STUDY2017-0948
Effective: 11/23/2025
Expires: 11/22/2026
UIC Office for the Protection of Research Subjects

University of Illinois at Chicago
Consent/Authorization for Participation in Research

Protocol Title: Switch to a Standardized Research E-cigarette (SREC)

Study Phone: (312) 413-8824

Principal Investigator: Dr. Robin Mermelstein, Ph.D.
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Study Sponsor: National Institute on Drug Abuse (NIDA)

Why am I being asked?

You are being invited to participate in a research study because you have indicated a willingness to cut down on the number of cigarettes you smoke. The current study will examine if health coaching and use of a standardized research electronic cigarette (SREC) can help people reduce their smoking and if there are health effects of switching to SREC (for example, changes in blood pressure and respiratory symptoms). About 120 people will participate in this research study. This study is being conducted by Dr. Robin Mermelstein, Director of the Institute for Health Research and Policy at the University of Illinois at Chicago (UIC) and is funded by the National Institute on Drug Abuse (NIDA).

Before you decide whether or not to participate, you should know what the study is about, the possible risks and benefits, and what you will be asked to do if you take part in this study. Our research staff will review the study purpose and procedures with you now. If after hearing this information you decide you would like to participate, we will ask you questions about the project to ensure that you fully understand what the study involves before you begin. Our research staff will answer any questions about the study that you may have.

Your participation in this study is voluntary. Your decision whether or not to participate will not affect your current or future relationship with the University. If you decide to participate, you are free to withdraw at any time without affecting that relationship. Please read this form and ask any questions you may have; if you decide to take part in the study, you will be asked to sign this form to verify that choice.

Important Information

This information gives you an overview of the research. More information about these topics may be found in the pages that follow.

WHY IS THIS STUDY BEING DONE?	We want to test whether health coaching and using a Standardized Research E-Cigarette (SREC) can help people cut down on the number of cigarettes they smoke. We are also interested in how certain health markers are affected by cutting down on cigarettes and using the SREC as well as people's opinions and feelings about using the SREC (such as taste, level of satisfaction).
WHAT WILL HAPPEN TO ME DURING THE STUDY?	Everyone who participates in this study will complete a variety of health assessments and surveys; receive 12 weeks of health coaching to help reduce the number of cigarettes they smoke; and carry an electronic diary for one week twice. Participants will receive 12 weeks of SREC supplies and will be assigned, by chance, to

STUDY2017-0948
Effective: 11/23/2025
Expires: 11/22/2026
UIC Office for the Protection of Research Subjects

	receive SREC pods with their usual flavor only or SREC pods with a free choice of flavors. About 50% of participants will receive either tobacco or menthol pods and 50% will be able to choose from four flavored pods throughout the treatment portion of the study. For more information, please see the "What Procedures Are Involved?" section below.
HOW MUCH TIME WILL I SPEND ON THE STUDY?	There are 8 study visits over 14 weeks. Before your first study visit, you will complete the informed consent process (15-20 minutes) and baseline questionnaire (30-40 minutes) online; you may choose to complete this in-person at your first study. The first visit will last about 40 minutes. Visits 2-4 will last between 40-60 minutes. Visits 5-7 last about 20 minutes. The final study visit will last about 60 minutes. Participants carry a study-provided electronic diary for 7-days and interact with it multiple times a day two times during the study. The first 7-days begins at the first study visit and the second 7-days at the third visit.
ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?	It is possible that you will not benefit from participation in this study.
WHAT ARE THE MAIN RISKS OF THE STUDY?	You may experience withdrawal symptoms when you reduce your smoking. Common withdrawal symptoms include feeling irritable, hungry, restless, impatient, craving cigarettes trouble concentrating, and insomnia. The most common side effects from using an e-cigarette include: throat and mouth irritation, dry cough, nausea, headache, and light-headedness. Shortness of breath and mouth ulcers have occurred, but are much less common. Participants who start using the SREC but do not cut down on their smoking, may increase their nicotine exposure. Common symptoms of nicotine overdose include stomach cramps, cold sweat, diarrhea, headache, confusion and weakness. The greatest risk of nicotine overdose is for children and pets. The SREC device is not childproof and could present a danger to children or pets who might consume or come into contact with the liquid. In 2019, there were cases of e-cigarette or vaping related lung injuries. The symptoms include coughing, shortness of breath, chest pain, fever, fatigue, nausea, vomiting, diarrhea, and/or abdominal pain. In the majority of cases, people experiencing these symptoms were using e-liquids containing THC (the main psychoactive compound in marijuana), and/or using e-cigarette devices and e-liquids that were mixed at home or purchased off market (such as purchasing an e-liquid or device on the street, not from a licensed retailer). For more information about these risks, please see the "What Are the Potential Risks and Discomforts of the Study" section below.
DO I HAVE OTHER OPTIONS BESIDES TAKING PART IN THE STUDY?	There are other options available. Nicotine replacement gum, lozenges, and patches can be purchased over the counter. You can ask your health care provider about prescriptions for quitting such as Zyban and Chantix. The Illinois Tobacco Quit Line (866-QUIT-YES or quityes.org) and the American Lung Association (www.lung.org/stop-smoking) can also provide assistance.
QUESTIONS ABOUT THE STUDY?	Study hotline at (312) 413-8824 Study Director, Dr. Kathleen Diviak at (312) 996-2327 or kdiviak@uic.edu Primary Investigator, Dr. Robin Mermelstein at (312) 996-1469 or robinm@uic.edu.

