BUTLER HOSPITAL CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT

Methadone-Maintained Smokers Switching to E-Cigarettes
Project SHINE: Switching for Health Improvements with Nicotine Replacement and E-Cigarettes

Sponsorship

This study is being paid for by the National Institute on Drug Abuse.

Research Project Summary

You are being asked to participate in a study designed to better understand the health effects of electronic cigarettes (EC) in smokers with opioid use disorder in methadone maintenance treatment (MMT). You are invited to participate in this study because you are a current cigarette smoker receiving MMT at CODAC Behavioral Healthcare, Stanley Street Treatment and Resources (SSTAR), or at another community-based MMT program who is interested in switching from cigarettes to a nicotine replacement product. Your participation in this study will last 10 weeks. There will be a total of 7 study visits at CODAC, SSTAR, or at Butler Hospital over the course of 6 weeks: baseline, 5 weekly brief check-in (CI) visits, and a 6-week assessment. Depending on what condition you get assigned, there may also be a final, brief, check-in by phone at 10-weeks. The baseline and 6-week assessment will take approximately 2-3 hours to complete. The weekly check-in visits will take up to 1 hour of your time. The final phone call will take approximately 5 minutes. Total study participation will take up to 11 hours of your time over the course of 6 weeks. You will be compensated up to $275 for full participation (see details below in this document).

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

Description of Procedures

Baseline Assessment

If you decide to participate, you will complete several interviews and be randomly selected by a computer to receive either: 1) 6 weeks of electronic cigarette materials (a device and JUUL 5% nicotine pods) or 2) 6 weeks of nicotine replacement therapy in the form of nicotine lozenges. Each part of the study that you will participate in is described below.

If you decide to participate, you will first meet with a research staff member at CODAC, SSTAR, or at Butler Hospital to review and sign this consent form. You will then be interviewed by a staff member to confirm that you are eligible for the study. In this interview, you will be asked questions about your mood and other psychological symptoms, physical health, and tobacco, alcohol, and drug use. This confidential interview will take approximately two hours and will be audio-recorded. These recordings will be reviewed by the researchers for training/supervision purposes. You may refuse audio-recording at any time by informing a research staff member. You will be asked to provide a urine sample for drug and pregnancy testing (if applicable) as well as to measure the amount of chemicals in tobacco that you've been exposed to. We will assess your lung capacity with a breathing test. During this test, a research staff member will ask you to take a deep breath and briefly hold your breath. You will then be asked to blow as much of this breath as possible into a small mouthpiece. We will ask you to do this at least three times in a row during this visit, allowing you time to rest in between. Further, we will ask you to provide a separate

breath sample to assess carbon monoxide (CO) level. You will be asked to provide a saliva sample to test the amount of nicotine in your body. We will give you 1-2 small plastic tubes and ask you to spit about a tablespoon of saliva into each tube. You will also be asked to complete questionnaires, on a laptop computer/tablet device or by paper and pencil, about your attitudes, mood, substance use, and thoughts and feelings relevant to your cigarette and your substance use. Questionnaires may also be sent via e-mail. You may skip any questions you do not wish to answer.

Before becoming a participant in this study, research staff and our study physician will review your current health status and medical history in order to determine whether participating in this study is a good option for you at this time. It is possible that, based on the baseline interview, you will not be found eligible to participate in this study. If you attend a community-based MMT program other than CODAC or SSTAR, you will be asked to sign a Release of Information form which will authorize us to communicate with the MMT program to verify your enrollment. If we are not able to verify your enrollment, you will not be eligible to participate in this study.

Program Conditions

After the baseline assessment, you will be randomly assigned by a computer to one of the study conditions. For every three people who join the study, two will receive electronic cigarettes (condition #1 described below) and one will receive nicotine lozenges (condition #2 described below).

1. **6 weeks of Electronic Cigarettes.** In this condition, you will be given JUUL e-cigarettes. Study staff will provide information about how much electronic cigarettes use is approximately equivalent to your baseline cigarette smoking rate. You will be given instructions on how to safely switch to the JUUL device and how the device works. You should use the electronic cigarettes whenever you experience a craving for nicotine. Two days after you receive the JUUL, we will contact you via phone to see if you have any questions or concerns. JUUL pods will be given to you on a weekly basis at your study visits.

