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COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT
200 FR. 1 (2016-2)

YALE UNIVERSITY
YALE UNIVERSITY SCHOOL OF MEDICINE

Study Title: Effects of Menthol in E-cigarettes on Nicotine Metabolism (K01 Metabolism substudy)

Principal Investigator: Suchitra Krishnan-Sarin, Ph.D.
Funding Source: NIDA

Research Study Summary:

- We are asking you to join a research study.
- The purpose of this research study is to investigate the impact of menthol in e-cigarettes on nicotine breakdown in African American adults who smoke.
- Study procedures will include an intake appointment and 2 laboratory sessions.
- 3 visits are required.
- The lab sessions visits will take 4.5 hours (9 hours total) and intake appointment will take 2 hours.
- There are some risks from participating in this study from administering nicotine; using an e-cigarette; vaping flavors, propylene glycol/vegetable glycerin; completion of rating scales and assessments; blood draws; breath, urine and saliva collection; limits to confidentiality. Others such as (but not limited to) mouth/throat irritation, dry cough, addiction/ dependence, nicotine withdrawal and respiratory flow.
- This study may have no benefit to you.
- Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You can also change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.
- If you are interested in learning more about the study, please continue reading, or have someone read to you, the rest of this document. Take as much time as you need before you make your decision. Ask the study staff questions about anything you do not understand. Once you understand the study, we will ask you if you wish to participate; if so, you will have to sign this form.

Invitation to Participate and Description of Project

You are invited to take part in a research study designed to study the subjective/physical effects of nicotine and menthol when administered in e-cigarettes. E-cigarettes contain a battery-operated atomizer and produces a vapor when a solution (also known as e-liquid or e-juice) is inhaled. This solution can contain nicotine, flavors, and chemical constituents. You have been asked to take part in this study because you are at least 21 years old, report regular menthol cigarette smoking, do not want to quit using cigarettes and have experience with e-cigarettes. If you take part in this research study, you will be asked to complete 2 lab sessions in which you

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will be asked to use an e-cigarette we will provide to you and to complete questionnaires and provide biological samples. We will assess your nicotine metabolism at baseline and seek to understand short term changes in subjective effects when nicotine and menthol is delivered via e-cigarettes. We plan to recruit 85 participants into this study.

In order to decide whether or not you wish to be a part of this research study, you should know enough about its risks and benefits to make an informed decision. This consent form gives you detailed information about the research study, which a member of the research team will discuss with you. This discussion should go over all aspects of this research: its purpose, the procedures that will be performed, any risks of the procedures, and possible benefits. Once you understand the study, you will be asked if you wish to participate; if so, you will be asked to sign this form.

This study is not designed to help you quit smoking. If you do wish to quit smoking, please inform the research assistant and he/she will give you referrals regarding treatment options. Smoking cessation materials/programs will be offered at the end of the study.

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.

Description of Procedures

If you agree to take part in this study, you will be asked to complete the following study related activities:

COVID procedures: We care about your safety as a research participant. Because participating in this study may involve travel outside of your home and exposure to others during a pandemic, we will discuss ways to minimize risks related to COVID-19. Before you decide whether to participate in this study, talk to your study doctor or the researcher about anything you do not understand or any concerns you may have. If you are eligible for the study, we will ask that you fill out a COVID symptom online questionnaire daily. This questionnaire will be sent to you via an online link to your cell phone or email (depending on your preference). Depending on symptoms, we may need to call you to follow up on your symptoms. You will not be allowed to attend in-person visits until your COVID symptom questionnaires are completed. If you are not able to fill out the online questionnaire, study staff can administer the questionnaire via phone.

Additionally, at all in-person appointments, participants will be asked to wear masks and study staff will wear masks and gloves. If you do not have a mask, one will be provided to you by study staff. Further safety information for the sessions is described below. During in-person appointments, you will again be asked about COVID symptoms, and a temperature check will be conducted. Participants who report symptoms or have a temperature of >100 will be asked to reschedule their visit and instructed to immediately contact their primary health care provide or call the Campus COVID Resource line (203-432-6604).

Intake Appointment: For your and the research team's health and safety, you can participate in much of the intake portion remotely via phone call or videoconferencing. During this appointment, you will provide personal information, including your medical history and your

current use of nicotine and tobacco products. Information will be collected both by you filling out questionnaires via a website and the researcher administering questionnaires. The researcher will be on the phone and/or videoconference with you for the entirety of this collection period. It should take approximately 1.5 hours to complete all parts of the remote intake. You will also have an opportunity to complete this portion in person.

