UCSF University of California San Francisco
IRB NUMBER: 19-28309
IRB APPROVAL DATE: 06/21/2022
IRB EXPIRATION DATE: 06/20/2023

Name:

DOB:

MRN #:

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

STUDY SUMMARY

Study Title: *"Evaluating the Comparative Pharmacokinetics of Nicotine after administration via JUUL or Tobacco Cigarettes"*

Introduction: We are asking you to consider taking part in a research study being done by the study researchers, Neal Benowitz, MD and Gideon St. Helen, PhD from the University of California, San Francisco Department of Medicine, are conducting this study and the Clinical Research Coordinator (CRC) will explain this study to you.

The first part of this consent form gives you a summary of this study. We will give you more details about the study later in this form. The study team will also explain the study to you and answer any questions you have.

Research studies include only people who choose to take part. It is your choice whether or not you want to take part in this study. Please take your time to make a decision about participating. You can discuss your decision with your family, friends and health care team.

Purpose of the study: This is a research study about better understanding the way the body processes nicotine, produced by vaping the JUUL e-cigarette, compared to smoking tobacco cigarettes, in e-cigarette and tobacco cigarette smokers.

Study Procedures: If you choose to be in this study, we will give you the JUUL e-cigarette device in our research center and tell you how to use it. You will be admitted to the research ward 5B at ZSFG for two Hospital Visit Days. On one of these days you will use the JUUL device and on the other you will use regular tobacco cigarettes. In addition, the main study procedures include a screening visit that entails: questionnaires, a preliminary drug test, applicable pregnancy test, saliva collection, and blood pressure/ heart rate. In addition, your orientation will consist of watching a JUUL training video, trying out JUUL flavors and collection of a urine sample. Conclusively, both Hospital Visit Days will consist of vaping or smoking, blood draws, breath test and questionnaires.

You will be in this study about 2-3 weeks and visit the research site approximately 4 times.

Possible Risks: There are risks to taking part in a research study. Some of the most likely risks of participation in this study include:

• Having a catheter placed in a vein to draw blood and other blood draws

• Blood Loss

• Procedures being inconvenient and tedious

• Feeling uncomfortable, irritable, restless or having difficulty concentrating when not vaping or smoking

• Uncomfortable disclosure of private information in our survey questionnaires

There are also rare but serious risks of participation, like:

• Injury or ill effects from using electronic cigarettes improperly

• Breach of confidentiality

We'll tell you about the other risks later in this consent form.

Possible Benefits:

There will be no direct benefit to you from participating in this study.

Your Other Options: You do not have to participate in this study. Your other choices may include:

• The only alternative is to not take part in this study.

Please talk to your doctor about your choices before agreeing to participate in this study.

Following is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, we will give you a signed copy of this form to keep for future reference.

DETAILED STUDY INFORMATION

This part of the consent form gives you more detailed information about what the study involves.

Research studies include only people who choose to take part. Please take your time to make your decision about participating. You may discuss your decision with your family and friends and with your health care team. If you have any questions, you may ask your study doctor.

You are being asked to take part in this study because you are currently a smoker of tobacco cigarettes and/ or electronic cigarettes.

Why is this study being done?

The purpose of this study is to examine the way the body absorbs, distributes and gets rid of nicotine, when smoking tobacco cigarettes or when vaping the JUUL electronic cigarette.

This study is funded by the National Institutes of Health (NIH).

How many people will take part in this study?

About 30 people will take part in this study.

What will happen if I take part in this research study?

If you agree, the following procedures will occur:

Screening Visit: This will be conducted across two types of visits: one remote visit via Zoom Online Conferencing ("Zoom") and one in-person visit at the UCSF Tobacco Research Center to see if you want to be in the study, and if you are a good match for the study. Before the remote visit, you will review this consent form and a PowerPoint explaining more about the study. We will ask you to sign the consent form via DocuSign before your remote visit. You will then be sent a survey link 24 hours before your scheduled remote visit and asked to complete all surveys & questionnaires beforehand.

At the remote visit, the CRC will first take time to answer any questions about the study.

