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Tobacco  
Research Center



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# **Cigarette Harm Reduction with Electronic Cigarette Use**

UCSF IRB #: 17-23142

Clinical Trials.gov #: NCT03473483

November 30, 2018

NAME:  
DOB:  
MRN#:

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

**Study Title:** “*Cigarette Harm Reduction with Electronic Cigarette Use*”

This is a research study about *nicotine exposure and safety of electronic cigarettes*. The study researcher, **Dr. Neal Benowitz, MD** from the University of California, San Francisco Department of Medicine, is conducting this study and the Clinical Research Coordinator will explain this study to you.

Research studies include only people who choose to take part. Please take your time to make your decision about participating, and discuss your decision with your family or friends if you wish. If you have any questions, you may ask the researchers.

You are being asked to take part in this study because you are a healthy smoker who smokes at least 10 cigarettes every day and has had experience using an electronic cigarette (e-cigarette) device.

**Why is this study being done?**

The purpose of this study is to learn more about nicotine exposure and safety of e-cigarettes, assessing key pharmacological factors associated with the potential addictiveness and health effects of these products.

Standardized Research E-Cigarettes (SREC), provided by the National Institutes of Health, will be used in this study and are considered experimental by the Food and Drug Administration and cannot be used outside of research studies.

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

**How many people will take part in this study?**

About 20 people will take part in this study at UCSF.

**What is the SREC E-cigarette?**

The Standardized Research E-Cigarette, or SREC, was developed by the National Institute of Drug Abuse (part of the NIH) to help researchers assess uncertainties in electronic nicotine delivery devices. You will be provided a handout that describes the SREC device, including its tank and battery characteristics, description of its use, and the composition of the e-liquid ingredients. The SREC devices are considered experimental by the Food and Drug Administration and cannot be used outside of research studies. The SREC device is currently only available in non-menthol, tobacco flavor, so you must be willing to use this flavor for the duration of the study.

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

If you agree, the following procedures will occur:

**Screening Visit:** This is an approximately 2 hour screening visit to see if you want to be in the study, and to see if you meet the qualifications to be in the study. You will first read this consent and ask any questions you wish. After reading the consent, you must sign it to continue the screening visit in order to be considered for participation in the study.

The following happens at this 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 tobacco, alcohol, caffeine, and recreational drugs). In addition, there are several forms specifically about your smoking behavior, history, and dependence on nicotine.
- **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 laboratory tests to confirm that you are a smoker.
- **Expired Carbon Monoxide (Expired CO):** You will be asked to breathe into a machine that records how much carbon monoxide is present in your lungs, in order to confirm your smoking status. If the testing indicates that you are not a smoker, you will be considered ineligible and dismissed without payment.
- **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 may be continued to be evaluated for eligibility.
    - If the results are positive for prescribed drugs, you may be continued to be evaluated for eligibility.
  - **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 will be discarded.

If the screening exam shows that you can be in the main part of the study and you choose to continue, this is what will happen next:

**Orientation Visit:** Once your smoking status is confirmed from the screening visit saliva sample, if eligible, you will be asked to come back to the UCSF Tobacco Research Center for an Orientation Visit.

At this visit, we will prepare you for **Study Week #1**.

- We will ask you **not to use any marijuana or other recreational drugs from today until the study is completed.**
- A computer generated program will assign you to start Week 1 in one of three possible groups; **e-cigarette only, tobacco cigarette only, or both e-cigarettes and tobacco cigarettes.**
- We will purchase your normally used tobacco cigarette products and/or provide you with the Standardized Research E-Cigarettes (SREC e-cig).
- You will use whichever product you are assigned for 4 days at home (aka: outpatient days) before you are admitted to the research ward.
- You will be given a study diary (smartphone app or paper) to track your product use (e.g., volume of e-liquid used and tobacco cigarettes smoked per day) and will record each evening an assessment of urges to smoke and nicotine withdrawal symptoms experienced throughout the day. You will also be asked to return all electronic cigarette products and tobacco cigarette butts so that we may assess the amount of nicotine consumed and tobacco burned.
- **Urine Collection:** A sample of your urine will be collected and tested for **nicotine breakdown by-products.**

### **Study Weeks 1, 2 & 3 Outpatient (aka: at home) Procedures:**

You will be able to use either your **e-cigarette only, tobacco cigarette only, or both e-cigarettes and tobacco cigarettes** as you wish (aka: ad lib) for **4 days** (Thursday-Sunday night).