If eligible following the remote portion of the visit, you will be asked to come in to collect a breath carbon monoxide (CO) sample, a urine sample to detect cotinine (a byproduct of nicotine) and to verify that you are not currently using other drugs or are currently pregnant. Both CO and cotinine samples will help us understand more about your current use of nicotine products. If you test positive for any drugs except marijuana at the in-person intake appointment, you will not be paid for the visit and will have the opportunity to reschedule this appointment one time. Additionally, we will collect blood pressure and heart rate. We will also collect pulse oximetry, which measures how well oxygen is being sent through the body. This is measured using a clip-like device on your finger and is quick and painless. We will also measure your saliva nicotine metabolite ratio which is an indicator of the rate your body breaks down nicotine. We will also measure your lung function (lung spirometry) where you are asked to blow into a small handheld device. This intake appointment will be conducted at our research site at the Connecticut Mental Health Center. It should take approximately thirty minutes to complete this portion. You also have the option of completing the entire intake appointment in person where all assessments can be completed, and biological samples collected at Connecticut Mental Health Center. This clinical research study will involve the Yale-New Haven Hospital (YNHH) affiliated site West Campus. As a participant in this clinical research study involving the Yale-New Haven Hospital (YNHH), it is important for you to know that if you do not already have a medical record at YNHH, one will be made for your admission. In addition, you need to know that if you have ever been a patient at YNHH at any time, your previous medical records of other visits or admissions will become available to the researchers and to the staff of the West Campus when today's information is added into the medical record. Your medical record will be accessed to determine if you are healthy enough to participate in this study based on the eligibility criteria. Medical record review will be limited to the just the elements needed to complete the study (i.e medical visits and prescribed medications). If you decide that you will be in this study, and you will be visiting the Connecticut Mental Health Center (CMHC) as part of your study procedures, some information about your participation in this research study will become part of your CMHC medical record that identifies you. If you do not already have a medical record at CMHC, one will be made for your visit. This chart will say you are/were a research participant at the CMHC

Training session: The first 10-15 minutes of Lab Session 1 will be used to familiarize you with the e-cigarette we will be using. You will also be shown the rating scales to make sure you understand how to complete them.

Lab Sessions (2 total): If you are a female, we will use a urine sample to administer a pregnancy test at baseline and prior to each vaping session. Nicotine intake during pregnancy may be associated with increased risk for spontaneous abortion, increased perinatal mortality and with low infant birth weights. Therefore, you will be excluded if you are pregnant or nursing.

All laboratory sessions will be conducted on weekdays; these sessions will be conducted at the West Campus Research Unit (WCRU) in Orange, CT. There will be a minimum of 24 hours between each session and the sessions will last for approximately 4.5 hours. We will try to complete all laboratory sessions within a 2-week period, depending on your schedule and availability of the lab. We will ask you to stop using all tobacco products (e.g., cigarettes, e-cigarettes) and marijuana for 12 hours prior to each laboratory session. Abstinence will be confirmed using breath CO levels ≤10 ppm. If your breath CO level indicate that you have used a tobacco product, your lab session may be canceled and rescheduled for a different day

An IV will be placed to avoid having to stick you more than once for the blood collections. A cuff will be placed on your arm to monitor your vital signs (e.g., blood pressure, heart rate) and the first blood sample will be collected. During the lab sessions you will be asked to inhale by taking a 3-second-long puff from an e-cigarette ten times (once every 30 seconds). You will also be asked to provide saliva samples. This is done by chewing on a cotton salivette (swab) around in your mouth for thirty seconds. Blood and saliva specimens will be obtained to measure nicotine levels before and 5, 15, 30, 45, 60 minutes after the e-cigarette administration session. Heart rate and blood pressure will be measured at baseline and 5, 15, 30 minutes after nicotine exposure. The e-cigarette will contain nicotine (59mg/ml(5%)) with menthol or tobacco for each lab session. The e-cigarette will be provided to you each session and sanitized between lab sessions. There will be one-hour break. Then you will be able to choose to freely vape the e-cigarette for a one-hour period. Blood and saliva specimens will be obtained before and 15-, 30-, and 60-minutes during part of the session you can freely vape the e-cigarette. Each laboratory session will be recorded on video. The purpose of this is to ensure that the lab sessions are conducted correctly and to assess puffing behavior. At each session 60ml (4 tablespoons) of blood will be drawn for a total of 120ml for the study which is below the IRB guidelines of 450 ml within eight research weeks.