The following happens at the screening visit:

- **Forms:** You will be asked to fill out forms to provide information about yourself (including age, racial/ethnic background, medical and social history,

use of prescription and over-the counter medications, and the use of nicotine, tobacco, alcohol, and recreational drugs). In addition, there are several forms specifically about your smoking/vaping behavior, history, and dependence on nicotine. You will also be asked to sign another consent form and two HIPAA forms (Permission to Use Personal Health Information for Research). These are needed for the hospital study days.

- **Physical Data**: Your height, weight, heart rate, and blood pressure will be collected.
- **Saliva Sample:** You will be asked to give a saliva sample for a laboratory test to confirm that you are a user of cigarettes and/or e-cigarettes.
    - If our tests of your saliva show that you **are not** a regular user of cigarettes and/or e-cigarettes, **you will not be compensated** for this screening visit.
- **Urine Sample:** A sample of your urine will be collected for:
    - **Drug Testing**
        - If the results are positive for substances other than marijuana or prescribed drugs, you **will not be eligible** to participate in the study. **You will be dismissed without compensation, and your urine will be discarded**. However, if you would like to rescreen for the study at a later time (within 30 days) we will give you the option to schedule another screening visit. Results must be negative at that time for you to receive compensation for the visit and continue in the study if otherwise eligible.
        - If the results are positive for marijuana, you will continue to be evaluated for eligibility.
        - If the results are positive for prescribed drugs, you will continue to be evaluated for eligibility.
        - We will ask you to avoid combusted marijuana up to 48 hours before each study visit. If you are unwilling or unable to do this, you will not be eligible for the study.
        - Any marijuana products used while enrolled in this study should be from licensed retail marijuana shops. If you are unwilling or unable to do this, you will not be eligible for the study.
    - **Pregnancy Testing** (if applicable)
        - If the results are positive for pregnancy, you will not be eligible to participate in the study. You will be compensated for the screening visit and your urine sample will be discarded.
    - **Smoking Status**
        - The urine sample may also be used for a laboratory test to confirm that you are a user of cigarettes and/or e-cigarettes.
        - If our tests show that you are not a regular use of cigarettes and/or e-cigarettes, you will not be compensated for this screening visit.

If the screening exam shows that you are eligible to participate in the study and you choose to continue, this is what will happen next:

Throughout the study: We will keep in touch with you via e-mail and your cell or home phone through calls or texts. Some of the things we may contact you about are visit reminders, clarifications of any medications you are taking, or questions about the products you are using.

Orientation Visit: You will be asked to engage in an online visit with your coordinator via Zoom followed by an in-person "curb-side" style visit. At this remote visit, we will prepare you for the study visit at the hospital research ward. At the "curb-side" visit, you will pick-up your product and drop off a urine sample (you will be provided with a collection cup at your screening visit).

- The CRC will review with you the hospital admission location, procedures and reminders to stop using combusted marijuana 48 hours before the hospital stay and to not smoke from 10PM the night before your hospital admission.
- You will then watch a training video on JUUL.
- You will be choosing between two flavors: menthol or tobacco. You will use this flavor during the hospital admission.
- You will need to collect a urine sample of 150 mL at the end of the Zoom visit in your home.
- You will come to the Tobacco Research Center to conduct a "curb-side" style visit. Here, you will drop off the urine cup and pick up the JUUL with your selected pods for you to try at home before the hospital admission.

Before your study visit

Due to the currently evolving COVID-19 pandemic, we will be asking all participants to comply with COVID-19 protocols as specified by CTSI. This may include participating in a pre-visit RT-PCR COVID-19 test. If a COVID-19 test is required, the test will either be completed at the research center, or you may be responsible for arranging this test on your own. The study team will provide you with all the resources and locations of testing sites to complete this test. This should be done at least 72 hours prior to your study visit to allow enough time for results. If your results are negative, the study will continue as scheduled. If your results are positive, the scheduled study day will be rescheduled. If your results are positive, you will receive a call from the testing agency with further instructions on how to proceed. Current guidelines suggest you will remain in self-quarantine and if your symptoms appear, or worsen, will have to seek the care of a provider. In order to continue with the study, you will be asked to re-test at least 14 days after your first confirmed positive result. If this next re-test result is negative, you will be allowed to continue your participation in the study.

