RESEARCH CONSENT FORM
Impact of e-cigarette training on puff patterns, cigarette smoking, and health outcomes among smokers with COPD

Sponsor: The University of Kansas Medical Center
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Key Information: You are being invited to consider a research study. Research studies are always voluntary. The first section of this form is a short summary of the study.

Purpose: We are doing this study with people who smoke and have chronic obstructive pulmonary disease (COPD). We are trying to find out if e-cigarettes can reduce tobacco-related harm among smokers. We want to know if training on e-cigarette use will help smokers switch to e-cigarettes. If training helps, how much training is needed for people to fully switch from cigarettes to e-cigarettes?

Other options: You can join the study or choose not to join. Either way you can continue with your regular healthcare. This study does not replace your regular healthcare.

Place: This study is an in-lab smoking study and randomized trial. The study takes place at the Main KUMC campus in Kansas City, KS. device. You will come to the lab on seven separate days. Between visits, you will use the study e-cigarette at home. We will call you before each visit to remind you of the visit.

Procedures: Each time you come in, you will fill out surveys about your tobacco use and use the study product. We will ask you to switch to the study e-cigarette for 12 weeks during the study. The study product is an e-cigarette device and is available for sale in the US. You will do a few different breathing tests where you blow into a machine, we will measure your blood pressure and pulse, we will do a short walking test. At three of the visits, we will ask you to use the e-cigarette for 30 minutes and take two blood samples. Each visit will last about 2-4 hours. There will be a total of seven visits. In between visits, we will ask you to use the e-cigarette.

Risks: There is a slight risk of discomfort, bruising, or infection with blood draws. You may experience effects of nicotine/tobacco abstinence, for example: irritability, restlessness, and difficulty concentrating. Use of the e-cigarettes might result in throat irritation, lightheadedness, dizziness, and nausea. Some known risks of e-ciggarettes, include dependence on nicotine and effects on cardiovascular health (e.g. endothelial dysfunction). Use of e-cigarettes introduces chemicals into the body and the effects are not yet fully understood by researchers.

If you decide to quit smoking, we can provide you information on how to do that.

Please review the rest of this document for details about these topics and important things you should know if you decide to join. Before you sign up for the study, please ask the study team to answer all your questions.

DETAILED INFORMATION

This research study will take place at the University of Kansas Medical Center (KUMC) with Dr. Elly Leavens as the researcher. About 45 people will be in the study.

Why is this study being done?

We are doing this study to learn more about using e-cigarettes as an alternative to smoking in order to reduce tobacco-related harm in cigarette smokers with chronic obstructive pulmonary disease (COPD). We hope to understand whether providing training on e-cigarette use will help smokers switch to e-cigarettes and if training does help smokers switch to e-cigarettes, how much training is needed to help smokers fully replace their cigarettes with e-cigarettes. We are also interested in how switching to an alternative nicotine system (i.e., e-cigarettes) will impact people's COPD-related symptoms. A smoker may want to switch to the study product because they may reduce symptoms of COPD and improve cardiovascular health. If you decide to quit smoking, we can provide you information on how to do that (e.g., referral to your primary care doctor, accessing the quitline at 1-800-QUITNOW).

What is being tested in this study?

You are being invited to participate in a research study to compare how well different types of e-cigarette training work to help smokers replace their cigarettes with e-cigarettes. The three types of training are Brief Advice, Single Training, or Training to Competency. Brief Advice involves basic e-cigarette education and advice to switch. Single Training is the same as Brief Advice but includes one session of real-time training on how to puff on the e-cigarette. Training to Competency is the same as Single Training but includes three real-time training sessions rather than one. This study is testing whether additional training on e-cigarette use improves switching.

How long will I be in the study?

We expect your participation to last between 12 weeks and 15 weeks (up to 2 weeks for screening, 12 weeks of using the e-cigarette, and up to 1 week for the post e-cigarette assessment), and will include up to 6 office visits to the clinic. Study staff will call monthly for three months after the study is complete to follow up.

What will I be asked to do?

The study will involve:

<u>Screening/Enrollment:</u> In this phase eligible participants will be asked to complete

baseline measures, including a breath test and cardiovascular assessment, and answer survey items.
Intervention and Follow-up: In this phase you will attend e-cigarette assessment and training sessions, including 5 sessions at the clinic. You will also receive your e-cigarette, answer survey items, and complete other study procedures. You will switch from cigarettes and any other e-cigarette to the study e-cigarette for 12 weeks.

