Official Title: Switching Individuals in Treatment for Opioid Use Disorder Who Smoke Cigarettes to the SREC (SWITCHED)

ClinicalTrials.gov ID (NCT Number): NCT05881304

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Mass General Brigham

Research Consent Form
General Consent Form Template
Version Date: November 2022

Subject Name:

MRN or DOB:

Subject Identification

Protocol Title: Switching Individuals in Treatment for Opioid Use Disorder Who Smoke Cigarettes to the SREC

Principal Investigator: Joanna Streck, PhD

Description of Subject Population: **Adults ages 18 and older, who smoke cigarettes and are not yet ready to quit, and are stable in Buprenorphine treatment for opioid use disorder at MGH.**

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

Key Information

We are asking you to be in a research study. This form will tell you what you should expect if you agree to be in the study. You will find more information about each of the following points later in this form.

It is your decision whether or not to join the study. We are asking you to be in this study because you are an adult aged 18 or older, who smokes cigarettes and is not yet ready to quit smoking, and you are stable in your Buprenorphine treatment for opioid use disorder at MGH. We are doing this research to test whether using e-cigarettes can help people reduce their cigarette smoking and harms from smoking. If you agree to participate, you will be provided with e-cigarettes to use for 8 weeks. You will be in the study for a maximum of 12 or 20 weeks (depending on the group you are randomized to) if you decide to stay for the whole study.

The main risk of being in the study is experiencing potential nicotine withdrawal symptoms, such as feeling irritable or restless.

You might benefit from being in the study because switching from cigarettes to nicotine e-cigarettes might reduce health risks from tobacco smoking.

If you decide not to be in the study, some other things that might help your condition are the Massachusetts State Quitline free quit smoking resources (you can call: 1-800-Quit-Now).

You will be paid up to $779 for taking part in this research study. We will be using an approved, outside vendor (Advarra) to make these payments to you via a reloadable credit card-based system, called Advarra Participant Payments. This secure system is similar to a gift card or credit card. You will find more information about the payment amount for each visit and a plan if you do not complete all study visits later in this form.

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Joanna Streck, PhD is the person in charge of this research study. You can call her at (617) 643-9977 [pager number 24966]. She is available M-F 9-5. You can also call Cecely Sterling-Maisel at 617-643-0949 (she is available M-F 9-5) with questions about this research study.

If you have questions about the scheduling of appointments or study visits, call Cecely Sterling-Maisel at 617-643-0949

If you want to speak with someone **not** directly involved in this research study, please contact the Mass General Brigham IRB. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research
- Any pressure to take part in, or to continue in the research study

Detailed Information

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.

Why is this research study being done?

We are doing this research to test whether using e-cigarettes can help people with opioid use disorder reduce their cigarette smoking and harms from tobacco smoking.

Since electronic cigarettes are relatively new products, little is known about their health effects compared to regular cigarettes. All participants will be provided with electronic cigarettes and asked to replace all of their regular cigarette use with electronic cigarette use over an 8-week period. During the time of the study, we will monitor your use of cigarettes and electronic cigarettes, and your exposure to nicotine and tobacco,

Electronic cigarettes are not approved the U.S. Food and Drug Administration (FDA) for smoking cessation, and this trial is not designed to evaluate whether electronic cigarettes help people to quit smoking.

Who will take part in this research?

We are asking you to be in this study because you are an adult age 18 or older, currently smoke cigarettes and are not yet ready to quit, and are stable in your Buprenorphine treatment for opioid use disorder at Mass General Hospital (MGH).

About 60 people will take part in this research study at MGH.

The National Institute on Drug Abuse (NIDA) is paying for this research study to be done.

What will happen in this research study?

If you choose to take part in this study, we will ask you to sign this consent form before we do any study procedures. It will take you about 3 to 5 months to complete this research study. During this time, we will ask you to make 7 or 11 study visits to MGH. If you have difficulty attending in person visits, we will try to accommodate you by conducting some study visits or procedures remotely.