- During your e-cigarette outpatient days, you will be given only the SREC e-cig device & cartridges.
- During your tobacco cigarette outpatient days, you will be given only your usual amount of tobacco cigarettes.
- During your dual use outpatient days, you will be given less than your usual amount of tobacco cigarettes plus the SREC e-cig device & cartridges.

We will ask that you use **only** the provided product(s) during these outpatient days and that you keep track of your product usage with the study diary given to you at Orientation. **You will be asked to abstain from smoking and vaping the night before your admission to the hospital, starting at 10:00pm.** You must complete your diaries and send to the study coordinator via text or email at the end of each outpatient day.

All inpatient, hospital study procedures will follow the 4 outpatient days, starting on Monday morning and ending Thursday morning. You may begin on any of the three groups: e-cigarette only, tobacco cigarette only, or both e-cigarettes and tobacco cigarettes.

**Inpatient Study Week SREC E-Cig (3 days):** You will be admitted to the ZSFG Clinical & Translational Science Institute (CTSI) clinical research site (CRS) as an inpatient for **3 24-hour days**.

During the admission, you will have a **pregnancy test (if female), medical history and physical examination** conducted by the Study Physician or a Nurse Practitioner. This is required for all hospital admissions and *these documents will become part of your permanent ZSFG medical record*. If you wish, the results of your physical examination will be shared with you by the health care provider.

On **Hospital Day 1** (Monday), the following will occur:

- You will be asked to arrive at the research ward at **7am** to begin your inpatient study days. You will be given a light breakfast and, if you normally drink caffeinated beverages, you will be allowed a cup of your usual beverage (e.g., coffee or tea).
- We will test your Expired CO again (the same test done at Screening visit) and a urine sample will be collected to make sure you were only using the products assigned to you and that you have abstained from smoking and vaping since 10pm last night.
- At approximately 8am, a plastic catheter (thin flexible tube) will be inserted into a vein on one of your forearms (this will be used to withdraw multiple blood samples and will be kept in place for about 10 hours).
- At approximately 9:00am, you will be asked to vape the SREC device in a standardized manner and to take puffs only at times signaled by the voice recorder.
- You will not be allowed to vape again until 4 hours later, at which time you will be given the SREC e-cig device and allowed to vape it in your usual way.
- Blood samples, about one-two teaspoons each, will be withdrawn just before vaping, and during the 4-hour abstinence period at 2, 5, 15, 30, 45, 60, 90, 120, 180, and 240 minutes after vaping.
- Heart rate will be collected at baseline, 5, 10, 15, 30, 45, 60, 90, 120, 180, and 240 minutes after vaping.
- You will be asked to fill out several *Questionnaires* about your vaping experience before and after using the product and during the 4 hours when you are not vaping.

On **Hospital Day 2** (Tuesday), the following will occur:

- You will be able to vape the SREC e-cig device as you wish from 8am to 12am midnight.
- The time of each SREC puff will be recorded using your smartphone diary application or paper log and SREC devices will be collected at the end of the day to determine product usage.
- You will wear a 24-hour ambulatory blood pressure and heart rate recorder for *cardiovascular monitoring* which will take a reading approximately every 30 minutes.
- You will be asked to fill out several *Questionnaires*.
- At 3pm we will ask you to stop vaping for 15 minutes, and we will collect a *saliva sample* (about half-1 teaspoon) at 3:15pm.

- There will also be 24-hour *urine collections*.

On **Hospital Day 3** (Wednesday), the following will occur:

- In the morning, an intravenous catheter (same as Day #1) will be placed for blood collections every four hours from 8am to midnight, and at 8am the next day (Thursday).
- You will continue to be able to vape the SREC e-cig device as you wish.
- The time of each SREC puff will be recorded using your smartphone diary application or paper log and all SREC devices will be collected at the end of the day to determine product usage.
- You will be asked to fill out several *Questionnaires*.
- There will also be 24-hour *urine collections*.

You will be discharged from the hospital at approximately 9-10am Thursday morning.