Morning of each Hospital Study Day Visit: Expired CO (or Breath Test)

You will be asked to breathe into a machine to see when you have last smoked. We call this a CO reading. If your CO reading is greater than 5 ppm, you may be dismissed from the study or procedures will be delayed. If you are dismissed from the study, you will not be paid for the visit, but we will give you the option to reschedule your visit. If your CO reading is less than or equal to 5ppm, you will be given a $50 cash bonus per morning admission for each Hospital Study Day Visit.

Hospital Activities Assignment:

You will spend a total of two days participating in smoking activities during your hospital stay. On one day you will use the JUUL device and on the other day tobacco cigarettes. The order in which this vaping or smoking activity will occur will be assigned at your Orientation visit.

Your hospital study visit will be at **the Zuckerberg San Francisco General Hospital** (ZSFG) Clinical Research Center. You will be admitted to the research ward 5B at ZSFG for two Hospital Visit Days. On one of these days you will use the JUUL device and on the other you will use regular tobacco cigarettes.

Hospital Study Visit Procedures (Day 1):

You will be admitted to the hospital research ward the morning of your study visit at approximately 8 AM. You will be in a hospital-approved smoking room with negative pressure and a fan ventilating to the outside.

The below describes procedures if Hospital Study Day 1 assignment was the JUUL e-cigarette.

The following will occur on your study day at the hospital:

You will start your day at **8:00 AM.**

Morning Procedures (8 AM -12 PM)

1. At 8 AM, you will begin study procedures
2. Breakfast will be served at 8:30 AM
3. First morning urine will be taken
4. Expired CO will be measured to ensure the participant did not smoke any tobacco cigarettes
   a. If the expired CO is ≤5ppm, you will receive a $50 cash bonus
   b. If the expired CO is >5ppm, the CRC must notify the PI (or co-I's) immediately. A decision regarding how to proceed will be made by the PI. This may include re-booking you at a later time or delaying all study procedures to allow nicotine levels to return to baseline.
5. At about 9 AM, an intravenous catheter will be placed in the forearm for blood sampling and light breakfast will be served
6. **Baseline questionnaires** will be collected
7. At approximately 9:15 AM, two blood samples will be collected
8. At approximately 9:15 AM, a urine sample will be collected
9. At approximately 9:15 AM, a heart rate and blood pressure will be measured
10. At approximately 9:24 AM, a heart rate and blood pressure will be measured
11. At 9:25:30 AM, you will vape the JUUL e-cigarette following a standard vaping session guide while answering a questionnaire.

12. **Skin blood flow** will be measured by laser Doppler Velocimetry. The probe will be placed on the right foot. Measurements will be taken 10 minutes before the standardized session, 5 minutes after the last puff, and 30 minutes after the last puff.
13. Blood samples will be collected at 9 time points after vaping
14. **Heart rate** will be collected at 12 time points after vaping
15. **Blood pressure** will be collected at 10 time points after vaping
16. Urine sample will be collected at 1 time point after vaping
17. **Questionnaires** will be administered
18. Lunch will be served around 11:30 AM

Afternoon – Evening Procedures (12 PM – 4 PM)

19. At approximately 12:00 PM, a 4 hour free-use session will begin and you will be allowed to use the JUUL as you wish
20. **Questionnaires** will be administered
21. Blood samples will be collected every 30 minutes during free use at 8 time points
22. Urine sample will be collected at 1 time point during free-use session
23. At 4:00 PM you will be discharged from the hospital ward

Hospital Study Visit Procedures (Day 2):

The schedule for the second day will be the same as the first day. However, instead of vaping, you will be smoking tobacco cigarettes, or, if you were assigned to smoke tobacco cigarettes on Hospital Study Day 1, on the second day you will vape a JUUL electronic cigarette.

Hospital Study Day 2 will occur directly after Hospital Study Day 1, however if it is more convenient for you to reschedule to a later time, that is fine as you may complete Hospital Study Day 2 between 2 days to one week from Hospital Study Day 1.

Study locations: The Screening and Orientation visits will take place at the UCSF Tobacco Research Center ([redacted] San Francisco, CA 94110) and the Hospital Study Days will take place at the CTSI-CRS ([redacted]) at Zuckerberg San Francisco General Hospital ([redacted]).