We will also ask you to complete some questionnaires on how nicotine and menthol makes you feel and about your mood during each session; these assessments will be completed multiple times during each session. If you feel any uncomfortable side effects during lab sessions (e.g., nausea, vomiting), you can discontinue the puffing bout at any time. We well also collect pulse oximetry, which measures how well oxygen is being sent through the body. This is measured using a clip-like device on your finger and is quick and painless.

For any in person appointments, we ask that you do not bring any weapons to any appointments you have with us. We also ask that you do not drink any alcoholic beverages for 12 hours prior to your appointment time. If we suspect that you may be intoxicated, we may do a breathalyzer, ask you to remain in the clinic until it is safe to leave, and may reschedule your appointment.

Risks and Inconveniences

COVID, Smoking and Vaping: Although scientific evidence is incomplete, some studies have suggested that use of e-cigarettes may add to your risk of getting COVID -19 and may contribute to the severity of illness if you do get the virus. Smokers and e-cigarette users have to take their face masks off when they smoke or vape. So even between puffs, you may be unknowingly infected with the coronavirus, you might exhale contagious droplets and aerosols into the air, which could be inhaled by others nearby. Secondhand cigarette smoke is known to cause health problems, and although there isn't yet scientific proof that it can spread the

coronavirus and cause COVID-19, it may be possible. Smoking or vaping inside is even riskier. In a closed environment, infectious droplets and particles can build up in the air, putting others in the room at risk if there's no ventilation.

The other potential risks in this study are related to: 1) Use of e-cigarette, 2) Nicotine Withdrawal, 3) Nicotine administration, 4) Flavor administration, 6) use of propylene glycol/vegetable glycerin, 7) Urine and saliva collections, 8) Tobacco use Drug use, 9) Blood Drawing and Intravenous Access, 10) Limits to Confidentiality and 111) Rating scales and assessments.

1) Use of e-cigarette: You were asked to participate because you have had some experience with e-cigarettes, therefore reducing the risk to experience any kind of adverse reaction to an e-cigarette. The e-cigarette delivers nicotine in much the same way that a regular cigarette does. It is easier to use nicotine in these devices and you could use more nicotine than anticipated using. However, in this study you will only be allowed to use a set amount of nicotine and the amount of nicotine you will use will not be greater than what you would be exposed to through a regular cigarette. As a current cigarette/cigar/little cigar smoker, you are already self-administering nicotine (as indicated by your CO/cotinine levels at Intake) and already have experience with tobacco products with and without various flavors. There may be a risk of e-cigarette dependence. However, this will not likely happen directly from the planned limited supervised e-cigarette exposures in this study. If you have a neutral or positive e-cigarette experience in this study, it could lead to increased use after the study is completed. Additionally, in rare cases there have been reports of e-cigarettes exploding and causing serious injury to people. Evidence suggests that these explosions are battery related. To avoid a vape related explosion the research staff has implemented the following Food and Drug Administration recommendations: 1) The research staff will keep loose batteries in a case to prevent contact with metal objects, 2) The research staff will always charge the battery with the charger that the e-cigarette came with 3) The e-cigarettes will not be charged overnight or left unattended 4) The research staff will replace the e-cigarette battery if it becomes wet or damaged. Furthermore, acute exposure to e-cigarette aerosol may result in mouth and throat irritation, dry cough at initial use and typical sensory effects of menthol in the mouth and throat.

The lab sessions will be conducted by trained research staff sensitive to tobacco users and trained to monitor any potential adverse effects. You should not experience any of these symptoms during the study since we will be exposing you to controlled low levels of nicotine but if you feel uncomfortable at any time, please tell us and we will stop the study procedures. After the last session you will be offered referral sources to quit tobacco use if you are interested.