#### **Inpatient Study Week Tobacco Cigarettes (3 days):**

This week will follow the same structure as the SREC week mentioned above, but instead you will be using your usual tobacco cigarettes. The following differences will occur:

- The morning of **Hospital Day 1**, you will be asked to smoke your tobacco cigarette in a standardized manner: 1 puff every 30 seconds until cigarette is complete.
- You will be given your usual amount of tobacco cigarettes for the remaining hospital days.
- You will complete your diary data for your tobacco cigarette use.
- You will collect all of your cigarette butts.

#### **Inpatient Study Week Both SREC & Tobacco Cigarettes (3 days):**

This week will be the same structure as the SREC only & Tobacco Cigarette only weeks, except for the following differences:

On **Hospital Days 1, 2 & 3 (Monday, Tuesday & Wednesday)**, the following will occur:

- At approximately 8am, you will be asked to smoke your first tobacco cigarette.
- You will be asked to smoke again at regular intervals throughout the day.
- You will be given less than of your normal tobacco cigarette amount.
- You will be given the SREC device to vape ad lib.
- The time of each cigarette or SREC puff will be recorded using your smartphone diary application or paper log and all cigarette butts and SREC devices will be collected at the end of the day to determine product usage.

**Study Schedule:** The order of weeks will be rotated across participants.

Study Week: SREC E-Cig Only						
Day 1	Day 2	Day 3	Day 4	Day 5 Hospital Day 1	Day 6 Hospital Day 2	Day 7 Hospital Day 3
Thurs	Fri	Sat	Sun	MONDAY	TUESDAY	WEDNESDAY
< ----- At Home ----- >				< ----- Hospital ----- >		

<b>SREC E-cig use only</b>  <b>Daily Diaries</b>  <b>Emailing or texting Diaries to the Study Coordinator end of day</b>	<b>Expired CO test and urine sample</b>  <b>Standardized Vaping Session</b>  <b>4-hr abstinence and blood draws</b>  <b>Followed by free use ad lib</b>	<b>Vaping ad lib</b>  <b>24-hr BP/HR monitoring</b>  <b>Saliva collection</b>  <b>24-hr urine collection</b>	<b>Vaping ad lib</b>  <b>Blood draws throughout 24-hours</b>  <b>24-hr urine collection</b>  <b><u>Discharge:</u> Thursday morning after final blood draw</b>
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Study Week: Tobacco Cigarette Only						
Day 1	Day 2	Day 3	Day 4	Day 5 Hospital Day 1	Day 6 Hospital Day 2	Day 7 Hospital Day 3
Thurs	Fri	Sat	Sun	MONDAY	TUESDAY	WEDNESDAY
< ----- At Home ----- >				< ----- Hospital ----- >		
<b>Tobacco Cigarette use only</b>  <b>Daily Diary</b>  <b>Emailing or texting Diaries to the Study Coordinator end of day</b>				<b>Expired CO test and urine sample</b>  <b>Standardized Smoking Session</b>  <b>4-hr abstinence and blood draws</b>  <b>Followed by Free use ad lib</b>	<b>Smoking ad lib</b>  <b>24-hr BP/HR monitoring</b>  <b>Saliva collection</b>  <b>24-hr urine collection</b>	<b>Smoking ad lib</b>  <b>Blood draws throughout 24-hours</b>  <b>24-hr urine collection</b>  <b><u>Discharge:</u> Thursday morning after final blood draw</b>

Study Week: Both SREC E-cig & Tobacco Cigarettes						
Day 1	Day 2	Day 3	Day 4	Day 5 Hospital Day 1	Day 6 Hospital Day 2	Day 7 Hospital Day 3
Thurs	Fri	Sat	Sun	MONDAY	TUESDAY	WEDNESDAY
< ----- At Home ----- >				< ----- Hospital ----- >		
<b>Tobacco Cigarette Use (<i>less than your normal amount</i>)</b>  <b>&amp;</b>  <b>SREC use ad lib</b>  <b>Daily Diary</b>  <b>Emailing or texting Diaries to the Study Coordinator end of day</b>				<b>Expired CO test and urine sample</b>  <b>Tobacco Cigarette Use (<i>less than your normal amount</i>)</b>  <b>&amp; SREC use ad lib</b>	<b>Tobacco Cigarette Use (<i>less than your normal amount</i>) &amp; SREC use ad lib</b>  <b>Saliva collection</b>  <b>24-hr CV monitoring</b>  <b>24-hr urine collection</b>	<b>Tobacco Cigarette Use (<i>less than your normal amount</i>) &amp; SREC use ad lib</b>  <b>Blood draws throughout 24-hours</b>  <b>24-hr urine collection</b>  <b><u>Discharge:</u> Thursday morning after final blood draw</b>