Baseline 1 Visit
We will ask you to come to a study visit which will take about an hour.

At this visit, we will:

- Ask you to complete a breath test where you blow into a tube attached to a handheld device so we can detect your smoking level
- Ask you to complete a breath test where you blow into a tube attached to a handheld device so we can detect your alcohol level
- Ask you to leave a urine sample to test for smoking and substance use. This information is confidential.
- Ask you questions about your tobacco use, substance use, mood, and medical history.
- We will set up a program that will send you text messages each day (referred to as a texting smoking diary) for you to record your daily smoking behavior. We will explain to you how this diary works.

Baseline 2 Visit
A week later, we will ask you to come to a second study visit which will take about an hour.

At this visit, we will:

- Ask you to complete a breath test where you blow into a tube attached to a handheld device so we can detect your smoking level
- Ask you to complete a breath test where you blow into a tube attached to a handheld device so we can detect your alcohol level
- Ask you questions about your tobacco use and medical history
- At the end of this visit, you will be randomly assigned to a study group; the random assignment determines during which 8 week period you will receive e-cigarettes to use. You have a 50% chance of receiving e-cigarettes immediately at the end of the Baseline 2 visit (Immediate Start Group), and a 50% chance of receiving e-cigarettes after an 8-week delay (at visit week 8; Delayed Start Group). In both groups, at any point during the study, you can request to no longer receive e-cigarettes if you do not wish to use them any longer.

At the end of this visit, if you are assigned to the Immediate Start Group we will:

- Provide you with a 2-week supply of e-cigarettes and pods to use in place of your cigarettes and be instructed how to use the e-cigarettes.
- Set up a program that will send you text messages each day for you to record your daily e-cigarette and smoking behavior. We will explain to you how this diary works.

At the end of this visit, if you are assigned to the Delayed Start Group we will:

- Not be given e-cigarettes right away, but will be asked to track your regular cigarette smoking habits for 8 weeks before you start your 8 weeks of e-cigarettes.
- We will set up a program that will send you text messages each day for you to record your daily smoking behavior. We will explain to you how this diary works.

Immediate Start Group

After the Baseline 2 visit, you will be asked to attend 5 study visits to assess your e-cigarette and cigarette use. These visits will occur every 2 weeks and take 30 minutes to an hour

At these visits, we will:

- Ask you to complete a breath test where you blow into a tube attached to a handheld device so we can detect your smoking level
- Ask you to complete a breath test where you blow into a tube attached to a handheld device so we can detect your alcohol level
- Ask you to leave a urine sample to test for smoking and substance use. This information is confidential.
- Ask you questions about your smoking, e-cigarette use, mood, and medical history

Delayed Start Group

After the Baseline 2 visit, you will be asked to attend 4 study visits to track your cigarette smoking behavior. These visits will occur every 2 weeks and take 30 minutes to an hour.

At these visits, we will:

- Ask you to complete a breath test where you blow into a tube attached to a handheld device so we can detect your smoking level
- Ask you to complete a breath test where you blow into a tube attached to a handheld device so we can detect your alcohol level
- Ask you to leave a urine sample to test for smoking and substance use. This information is confidential.
- Ask you questions about your tobacco use, mood, and medical history.

At the 4th visit (roughly 8 weeks after Baseline 2), you will attend another study visit. In addition to the tasks above, at this visit, we will also:

- Provide you with a 2-week supply of e-cigarettes and pods to use in place of your cigarettes and be instructed how to use the e-cigarettes.
- Set up a program that will send you text messages each day for you to record your daily e-cigarette and smoking behavior. We will explain to you how this diary works.

After we provide you with e-cigarettes, we will ask you to attend 5 additional study visits to assess your e-cigarette and cigarette use. These visits will occur every 2 weeks and take 30 minutes to an hour.

