decide that you do not want to participate.

<u>Your participation in this screening interview is voluntary, which means that you can leave at any time if you lose interest or are uncomfortable</u>.

Experimental Phase Procedures

If the study medical provider decides that you are able to be in the study and you decide to participate, you will be randomly assigned to one of two study conditions. Random assignment is a procedure similar to flipping a coin. You have an equal chance of being in one condition or the other. If you are assigned to one condition, you will be trying cigarettes that contain a different amount of nicotine than what is found in most brands. If you are assigned to the other condition, you will be trying cigarettes that have levels of nicotine that are similar to cigarettes available in stores. You will not be told the nicotine content of your study cigarettes until after the study has been completed.

Also, everyone will try a vaping device in the laboratory during the study. You will sample vaping devices that have different amounts of nicotine. You will not be told the nicotine content of your vaping device during the session. The researchers will also not know the nicotine content. This information needs to be kept secret so that the study is based on scientific results, not on peoples' opinions. You will choose the flavors for your vaping device during the lab sessions. Depending on the session, you may either choose between different cigarette flavors (like tobacco and menthol) or non-cigarette flavors (like fruit and candy).

After the screening/baseline session, you will come back to the lab for five more visits over the next 2 to 4 weeks. On the day of each lab visit, **it is important that you not smoke cigarettes or use any other form of tobacco.** We will get a breath sample at each session to measure how much you have been smoking. If the breath sample indicates that you have been smoking, we will reschedule your appointment for another day. If you reschedule more than 3 visits, you may be withdrawn from the study.

If you are female, we will ask you to provide a urine sample for a pregnancy test at each visit. If the test shows that you are pregnant, you will be withdrawn from the study. If you are withdrawn from the study, you will be paid for all the sessions you completed.

At each lab visit, we will ask you questions about your health, smoking, and mood. During the First Lab Session Visit you will try the study cigarette in the lab and complete some questionnaires about it. Next, you will complete a preference task. In this task, you will choose whether to take two puffs of the cigarette, or choose not to take any puffs. You will make this choice 10 times in a row. Finally, you will practice using the vaping device and sample the e-liquid flavors.

During Lab Visits 2 through 5 you will try both the study cigarette and the vaping device in the lab. You will complete some questionnaires about each one. You will complete a preference task. In this task, you will choose whether to take two puffs of the vaping device, two puffs of the cigarette, or not to take any puffs. You will make this choice 10 times in a row.

After you complete the study, we will talk to you about the risks from using different kinds of tobacco products. Also, we will talk to you about the benefits of becoming smoke-free. We will give you information about quitting smoking. One month after the last study visit, we will call you to ask about your smoking behavior since the study ended.

If you become pregnant during the study, our study's medical provider will contact you after the baby's delivery to check on your health and your baby's health. If you experience a serious adverse event that is related to the study, our study's medical provider will continue to contact you until the problem is resolved (over) or stable (not getting worse). The medical provider will also stop contacting you about the event if we find that it is not related to the study.

If you quit smoking before completing this study, we will give you information about stopping smoking and information about where you can get help or treatment. If you quit smoking, we will withdraw you from the study because using tobacco products in the laboratory sessions would end your quit attempt.

The samples we collect from you during this study (urine and saliva) will be sent to the University of Minnesota (UMN) Masonic Cancer Center in Minneapolis, MN. The samples will be stored and analyzed at UMN. The research staff at UMN will not have access to your name or other information that can identify you.

If, during the study, we learn things about your health, for example if your blood pressure is abnormal, or if a pregnancy test is positive, we will provide this information to you.

Compensation:

The table below shows the amount you can earn for completing each visit. Because it is very important that you complete the entire study, we will give you a bonus payment of $125 to reward you for completing all 6 visits.

Screening and Baseline Visit	$70.00
Lab Visits 1, 2, 3, 4, and 5 ($75/visit)	$375.00
Bonus for completing all 6 sessions	$125.00
Total	$570.00

You are free to stop being in the research study at any time. You will receive compensation for the sessions you complete at the same rate as participants who complete the study. However, you will not receive the completion bonus.

Payment for participating in this study will be made using a pre-paid card that works like a bank debit card. We will give you the debit card. You will be issued one card for the duration of your participation and this card may be used to pay you in any future Brown University studies you choose to participate in. You will also receive information about how to use this card and whom to call if you have any questions. Be sure to read this information, including the cardholder agreement.

Money will be added to your card according to the study's payment schedule. You may use this card at any store that accepts Mastercard. You may also use an ATM with the Mastercard logo to withdraw cash. If you use the card to withdraw cash, or if the card is not used within any six (6) month period, you will be charged a fee that will reduce the total amount of money left on the card. Please read the FAQ information sheet for details about fees.

We will use your social security number in order to process your payments. Brown will issue an IRS 1099 form if you earn $600 or more from Brown University in a single calendar year (either in a single study or across multiple studies). This may affect your taxes. Only payments for being in research studies will be used to decide if you should receive the IRS form. Money for study-related parking, food and other expenses are not included in this IRS disclosure.

This card is administered by an outside company called Greenphire. Greenphire will be given your name, address, date of birth and social security number. They will use this information only as part of the payment system and it will not be given or sold to any other company. Greenphire will not receive any information about your health status or the study in which you are participating.

If your card is lost or stolen, please call 401-863-6402 or ask the study coordinator for a replacement card. You may be charged a fee if you request a replacement card from Greenphire directly.

