IRB Protocol# 2000031495
NCT05257109

COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH STUDY

YALE UNIVERSITY
YALE UNIVERSITY SCHOOL OF MEDICINE

Study Title: Examining the Effect of Varying Water Content of E-liquids on Sensory Experience

Principal Investigator (the person who is responsible for this research):

Danielle Davis, PhD
Rm S-21434 Park Street
New Haven, CT 06511
Phone Number: **203-974-7607**

Research Study Summary:

- We are asking you to join a research study.
- We plan to enroll 30 people in this research study.
- The purpose of this research study is to investigate if adding water to certain nicotine containing e-cigarette flavors that contain flavor chemicals called aldehydes reduce how irritating inhaling the e-cigarette vapor feels and if adding water makes the experience of vaping less enjoyable. We plan to examine this by having e-cigarette users vape flavors that do and do not contain flavor chemicals called aldehydes with and without different levels of water added to the e-liquid.
- Study procedures will include an intake visit to determine if you are eligible and two lab sessions. At each lab session, we will ask participants to sample two flavors when they have no water added and when they have three different amounts of water added. Participants will take two puffs of each water/flavor combination.
- There is an intake appointment to determine if you are eligible. That can be completed in two parts (remotely or in person) or in one part (fully in person). The full intake appointment will take approximately two hours. If eligible, participants will take part in two lab sessions that take two hours each.
- In total, the study will take participants 6 hours to complete.
- There are some risks from participating in this study. The risks include the risk of vaping an e-cigarette, being exposed to nicotine and flavors in an e-cigarette, being exposed to e-cigarettes with different water concentrations, keeping study data confidential, collecting urine samples, and completing rating scales and assessments. We will describe these risks in detail in this consent.
- The study may have no benefits to you. If you vape THC/CBD, this study may benefit you, as we monitor your health as a part of this study.
- 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.

APPROVED BY THE YALE UNIVERSITY IRB 6/12/2022

Why is this study being offered to me?
We are asking you to take part in a research study because you are at least 21 years old, report being a regular e-cigarette user who uses e-cigarettes that contain both nicotine and flavoring. We are looking for 30 participants to be part of this research study.

Who is paying for the study?
This study is funded by the National Institute of Health's National Institute of Drug Abuse (NIDA).

What is the study about?
The purpose of this study is to investigate if adding water to certain nicotine containing e-cigarette flavors that contain flavor chemicals called aldehydes reduce how irritating inhaling the e-cigarette vapor feels and if adding water makes the experience of vaping less enjoyable. We also want to assess if adding water to e-cigarettes without aldehyde flavor chemicals has any effect on the e-cigarette user experience (for example, the irritation and appeal). If adding water to e-cigarettes reduces irritation without lowering appeal, this may be an action for agencies who make laws, like the FDA, to take to make e-cigarettes safer.

What are you asking me to do and how long will it take?
If you agree to take part in this study, you will be asked to participate in the following visits:

- **COVID-19 related 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. All study participants must be fully vaccinated against 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.** This is an appointment to confirm if you are eligible for this study. For the health and safety of everyone, you will have the option to complete much of this visit via videoconference. If you do not have the technology available to complete this visit via videoconference, you can complete this visit in person. During this appointment, you will provide personal information, including your medical history and other health information and your history and current use of nicotine and tobacco products. We will collect this information by filling out questionnaires via a website and by a member of our

research team asking you questions. If on videoconference, the researcher will be with you for the entirety of this collection period.

Once this portion of the intake is completed, if completing via videoconference, you will be asked to come in to our research site at the Connecticut Mental Health Center (34 Park Street) for a short visit (10-15 minutes), in which we will collect a breath carbon monoxide (CO) sample, a saliva sample to detect nicotine/cotinine, and 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. Nicotine intake during pregnancy may be associated with increased risk for spontaneous abortion, increased perinatal mortality and with low infant birth weights. Pregnant females will not be allowed to participate. If you test positive for any drugs aside from marijuana, 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, heart rate, spirometry (a measure of lung function), and 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 all in person appointments, we ask that you do not bring any weapons to 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.