At these visits, we will:

- Ask you to complete a breath test where you blow into a tube attached to a handheld device so we can detect your smoking level
- Ask you to complete a breath test where you blow into a tube attached to a handheld device so we can detect your alcohol level
- Ask you to leave a urine sample to test for smoking and substance use. This information is confidential.
- Ask you questions about your smoking, e-cigarette use, mood, and medical history

Early Study Exit:
If you decide to leave the study early, we may contact you to ask you several questions about your decision to leave, however you are not required to answer any questions you do not wish to.

Mass General Brigham Alert System

Mass General Brigham has an electronic system that lets your study doctors know if you are admitted to a Mass General Brigham Hospital, or if you visit a Mass General Brigham Hospital Emergency Department. We want to make sure the study doctors know about any possible problems or side effects you experience whileyou are taking part in the study.

Study Information Included in Electronic Medical Record

A notation that you are taking part in this research study may be made in your electronic medical record. Information from the research that relates to your general medical care may be included in the record (for example, list of allergies, results of standard blood tests done at the hospital labs). Please ask your study doctor if you have any questions about what information will be included in your electronic medical record.

If you decide to participate in this study, you will be opting to receive text messages regarding your participation in the study. Text messages by mobile/cell phones are a common form of communication to study participants. This research study will involve sending you text messages to complete cigarette and e-cigarette diaries, as well as sending you visit reminders.

There are some important things to know about texting in this research study:

- Texting over mobile/cell phones carries some security risks. Mass General Brigham is not responsible for any capture of messages sent through texts.
- You will be responsible for any of your carrier service fees. This research study and Mass General Brigham are not responsible for any increased charges, data usage against plan limits or changes to data fees from the research texts.
- Text messaging the study team should not be used in case of an emergency. If there is an emergency, call 911 or go to the nearest hospital emergency department.
- You can opt out of receiving text messages at any time by texting "STOP" to the text.
- Agreeing is for this study only.
- It is your responsibility to update your mobile/cell phone number with our study staff if it changes at any time.

How may we use and share your samples and health information for other research?

The information we collect in this study may help advance other research. If you join this study, we may remove all information that identifies you (for example, your name, medical record number, and date of birth) and use these de-identified samples and data in other research. It won't be possible to link the information or samples back to you. Information and/or samples may be shared with investigators at our hospitals, at other academic institutions or at for-profit, commercial entities. You will not be asked to provide additional informed consent for these uses.

Will you get the results of this research study?

No. The research study we are doing is only a stepping stone in understanding whether using e-cigarettes can help people reduce their cigarette smoking and harms from smoking**.** Therefore, no information about the results of this research study or the results of your individual participation in the research study will be given to you or your doctor. Tests done for the research using your samples will not be useful in directing your medical treatment. The results of the tests will not be placed in your medical record.

What are the risks and possible discomforts from being in this research study?

There are some potential physical risks associated with using electronic cigarettes. There have also been reports of seizure, burns caused by e-cigarette devices/malfunction, and other adverse events such as headache, nausea/vomiting, dizziness, confusion, blurry vision, throat irritation, abdominal pain, and sleepiness in individuals who use electronic cigarettes. Abruptly quitting e-cigarettes could cause withdrawal symptoms similar to those from quitting tobacco cigarettes but slightly less severe. The most common side effects include dry mouth, irritation of the throat and mouth, and mild cough.

To reduce these risks, you will be instructed not to modify the devices in any way, and to charge the devices per the manufacturer's instructions, to minimize the possibility of malfunction.

You may have heard that e-cigarettes, or "vapes," can explode and seriously injure people. Although this has not been reported with the SREC (our study e-cigarette device that you will receive), when you receive your study e-cigarettes, study staff will provide you with written and verbal instructions on how to safely use and store your e-cigarette device. For example, you will be instructed to keep your e-cigarettes away from other metal objects, not charge the device with a phone or tablet charger, and not charge the e-cigarette overnight or leave it charging unattended, and to stop using the e-cigarette immediately if the batteries get damaged or wet.

