Reduced Nicotine Cigarette Purchasing Decisions

NCT04999644

Last Updated 11/22/2021

COMBINED RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: Reduced Nicotine Cigarette Purchasing Decisions

Application No.: IRB00288837

Funded By: National Institutes of Health (NIH)

Principal Investigator: Justin C. Strickland, PhD
5510 Nathan Shock Drive
Baltimore, MD 21224
Phone 410-550-1975
Fax: 410-550-0030

You are being asked to join a research study. Participation in this study is voluntary. Even if you decide to join now, you can change your mind later

1. Research Summary (Key Information):

The information in this section is intended to be an introduction to the study only. Complete details of the study are listed in the sections below. If you are considering participation in the study, the entire document should be discussed with you before you make your final decision. You can ask questions about the study now and at any time in the future.

This research is being done to understand how people like cigarettes with differing nicotine amounts, compared to cigarettes with standard amounts, and how people make decisions about smoking. In this study, there is 1 screening session and 5 laboratory sessions. During the screening session, you will be asked questions about your health and medication use, provide a urine sample, and undergo a breath test and physical exam. If you are eligible to continue in the study after the screening visit, you will be asked not to smoke for at least 6 hours before laboratory sessions which each last about 4 hours. During the laboratory sessions, you will be asked to provide a urine sample, undergo a breath test, sample cigarettes that differ in nicotine content, and complete tasks on the computer. We hope that the results of this study may help us to understand factors that contribute to cigarette smoking.

Taken together, study participation is expected to last about 2 weeks. There are risks to this study that are described in detail later in this document. The primary risks are related to potential side effects and adverse effects after smoking cigarettes and experiencing tobacco withdrawal symptoms. There is no benefit or cost to you for taking part in this study. You may earn up to $530 for completing the study.

2. Why is this research being done?

This research is being done to understand how people like different types of cigarettes that vary in the amount of nicotine and how people make decisions about smoking different cigarettes. We hope that the results of this study may help us to understand factors that contribute to cigarette smoking.

Are there any investigational drugs/devices/procedures?

The cigarettes being evaluated in this study are investigational tobacco products. The word "investigational" means these investigational tobacco products cigarettes have not been authorized for marketing by the Food and Drug Administration (FDA). The FDA Center for Tobacco Products is allowing the use of these investigational tobacco products in this study.

Who can join this study?

People who smoke tobacco cigarettes and are older than 21 may join.

3. What will happen if you join this study?

If you agree to be in this study, we will ask you to do the following things:

The study is organized so that you will complete it in the following order:

1.) 1 screening session
2.) 1 practice session
3.) 4 experimental sessions

First, you will complete Screening to see if you are able to continue to take part in this study. For screening, you will be asked to:

- Complete questionnaires and interviews about your mental health history, your health history, and drug use history
- Provide a breath sample
- Provide a urine sample
- You may undergo a pregnancy test if you are a woman capable of becoming pregnant
- Have a physical examination

The screening should take about 3 hours

If after screening, you are eligible and agree to continue to take part, you will be scheduled to come to the laboratory at the Behavioral Pharmacology Research Unit (BPRU) for 1 practice session and 4 "experimental" sessions lasting about 4 hours each.

During these practice and experimental sessions, you will be instructed on how to complete the various study measures and use the cigarettes. You will be asked to not smoke for 6 hours or more before the beginning of each brand sampling and experimental sessions. We will collect a breath sample to measure carbon monoxide, which is an indicator of how much you have smoked recently.

During the **practice sessions,** you will be asked to smoke cigarettes from your preferred brand that we (the study team) purchase. You will be free to smoke the cigarettes in any manner you choose during these sessions so long as you smoke the cigarettes through the small cigarette holder connected to our existing computer equipment. You will also be introduced to how to complete the measures we will collect in the study.

During the **experimental sessions**, you will be asked to smoke cigarettes that we (the study team) are interested in. These cigarettes will vary in the amount of nicotine they have and we will tell you about what the nicotine content is relative to the "average" nicotine in each session. However, you and the study team will not know the specific amount of nicotine in the cigarette. In the case of an emergency, the study doctor can quickly find out the amount of nicotine. You will also be free to smoke these cigarettes in any manner you choose during these sessions so long as you smoke the cigarettes through the small cigarette holder connected to our existing computer equipment. You will complete measures on the computer during these sessions.