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.

- **Lab Sessions (2 Total).** If you are a female, we will use a urine sample to administer a pregnancy test at intake (baseline) and prior to each vaping session. 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 J.B. Pierce Laboratory at 290 Congress Ave in New Haven, CT. There will be at least 24 hours between lab sessions. Lab sessions will last for approximately two hours. We will try complete both lab sessions in the same week.

  During the first lab session, you will spend 10-15 minutes to familiarize yourself 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. During this practice, an e-cigarette without nicotine or any flavors will be used.

  We will ask that you do not use any nicotine or tobacco products two hours before your sessions. For your safety, all lab sessions take place in a private environmentally controlled room that utilizes continuous floor-to-ceiling airflow to limit exposure. The rooms have plexiglass dividers to adhere to social distancing guidelines when in-person interactions are necessary. Other times, instructions and communication will occur remotely using a 2-way audio system. Hand sanitizer will be available, and you will be asked to wear a mask when possible during the session and gloves for the duration of the lab session.

During each lab session, you will sample a total of 2 flavored e-liquids. Each flavor will be presented four different times; once with no adjustments made to the e-liquid flavor and three times with different amounts of water added. All flavors will contain a moderate amount of nicotine, similar to what is commonly available in commercial cigarettes.

For each flavor you sample we will ask you to take two directed puffs. For each puff we will ask you to inhale for 3 seconds and wait 30-seconds before taking the next puff. After taking the two puffs, you will complete a few questionnaires asking about your experience with the e-cigarette. The questionnaires will ask you about how the e-cigarette tasted, if you liked it, if it felt irritating in your chest/throat, and other sensory experiences. You will wait 10 minutes and then take the next set of two puffs. At each lab session you will take 16 e-cigarette puffs total.

The e-cigarette will be provided to you each session and sanitized between lab sessions. Only you will be using the e-cigarette you are given. If you feel any uncomfortable side effects during lab sessions (e.g., nausea, vomiting), you will be told that you can discontinue the puffing bout at any time. Additionally, we will collect blood pressure, spirometry (a measure of lung function), and heart rate. We well also collect pulse oximetry. We will also measure any changes any health at the beginning of each lab session. Each lab session will take approximately two hours total.

At the end of the second lab session, we will ask you about all the flavors you have tried and give you some information on quitting tobacco products. We will not tell you which flavors you tried, the amount of nicotine in the e-cigarettes, or the amounts of water that were added. This is because we do not want your knowledge of the flavors, nicotine, or water level to influence your response or others' responses on questionnaires. If you are interested in learning what flavors were sampled and how much water and nicotine was in your e-cigarette, we will ask if you would like to be contacted after all 30 subjects have been completed and we can inform you at that time.

What are the risks and discomforts of participating?

The potential risks related to the study are (1) COVID & tobacco product use, (2) e-cigarette exposure, (3) e-liquid water manipulation, (4) nicotine exposure, (5) flavor exposure, (6) urine collection, (7) rating scales and assessments, (8) limits to confidentiality.

1. **COVID & Tobacco Product Use.** Although the science on the relationship between getting COVID and using tobacco products like cigarettes and e-cigarettes is still not clear, you should remember that using tobacco products can lead to respiratory conditions like asthma. Therefore, if you use tobacco products and become infected with COVID-19, there is a potential that you could have worse health outcomes. 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. We recommend you follow the CDC guidelines for the most up to date information about ways to reduce your risk for exposure to COVID-19. https://www.cdc.gov/coronavirus/2019-ncov/index.html If you develop symptoms for COVID-19 (fever, cough, shortness of breath, difficulty breathing, muscle aches, sore throat, congestion or runny nose, nausea or vomiting, diarrhea, new loss of taste or smell) or have known or suspected exposure, please self-isolate and contact your healthcare provider to discuss obtaining a test for COVID-19.

Please inform research staff if you develop any of these symptoms or have known/suspected exposure to COVID-19. If you become infected with COVID-19, we recommend you stop using all tobacco products.