3. DISCOMFORTS OR RISKS:

1) Survey Questionnaires: We will ask you questions about your medical history, drug and alcohol use, and mood. Answering personal questions could make you feel uncomfortable. However, the questions we ask are commonly used in research and clinical practice. Answers to these questions will be kept confidential. Also, you do not have to answer any question you are not comfortable answering.
2) Obtaining blood pressure: The blood pressure cuff might be a little uncomfortable. In obtaining blood pressure, researchers may find out that you have abnormal blood pressure.
3) Smoking Cigarettes: All cigarettes are harmful to a person's health. Smoking can lead to severe or fatal medical problems. These include heart disease, breathing problems, cancer, diabetes, and other health risks. The study cigarettes do not provide any less risk than your usual brand cigarette.
4) Vaping device: Vaping devices contain harmful chemicals, including nicotine. Nicotine, which is also in cigarettes, may lead to some of the same diseases as smoking. The chemicals in vaping devices, and the harm they may cause, are not completely understood. E-cigarette vapor is not harmless "water vapor", although it generally contains fewer toxic chemicals than cigarettes. The most common side effects from vaping are: changes in taste, mucus in throat/sinus, dry mouth, dry cough, throat irritation, sore throat, mouth ulcers, dizziness, headache, and nausea. On rare occasions, batteries from vaping devices have exploded and injured users. This is extremely unlikely to happen in this study. Some users and non-users have reported allergic responses to vaping devices. If you have severe food allergies, or if you have ever had an allergic response to a vaping device, you should not participate in this study. If you experience an allergic reaction (such as difficulty breathing or swelling of your lips, tongue or throat) while vaping in the lab, please stop vaping immediately and tell the researcher, who will contact the study's medical monitor.

   The U.S. Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) are investigating recent reports of serious lung disease associated with the use of vaping/e-cigarette devices. Many of the illnesses are related to vaping cannabis oil. FDA has advised people to avoid buying vaping products on the street, to refrain from vaping THC oil, and warned against modifying or adding any substance to products purchased at stores. If you use a vaping device/e-cigarette products, you should watch for symptoms such as cough, shortness of breath, chest pain, nausea, vomiting, diarrhea, abdominal pain, fatigue, fever, and weight loss, and get medical attention right away for any health concerns. You can also call your local poison control center at 1-800-222-1222.
5) Nicotine is an addictive chemical. All products containing nicotine can become addictive and lead to longer-term use in the future. Your exposure to smoke and nicotine in this study will be carefully supervised and limited. Only those teenagers who are daily cigarettes smokers will be allowed to participate. Symptoms of too much nicotine include headache, dizziness, shakiness, nausea, vomiting or diarrhea, weakness, and fast heartbeat. You will be observed for any of these side effects and if they occur, we may stop the session.
6) Smoking Withdrawal: You may feel discomfort from not smoking on the days of your lab visits. Symptoms can include irritability, frustration, anxiety, sadness, craving to smoke, difficulty concentrating, and increased hunger. These feelings can be uncomfortable but they are normal, temporary, and usually mild.

Avoiding Risks during Pregnancy

Smoking during pregnancy can lead to miscarriage, preterm (early) delivery, stillbirth, birth defects, and other problems. To avoid these risks, it is important that you are not pregnant during this study. If you become pregnant during the study, you will be withdrawn from the study.

4. BENEFITS

There are no immediate benefits from participating in the study. You will have the chance to learn more about the effects of smoking. Also, you will help us learn more about how nicotine in cigarettes affects teen smoking. The information we get from this study may help the Food and Drug Administration (FDA) decide how to regulate tobacco products to improve public health.

5. CONFIDENTIALITY

Participation in this study and information gathered from the study will be kept confidential to the extent allowable by law. All information that you give us will be identified only by a code number, not your name. Your answers and test results are confidential and will not be shared with your parents, or anyone else who is not involved in conducting, overseeing, or monitoring the research. There are two exceptions to this. The first is if you report any plans to hurt yourself or anyone else. The second is if you report any physical or sexual abuse of yourself, other minors, or elderly people. If you report these things, then we are ordered by law to report them to the proper agency, to help keep you and other people safe. Also, if you report plans to harm yourself, we will share that information with our medical provider, who will talk with you about it, to help keep you safe.

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. Data from this project will be shared with collaborating investigators at the University of Minnesota and Wake Forest University. 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 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 clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Website at any time.

Certificate of Confidentiality

To help us protect your 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 you, 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 should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about you and your 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 you report child or elder abuse, or plans to hurt yourself or others.

6. DECISION TO PARTICIPATE AND RIGHT TO QUIT AT ANY TIME

Your decision whether to be in this study is completely up to you. Participation is voluntary. If you decide now to participate, you will be able to change your mind and withdraw from the project at any time without any consequences. We will keep the data and specimens we collected from you prior to your withdrawal.

7. WHO TO CALL

Please ask any questions you may have now. Questions about the study should be directed to Dr. Suzanne Colby at 401-863-6655. Questions about your rights as a research participant should be directed to the Brown University Research Protections Program at 401-863-3050.

8. CONSENT TO PARTICIPATE

Your signature below means that you have read the information on this form, have asked any questions you have about the project, and would like to participate in this study. You will be given a copy of this form to keep.

_____ _____

Signature of participant **Date**

_____ _____

Signature of staff member obtaining consent **Date**

Optional

I agree	**I disagree**	
_____	_____	The researcher may contact me in the future to see whether I am interested in being in other studies by researchers working at the Center for Alcohol and Addiction Studies at Brown University.