STUDY2017-0948
Effective: 11/23/2025
Expires: 11/22/2026
UIC Office for the Protection of Research Subjects

	If you have questions about your rights as a study subject; concerns or complaints, or if you feel you have not been treated according to the description in this form; or to offer input you may call the UIC Office for the Protection of Research Subjects (OPRS) at 312-996-1711 or 1-866-789-6215 (toll-free) or e-mail OPRS at uicirb@uic.edu.

What is the purpose of this research?

The purpose of this research is to test whether health coaching and use of the SREC can help people cut down on the amount of cigarettes they smoke as well as to determine how certain health markers are affected by the change in the number of cigarettes smoked and amount of SREC use. We are also interested in learning more about people's opinions about using the SREC and their subjective feelings after they use it (such as pleasure, taste, level of satisfaction).

What procedures are involved?

Participation in this research study will involve participating in health coaching and using different strategies to reduce the amount of cigarettes you smoke. Throughout the study you will also complete various research components such as: questionnaires, interviews, vital signs, short surveys, and an Electronic Diary.

HEALTH COACHING AND SMOKING REDUCTION: This part of the study will last for 12-weeks and starts during your second study visit. You will meet with a coach from our research staff who will work with you to develop a range of strategies for cutting down your smoking. You will receive a SREC device and learn how to use it. One of the reduction strategies your coach will suggest is using the SREC in place of some of your cigarettes during the day. You will receive SREC refills from the research team during the 12 weeks of treatment. We will ask that you return all refill pods, regardless of whether they are empty or full, to the research staff at each of your study visits in order for us to accurately assess your use of the SREC. We ask that you work with your health coach over the 12-weeks of treatment to cut down on your smoking. If you decide you are ready to quit, your health coach will work with you to set a quit date and develop quitting strategies. If you decide to stop using the SREC and/or stop cutting down, you can still continue to participate in the research study by reporting your cigarette use on the daily surveys, completing the surveys/questionnaires at each study visit, and sharing your honest thoughts and reactions to the coaching and SREC. In order for us to accurately assess the effectiveness of using SREC to reduce smoking, we need to understand how a wide variety of smokers respond to the coaching and the SREC device (including those who don't like it or decide to stop cutting down). If after trying the SREC, you decide you no longer want to use it or if you no longer wish to cut down, just let the research team know and your coach can help you figure out the next steps.

SREC PODS: As part of this research study, we want to determine the extent to which choice of e-cigarette flavors can help smokers switch to the SREC and cut down on their cigarette smoking. A computer program will randomly assign about 50% of the participants to receive SREC pods that contain their usual flavor: tobacco pods for regular cigarette smokers and menthol pods for menthol smokers. The other 50% will be assigned to a free choice condition and will be able to select from tobacco, menthol, watermelon, and blueberry pods throughout the treatment portion of the study. The random assignment works like flipping a coin; it is chance that determines which type of pod you will receive.