2. **E-cigarette Exposure.** You were asked to participate in this study because you are a regular e-cigarette user who uses e-cigarettes with nicotine and flavors, therefore reducing your risk to any kind of adverse reaction to an e-cigarette. As an e-cigarette user, you are already using an e-cigarette to vape nicotine and flavors. The lab sessions will be conducted by trained research staff sensitive to tobacco users and trained to monitor any potential adverse effects.

   E-cigarettes contain other chemicals besides nicotine including propylene glycol and vegetable glycerin. Some people are allergic to propylene glycol. You should not participate if you are allergic to propylene glycol. We will be using e-liquids that are created to be like commercially available e-cigarettes and 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. All levels of e-liquids administered in this research study are below any potentially harmful levels. 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. You can stop the study at any point.

   We also want to make you aware of a lung illness called **E-cigarette and vaping lung injury (EVALI).** There have been reported cases of severe pulmonary illness linked to "vaping" or e-cigarette use, called "E-cigarette or vaping product use associated lung injury (EVALI)". EVALI was first discovered in late Summer 2019. 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 e-cigarettes and e-liquid pods that we use in the current study are purchased only from a licensed retailer and do not contain CBD, THC, or Vitamin E Acetate. The pods we are giving you contain nicotine, solvents, and flavorings.

   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, contact the study team as soon as possible.

   We will assess your health at the intake to make sure you are healthy prior to participating and will continue to monitor your health closely during the study. If you experience any symptoms (such as abdominal pain, nausea, vomiting, diarrhea, cough, shortness of breath,

chest pain) or have other concerns, please let us know and let your doctor know right away. Go to the emergency room right away if your symptoms are severe or 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 could contain the name and address of the person who is ill.

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.

3. **E-liquid Water Manipulations:** Some of the e-liquids you will sample as a part of this study will have water added to the e-liquid. This is done simply by mixing water with the e-liquid. All e-liquids already contain a small amount of water. There is no evidence that the addition of water will produce any additional harm to e-cigarette users. In fact, evidence suggests that addition of water may reduce the irritation associated with e-cigarette use.

4. **Nicotine Exposure:** 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. **Flavors in E-liquids.** 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 were developed for commercial use 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, we will not be administering doses higher than what is available in commercial products. 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. **Urine Collection.** Urine collections will be done at your in-person intake appointment to measure the amount of cotinine in your body and to test if you have recently used illicit "street" drugs. If you are currently using illicit drugs, you may be not be eligible to participate. If you are female, we will also administer a pregnancy test at all visits.

7. **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.

8. **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.

How will I know about new risks or important information about the study?
We will tell you if we learn any new information that could change your mind about taking part in this study.

How can the study possibly benefit me?
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.

How can the study possibly benefit other people?
We expect that the results of the study, will benefit science and others through increasing our knowledge of how e-cigarettes can be altered to be less harmful.

Are there any costs to participation?

You will not have to pay for taking part in this study. The only costs include transportation and your time coming to the study visits.

Will I be paid for participation?

You will be paid for taking part in this study. You will be compensated up to $275 for completing all parts of the study. For eligible participants who are enrolled in the study, we will use cash payments for taking part in this study. Those who are ineligible, but complete the remote portion of the intake will receive payment in the form of an electronic gift card to a store of their

choosing. Participants will receive $30 for the remote intake, $20 for the in person portion, $75 for Lab 1 and $75 for Lab 2. In addition, if providing their own travel, participants will be compensated $25/visit for travel (up to $75) if not utilizing travel services provided by the study (i.e. you would not receive travel payment if the study arranges a cab service to take you to your appointment). We can also validate parking in the Air Rights parking garage. You are responsible for paying state, federal, or other taxes for the payments you receive for being in this study. Taxes are not withheld from your payments.

Study Payment Schedule

Study Appointment	**Payment**	**Travel Payment**
Remote Intake	$30	N/A
In-person Intake	$20	$25
Lab Visit 1	$75	$25
Lab Visit 2	$75	$25

How will you keep my data safe and private?