2. **6 weeks of Nicotine Lozenges.** In this condition, you will be given a box of Nicorette mini lozenges. You will be given instructions on how to safely use the lozenges. You should consume a lozenge every 1-2 hours, whenever you experience a craving for nicotine. Two days after you receive the lozenges, we will contact you via phone to see if you have any questions or concerns. Lozenges will be given to you on a weekly basis at your study visits. At the end of the 6-weeks, you will be given a JUUL e-cigarette device and a JUUL pod.

Smoking and Treatment Health Referrals. Regardless of the condition to which you are assigned, you will receive information about the negative health effects of cigarette smoking and the short and long-term benefits of quitting cigarettes. At the end of the 6-week program, if you are interested in additional help to reduce or quit cigarette smoking, study staff will provide referrals to local quit smoking resources and phone services.

Follow-up Assessments

1. **Weekly Check-In Visits.** You will attend 5 brief, weekly visits at CODAC or SSTAR starting 1 week after you are enrolled in the study. At the beginning of each weekly check in, you will be asked to provide a breath sample to assess CO level. At the weekly check in, you will be asked questions about your mood and other psychological symptoms, physical health, and tobacco, alcohol, and drug use. We will ask you about any side effects that you may have experienced from the electronic cigarettes or lozenges. You will be asked to bring any unused JUUL pods or lozenges to the weekly check in meetings so that research staff can assess how much more you need for the next week. At the end of the check in, you will be given the next week's supply of electronic cigarettes or lozenges, as needed.
2. **6-week Assessment Visit.** At this visit, you will be asked questions about your mood and other psychological symptoms, physical health, and tobacco, alcohol, and drug use. You will be

asked to provide a urine sample for drug testing and to assess biomarkers of tobacco exposure. We will test your lung capacity through a breathing test that is the same as the one done during your baseline assessment. Further, you will be asked to provide a separate breath sample to assess CO level and a saliva sample to test the amount of nicotine in your body. You will also be asked to complete questionnaires either as an interview with the research staff, or on a laptop computer/tablet device, or by paper and pencil, about your attitudes, mood, substance use, and thoughts and feelings relevant to your substance use. Questionnaires may also be sent via e-mail. You will be provided with smoking and health treatment referrals upon request.

3. **10-week phone call.** If you are assigned to condition #1 (JUUL e-cigarette), four weeks after the end of the study, research staff will call you for a brief (5-minute) discussion about any combustible cigarette, e-cigarette, or other nicotine products you may have used in the past month.

Risks and Inconveniences

There are minimal risks associated with participating in this study. You may experience no or mild nicotine withdrawal symptoms with use of the JUUL or nicotine lozenges. In addition, if you stop using cigarettes during the study and use less JUUL or lozenges than recommended, you may experience nicotine withdrawal symptoms. These symptoms include anxiety, restlessness, irritability, impatience, difficulty concentrating, increased appetite, insomnia, and desire to smoke. These are moderately uncomfortable but have minimal risk of physical harm.

Risks Associated with the use of the JUUL. You may experience mild side effects; these may be mouth or throat irritation, dry cough or mouth, nausea, sore throat, headache, and mouth ulcers. Any side effects are likely to be mild and diminish over time. On June 23, 2022, after a review of the JUUL product, the Food and Drug Administration (FDA) determined that JUUL Labs (the maker of the JUUL e-cig) had not provided sufficient information to determine the safety of JUUL e-cig use. The FDA asked JUUL Labs to stop selling JUUL e-cigs as it completes its review of additional scientific data, but JUUL e-cigs remain on the market pending this review and at present, there is no way to know if there are any new potential harms associated with JUUL e-cigarette use.

Risks Associated with the use of nicotine lozenges. You may experience mild side effects; these may be nausea, dizziness, and irritation inside of mouth. Rarer side effects include chest pain and heart palpitations. At the weekly check-ins, we will ask you about any side effects that you may have experienced. Depending on the side effects, a decision may be made to reduce your lozenge dosage or, if necessary, discontinue your use of the lozenges.