RESEARCH ASSESSMENTS. This part of the study lasts for 18 weeks and starts with your first study visit. As part of the research assessments, you will have certain vital signs measured, such as blood pressure, pulse, height, and weight. At each study visit, we will also measure the amount of carbon

STUDY2017-0948
Effective: 11/23/2025
Expires: 11/22/2026
UIC Office for the Protection of Research Subjects

monoxide (CO), a byproduct of cigarette smoking, in your breath by asking you to blow into a digital device. Additionally, we will collect three urine pregnancy test results from female participants of childbearing age (55 years old and younger) every 5-6 weeks during the course of the study. Over the course of the study, you will be asked to complete different types of questionnaires, interviews, and short surveys about your history and experiences with cigarettes, the SREC device, and other e-cigarettes or nicotine vaporizers. These are detailed questionnaires that will be completed on a computer in a private room with a study staff member during your first study visit and at the end of the treatment component of the study. These questionnaires will take approximately 30 - 40 minutes to complete. There will be short interviews and questionnaires during some of your visits that will take anywhere from 5 to 20 minutes to complete.

ELECTRONIC DIARY (ED): We will ask you to carry a study provided smartphone (we refer to it as the ED) for a one-week period on two separate occasions during the course of the study. The first time is during the first week of the study (starting at today's visit) and the second time will begin in two weeks during the third study week. The ED will "beep" between 5 -7 times a day during your waking hours and will ask questions such as what you are doing, who you are with, and how you are feeling. The ED will also ask you about your use of cigarettes and e-cigarettes, as well as marijuana and alcohol use. These interactions with the ED take about two minutes each to complete. While carrying the ED, you will also be asked to record all use of cigarettes, SREC, and any other e-cigarette device or nicotine vaporizer. Each time you make one of those recordings, the ED will ask you a series of short questions that will take about two minutes each to complete. We will show you how to use the ED during your first study visit and talk about how to fit the ED into your day to day life over the next 7 days.

BRIEF DAILY USE SURVEYS: For 12 weeks, starting after your second study visit in week two and lasting until the end of treatment in the fourteenth week, we will send you an email/text once a day that links to an online survey to record your total use of cigarettes, SREC, and any other e-cigarettes during the previous day. These very brief surveys will take about 1-2 minutes to complete.

If you are pregnant, trying to get pregnant, or breast-feeding/nursing, you may not enroll in this study. **If you are female and of childbearing age**, you may enroll in this study after our research staff conducts a urine pregnancy test that shows you are not pregnant. You must agree to use an effective form of birth control or remain abstinent for the duration of the treatment component of this study (the 12 weeks you receive the SREC pods). Once enrolled, you must provide urine samples every 5-6 weeks during the study to conduct the required pregnancy testing at the 6- and 11-week visits in order to continue receiving SREC pods. If you become pregnant during the course of the study, you will no longer receive SREC pods and will be removed from the study.

You will be asked to provide verification of your identify, such as a driver's license, state ID, or other official picture ID upon enrollment in order to comply with federal and state requirements. You will also be asked to complete a Pre-Health Check that will allow us to confirm that you are able to attend each in-person visit.

Overall, the study lasts for 18 weeks. All study visits take place at our UIC research office. There are eight in-person visits over 14 weeks and one follow-up survey that will be completed online or by phone 18 weeks after your first study visit (see the study visit table on page 6 for more details).

What are the potential risks and discomforts of participating?

One potential risk is that you may feel a bit uncomfortable or uneasy answering personal questions. The

STUDY2017-0948
Effective: 11/23/2025
Expires: 11/22/2026
UIC Office for the Protection of Research Subjects

questions we will ask are similar to the questions we've asked in previous studies. During previous studies, we have asked these same questions to hundreds of participants without anyone experiencing significant discomfort. We therefore believe that the risk of discomfort in this study is minimal.