**Study locations:** The Screening and Orientation Visits will take place at the UCSF Tobacco Research Center (3130 20<sup>th</sup> Street, Suite 308) and the Inpatient Study Days will take place at the CTSI-CRS (5B Research Ward) at Zuckerberg San Francisco General Hospital (1001 Potrero Avenue, 5<sup>th</sup> floor).

## **How long will I be in the study?**

Participation in the study will consist of a screening visit (1-2 hours), Orientation visit (1-2 hours), 12 outpatient days, 9 inpatient days for a total of **23 days**.

## **Throughout the study**

We will keep in touch with you via 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. You will also use email and text to send us your diaries to review.

## **Can I stop being in the study?**

Yes. You can decide to stop at any time. Tell the Clinical Research Coordinator, your CTSI-CRS nurse, or the Study Physician or Nurse Practitioner if you are thinking about stopping or decided to stop.

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/Nurse Practitioner may stop you from continuing the study. In this case, you would be compensated for that study day and withdrawn from the rest of the study.

The Clinical Research Coordinator, Study Physician or 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

***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 upon the severity.

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

Risks and side effects related to the study procedures include:



- **Venipuncture and Catheterization:** 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 lose a total of about 1 cup of blood during the entire study. This amount of blood loss poses no risk to healthy individuals.
- The **Study Procedures** may be inconvenient and tedious (filling out forms, spending time in the hospital, providing specimens, etc.) and you may have trouble staying awake as required.
- During **abstinence**, you may feel withdrawal symptoms from smoking/nicotine withdrawal. The symptoms can be uncomfortable but are typically of minimal risk. These symptoms can include anger, irritability, frustration, anxiousness, nervousness, depressed mood/sadness, craving for a cigarette, difficulty concentrating, increased appetite or hunger, weight gain, sleep problems, restlessness, difficulty concentrating, impatience, constipation, dizziness, coughing, dreaming or nightmares, headaches, nausea, and sore throat.
- You may also feel uncomfortable when getting your **blood pressure** taken depending on the tightness of the cuff.
- **Risks of Electronic Cigarette Use:** The health effects of e-cigarettes are not known. While not harmless, e-cigarettes generally exposes users to fewer toxins than smoked tobacco products. A notice from the FDA about the safety of this product says they do not know whether e-cigarettes are safe for their intended use, how much nicotine or other potentially harmful chemicals are being inhaled during use, or if there are any benefits associated with using these products. Side effects may include: sore throat, burning in the throat, dizziness, headache, coughing, change in taste and others. Although uncommon, batteries in e-cigarettes have exploded and injured users or overheat and cause burns. Defective cartridges, tanks or devices may leak e-liquid. If this should happen, wash the exposed area to remove the e-liquid immediately. On rare occasions, allergic reactions have occurred. Let us know if you have allergies to propylene glycol or glycerin or any foods. The liquid in e-cigs (often called e-liquid or e-juice) can contain nicotine that can cause harm and possible death if the e-liquid or the refill cartridges containing e-liquid are swallowed. Keep all e-liquid and cartridges away from children and pets.

### **Are there benefits to taking part in the study?**

There will be no direct benefit to you from participating in this study. However you may benefit from the knowledge that you are contributing in a very important way to further scientific knowledge concerning harm reduction and health risks for tobacco and e-cigarette users.

### **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.

## **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.

Organizations that may look at and/or copy your research records for research, quality assurance, and data analysis include: Representatives of the University of California, the Study Sponsor (National Institutes of Health), and 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. Two kinds of “charts” are created when you take part in one of our studies:

1. A medical record at the 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, the generic testing results, 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 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.