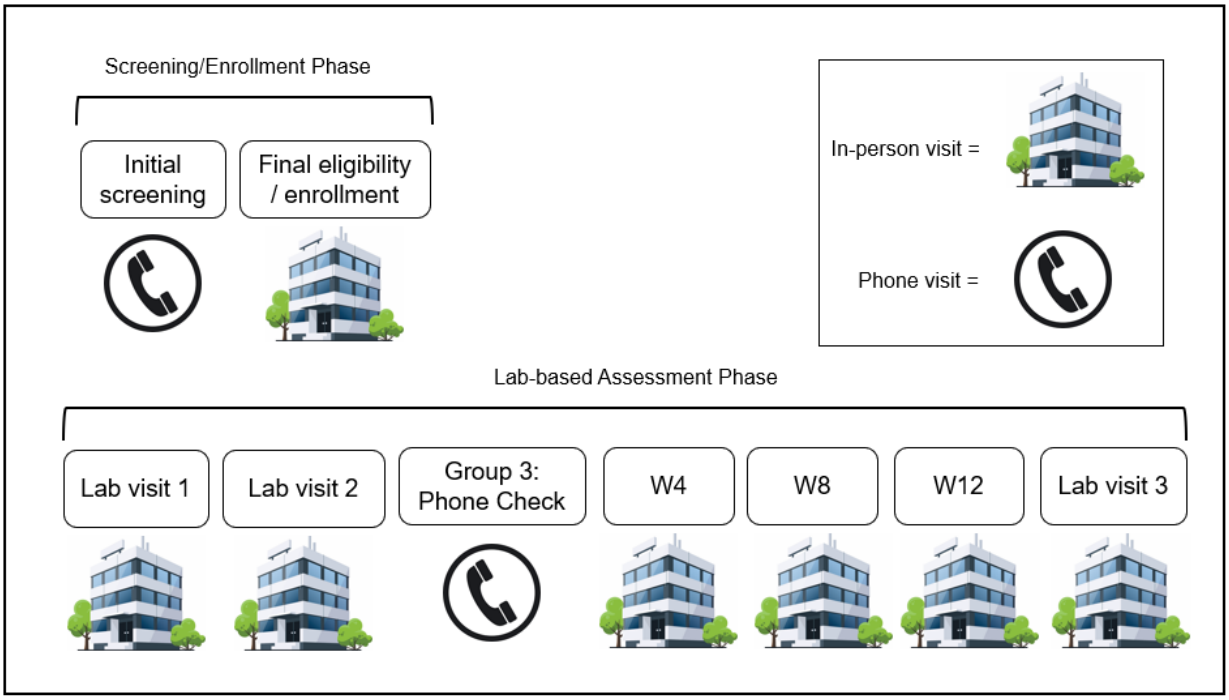
You will be randomized (like flipping a coin) to one of three groups. You will have a 33% chance of being in group 1, a 33% chance of being in group 2, and a 33% chance of being in group 3.

- **Group 1 (Brief Advice):** This group will receive brief advice on how to use the e-cigarette and instructions on how to switch to using the e-cigarette.
- **Group 2 (Single Episode Training):** This group will receive brief advice on how to use the e-cigarette and instructions on how to switch to using the e-cigarette and will receive a single session of real-time feedback on their e-cigarette puff patterns.
- **Group 3 (Training to Competency):** This group will receive brief advice on how to use the e-cigarette and instructions on how to switch to using the e-cigarette and repeated sessions of real-time feedback on their puff patterns, consisting of a follow-up phone call and three real-time training sessions.

Below you will find a schedule of events listing all procedures that will occur at each study visit.

Schedule of Events	Final Screening	Visit 1	Visit 2 / Week 0	Week 4	Week 8	Visit 3 / Week 12
Eligibility Screening: questions and tests to see if you are eligible	X					
Informed Consent: go through the consent form and sign if you give your consent	X					
Pregnancy Test (women only): Urine test for women of childbearing age	X					
Abstain from tobacco/nicotine for 12 hours prior		X	X			X
Measure Puff Patterns: use the e-cigarette as you normally would while a machine measures how you puff.		X	X	X	X	X
Blood Sample: we will take two blood samples at the visits indicated.		X	X			X
Carbon Monoxide Breath Test: blow into a tube	X	X	X	X	X	X
Respiratory and Lung Tests: blow into a tube		X				X
Cardiovascular Tests: blood pressure, pulse, and oxygen level measurements		X				X
6-Minute Walk Test: walk for 6		X				X

minutes and we will measure the distance						
Surveys: completed with the researchers during visits	X	X	X	X	X	X



What are the possible risks or discomforts?