How long will I be in the study?

Participation in the study will consist of a screening visit (45 minutes), orientation visit (~1 hour) and 2 hospital outpatient study visits (~10 hours each: 8am-4:00pm) over the course of **approximately 2-3 weeks**.

Can I stop being in the study?

Yes. You can decide to stop at any time. Just tell any member of the research personnel right away if you are thinking about stopping or wish to stop being in the study.

The Clinical Research Coordinator, Study Physician, or the Principal Investigator may stop you from taking part in this study at any time if he or she believes

- it is in your best interest
- if you do not follow the study rules
- if the study is stopped

In rare cases, people are unable to give blood even if a catheter is placed correctly. If this happens while you are on the study, the Study Physician may stop you from continuing the study. You would be compensated for that study day and withdrawn from the study.

Behavior Policy at the UCSF Tobacco Research Center: We may restrict your time here and withdraw your participation to ensure the health and safety of other research participants, staff, and visitors at our center. This may occur under the following circumstances that include, but are not limited to: inappropriate, abusive or threatening behavior at study visits; violation of smoking, drug, or alcohol policies at visits; excessive number of personal guests; and/or interference with the participation of other study participants.

What side effects or risks can I expect from being in the study?

You may have side effects while on the study. If you develop side-effects, your participation in the study may be stopped, depending on the severity.

You should talk to the Clinical Research Coordinator, your study nurse, or the Study Physician about any side-effects you experience while taking part in the study.

Risk and side-effects related to the study procedures include:

- **Having a catheter placed in a vein to draw blood and other blood draws:** A catheter (small plastic tube) will be placed in a vein in one forearm in order to make it easier to take the multiple blood samples. The catheter will remain in place for about 10 hours. There is a small risk of pain, swelling, bruising, or infection.
- **Blood Loss:** You will give a total of about 2/3 pints of blood (approximately 320 mL) during the study. This amount of blood loss poses no risk to healthy individuals.
- **Procedures** may be inconvenient and tedious (filling out forms, spending time in the hospital, providing specimens, etc.).

- **When you are not vaping or smoking:** you may feel uncomfortable, irritable, restless, or have difficulty concentrating due to possible nicotine withdrawal. This may result in headaches, nausea, fatigue, or changes in mood.
- **Electronic Cigarettes (i.e., e-cigarettes, vaporizers, etc.):** Long-term consequences or effects are uncertain. A 2018 report from the National Academies of Sciences show that use of e-cigarettes could increase dependence on e-cigarettes; increase blood pressure and heart rate, coughing and wheezing; exacerbate asthma symptoms; increase risk of using tobacco cigarettes and exposure to e-cigarette aerosols that can increase risk of cancer and adverse reproductive outcomes. E-cigarette devices can explode and cause burns and projectile injuries. Intentional or accidental exposure to e-liquids (from drinking, eye contact, or skin contact) can result in adverse health effects including, but not limited to seizures, anoxic brain injury, vomiting, and lactic acidosis; intentionally or unintentionally drinking or injecting e-liquids can be fatal. When you are vaping JUUL, if you receive a higher dose of nicotine then you are used to, you may experience feeling dizzy, light-headed, or nauseous. Vaping can also cause a sore or irritated throat.
- There have been recent cases of lung injury from vaping. Most of these cases have occurred while vaping THC, but some may have occurred while vaping nicotine. The exact causes of lung injury in vapers is being investigated by the CDC and other government agencies. The risks of lung damage from vaping branded e-cigarettes, such as JUUL, are thought to be low.
- **Survey Questionnaires:** You will be asked to answer personal and private questions during this study, including about your medical history, drug and alcohol use, breath sample measurements, urine tests of drug use and pregnancy, and questionnaires about your mood. Answering these personal questions could make you feel uncomfortable. The only risk of this interview is your loss of privacy if other people find out about your results. All efforts are made to keep your information confidential, but confidentiality is not absolute.

For more information about risks and side effects, ask one of the researchers.

Are there benefits to taking part in the study?

There will be no direct benefit to you from participating in this study. However, the information that you provide will contribute to novel data that may help health professionals better understand the health consequences of e-cigarette use.