Use of either JUUL or lozenges while continuing your current level of tobacco cigarettes can lead to higher levels of nicotine in your body and produce nausea, vomiting, abdominal pain and diarrhea.

Risks Associated with Questionnaires. You may experience discomfort from some of the interview questions or discussion points during the study visits. You may refuse to answer any questions that make you feel uncomfortable and you can stop participating in the discussion at any time. All information obtained will be confidential. Your responses to the questions will not be linked to any information that can identify you. Your information will be available only to our research staff. Your name will never be associated with publications from this project. We will make every effort to lessen any discomfort you may feel during this process (example, you may take a short break from the questionnaires if needed).

Women Please Note

Similar to tobacco cigarettes, electronic cigarettes and nicotine lozenges are not recommended for use during pregnancy. Electronic cigarettes and nicotine lozenges may be harmful to a developing fetus. Therefore, you may be tested for pregnancy at the time of your admission to the study. Prior to your

beginning the study we will discuss with you in more detail the importance of avoiding pregnancy. We will specifically ask you to let us know if you intend to become pregnant or become pregnant during the study.

Audio/Video Recording

During the study, we will audio-record interviews. We do this to make sure that study staff are following study procedures in the correct way and also to make sure that we have correctly recorded information that you share with us. We will tell you whenever we plan to use an audio-recorder. You may refuse audio-recording of interviews at any time and still participate in the study.

E-mail

Some of the follow-up interviews can be done remotely, through secure, online databases. To do this, we would contact you by email to set you up with web links, which will take you online to a secure database where you can complete various study assessment forms ("surveys') during participation in this research project. If you are unable to attend a check-in session, we may email you the survey link so you can complete the assessment at home. Even if you prefer to do the assessments in person, we ask for your email in case we need to rely on remote options.

How do e-mail research surveys work?

You will receive an e-mail message from our research team sent to you from a secure Care New England-hosted research data system called "REDCap." The message will include a link for you to click. Clicking the link will securely connect you with REDCap, where you will see your study survey. You will respond by clicking on buttons you see on the screen. The e-mail messages you receive will not identify you by name, and the links to surveys you get through REDCap will be associated only with your e-mail address. Your e-mail address and any other information that personally identifies you will be removed from the final research database when the study is over. We will only use e-mail to send you research surveys associated with participation in this study. We will not send e-mail messages that contain personal messages to you.

Using this secure e-mail system will help reduce the chance that you will experience loss of confidentiality when using e-mail. If you share a home computer with other family members and do not want them to know you are participating in this study, make sure you provide an e-mail address that only you can access. Your employer or school will have access to any e-mail communications sent or received on a work or school computer. Additionally, when using any public computer, you should be careful to protect your username and password, and make sure you log-out before getting up from the computer.

Can we send you links to survey assessments via email? ☐Yes _____initials ☐No _____initials

Texting

We would like to contact you by text message for the purposes listed below:

1. To schedule research-related appointments
2. To send reminders about appointments

How do Text Communications with Care New England Researchers Work?

Text messages (SMS) from the study staff will be sent from a phone that is dedicated for use in this research study. The phone will not be monitored for return messages, but it will be checked periodically during regular office hours. You can respond to messages from researchers by sending them text messages, but there are only certain things you should communicate via text message.

Risks Related to Text Communication (SMS)

You should be aware that there are risks associated with sending your health information via text. There is always a risk that the message could be intercepted or sent to the wrong number. Text messages from

research staff may contain health information that identifies you. Only the research team will have access to your text communications. We will only communicate by text to send you the information listed above. We will not send text messages that contain urgent information. We will not send text messages to a group of recipients. If you share your mobile phone or messages with others, you risk losing privacy surrounding your health information and loss of privacy surrounding your participation in this study. You should make sure to protect your phone with a password if you send or receive text messages during participation in this study. If your phone plan has a limit on SMS text messages, you may incur fees related to text messaging with researchers.