Another potential risk is the loss of privacy (revealing to others that you are taking part in this study) or confidentiality (revealing personal information to those whom you have not given permission). All study personnel are very serious about protecting your privacy and confidentiality. We have multiple study procedures in place to protect your privacy and prevent others from finding out your test results (e.g., urine pregnancy, CO, etc.) as well as how you answered your questions on the ED or other surveys (see below for more information on privacy and confidentiality).

When you are completing the CO measurement, you will be asked to hold your breath for 15 seconds before blowing into the digital monitor. This may cause you to feel light-headed. Measuring CO level in this way is commonly used in smoking cessation treatment programs to provide feedback to participants. The risk of feeling light-headed is minimal.

There are potential discomforts that may come from reducing your smoking; you may experience withdrawal symptoms when you reduce your smoking. Common withdrawal symptoms include feeling irritable, hungry, restless, and impatient; craving cigarettes; having trouble concentrating; and insomnia. Everyone's experience is different; some people have only one or two symptoms while others have more. Symptoms can range in their intensity as well. Please talk with your health coach about any withdrawal symptoms you may be experiencing so that together you can make a plan for managing them.

There are potential risks associated with using the SREC device. Possible side effects of using e-cigarettes, whether the SREC or any other electronic cigarette, include throat irritation, dry cough, mouth irritation, nausea, headaches, and dizziness. Less frequently reported side effects include: sore throat, dry mouth, shortness of breath, and mouth ulcers. Using both cigarettes and the SREC over time, particularly if you don't cut back on your smoking, may increase your overall exposure to nicotine. If you maintain an increased level of use over time, this could increase the withdrawal symptoms you might experience during a future quit attempt. Your health coach will work with you to cut down on your smoking to minimize the likelihood of this happening. In addition, your health coach will review your reports of cigarettes and SREC use at each study visit using your daily survey responses and the weights of returned SREC pods to provide you with feedback about your overall nicotine exposure. An additional risk is nicotine overdose. The SREC device and pods should only be used by you as instructed in the project materials. If you are a very heavy smoker and become a very heavy SREC user without cutting back your smoking, you may be exposed to too much nicotine. Symptoms of nicotine overdose include abdominal cramps, cold sweat, diarrhea, headache, dizziness, fainting, tremor, agitation, mental confusion, and weakness. However, this is very unlikely as there are many smokers who both continue to smoke and use e-cigarettes without any of these problems. **The greatest risk of nicotine overdose is for children and pets**. The SREC device is not childproof and could present a danger to children or pets who might consume or come into contact with the liquid. There are some child resistant features of the device and pod; however, the best protection is to **keep the device and pods out of the reach of children, pets, and others who have limited capacity to read, understand, and keep themselves safe.**

There have been recent reported cases of pulmonary illnesses linked to e-cigarette use. These cases included symptoms such as coughing, shortness of breath, chest pain, fever, fatigue, nausea, vomiting,

STUDY2017-0948
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Expires: 11/22/2026
UIC Office for the Protection of Research Subjects

diarrhea, and/or abdominal pain. Some patients reported symptoms to have occurred over a few days and some reported to have occurred over a few weeks. In the majority of these cases, people experiencing these symptoms were using e-liquids containing THC (the main psychoactive compound in marijuana), and/or were using e-cigarette devices and e-liquids that were mixed at home or purchased off market (such as purchasing an e-liquid or device on the street, not from a licensed retailer). The e-cigarettes and e-liquid pods that we use in this study are purchased only from a NIDA-approved SREC manufacturer and do not contain THC. At this time, there are no immediate known risks associated with the use of the e-cigarette and e-liquids that we will use in this study, although there may be unforeseen risks (such as allergic reactions). If you participate in this study, we ask that you agree to only use the e-cigarette and e-liquid provided by study staff and do not attempt to modify the e-cigarette device or e-liquid in any way.