There are no physical risks involved in collecting information about you. There is a small risk of breach of confidentiality. For that reason, your information will be protected as described in the Privacy section below.

There is a slight risk of discomfort, bruising, or infection with blood draws and IV catheter placement. All blood draws and IV catheter placement will be conducted by a nurse.

You may experience the unpleasant effects of nicotine/tobacco abstinence, for example: irritability, restlessness, and difficulty concentrating.

Use of unfamiliar products like e-cigarettes might result in symptoms such as throat irritation, lightheadedness, dizziness, and nausea.

Nicotine is an addictive drug, regardless of the delivery system. While the health hazards of smoking cigarettes are well known including but not limited to cancer and heart disease, the long-term health effects of e-cigarettes are yet unknown. Some known risks of e-ciggarettes, include dependence on nicotine and effects on cardiovascular health (e.g. endothelial dysfunction). Use of e-cigarettes introduces chemicals into the body and the effects are not yet fully understood by researchers.

Pregnancy Risks

Pregnant women should not participate in this study because nicotine and tobacco products may cause birth defects and other harm to the fetus. Because of this, we will conduct a urine pregnancy test for women before enrolling in the study. We will perform the pregnancy test by using a dip-stick pregnancy test before providing you with study products.

Are there benefits to being in this study?

You will not get personal benefit from being in this study. Researchers hope this study may benefit other people with COPD or other people who smoke cigarettes in the future.

Will it cost anything to be in the study?

There are no costs for being in the study. The e-cigarette and e-liquid will be supplied by the research team at no cost to you while you take part in the study. Any medical visits and procedures you have that are unrelated to the study will be billed to your insurance through normal hospital billing practices. Your insurance may not cover some or all the services if you are part of a research study. Pre-Certification is not a guarantee of payment. You may want to talk to your insurance company and review your specific benefits and coverage before deciding to participate. You will be responsible for normal co-pays, deductibles and non-covered services that are not the responsibility of the study.

Will I get paid for participation?

In appreciation of your time, we will pay you $10 at the final screening visit. In addition, if you are eligible, you will be compensated $50 each for visit 1, 2, and 3 (~week 12). You will be compensated $20 each for the week 4 and week 8 study visits and $10 for week 12. In total, you can earn up to $210 for participating in this research.

You will be given a ClinCard, which works like a debit card. After a study visit, payment will be added onto your card by computer. The money will be available within 1 business day. You can use the ClinCard at an ATM or at a store. No one at KUMC will know where you spent the money. You will be given one card during the study. If your card is lost or stolen, please call (866) 952-3795.

The KUMC Research Institute will be given your name, address, social security number, and the title of this study to allow them to set you up in the ClinCard system. Study payments are taxable income. A Form 1099 will be sent to you and the Internal Revenue Service if your payments are $600 or more in a calendar year. If you do not provide a valid social security number or tax identification number, 30% of your payments will be set aside by KUMC and sent to the IRS for withholding on your behalf.

Your personal information will be kept on a secure computer. It will be removed from the

computer after the study is over and the money on the card has been used. Your information will not be shared with other businesses. It will be kept completely confidential.

What are the financial arrangements for this study?
The research team and the institution (KUMC Research Institute, Inc.) are not being paid to conduct this study.

What happens if I get hurt or sick during the study?
If you have a serious side effect or other problem during this study, you should immediately contact Dr. Leavens at 913-945-7875 or 913-972-8841. A member of the research team will decide what type of treatment, if any, is best for you at that time.

If you have a physical injury as a result of participating in this study, treatment will be provided for you at the usual charge. Treatment may include first aid, emergency care and follow-up care, as needed. Claims will be submitted to your health insurance policy, your government program, or other third party. You will be billed for the costs that are not covered by the insurance. You do not give up any legal rights by signing this form.

What other choices do I have?

You can choose not to be in the study. You can decide to leave the study at any time. Leaving will not affect the treatment or services you get at KUMC.

How will my information be protected?

The researchers will keep your identity confidential, as required by law. Absolute confidentiality cannot be guaranteed because persons outside the study team may need to look at your study records. The researchers may publish the results of the study. If they do, they will only discuss group results. Your name will not be used in any publication or presentation about the study.