Cautions related to text messages with researchers

Text messages may not be received by researchers on a regular basis. It is possible that a message you send will go unnoticed or will not be read by the research team for days or weeks. ***You should use the telephone to contact the research team for any urgent matters. Medical issues (symptoms, side effects, injuries, concerns about effects of study procedures, etc.) should NOT be communicated by text message.*** These should be directed to the research staff by telephone or in person. To discuss medical issues, please contact our office at 401-430-0034.

Can we contact you via text message? ☐Yes _____initials ☐No _____initials

Benefits

If you replace tobacco cigarettes with electronic cigarettes or nicotine lozenges, you may reduce your exposure to inhaled tar and other toxic substances. We cannot and do not guarantee or promise that you will receive any benefits from this study. However, the knowledge gained in the study may further our understanding of the role of the behavioral and health effects of electronic cigarettes and nicotine replacement treatments like nicotine lozenges in smokers with opioid use disorder in methadone maintenance treatment.

Economic Considerations

You will be compensated up to $275 for completing all study visits/procedures. You will receive $75 for the baseline assessment, $25 for each of the 5 weekly check-ins, and $75 for the 6-week follow-up assessment. You will receive $10 each week you bring back all your unused Juul pods or lozenges. If you bring back some of these unused products but not all, you may receive $5 that week. You will be given the option to receive these payments by a check from Butler Hospital or gift cards to a local store.

Depending on the amount of payment you might receive for your participation in this study, together with payments you might receive in participation in other CNE Research Studies, you might have to provide your name, address, and taxpayer ID or Social Security number to the Butler/CNE Research Accounting Department. In order to receive payment of $300 or more for participation in research, you will have to complete and sign a W-9 form. If you are paid $600 or more in any calendar year for research participation, the IRS will be notified of the total amount you were paid, in accordance with federal regulations. You should ask the researcher for more information if you have questions about this process.

Alternative Treatments/Alternative to Participation

If you choose not to participate in this research, you may still receive services at CODAC or SSTAR. Electronic cigarettes and nicotine lozenges are available over the counter and are widely accessible. Alternatives for smoking reduction and cessation include FDA-approved pharmacotherapies such as nicotine replacement therapy (patch, lozenge, gum), bupropion, varenicline, as well as state sponsored Quitlines and behavioral counseling.

Financial Disclosure

None.

Voluntary Participation

You are free to decide whether or not to participate in this study, and you are free to withdraw from the study at any time. A decision not to participate or to withdraw from the study will not adversely affect your current or future interactions with Butler Hospital, Care New England, CODAC or SSTAR. Your participation in the study may be terminated by the researchers without regard to your consent; in that case, you are entitled to an explanation of the circumstances leading to that decision.

Confidentiality

Personal identifiers will be removed from any identifiable private information about you or your biospecimens in the final research dataset created by this study. The de-identified information may be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you (or from your legally authorized representative).

You will not be personally identified in any reports or publications that may result from this study. The confidentiality of the information you provide to us will be maintained in accordance with state and federal laws. If you tell us something that makes us believe that you or others have been or may be physically harmed, we may report that information to the appropriate agencies.

Clinically relevant research results, including individual research results, will not be disclosed to you.

To keep your information safe, we will store all information in locked file cabinets and on password protected secure computer servers. To the extent possible, we store identifying information (such as your name or address) separately from study data (such as questionnaires that you complete). You will not be identified on audio recordings and they will be stored on a secure server which is password protected and only accessible to research staff. All identifying information will be destroyed 7 years after the completion of the study.

General information about this study has been or will be submitted to the federal clinical trial registry databank, which can be accessed on the Internet at www.ClinicalTrials.gov.

The saliva and urine specimens collected from you will only be used for the purposes described above. This research will not include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

This research is covered by a Certificate of Confidentiality. Unless you give special written permission, the researchers and Butler Hospital cannot give out any information about you that could potentially identify you or be used as evidence in a legal case (including any federal, state, or local civil, criminal, administrative, or legislative case).

We will not share any information or test results that are part of this study with your providers at CODAC. The only situations where researchers would share your information with others are:

(1) when a specific law (federal, state, or local) requires that potentially harmful things be reported to the authorities (such as reporting child abuse, elder abuse or spread of communicable diseases);
(2) when you have given permission (consent) for the information to be shared in order to help your medical treatment; or
(3) when your information will be used for other scientific research, as allowed by federal regulations protecting research subjects.