In response to the recent illnesses related to vaping, the Centers for Disease Control (CDC) has issued the following recommendations for adult e-cigarette users:

- CDC and FDA recommend that people should not use THC-containing e-cigarette, or vaping, products, particularly from informal sources like friends, family, or in-person or online sellers.
- Vitamin E acetate should not be added to e-cigarette, or vaping, products. Additionally, people should not add any other substances not intended by the manufacturer to products, including products purchased through retail establishments.
- Adults using nicotine-containing e-cigarette, or vaping, products as an alternative to cigarettes should not go back to smoking; they should weigh all available information and consider using FDA-approved smoking cessation medications. If they choose to use e-cigarettes as an alternative to cigarettes, they should completely switch from cigarettes to e-cigarettes and not partake in an extended period of dual use of both products that delays quitting smoking completely. They should contact their healthcare professional if they need help quitting tobacco products, including e-cigarettes, as well as if they have concerns about EVALI.
- E-cigarette, or vaping, products (nicotine- or THC-containing) should never be used by youths, young adults, or women who are pregnant.
- Adults who do not currently use tobacco products should not start using e-cigarette, or vaping, products.
- THC use has been associated with a wide range of health effects, particularly with prolonged frequent use. The best way to avoid potentially harmful effects is to not use THC-containing e-cigarette, or vaping, products.

Persons engaging in ongoing cannabis use that leads to significant impairment or distress should seek evidence-based treatment by a healthcare professional. You can review the most current information on the CDC's website at:
www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease/need-to-know/index.html

In addition, there may be unforeseeable health risks associated with the use of the SREC as e-cigarettes are a relatively new product and there are limited data on the health effects of its use. Any new findings on the health effects of e-cigarette use that would affect the risks and benefits to you or your willingness to continue with the study will be communicated to you as we learn them. If you experience any of the side effects mentioned in this consent form or if you have any concerns about your health during the study, please inform your health coach or a member of the research staff.

If you are female, you must **not be breast-feeding/nursing, pregnant, or become pregnant during the course of the study**. If you are a woman of childbearing age, you must agree to use a medically accepted form of birth control (e.g., hormonal contraception, IUD, condom) should you have sexual

STUDY2017-0948
Effective: 11/23/2025
Expires: 11/22/2026
UIC Office for the Protection of Research Subjects

intercourse during the course of the study. Women who are currently pregnant, trying to get pregnant, or breast-feeding **may not** participate in this study. If you become pregnant during the study, you must immediately inform the research staff. Study staff will collect urine pregnancy test results every 5-6 weeks through the duration of the study; any positive test result (indicating pregnancy) will result in your being removed from the study.

Are there benefits to taking part in the research?
It is possible that you may not benefit from participation in this study.

What other options are there?
You have the option to not participate in this research project. You do not need to participate in this program to cut down or stop smoking. There are many treatment options available. Nicotine replacement gum, lozenges, and patches can be purchased over the counter at grocery, drug, or convenience stores. There are prescription medications to stop smoking such as Zyban and Chantix; you can ask your primary care physician about these medications. In addition, there are many other treatment options you can pursue including the Illinois Tobacco Quit Line (866-QUIT-YES or quityes.org) and the American Lung Association (www.lung.org/stop-smoking).

Will I be told about new information that may affect my decision to participate?
During the course of this study, you will be informed of any significant new findings (either good or bad), such as changes to the risks or benefits resulting from participation in this study or new alternatives to participation that might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue in the study will be re-obtained.

What about privacy and confidentiality?
Study staff protect your personal information closely so that no one will be able to connect your questionnaire responses and study health assessments with information that identifies you. The confidentiality of your responses is protected by the following procedures:

- We never place your name on the ED, study questionnaires, or study health assessment results; only a study identification number is used.
- The ED is password protected so that only you can open the program. Only research staff can access your interview responses stored on the ED.
- The master list of participant names, contact information, and their corresponding identification numbers is kept in a restricted access, locked computer file, separate from completed questionnaires and recorded health assessment results. Access to the master list is restricted to research staff who require it to do their jobs only. This master list will be destroyed after all data have been collected, the data have been verified, and the study is over.
- We never share your individual ED responses, questionnaire responses, or the results of other health assessments (e.g., CO, pregnancy, etc.) with information that could identify you; you can answer questions honestly without fear that your private responses will be seen.
- There is no set time for destroying the data you provide and no time limit for their use. Researchers continue to analyze data for many years after information is collected and it is not possible to know when they will be done.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

STUDY2017-0948
Effective: 11/23/2025
Expires: 11/22/2026
UIC Office for the Protection of Research Subjects

Be assured that when the results of the research are published or discussed in conferences, no information will be included that would reveal your identity. Any information that is obtained in connection with this study and that could be connected with you will remain confidential and will only be disclosed with your permission, or if necessary to protect your rights or welfare or if required by law.