What other choices do I have if I do not take part in this study?

You are free to choose not to participate in the study. If you decide not to take part in this study, there will be no penalty to you. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

How will my specimens and information be used?

Researchers will use your specimens and information to conduct this study. Once the study is done using your specimens and information, we may share them with other researchers so they can use them for other studies in the future. We will not share your name or any other personal information that would let the researchers know who you are. We will not ask you for additional permission to share this de-identified information.

Research results: There may be times when researchers using your information *and/or specimens* may learn new information. The researchers may or may not share these results with you, depending on a number of factors.

Will information about me be kept private?

We will do our best to make sure that the personal information gathered for this study is kept private. However, we cannot guarantee total privacy. **Your personal information may be given out if required by law.** If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of the National Institutes of Health
- Representatives of the University of California
- Representatives of the Food and Drug Administration (FDA)

Participation in research may involve a loss of privacy, but information about you will be handled as confidentially as possible. A medical record will be created because of your participation in this study. Your consent form and some of your research test results will be included in this record. Therefore, your other health care providers may see your test results and become aware of your participation. Hospital regulations require that all health care providers treat information in medical records confidentially.

Two kinds of "charts" are created when you take part in one of our studies:

1. A medical record at *Zuckerberg San Francisco General Hospital* will be created because of your participation in this study. Your consent form, hospital nursing forms, and some of your hospital laboratory test results will be included in this record. Therefore, other health care providers may see your test results and become aware of your participation. Hospital regulations require that all health care providers treat information in medical records confidentially. The forms you fill out during your screening visit, many of the forms filled out during the study and the results of assays on the biological specimens collected on the study will not become part of your hospital records.

2. We make a "research chart" specifically to hold the forms and sample testing results that do not appear in the ZSFG medical record. You will be given a unique study identification number that will be used in this research chart and on your study samples. This number is different from your medical record number. While the study is in process, we keep some identifying information in this chart so that we are able to contact you, process payments, etc. Once the study is completed, identifying information is removed from the chart and stored separately where it is only available to research personnel who need access to it. Charts and samples are always kept in locked rooms. We keep the link between your identity and your study number and your samples (if you allow us to keep them) for several reasons. We may want to contact you (with your agreement) to see if you want to participate in additional studies. We also need to keep track of when a subject participates in more than one study so that certain tests are not repeated. Or you may want to contact us later on to ask that your samples be destroyed, and we cannot do this unless we know the link to your research study number.

Certificate of Confidentiality
This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Are there any costs to me for taking part in this study?

No. The sponsor has agreed to pay for all items associated with this research study; you or your insurer will not be billed.

Will I be paid for taking part in this study?

You will be paid $30 for today's screening visit, however you **MAY NOT RECEIVE payment for this visit if:**

- You ARE NOT interested in consenting, screening for this visit, or completing the study
- If there are discrepancies between your email/phone screen responses and your responses today
- If our tests show that you ARE NOT a regular smoker of tobacco cigarettes

In return, for your time and effort in study participation, you will be compensated a total of $850 if all parts of the study are completed. This includes the following:

- Screening Visit: $30 (via check)
- RT-PCR COVID-19 test prior to the hospital study days and returning the results to the study team (if required by CTSI): $20 (via check)
    - If repeat testing is needed for the study, you will be compensated again
- Day 1 Hospital Study Visit: $300 (via check)
    - $50 for expired CO ≤5ppm (via cash)
- Day 2 Hospital Study Visit: $300 (via check)
    - $50 for expired CO ≤5ppm (via cash)
- Bonus for completion of study: $100 (via cash)
    - Complying with study procedures and its entirety.

How do I get the study bonus?

You will be eligible for the study bonus if you complete all parts of the study including all study visits, and returning all products.

Your compensation for this study will be in the form of a check sent to your home address, except for your study bonus, which you will receive in cash. If you complete all portions of the study, **you will receive either 1 or 2 checks** (If one check, it will be a bundle of $30 for the screening visit and either $300 or $600 depending upon whether you completed one or both hospital days. If two checks, you will receive one for **$30 screening visit**, and one for either **$300 or $600** depending upon whether you completed one or both hospital days.) the number of checks received will be up to CRC discretion. If a COVID-19 test is required per CTSI protocol, an additional $20 will be added to the checks.