Information Related to Cases of Severe Pulmonary Illness and Vaping: There have been recent reported cases of severe pulmonary illness linked to "vaping" or e-cigarette use. These cases included symptoms such as coughing, shortness of breath, chest pain, fever, fatigue, nausea, vomiting, diarrhea, and/or abdominal pain. Some patients reported symptoms to have occurred over a few days and some reported to have occurred over a few weeks. Vaping-related disorders have ranged from mild to severe with hospitalization, intensive care with breathing machines and in some cases death. In most cases, but not all, people experiencing these symptoms were using cannabidiol (CBD) and marijuana (THC) e-liquids, and/or using e-cigarette devices and e-liquids that were mixed at home or purchased off market (such as purchasing an e-liquid or device on

the street, not from a licensed retailer). Laboratory data show that Vitamin E Acetate, an additive in some THC-containing e-cigarette or vaping products is strongly linked to EVALI.

The Center for Disease Control (www.cdc.gov) has issued the following information on vaping:

- CDC and FDA recommend that people not use THC-containing e-cigarette, or vaping, products, particularly from informal sources like friends, family, or in-person or online dealers.
- Vitamin E acetate should not be added to any e-cigarette, or vaping, products. Additionally, people should not add any other substances not intended by the manufacturer to products, including products purchased through retail establishments.
- Adults using nicotine-containing e-cigarette, or vaping, products as an alternative to cigarettes should not go back to smoking; they should weigh all available information and consider using FDA-approved smoking cessation medications. If they choose to use e-cigarettes as an alternative to cigarettes, they should completely switch from cigarettes to e-cigarettes and not partake in an extended period of dual use of both products that delays quitting smoking completely. They should contact their healthcare professional if they need help quitting tobacco products, including e-cigarettes, as well as if they have concerns about EVALI.
- E-cigarette, or vaping, products (nicotine- or THC-containing) should never be used by youths, young adults, or women who are pregnant.
- Adults who do not currently use tobacco products should not start using e-cigarette, or vaping, products.
- THC use has been associated with a wide range of health effects, particularly with prolonged frequent use. The best way to avoid potentially harmful effects is to not use THC-containing e-cigarette, or vaping, products.
- Persons engaging in ongoing cannabis use that leads to significant impairment or distress should seek evidence-based treatment by a healthcare professional.

Although there is much research devoted to EVALI, the exact cause of this lung injury remains unknown. Therefore, we ask you to abstain from using tobacco and THC-containing products from unknown sources, as they may not comply with standards set by Good Manufacturing Practices and could contain contaminants. The symptoms of EVALI can include cough, shortness of breath, chest pain, nausea, vomiting, stomach pain, diarrhea, fever, chills, or weight loss. If you feel sick or experience any of these symptoms, get care and contact the study team as soon as possible

The e-cigarettes and e-liquid pods that we will use in the current study are purchased only from a licensed retailer and do not contain CBD, THC, or Vitamin E Acetate. At this time, we don't know what the risks associated with the use of the e-cigarettes and e-liquids, flavors, etc. that we use in this study are, and who might develop symptoms. The pods we are giving participants contain nicotine, solvents, and flavorings. We will ask participants to only use the e-cigarette pods provided and inform them not attempt to hack or modify the e-cigarette device in any way.

Participants will be asked not to participate if they have known allergies to propylene glycol (a constituent in e-liquids), known allergies to any e-liquids and/or nut allergies (as our e-liquids

are made in a facility in which they could have come in contact with nuts). All participants will report on their general health at intake to make sure you are healthy prior to participating and will continue to monitor your health closely during the study. If participants experience any symptoms (such as abdominal pain, nausea, vomiting, diarrhea, cough, shortness of breath, chest pain) or have other concerns, we will instruct them to let us know and let their doctor know right away. They will be instructed to go to the emergency room right away if their symptoms increase rapidly. It is possible that the hospital may report cases of illness after using e-cigarettes to the State Health Department and the CDC. The report will contain the name and address of the person who is ill.

3) Nicotine withdrawal: During the abstinence period prior to the lab sessions, you may experience symptoms of nicotine withdrawal, such as craving cigarettes, mild anxiety, restlessness, irritability, difficulty concentrating, loss of energy and excessive hunger. These are normal symptoms that people experience when they stop tobacco use and they can be uncomfortable, but they are not life threatening.