We will keep information we collect about you confidential. We will share it with others if you agree to it or when we have to do it because U.S. or State law requires it. For example, we will tell somebody if you we learn that you are hurting a child or an older person. 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.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

If you decide to be in the study we will collect information that can identify you (like your name and telephone number). This information will not be stored with any information collected as part of the study. All information collected as part of the study will use a “Study ID” instead of your name to identify it. This is a set of numbers and letters that is not connected to your personal information. The principal investigator will keep a link that identifies you to your Study ID, and this link will be kept secure and available only to the principal investigator 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.

All paper research materials will be stored in a locked cabinet in a locked office. All online materials will be stored in secure servers only accessible to those in the study.

When we publish the results of the research or talk about it in conferences, we will not use your name. If we want to use your name, we would ask you for your permission.

We also may share information about you with other researchers for future research but we will not use your name or other identifiers. We will not ask you for any additional permission.

What Information Will You Collect About Me in this Study?

The information we are asking to use and share is called "Protected Health Information." It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission. If you want, we can give you more information about the Privacy Rule. Also, if you have any questions about the Privacy Rule and your rights, you can speak to Yale Privacy Officer at 203-432-5919.

The specific information about you and your health that we will collect, use, and share includes:

- Research study records and visits
- Laboratory records of only those services provided in connection with this study (for example urine tests).

How will you use and share my information?

We will use your information to conduct the study described in this consent form.
We may share your information with:

- The U.S. Department of Health and Human Services (DHHS) agencies
- Representatives from Yale University, the Yale Human Research Protection Program and the Institutional Review Board (the committee that reviews, approves, and monitors research on human participants), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.
- Government health agencies (such as the Food and Drug Administration) in the US
- The principal Investigator of the study, Dr. Danielle Davis and members of the Research Team
- Data and Safety Monitoring Boards and others authorized to monitor the conduct of the Study

We will do our best to make sure your information stays private. But, if we share information with people who do not have to follow the Privacy Rule, your information will no longer be protected by the Privacy Rule. Let us know if you have questions about this. 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.

Why must I sign this document?

By signing this form, you will allow researchers to use and disclose your information described above for this research study. This is to ensure that the information related to this research is available to all parties who may need it for research purposes. You always have the right to review and copy your health information in your medical record.

However, this is a double blinded treatment study (meaning you are not informed of the e-liquid flavor you are assigned) and if you sign this permission form, you will not be allowed to look at or copy your study related information until after the research is completed.

What if I change my mind?

The authorization to use and disclose your health information collected during your participation in this study will never expire. However, you may withdraw or take away your permission at any time. You may withdraw your permission by telling the study staff or by writing to **Danielle Davis, PhD; Room S-214, 34 Park Street, New Haven, CT 06511.**

If you withdraw your permission, you will not be able to stay in this study but the care you get from your doctor outside this study will not change. No new health information identifying you will be gathered after the date you withdraw. Information that has already been collected may still be used and given to others until the end of the research study to insure the integrity of the study and/or study oversight.

Who will pay for treatment if I am injured or become ill due to participation in the study?

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. do not give up any of your legal rights by signing this consent form.

What if I want to refuse or end participation before the study is over?

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 also can 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.

Not participating or withdrawing later will not harm your relationship with your own doctors or with this institution.

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.

The researchers may withdraw you from participating in the research if necessary. The research team may decide to withdraw you if you do not follow directions of the study, we decide the study is not in your best interest, you become pregnant or intend to become pregnant during the study.

What will happen with my data if I stop participating?

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 insure 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.

Who should I contact if I have questions?

Please feel free to ask about anything you don't understand.

If you have questions later or if you have a research-related problem, you can call the Principal Investigator at **203-974-7607.**

If you have questions about your rights as a research participant, or you have complaints about this research, you call the Yale Institutional Review Boards at (203) 785-4688 or email hrpp@yale.edu.

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.

Authorization and Permission

Your signature below indicates that you have read this consent document and that you agree to be in this study.

We will give you a copy of this form.

Participant Printed Name	Participant Signature	Date

Person Obtaining Consent Printed Name	Person Obtaining Consent Signature	Date