Mass General Brigham

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

Subject Name:

MRN or DOB:

Subject Identification

Protocol Title: Assessing e-cigarettes for tobacco harm reduction in the context of lung cancer screening

Principal Investigator: Nancy A. Rigotti, MD

Site Principal Investigator:

Description of Subject Population: Adults ages 50 and older, who smoke cigarettes and are not ready to quit smoking cigarettes and are not currently using electronic cigarettes.

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 50 years or older who smokes cigarettes and is not ready to quit smoking but is willing to try and switch to electronic cigarettes from combustible cigarettes. We are testing whether using electronic cigarettes can help people reduce their cigarette smoking and reduce their health risks from cigarette smoking. If you agree to participate, you will be provided with an electronic cigarette device and pods that contain the e-liquid for 4 weeks. The e-cigarette we are using is a product that is authorized to be sold as a consumer product in the U.S. by the Food and Drug Administration's Center for Tobacco Products. You will be in the study for 8 weeks. This includes an additional 4 weeks after we stop providing electronic cigarettes to you.

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

You will be paid up to $240 for taking part in this research study. We will be using physical gift cards to make these payments to you. 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.

Nancy Rigotti, MD, is the person in charge of this research study. You can call her at 617-724-3548 (available M-F 9-5). You can also call Caitlin McCann at 617-724-1065 (available 9-5) with questions about this research study.

If you have questions about the scheduling of appointments or study visits, call Caitlin McCann at 617-724-1065.

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 reduce their cigarette smoking. Because e-cigarettes expose users to many fewer harmful chemicals in cigarette smoke, they may reduce a person's health risks compared to continuing to smoke cigarettes. Since electronic cigarettes are relatively new products, less 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 cigarettes use with electronic cigarette use over a 4-week period. During this 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 by 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. However, the electronic cigarette we will be using has been authorized by the U.S. Food and Drug Administration's Center for Tobacco Products to be sold in the U.S. as a consumer product.

This is a pilot study. Pilot studies are done on a small group of subjects to learn if a larger study would be useful.

Who will take part in this research?

We are asking you to take part in this research study because you are an adult age 50 or older, currently smoke cigarettes and are not currently ready to make an attempt to quit smoking completely.

About 30 people will take part in this research study at Massachusetts General Hospital.

The National Cancer Institute (NCI) 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 8 weeks to complete this research study. During this time, we will ask you to make 3 in-person visits and complete 3 questionnaires over email, text or the phone.

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

At this visit, we will:

- Review the consent form and answer any questions
- 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 leave a urine sample to test for nicotine level
- Ask you questions about your tobacco use
- Provide you with an e-cigarette and pods to use in place of your cigarettes and instruct you how to use the e-cigarettes.
- Review the NJoy Ace Device Electronic Cigarette Instructions. (As stated in the NJoy Ace Device Electronic Cigarette Instructions, please do not share your e-cigarette and remember it is important to keep the device and pods away from children and pets.)

Phone Visit 1 at Week 1
One week later, we will call you to complete a questionnaire. It will take about ten minutes.

At this visit, we will:

- Ask you questions about your tobacco and e-cigarette use
- Ask you questions about any side effects from using e-cigarettes
- Ask you about your experience using the product

In-Person Visit 2 at Week 2
Two weeks after your first in-person visit, we will ask you to come in for a second in-person visit. It will take about 30 minutes.

At this visit, we will:

- Provide you with a new 2-week supply of e-cigarettes and pods to use in place of your cigarettes
- 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 leave a urine sample to test for nicotine level
- Ask you questions about your tobacco and e-cigarette use
- Ask you about any side effects from using the product
- Ask about your experience using the product
- Ask you to bring in all your pods so that we can collect and count the used and unused pods

Phone Visit 2 at Week 3
A week after your second in-person visit, we will call you to complete another questionnaire. It will take about ten minutes.

At this visit, we will:
- Ask you questions about your tobacco and e-cigarette use
- Ask you questions about any side effects
- Ask you about your experience using the product

In-Person Visit 3 at Week 4
Two weeks after your second in-person visit, we will ask you to come in for a third in-person visit. It will take about an hour.

At this visit, we will:
- Ask you questions about your tobacco and e-cigarette use
- 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 leave a urine sample to test for nicotine level
- You will be asked to complete an interview regarding your thoughts about the study procedures, experience using the e-cigarettes and barriers to use during the study or to continuing to use e-cigarettes, if you choose to do so
- Ask you to bring in all your pods so that we can collect and count the used and unused pods

Phone Visit 3 at Week 8
Four weeks after your third in-person visit, we will call you to complete a questionnaire. It will take about ten minutes.

At this visit, we will:
- Ask you questions about your tobacco and e-cigarette use
- Ask you about any new symptoms or new health problems

Study Information Included in Your Electronic Medical Record

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.

Research Consent to Receive Unencrypted Text Message Communications

Text messages by mobile/cell phones are a common form of communication. The Screen Assist Vaping research study involves sending you text messages that are relevant to the research study. Texting over mobile/cell phones carries security risks because text messages to mobile/cell phones are not encrypted. This means that information you send or receive by text message could be intercepted or viewed by an unintended recipient, or by your mobile/cell phone provider or carrier.

Below are some important points about texting in this research study.

- Text messages are not encrypted, and therefore carry security risks. This research study and Mass General Brigham are not responsible for any interception of messages sent through unencrypted text message communications.

- You will be responsible for all fees charged by your carrier's service plan for text messaging. 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 messages will only be read during regular business hours Monday-Friday. Texts send on nights or weekends will not be read until 8 AM of the following business day.

- Text messaging should not be used in case of an emergency. If you experience a medical emergency, call 911 or go to the nearest hospital emergency department.

- You may decide to not send or receive text messages with staff associated with this

research study at any time. You can do this in person or by sending the research number a text message that says "Stop Research Text."

- Your agreement applies to this research study only. Agreeing to other texts from Mass General Brigham, for example appointment reminders, is a separate process. Opting out of other texts from Mass General Brigham is a separate process as well.

- It is your responsibility to update your mobile/cell phone number with this research study in the event of a change.

I have had the chance to ask questions about texting with staff associated with this research study. I have been informed of the risks and other information covered above and consent to the use of unencrypted text communications associated with this research study.

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

Your samples or health information collected for this study will NOT be used or shared for other research, even if we remove identifiable information like your name, medical record number, or date of birth.

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 been reports of 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 NJOY (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. 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.

Subjects' urine samples will also be identified solely by subjects' 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 you may be uncomfortable answering questions about your 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 exposure to harmful chemicals in cigarettes. 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 and are not interested in quitting cigarettes can participate in counseling to help them learn more about why and how to quit by calling 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 $240 for your study participation. Compensation will not be dependent on your e-cigarette use. You will be paid for each of the study visits you complete.

You will be paid $50 for your baseline visit, $50 for your week 2 in-person visit, $80 for your week 4 in-person visit, $30 for a week 8 phone visit and $15 for the phone calls in weeks 1 and 3.

You will also be provided with validated parking vouchers for each of your in-person visits.

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. Study funds will pay up to $4.50 per visit to cover transportation costs. You will be responsible for paying for your transportation or parking to the visit site that exceeds the amount provided by 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
- Other researchers 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:

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 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.

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)

Consent Form Version: 07/18/2024