4) Nicotine administration: Common side effects of nicotine include nausea, vomiting, heartburn, and elevated heart rate and blood pressure. Since nicotine intake during pregnancy may be associated with increased risk for spontaneous abortion, increased perinatal mortality and with low infant birth weights, we will exclude women who are pregnant or nursing from this study. Toxic doses of nicotine may cause abdominal pain, hyper salivation, diarrhea, dizziness, confusion, hearing and vision problems, fainting, seizures, hypotension (low blood pressure), irregular pulse, and death. However, these toxic effects occur at doses 40 to 50 times higher than those that will be used in this study. Also, since you are a tobacco user, it is not likely that you will experience side effects. Again, if you experience any side effects or feel uncomfortable, you can stop the session at any point.

5) Use of flavors: At this time, there is little known about the short and long-term effects of inhaling flavorants. There may be unforeseen risks (such as allergic reactions). We will be using e-liquids that are freely available for purchase and the flavor doses will be what is available in these e-liquids. Some research has indicated that certain chemicals used in some flavored e-liquids may be harmful in large doses. However, if you experience any side effects, you can stop the session at any point. Research staff will monitor e-cigarette use during the lab session. If you feel any discomfort or need to stop for any reason, please let the researcher know.

6) Use of propylene glycol/ vegetable glycerin: At this time, there are no immediate known risks associated with the use of propylene glycol/ vegetable glycerin we may use in this study. It is important to note that there may be unforeseen risks (such as allergic reactions). We will be using e-liquids that are freely available for purchase and the propylene glycol/vegetable glycerin doses will be what is available in these e-liquids. Some research has indicated that in large doses propylene glycol and vegetable glycerin can be harmful. However, if you experience any side effects, you can stop the session at any point. Research staff will monitor e-cigarette use during the lab session. If you feel any discomfort or need to stop for any reason, please let the researcher know.

7) Urine and saliva collections: Urine collections will be done at your intake appointment to measure the amount of cotinine in your body. Saliva samples will be collected at intake and

during the lab sessions to determine nicotine and cotinine levels. This is done by chewing on a cotton salivette (swab) around in your mouth for thirty seconds. Urine and saliva sample collection are not risky.

8) Tobacco Use and Drug use: You will be asked about current and past use of illicit "street" drugs at the intake to rule out substance abuse. If you are currently using drugs, you may not be eligible to participate. If at any time during your participation you report you want to hurt yourself or hurt anyone else, we will immediately direct you to appropriate authorities to ensure your safety.

9) Blood Drawing and Intravenous Access: Drawing blood is a safe and standard medical procedure. Sometimes a bruise will occur at the puncture site and rarely a blood clot or infection will occur in the vein. Certain individuals may feel light-headed during venipuncture. Insertion of an intravenous catheter involves risk for hematoma at the site of the venous puncture. Very rarely, venous puncture can also result in a blood clot or infection. To minimize risks associated with blood draws and IV-line insertion, experienced venipuncture-certified personnel will do all the blood-drawing procedures. You will have approximately 60 ml (4 tbsp) of blood drawn at e-cigarette exposure lab session. The total amount of blood drawn during this study is 120 ml (1/2 cup). You are advised not to donate blood for at least 4 weeks after the study ends.

10) Limits to confidentiality: We do not reveal any personal information collected as part of the research procedures, including your reported tobacco use and other substance use history. However, there is always the possibility that if you participate in the study, others, including friends, may become aware of your tobacco use status. If you do not feel comfortable with this, you should not participate in the project.

11) Rating scales and assessments: These are all noninvasive and should add no risk. The major disadvantages are the time taken to complete them, and possible breach of confidentiality. You can choose not to answer any questions that may make you feel uncomfortable.

There may be additional risks related to this study that are not yet known. You will be told of any new findings that may affect your decision to participate in the research.

Benefits

In this study we monitor for the symptoms of EVALI, which is a direct benefit for those who may be at risk for developing this condition. There are no other direct benefits of this study. We expect that the results of the study, however, will benefit science and others through increasing our knowledge of how nicotine in e-cigarette alter smoking behavior.

Treatment Alternatives/Alternatives

This is not a treatment study. If you are currently interested in quitting tobacco product use, we will provide you with a treatment referral and you will not be eligible to participate in this study.

Participant Obligation

You should be aware that as a participant in a research study, you have certain requirements and responsibilities. Your requirements/responsibilities during the study are to:

1. Not use any illegal drugs during your participation in the study.

2. Report all changes in your physical or mental condition during the course of the study to the study staff whether or not they are related to study procedures.