Since e-cigarettes are relatively new products, there may be other risks that are currently unknown.

Loss of confidentiality is another potential risk, though unlikely, for survey questions and/or for drug testing results. We will ensure that maximal care is taken to protect participant confidentiality to the highest extent possible. Questionnaire data will be collected and stored electronically using secure systems. Survey data will not include any identifying information.

Patient's urine samples will also be identified solely by patient's unique study ID and they will be kept in a secure MGH freezer until they are shipped in batches to the lab for analysis.

There is minimal emotional discomfort or psychological risk associated from discussion of tobacco use and related symptoms proposed in this study. It is possible that patients may be uncomfortable answering questions about their tobacco use due to stigma associated with use, however these questions are not anticipated to cause significant embarrassment or emotional distress based on our prior work in this population. If throughout the course of participation in our study, we learn that you have any thoughts of ending your life or harming yourself, you will be immediately referred to our study clinician who will ask you questions and assess your risk and may refer you to mental health resources.

What are the possible benefits from being in this research study?

You will be instructed to reduce your combustible (regular) daily cigarette use and to substitute e-cigarette use for cigarette use. This approach aims to help you reduce your cigarettes smoked per day and tobacco exposure. Preliminary data in the literature suggests e-cigarettes are likely to help reduce cigarette use in patients.

In the qualitative interview, you will also have the opportunity to discuss your attempts to reduce your cigarette use which could help increase your awareness of your cigarette use, what maintains use, and obstacles to stopping use which could help you quit smoking cigarettes.

What other treatments or procedures are available for your condition?

People who smoke that are not interested in quitting cigarettes can participate in counseling to help with increasing motivation to quit smoking. You can call the Massachusetts State Quitline Quit Smoking Resources (1-800-Quit-Now). Individuals interested in quitting smoking can also call this resource for assistance with quitting smoking.

Can you still get medical care within Mass General Brigham if you don't take part in this research study, or if you stop taking part?

Yes. Your decision won't change the medical care you get within Mass General Brigham now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should you do if you want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will you be paid to take part in this research study?

If you enroll in this study, you could be paid up to $779 for your study participation. You will be paid for each of the study visits you complete.

If you are in the Immediate Start Group, there will be a total of 7 study visits, and you will be paid $50 for each study visit you attend. You will get $1 for each daily text message answered within 24 hours during the week between the first and second visit, which would be a total of $7. You will also get $1 for each daily text answered during the 8 weeks you are using the electronic cigarettes. If you answer all 56 messages during this 8 week period, you will be given a $10 bonus. You will also be paid $50 for a telephone interview (also called a qualitative survey) at the end of the study. All patients will receive a $50 bonus for completing all study visits. Thus, in total you could earn $523 for participation in this group.

If you are in the Delayed Start Group, there will be a total of 11 study visits, and you will be paid $50 for each visit you attend. You will get a $1 for each daily text message answered within 24 hours during the week between the first and second visit, which would be a total of $7. You will also get$1 for each daily text answered during the 8 weeks you are using the electronic cigarettes. If you answer all 56 messages during this 8 week period, you will be given a $10 bonus. The Delayed Start Group will also receive $1 for each daily text answered during their 8-week delay period. You will also be paid $50 for a telephone interview (also called a qualitative survey) at the end of the study. All patients will receive a $50 bonus for completing all study visits. Thus, in total you could earn $779 for participation in this group.

We will be using an approved, outside vendor (Advarra) to make these payments to you via a reloadable credit card-based system, called Advarra Participant Payments. This secure system is similar to a gift card or credit card. You will be given a Participant Payments Visa card when you enroll in the study. Once the card is activated, the study team will add a payment after each paid visit you complete. The payment should be available to you within a day. You may use the card anywhere Visa cards are accepted, such as at a grocery store. We will need to collect your Social Security number in order to make these payments, and it will be shared securely with the company that runs the card-based system. Payments like this are considered taxable income. If you receive more than $600, the payment will be reported to the IRS as income by the hospital. If you provide a receipt for something like travel expenses and we can cover that, that is not considered taxable income. Reimbursement of expenses will not be made using the Participant Payments card.