During all sessions, you will first sample that day's cigarette that is available. Then you will be provided with money ($50) that you may use to purchase cigarettes of that type to smoke later in your session. You may choose to use any, some, or none of this money. Whatever money you do not use will be added to your session payment.

During all sessions, you will be allowed to read magazines, but you will not be allowed to use your cell phone or read or work on other materials including work or schoolwork. For this reason, if you have a cell phone on you it will be stored in a secure and locked location during the sessions.

If an unforeseen issue arises during session (such as a fire alarm or technical difficulties), you may be asked to repeat a session.

You will also be asked to complete questionnaires and computer tasks, and answer questions about how you like the cigarettes, cravings and withdrawal symptoms.

Listed below are details about the study tests and procedures that will be done.

- You will be asked to provide a urine sample and breath samples at the beginning of each visit. You must not be under the influence of alcohol or any drugs on the days of your study visits. Otherwise your session will be rescheduled and you will not be paid for the session. Repeated instances may result in ending your study participation and loss of bonus payment. Breath samples will test for alcohol and for carbon monoxide, an indicator of recent smoking.
    - You will need to not smoke for 6 hours or more before the beginning of each practice and experimental session. Whether you have not smoked for long enough will be determined by a breath sample that measures carbon monoxide, which is an indicator of how much you have smoked recently. Your carbon monoxide level will need to equal or be lower than a specific level which will be determined for you based on individual factors. Some people may take longer than 6 hours to reach this level, for example 8 or 10 hours. The requirement is that you meet your target carbon monoxide level, regardless of the time it takes to abstain from smoking to meet this target. If you do exceed your target level when reporting for a session, we will reschedule your session for another day and you will not be paid for that session. If this happens repeatedly we may take you out of the study.
- **Pregnancy Testing**: Pregnancy testing will be repeated before the start of smoking administration sessions (all laboratory sessions in which cigarettes are available).
- **Questionnaires**: Some questions will ask you about smoking behaviors, how you like the cigarettes, and craving, and withdrawal. For example, you will be asked "Do you like the cigarette?", "Does the cigarette have any good effects?" Other questions will ask how many cigarettes you have smoked recently.
- Please maintain your normal schedule during the study, for example, be sure to get the amount of sleep you are used to.
- If you regularly drink caffeine-containing beverages like coffee, tea, or soda in the morning, please continue to do so throughout the study.
- You will be asked to wear a properly fitting surgical grade face mask to reduce COVID-19 transmission risk while in the laboratory area and while interacting with study staff. If you do not have a mask, we will provide one to you at no cost.

Will research test results be shared with you?

This study involves research tests that we do not expect will be useful for your clinical care. We will not share these results with you.

How long will you be in the study?

You will be in the study for one screening session (about 3 hours), 1 practice session (about 4 hours each), and 4 experimental sessions (about 4 hours each). Depending on your availability the expected duration of this study will be about 2 weeks, but may be less or more considering scheduling.

4. What happens to data and biospecimens that are collected in the study?

If you join this study, your data and biospecimens will be used to answer the research question and your data will be used to publish the findings of this study. Biospecimens may include any of the following: blood, tissue, saliva, urine, bone marrow, cells, etc. Most biospecimens contain DNA, which is the genetic code for each person.

You will not own the data and/or biospecimens collected from you as part of this research study. If researchers use them to create a new product or idea, including those that may have commercial value, you will not benefit financially from those efforts.

Johns Hopkins researchers and their collaborators may use the data/biospecimens collected in this study for future research purposes and may share some of the data/biospecimens with others.

Because science constantly advances, we do not yet know what future use of research data or biospecimens may include. This future research may be unrelated to the current study and may include outside collaborators.

Sharing data and/or biospecimens is part of research and may increase what we can learn from this study. Often, data/biospecimen sharing is required as a condition of funding or for publishing study results. It also is needed to allow other researchers to validate study findings and to come up with new ideas. Your data and/or biospecimens may be shared with researchers at Johns Hopkins and other institutions, for-profit companies, sponsors, government agencies, and other research partners. Your data and/or biospecimens may also be put in government or other databases/repositories.

We (Johns Hopkins) will do our best to protect and maintain your data/biospecimens in a safe way. One of the ways we protect data/biospecimens is by limiting the uses of the information and the type of information that is shared, especially your personal information. This may occur through data/specimen sharing agreements and review by oversight groups within Johns Hopkins.

If data/biospecimens are used or shared with types of information that may be likely to identify, you such as your name, address or medical record number, further institutional review and approval would be required. In these cases, Johns Hopkins will review whether additional consent from you is required.