3. If you need to have any emergency medical procedures while you are participating in this study, please let the research staff know immediately.

4. Tell the research staff immediately if you have:
   - A side effect or symptoms, including but not limited to shortness of breath, excessive fatigue, chest pain, fever, fatigue, diarrhea, nausea, vomiting, and/or abdominal pain you did not experience prior to the study;
   - An injury; and/or
   - Any symptom or complaint

If you have questions, an injury or any symptom or complaint, you should contact the Principal Investigator for this study, Dr. Krishnan-Sarin (203)974-7595.

Economic Considerations

There will be no charge to you or your insurance company for study-related procedures or study visits during your participation in this study. You will be compensated up to a total of $530 for completing the study. You will receive $30 for the intake, $20 for collection of biochemical measures, $200 each of the 2 laboratory sessions. After completion of the lab sessions, you will get $50 completion bonus. You will be compensated $10/day for travel to appointments after the initial intake (up to a total of $30), and we will also validate parking in the Air Rights parking garage. We will provide round trip cab/uber transportation to appointments if transportation is an issue. Those who are ineligible for the remote intake will be paid in the form of a $30 gift card of their choosing (such as Amazon, Target, Wal-Mart, Stop and Shop). All other payments are cash. If you must drop out of the study, then you will be paid for the portions that you complete.

You may earn a $10 referral bonus for each friend that you refer to participate in this study. In order to receive this bonus, your friend(s) must complete the intake appointment.

According to the rules of the Internal Revenue Service (IRS), payments that are made to you as a result of your participation in a study may be considered taxable income.

Confidentiality and Privacy

Any identifiable information that is obtained in connection with this study will remain confidential and will be disclosed only with your permission or as required by U.S. or State law. If you tell us that you are planning to hurt yourself or someone else or know of a child or elderly person being abused, we will notify the appropriate authorities. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity unless your specific consent for this activity is obtained.

We understand that information about you obtained in connection with your health is personal, and we are committed to protecting the privacy of that information. If you decide to be in this study, the researcher will get information that identifies you and your personal health information. This may include information that might directly identify you, such as your name and demographic information. This information will be de-identified at the earliest reasonable time after we receive it, meaning we will replace your identifying information with a code that does not directly identify you. The principal investigator will keep a link that identifies you to your coded information, and this link will be kept secure and available only to the PI or selected members of the research team. Any information that can identify you will remain confidential. The research team will only give this coded information to others to carry out this research study. The link to your personal information will be kept for 7 years after the conclusion of the study, after which time the link will be destroyed and the data will become anonymous. The data will be kept in this anonymous form indefinitely.

Who will receive my health information?

Your study information may be shared with the following people or groups:

- The U.S. Department of Health and Human Services (DHHS) agencies
- The funding agency (NIDA).
- The institutional review board at Yale University that approved this study and any other committees responsible for overseeing the research.
- Food and Drug Administration
- Dr. Suchitra Krishnan-Sarin, Ph.D., Principal Investigator, and her research team conducting the study.
- Health care providers who provide services to you in connection with this study.
- Laboratories and other individuals and organizations that analyze your health information in connection with this study, according to the study plan.
- Co-Investigators and other investigators
- Study Coordinator and Members of the Research Team
- Data and Safety Monitoring Boards and others authorized to monitor the conduct of the Study

What information will be collected about you as part of this research?

The information about your health that will be collected in this study includes:

- research study records (interviews, assessments, objective measures of smoking behavior, and self-reports).
- Medical and laboratory records of only those services provided in connection with this study (eg. lab tests)
- A video recording will be made of your e-cigarette use session. This recording will be labeled with an anonymous identifier and not your name.

By signing this form, you authorize the use and/or disclosure of the information described above for this research study. The purpose for the uses and disclosures you are authorizing is to ensure that the information relating to this research is available to all parties who may need it for research purposes.

Will my authorization ever expire?
This authorization does not have an expiration date. The study team may need to correct or provide missing information about you even after your study participation is over. The review of your study health records (described above) may also take place after the study is over.

May I take back my authorization?
You have the right to take back (revoke) your authorization at any time by writing to: Dr. Suchitra Krishnan-Sarin, 34 Park Street, Rm. S-208, New Haven, CT, 06519.