If your CO reading is less than our equal to 5ppm, you will be given **$50 cash** bonus for each hospital study visit.
Your study bonus you will receive as **$100 cash** if you complete all parts of the study.

A check will be mailed to you after completion of applicable portions of the study and it may take up to 4-6 weeks for you to receive your check

You will need to provide your home address and social security number for reporting purposes and to receive payment. If your *payment checks are not received by the end of 6 weeks* from the last day of your study visit for that portion of the study, please contact *the Clinical Research Coordinator*.

What happens if I am injured because I took part in this study?

It is important that you tell the study personnel if you become sick or injured. You may

directly tell the Clinical Research Coordinator, the Study Physician/ Principal Investigator (Neal Benowitz, MD at [redacted]) or the Principal Investigator (Gideon St. Helen, PhD [redacted]) if you feel that you have been injured because of taking part in this study.

> **Treatment and Compensation for Injury:** If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California, depending on a number of factors. The University does not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Institutional Review Board at 415- 476-1814.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you in any way. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.
In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the study?

You can talk to the Clinical Research Coordinator, the Study Physician/ Principal Investigator (Neal Benowitz, MD [redacted]), or the Principal Investigator (Gideon St. Helen, PhD [redacted]) about any questions, concerns, or complaints you have about this study. *If your payment check is not received by the end of 6 weeks from the last day of your study, please contact the Clinical Research Coordinator.*

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Institutional Review Board at 415-476-1814.

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.

Re-contact for Future Studies: The researchers in the Division of Clinical Pharmacology and Experimental Therapeutics at UCSF would like to know if you are

interested in participating in future studies for which you may be eligible. By initialing this section of the form, you are giving them permission to keep a file of your information (name, contact information, date of birth, laboratory results, and completed questionnaires) and to re-contact you. You will be under no obligation to actually participate in any new study, and whether or not you initial this section will have no effect on your participation in the current study. You may withdraw permission to be re-contacted at any time by calling the research coordinator or emailing research staff at tobaccocoord@ucsf.edu.

_____I agree to allow the researchers in the Division of Clinical Pharmacology and Experimental Therapeutics at UCSF to keep my information on file as described above so that I may be re-contacted for possible participation in future nicotine and/or smoking related studies for which I may be eligible.

Optional Storage for Future Research: Your agreement to allow your leftover blood and urine samples to be used in any future research is voluntary, and if you choose not to participate it will in no way affect your participation in the current study. These samples may be used for other research not related to this study. These samples will be retained in non-identifiable form, meaning that there will be no information associated with the blood or urine samples that will allow anyone to know your identity. The samples will be stored at the Tobacco Biomarker Laboratory at ZSFG and they will be kept until they are used up or no longer needed. Only UCSF researchers or other academic institutions working in collaboration with the study investigators will be allowed access to the samples and data. The samples may be used in the development of tests, products, or discoveries that may have potential commercial value, you will not share in any financial benefits. You may at any time ask to have your samples withdrawn from research use by emailing research staff at [redacted] and any identifiable samples and associated data still in their possession will be destroyed. Please indicate whether you are willing to allow your samples to be saved and used for future research by initialing one of the lines below:

_____**Yes,** The researchers may keep my blood and urine samples for future related research.

_____**No,** I do not want my blood and urine samples used for any research tests other than those needed for the current study.

Video Taped Vaping Sessions

This study involves the video recording of vaping sessions at the hospital. Neither your name nor any other identifying information will be associated with the video or video recording, other than your image. The data from the recordings will be coded and then destroyed. The recordings will be used for research purposes only, and only the research team will be able to view to the recordings. By initialing this section of the form, you are giving them permission to record you as part of this research, please initial below.

_____I agree to allow the researchers in the Division of Clinical Pharmacology and Experimental Therapeutics at UCSF to record vaping sessions during the hospital visit.

CONSENT

You have been given a copy of this consent form and the Experimental Subject's Bill of Rights to keep. You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to be in this study, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

_____	_____
Date	Participant's Signature for Consent
_____	_____
Date	Person Obtaining Consent