Generally, if your data/biospecimens are used/shared without any personal identifiers or with information that is less likely to identify you (such as the date of a procedure), further review and approval is not needed.

Data/biospecimen sharing could change over time, and may continue after the study ends.

The use and sharing of your data and biospecimens is required for participation in this research study. If you are not comfortable with the use and sharing of your data/biospecimens in future research without further consent, you should not participate in this study.

5. What are the risks or discomforts of the study?

<u>Cigarettes</u>

It is unlikely, but there may be some potential side effects and adverse effects after smoking any cigarette. After puffing a cigarette, you may experience side effects from exposure to the cigarettes. Before or during sessions, you may experience tobacco withdrawal symptoms which may be unpleasant.

Taking cigarette exposure and/or withdrawal into account, these side effects could include dizziness, nausea, headache, cough, sore throat, increased heart rate, and increased blood pressure. Side-effects of the cigarettes would be temporary.

Interviews and questionnaires

You may get tired or bored when we are asking you questions or you are completing questionnaires. You do not have to answer any question you do not want to answer. Questions about sensitive issues (such as alcohol use, illegal drug use, and your mood) could make you feel uncomfortable and lead to feelings such as anxiety, distress, sadness, or embarrassment.

Identifiable private information

There is the risk that information about you may become known to people outside this study. This study involves the collection of sensitive data (including drug testing and diagnosis of disease). Steps are taken to protect your confidentiality as outlined below, but a breach of confidentiality could be embarrassing, or even affect employment.

There is a very small risk that someone could get access to the data we have stored about you. If those data suggest something serious about your health, it could be misused. For example, it could be used to make it harder for you to get or keep a job or insurance. There are laws against this type of misuse, but they may not give full protection. There may be risks related to the storage of information that we do not yet know. There is a very small chance that there could be a computer security breach when data is kept electronically. But computers used in this study are password protected with limited access.

COVID-19

There is a possibility that participation in this research may increase your risk of COVID-19 transmission. Several procedures have been put into place to minimize this risk including the requirement that you wear a mask at all times while interacting with study staff or in the shared laboratory space, limiting the amount of person-to-person interactions you may have, and monitoring COVID-19 symptoms among all study participants.

6. Are there risks related to pregnancy?

If you are pregnant or become pregnant, you will not be able to take part in this study. If you think you might be pregnant, you will not be able to be in the study. Cigarette smoking during pregnancy has been found to increase the risk of premature birth and stillbirth, and reduced growth of the fetal brain, lungs and kidneys. Cigarette smoking during pregnancy is also associated with lower birth weights and can negatively impact fetal circulation. By signing this consent form you are also agreeing to practice an effective means of birth control if you are having sex over the course of the study.

7. Are there benefits to being in the study?

There is no direct benefit to you from being in this study. If you take part in this study, you may help others in the future through the knowledge gained from this study.

8. What are your options if you do not want to be in the study?

You do not have to join this study. If you do not join, your care at Johns Hopkins will not be affected.

9. Will it cost you anything to be in this study?

No.

10. Will you be paid if you join this study?

You will be paid $30 for completing the in-person screening, which takes about 3 hours.

If you are found to be eligible, you will be asked to return to the laboratory for 1 practice session (lasting about 4 hours each) for which you will be paid $50. Then, you will be asked to come to the laboratory for 4 experimental sessions (lasting about 4 hours each) for which you will be paid $50 each. You will receive an additional $50 experimental income during each session that you may use any, some, or none of. Any money that you do not use will be added to your session payment.

We ask that you follow directions during experimental sessions. If we end your participation for no fault of yours, before study completion, you will receive payment for the sessions completed.

Total compensation for completing the study is up to $530.

You may be required to provide your social security number to be paid for taking part in this study. Federal tax law requires that you report your research payments when you file your taxes. If your total payments from Johns Hopkins exceed $600 per year, Johns Hopkins will report these payments to the Internal Revenue Service and you will receive a 1099-MISC form from us.

11. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.

If you leave the study early, Johns Hopkins may use or share your health information that it has already collected if the information is needed for this study or any follow-up activities.

12. Why might we take you out of the study early?

You may be taken out of the study if:

- Staying in the study would be harmful.
- You need treatment not allowed in the study.
- You fail to follow instructions.
- You become pregnant.
- The study is cancelled.
- There may be other reasons to take you out of the study that we do not know at this time.