Authorization for use/disclosure of your Identifying Health Information, to Conduct this Research Study

If you sign this document, you authorize the research staff in the Behavioral Medicine and Addictions Research Unit at Butler Hospital to receive and use your health information at CODAC or SSTAR that identifies you, for the purpose of conducting the research study described above. You also give permission to the researchers at Butler to use your health information that is gathered or created during your participation in this study.

Your health information related to this study may also be shared with and used by individuals outside of Butler Hospital, including:

- Specialty mental health care providers for whom you provide a release of information. If there is a change to your mental health status (e.g., you become more depressed or experience new symptoms and may need more treatment), we will communicate with your mental health provider about this.
- Other healthcare and public safety professionals, if we are concerned that you are at risk of hurting yourself or others.

The health information that we may use or share with others for research purposes includes your diagnosis and treatment at CODAC or SSTAR, urine toxicology results from your CODAC or SSTAR medical record, any information that you give us as part of your study participation, and results of any assessments that we do as part of the study.

Your health information may also be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, and conducting public health surveillance, investigations, or interventions. The U.S. Food and Drug Administration (FDA) may inspect all study records to ensure that the study is being conducted in accordance with FDA regulations.

Butler Hospital and CODAC or SSTAR are required by law to protect your health information. Individuals outside of Butler that receive your health information may not be required by Federal privacy laws (such as the HIPAA Privacy Rule) to protect it, so we cannot guarantee that they will not share it without your permission.

Please note that:

- You do not have to sign this consent form, but if you do not, you may not participate in or receive research-related treatment in this study.
- Butler Hospital and CODAC or SSTAR or your current MMT program may not withhold treatment or refuse to treat you, based on whether you sign this consent form.
- You may change your mind and revoke (take back) this consent and authorization at any time. If you no longer want to give us permission to use your health information for this research study, you must contact the Principal Investigators, Drs. Stein and Abrantes, and you will be instructed to provide a written statement.
- Even if you revoke (take back) this consent and authorization, the researchers may still use or share health information about you that they already have obtained, when doing so is necessary to maintain the integrity or reliability of the current research.
- You generally will not have access to your personal health information related to this research until the study is completed. At the conclusion of the research and at your request, you will have access to your health information that Butler Hospital maintains in a designated record set, according to the Notice of Privacy Practices provided to you by Butler Hospital. A designated record set includes medical information or billing records used by doctors or other health care providers at Butler Hospital to make decisions about individuals.

- Your health information will be provided to you or to your physician if it is necessary for your care.
- If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

This Authorization will expire when all the activities associated with this research study have concluded.

Questions

Taking part in this study is entirely voluntary. We urge you to discuss any questions about this study with our staff members. You should take as much time as you need to make your decision. If you decide to participate, you must sign this form to show that you want to take part.

Authorization:

I have read this form and decided that I _____
(printed name of participant)
will participate in the project described above. Its general purposes, the nature of my involvement, and possible hazards and inconveniences have been explained to my satisfaction.
I have received a copy of this consent form.

_____ _____
Signature of Participant Date

_____ _____
Signature of Principal Investigator Date
~or~

_____ _____
Signature of Person Obtaining Consent Date

Telephone Number of Principal Investigator or Person Obtaining Consent_____

If you have further questions about this project or about research-related injuries, please contact Michael Stein, M.D., at 617-358-1956 OR Ana Abrantes, PhD, 401-455-6440. If you have questions about your rights as a research subject, please contact Linda L. Carpenter, M.D., Chair, Butler Hospital Institutional Review Board, at 401-455-6349.

THIS FORM IS NOT VALID UNLESS THE FOLLOWING BOX HAS BEEN COMPLETED BY THE IRB OFFICE

THIS FORM IS VALID UNTIL

DATE: January 31, 2025

IRBNET ID# 1702236

BUTLER IRB REFERENCE# 2102-001

BY (ADMINISTRATOR): *C. Cordeiro*