Your study information will be labeled with your research ID number. The study team will keep a separate list that matches your name to the research ID number. These steps will lessen the risk that your personal identity and information will be seen by others who shouldn't have it.

If you sign this form, the research team will collect, use and share your private health information as described below. If you decide not to sign this form, you cannot be in the research study.

Study data includes information from your study activities and from your medical record. Your health care providers may release your private health information to Dr. Leavens and the research team. The team may use any and all of your information needed for the study. Your medical records may contain your name, address, phone, date of birth, social security number, or other identifiers. Others at KUMC might need to look at your research records. They include KUMC Research Institute, the Institutional Review Board or other committees and offices that review and monitor research studies.

Your participation in this study and your study information may be put into the University of Kansas Health System electronic medical record and combined with your health information from your clinical care. The health system may use and share this information for other purposes described in the Notice of Privacy Practices.

You may not be able to see your records relating to the study until after the study is over and the results are known. Any research information that is put in your medical record will be kept indefinitely.

The research team will share your study data with people outside KUMC. These groups or agencies may make copies of study data for audit purposes. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may not protect it. These groups may include:

- Federal agencies that oversee human research (if a study audit is performed)
- Experts who inspect the study information to see if the study is being done correctly and if it is still safe to continue
- The FDA and similar groups in foreign countries
- Other groups that help manage or provide services to support the study
- Ethics committees that review the study for other locations

Your permission to use and share your health information will not expire unless you cancel it. To cancel your permission, please write to Dr. Leavens. The mailing address is Elly Leavens, University of Kansas Medical Center, 3901 Rainbow Boulevard, Kansas City, KS 66160. If you cancel your permission, you will be withdrawn from the study. The researchers will stop collecting any additional information about you. They are permitted to use and share information that was gathered before they received your cancellation.

The researchers may publish the results of the study. If they do, they will only discuss group results. Your name will not be used in any publication or presentation about the study.

Will I be told about research results?

You will be told about any study results that directly affect your personal medical care. Otherwise, you will not receive information about the results of the study.

How will my research information and specimens be used in the future?

In the future, researchers at KUMC and at other locations might re-use the information and specimens from this study for other research. If that happens, information that could identify you will be removed first. You will not be asked if you agree to the future research that has identifiers removed.

Can I stop being in the study?
You may stop being in the study at any time. Stopping will not prevent you from getting

treatment or services at KUMC.

Could my participation be stopped early?
This study might be stopped, without your consent, by the investigator, the sponsor or by the FDA. Your participation also might be stopped by the investigator or by the sponsor if it is in no longer safe for you or if you do not follow the study requirements.

The University of Kansas Medical Center, the sponsor, and the investigator are not obligated to provide you with any treatment if the study is stopped early. Your physician will decide about future treatment, if it is needed.

Who can I talk to about the study?

Dr. Leavens or other members of the study team should answer all your questions before you sign this form. They will also tell you if they learn anything new that might affect your decision to stay in the study. You can talk to the researchers if you have any more questions, suggestions, concerns or complaints. If you have questions about your rights as a research subject, or if you want to talk with someone who is not involved in the study, you may contact the KUMC Institutional Review Board at (913) 588-1240 or humansubjects@kumc.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.

CONSENT

Dr. Leavens or the research team has given you information about this research study. They have explained what will be done and how long it will take. They explained any inconvenience, discomfort or risks that may be experienced during this study.

By signing this form, you say that you freely and voluntarily consent to participate in this research study. You have read the information and had your questions answered.
You will be given a signed copy of the consent form to keep for your records.

_____
Print Participant's Name

_____ _____ _____
Signature of Participant Time Date

_____
Print Name of Person Explaining Consent

_____ _____ _____
Signature of Person Explaining Consent Time Date

I want to receive visit reminders by (check all that apply):
Note: If I opt in to text message updates regarding appointments, standard messaging rates will apply. Only appointment times and dates will be sent via text message.

Email _____ (your email)
Text message _____ (your cell phone number)
Not at all

_____ _____
(Date / Time) (Printed Name of Participant)

_____
(Signature of Participant)

PERMISSION TO BE CONTACTED ABOUT FUTURE STUDIES

I give permission to be contacted about future studies that might require more information:

	YES	NO
About smoking		
About any other health related issues		

_____ _____
(Date / Time) (Signature of Participant)