## **Will any research-related procedures be billed to me?**

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

## Will I be paid for taking part in this study?

In return for your time and effort, you could be compensated up to a total of \$2,500 if all parts of the study are completed. This includes the following:

- Screening Visit: \$20
- Study Week #1 (4 days Outpatient, 3 days Inpatient): \$620
  - Abstaining from smoking & vaping: \$40
- Study Week #2 (4 days Outpatient, 3 days Inpatient): \$620
  - Abstaining from smoking & vaping: \$40
- Study Week #3 (4 days Outpatient, 3 days Inpatient): \$620
  - Abstaining from smoking & vaping: \$40
- Bonus for Completion of Study: \$500

You will be compensated \$20 for today's Screening Visit as long as your drug test is negative (marijuana is okay) and the saliva lab results indicate that you are a regular user of the tobacco and the e-cigarette products you reported.

You will be compensated \$40 for abstaining from smoking & vaping before each hospital admission. You will need to stop smoking & vaping at 10pm Sunday night. We test this with a carbon monoxide reading Monday morning, and your levels must be below 8ppm.

**If our tests show that you have not abstained, you will not receive the \$40. Additionally, all study procedures will be delayed while we wait for your levels to decrease.**

Below is your schedule for compensation. If you complete the entire study & you receive the study bonus, you will receive 4 checks and the money for abstaining from smoking & vaping in cash.

### **Schedule for Compensation**

<b><u>Visit</u></b>	<b><u>Amount</u></b>	<b><u>Processing</u></b>
Screening	\$20	#1 Check (processed after visit)
Study Week 1, Abstaining	\$40	Cash
Study Week 1, 7-days	\$620	#2 Check (processed after discharge)
Study Week 2, Abstaining	\$40	Cash
Study Week 2, 7-days	\$620	#3 Check (processed after discharge)
Study Week 3, Abstaining	\$40	Cash
Study Week 3, 7-days	\$620	#4 Check (processed after discharge)
Study Bonus	\$500	With #4 Check in mail

Checks will be mailed to you via the schedule above 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** 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 *Ms. Patricia Winston* at 415-206-8326.

You should be aware that the income you receive from being in the study may need to be reported to the IRS on your income tax return. If you receive more than \$600 in a calendar year, the income will be reported to the IRS and an IRS Form 1099 will be sent to you.

### **How do I get the study bonus?**

You will receive the study bonus if you complete all parts of the study, both outpatient (at home) procedures and the inpatient hospital stay, **and** you use only the assigned products we give you. This includes following all study rules, accurately keeping track of your study products, completing your diaries, providing all samples & measurements, and attending all of your visits. ***If you are having difficulty completing any of the study activities, let your Clinical Research Coordinator know right away, so our team can help you.*** We will collect a urine sample from you at each hospital admission and will test it to make sure during your at-home study days that you **only** used the products we gave you.

### **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 your Study Nurse Practitioner, Ralf Burgert (415-206-8902) or the Principal Investigator, Neal Benowitz, MD (at 415-206-8324) 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 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 and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get medical care from our institution.

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, Lisa Harms, 415-608-4864) the Project Manager (Natalie Nardone, PhD at 415-514-1450), the Study Nurse Practitioner, Ralf Burgert

(415-206-8902) or the Principal Investigator (Neal Benowitz, MD at 415-206-8324) about questions or concerns you have about this study.

**For questions about your rights while taking part in this study**, you may call the Office of the Institutional Review Board (a group of people who review the research to protect your rights) at **415-476-1814**.

A description of this clinical trial will be available on <http://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 website at any time.

***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](mailto: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 smoking related studies for which I may be eligible.

**Specimen storage:** 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 [tobaccocoord@ucsf.edu](mailto:tobaccocoord@ucsf.edu), 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 main research study.

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## CONSENT

You have been given a copy of this consent form and the Experimental Subject's Bill of Rights to keep.

**PARTICIPATION IN RESEARCH IS VOLUNTARY.** You have the right to decline to participate or to withdraw from the study at any time without penalty or loss of benefits to which you are otherwise entitled. If you are a student or employee of the University, refusal or withdrawal will not affect your grades or employment status. You may be withdrawn from the study without your consent if the researchers believe that it is in your best interest or if you fail to follow study procedures (for instance, failure to keep appointments or to provide specimens).

If you wish to participate in this study, you should sign below. In addition, you will be asked to sign a separate form authorizing access, use, creation or disclosure of health information from you.

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