What will you have to pay for if you take part in this research study?

Study funds will pay for certain study-related items and services. Study funds will pay for all electronic cigarettes and cartridge refills during the study. Study funds will also pay for the breath tests and urine sample testing that will be done during the study. We may bill your health insurer for, among other things, routine items and services you would have received even if you did not take part in the research. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care. If you have any questions about costs to you that may result from taking part in the research, please speak with the study doctors and study staff. If necessary, we will arrange for you to speak with someone in Patient Financial Services about these costs.

What happens if you are injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the beginning of this consent form.

If you take part in this research study, how will we protect your privacy?

Federal law requires Mass General Brigham to protect the privacy of health information and related information that identifies you. We refer to this information as "identifiable information."

In this study, we may collect identifiable information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable information and why they may need to do so:

- Mass General Brigham researchers and staff involved in this study
- The sponsor(s) of the study, and people or groups it hires to help perform this research or to audit the research
- Other researchers and medical centers that are part of this study
- The Mass General Brigham ethics board or an ethics board outside Mass General Brigham that oversees the research
- A group that oversees the data (study information) and safety of this study
- Non-research staff within Mass General Brigham who need identifiable information to do their jobs, such as for treatment, payment (billing), or hospital operations (such as assessing the quality of care or research)
- People or groups that we hire to do certain work for us, such as data storage companies, accreditors, insurers, and lawyers
- Federal agencies (such as the U.S. Department of Health and Human Services (DHHS) and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections), state agencies, and foreign government bodies that oversee, evaluate, and audit research, which may include inspection of your records
- Public health and safety authorities, if we learn information that could mean harm to you or others (such as to make required reports about communicable diseases or about child or elder abuse)
- Other:

Some people or groups who get your identifiable information might not have to follow the same privacy rules that we follow and might use or share your identifiable information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your identifiable information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your identifiable information only when we must, and we ask anyone who receives it from us to take measures to protect your privacy. The sponsor has agreed that it will not contact you without your permission and will not use or share your identifiable information for any mailing or marketing

list. However, once your identifiable information is shared outside Mass General Brigham, we cannot control all the ways that others use or share it and cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your identifiable information. Your permission to use and share your identifiable information does not expire.

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifiable information **will not** be used for these purposes without your specific permission.

Certificate of Confidentiality

A federal Certificate of Confidentiality (Certificate) has been issued for this research to add special protection for information and specimens that may identify you. With a Certificate, unless you give permission (such as in this form) and except as described above, the researchers are not allowed to share your identifiable information or identifiable specimens, including for a court order or subpoena.

Certain information from the research will be put into your medical record and will not be covered by the Certificate. This includes records of medical tests or procedures done at the hospitals and clinics, and information that treating health care providers may need to care for you. Please ask your study doctor if you have any questions about what information will be included in your medical record. Other researchers receiving your identifiable information or specimens are expected to comply with the privacy protections of the Certificate. The Certificate does not stop you from voluntarily releasing information about yourself or your participation in this study.

Even with these measures to protect your privacy, once your identifiable information is shared outside Mass General Brigham, we cannot control all the ways that others use or share it and cannot promise that it will remain completely private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your identifiable information. Your permission to use and share your identifiable information does not expire.

The results of this research may be published in a medical book or journal, or used to teach others. However, your name or other identifiable information will not be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your identifiable information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your identifiable information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others, and such information may continue to be used for certain purposes, such as to comply with the law or maintain the reliability of the study.

You have the right to see and get a copy of your identifiable information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above.

Print Name

Subject Signature | Date | Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

Print Name

Signature of Study Doctor or Person Obtaining Consent | Date | Time (optional)

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