If you are taken out of the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities**.**

13. How will your privacy be maintained and how will the confidentiality of your data be protected?

HIPAA Authorization for Disclosure of Protected Health Information

What information is being collected, used, or shared?

To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Johns Hopkins Medicine and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?

The people who may request, receive, or use your private health information include the researchers and their staff who may be a part of Johns Hopkins Health System, Johns Hopkins University or the Johns Hopkins Applied Physics Laboratory. Additionally, we may share your information with other people at Johns Hopkins, for example if needed for your clinical care or study oversight. To improve coordination of your research and clinical care, some information about the study you join will be included in your electronic medical record.

By signing this form, you give permission to the research team to share your information with others outside of Johns Hopkins. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team.

We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

How will your information be protected?
Any paper copies of your study information, including this Informed Consent Form and study lab reports, will be stored securely. Paper copies will be kept and destroyed according to FDA requirements.

We might talk about this research study at meetings. We might also publish the results of this research study in relevant journals. You will not be identified in any publication or in the sharing of your data about this study. We will always keep the names of the research participants, like you, private. After the study is completed, the data may be placed in a central storage location and stored indefinitely. These data will not include your name or other information that can identify you. The purpose is to make study data available to other researchers.

14. Will the study require any of your other health care providers to share your health information with the researchers of this study?

As a part of this study, the researchers may ask to see your health care records from your other health care providers.

15. What is a Certificate of Confidentiality?

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.

16. What treatment costs will be paid if you are injured in this study?

Johns Hopkins and the federal government do not have programs to pay you if you are hurt or have other bad results from being in the study. However, medical care at Johns Hopkins is open to you as it is to all sick or injured people.

The costs for any treatment or hospital care you receive as the result of a study-related injury that are not covered by a health insurer will be billed to you.

By signing this form you will not give up any rights you have to seek compensation for injury.

17. What other things should you know about this research study?

During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time. If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.

During this study, you will not have access to certain medical information and test results collected for study purposes. If an emergency occurs while you are in the study, medical information needed for your treatment can be made available to your study doctor and other physicians who treat you. When the study is completed, all the information in your medical record will be available to you.

What is the Institutional Review Board (IRB) and how does it protect you?

This study has been reviewed by an Institutional Review Board (IRB), a group of people that reviews human research studies. The IRB can help you if you have questions about your rights as a research participant or if you have other questions, concerns or complaints about this research study. You may contact the IRB at 410-502-2092 or jhmeirb@jhmi.edu.

What should you do if you have questions about the study, or are injured or ill as a result of being in this study?

Call the principal investigator, Justin Strickland at 410-550-1975. If you wish, you may contact the principal investigator by letter. The address is on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-502-2092.

If you have an urgent medical problem or think you are injured or ill because of this study, call 911 or go to your local emergency department. You should also call the BPRU nursing desk at (410) 550-0052 during regular office hours and at (443) 857-5738 after hours and on weekends.

18. Optional Study Components:

This part of the consent form is about optional component(s) of the study that you can choose to take part in or not. You can still take part in the main study even if you say "no" to this/these optional component(s).

Future Contact

We would like your permission for our research team to contact you in the future. Please note that your decision below does not prevent other researchers at Johns Hopkins from contacting you about other research.

Please sign and date your choice below:

YES _____ _____
Signature of Participant Date

NO _____ _____
Signature of Participant Date

19. What does your signature on this consent form mean?

Your signature on this form means that you have reviewed the information in this form, you have had a chance to ask questions, and you agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Participant	(Print Name)	Date/Time

Signature of Person Obtaining Consent	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR AND A COPY MUST BE GIVEN TO THE PARTICIPANT. IF APPROPRIATE FOR THIS STUDY, A SCANNED COPY OF THE SIGNED CONSENT FORM SHOULD BE UPLOADED TO THE PARTICIPANT'S EPIC/EMR RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

DOCUMENTATION OF PHYSICIAN/MID-LEVEL PROVIDER CONSENT PROCESS

My signature below indicates that I have discussed the risks, benefits, and alternatives, answered any questions, and believe the participant is able to make an informed choice to join the study.

Signature of Physician/Mid-Level Provider	(Print Name)	Date/Time

Signature of Participant	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR AND A COPY MUST BE GIVEN TO THE PARTICIPANT. IF APPROPRIATE FOR THIS STUDY, A SCANNED COPY OF THE SIGNED CONSENT FORM SHOULD BE UPLOADED TO THE PARTICIPANT'S EPIC/EMR RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).