If you revoke your authorization, the study team will not collect any new health information about you and your participation in this study will be discontinued. However, the research team can continue to use information that has already been collected.

Is there anything the research team is legally required to report?
The research team is not legally required to report anything but will disclose any instances of abuse of a child or elderly person, or if you report an intent to harm yourself or others.

We are granted a Certificate of Confidentiality (CoC) from the National Institutes of Health. The CoC is issued to protect the investigators on this study from being forced to tell people that are not connected with this study about your participation in this study, even under a subpoena. The protection offered by the CoC does not stop us from voluntarily reporting information about suspected or known sexual, physical, or other abuse of a child or older person, or a subject's threats of violence to self or others. If any member of the research team is given such information, he or she will make a report to the appropriate authorities. Even when a CoC is in place, you must still continue to actively protect your own privacy. If you voluntarily give your written consent to anyone, or share/discuss with anyone information about your participation in the research, then we may not use the CoC to withhold this information.

If you sign this consent form, you are giving permission for the use and disclosure of your health information for purposes of this research study. You do not have to give this permission. However, if you do not, you will not be able to take part in the study.

All health care providers subject to HIPAA (Health Insurance Portability and Accountability Act) are required to protect the privacy of your information. The research staff at the Yale School of Medicine and the Connecticut Mental Health Center are required to comply with HIPAA and to ensure the confidentiality of your information. Some of the individuals or agencies listed above may not be subject to HIPAA and therefore may not be required to provide the same type of confidentiality protection. They could use or disclose your information in ways not mentioned in this form. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

You have the right to review and copy your health information in your medical record in accordance with institutional medical records policies. However, by deciding to take part in a single or double blinded treatment study and sign this permission form, you will not be allowed to look at or copy your study related information until after the research is completed.

In Case of Injury

If you are injured because of your participation in this study, treatment will be provided. You or your insurance carrier will be expected to pay the costs of this treatment. No additional financial compensation for injury or lost wages is available. You do not give up any of your legal rights by signing this consent form.

Voluntary Participation and Withdrawal

Participating in this study is voluntary. You are free to choose not to take part in this study. Refusing to participate will involve no penalty or loss of benefits to which you are otherwise entitled (such as your health care outside the study, the payment for your health care, and your health care benefits). However, you will not be able to enroll in this research study and will not receive study procedures as a study participant if you do not allow use of your information as part of this study.

Withdrawing from the Study:
If you do become a subject, you are free to stop and withdraw from this study at any time during its course.

To withdraw from the study, you can call a member of the research team at any time and tell them that you no longer want to take part. This will cancel any future appointments.

The researchers may withdraw you from participating in the research if necessary. The study team may decide to take you out of the study without your agreement if:

- You do not follow the directions of the study team.
- The study team decides that the study is not in your best interest.
- You become pregnant, intend to become pregnant or are nursing a child during this study.

Withdrawing from the study will involve no penalty or loss of benefits to which you are otherwise entitled. It will not harm your relationship with your own doctors or with Yale University or the Connecticut Mental Health Center.

When you withdraw from the study, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others until the end of the research study, as necessary to ensure the integrity of the study and/or study oversight.

If you withdraw from the study, biological samples (for example, urine samples) that have been collected from you can be withdrawn if they have not yet been analyzed or destroyed. If you want your samples withdrawn, you must tell the study team before or at the time you leave the study.

Questions

We have used some technical terms in this form. Please feel free to ask about anything you don't understand and to consider this research and the consent form carefully – as long as you feel is necessary – before you decide.

Authorization and permission:

I have read (or someone has read to me) this form and have decided to participate in the project described above. Its general purposes, the particulars of my involvement and possible hazards and inconveniences have been explained to my satisfaction. My signature also indicates that I have received a copy of this consent form.

Name : _____

Signature: _____

Date: _____

_____ _____
Signature of Principal Investigator Date

or

_____ _____
Signature of Person Obtaining Consent Date

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator, Suchitra Krishnan-Sarin, PhD, at (203)974-7595. *If you would like to talk with someone other than the researchers to discuss problems, concerns, and questions you may have concerning this research, or to discuss your rights as a research subject, you may contact the Yale Human Investigation Committee at (203) 785-4688. If after you have signed this form you have any questions about your privacy rights, please contact the Yale Privacy Officer at 203-436-3650.*