Our research team is responsible for protecting your privacy and will keep the information you provide to us confidential. With the few exceptions noted below, we will not reveal that you are a research participant to anyone outside our research team. Because you will receive money for participating in this research study, we are required to share your name, mailing address, and social security number with UIC's Accounts Payable Department in order to comply with state and federal financial and tax laws. This office is responsible for distributing, tracking, and reporting incentive payments you will receive from this study. UIC's Accounts Payable office staff will NOT have access to any other information you provide, only your name, mailing address, social security number, and the amount of your compensation.

Also, the UIC Office for the Protection of Research Subjects (OPRS), the state of Illinois, NIDA, and the FDA may also know that you are a research participant in this study. These groups may monitor our research procedures to protect your rights and privacy as well as to ensure that our research is conducted properly and according to high scientific and ethical standards. If either of these offices monitors our research, they may have access to this signed consent form that identifies your name as a participant in this study. They may also review study materials, but only to ensure that we have not collected data from individuals who did not agree to participate; they will not review any of your specific responses to the questionnaires or interviews or other data that is collected during the study.

Any personal information that could identify you will be removed or changed before the study data files are shared with other researchers or results are made public. Other researchers and the public will not be able to determine who participated in this study.

What if I am injured as a result of my participation?

If you get ill or injured from being in the study, UIC will help you get medical treatment. You should let the study staff know right away that you are ill or injured. If you believe you have become ill or injured from this study, you should contact Dr. Robin Mermelstein at (312) 996-1469 or Dr. Kathleen Diviak at (312) 996-2327.

You should let any health care provider who treats you know that you are in a research study. If you do seek medical treatment, please take a copy of this document with you because it may help the doctors where you seek treatment to treat you. It will also provide the doctors where you seek treatment with information they may need if they want to contact the research team.

You or your health insurance plan will be billed for any medical treatment you receive. Health insurance plans may or may not cover costs of research-related injury or illness. Costs not covered by insurance could be substantial. UIC has not set aside any money to pay you or to pay for your treatment if you get ill or injured from being in the study. There are no plans for the University to provide other forms of compensation (such as lost wages or pain and suffering) to you for research related illnesses or injuries. The only exception to this policy is if it is proven that your injury or illness is directly caused by the negligence of UIC. By signing this form, you are not giving up any legal rights to seek compensation of injury.

STUDY2017-0948
Effective: 11/23/2025
Expires: 11/22/2026
UIC Office for the Protection of Research Subjects

What are the costs for participating in this research?

You are responsible for all travel costs to and from the study research offices, except for the costs to park in the designated UIC meters during study visits. There are no other costs to you for your participation in this research. Coaching, the SREC device, and refills will be provided at no cost to you during your participation in the treatment part of this study.

Will I be reimbursed for any of my expenses or paid for my participation in this research?

Yes. Please see the table below for the visit and payment schedule.

Week	Procedures	Duration of Study Visit	Participant Payment
1	Review study procedures, complete questionnaire, pregnancy test, vital signs, height and weight, ED instructions, go home with ED	In-person visit; 90-120 minutes	$20
2	Review ED week, coaching on cutting down and using the SREC, short questionnaire, go home with SREC, daily use surveys begin, vital signs	In-person visit; 60 minutes Daily reports 1-2 mins/day	$50 + $20 (compliance bonus)
3	Bring in all SREC pods, vital signs, coaching, short questionnaire, go home with ED and SREC pods	In-person visit; 40 minutes Daily reports 1-2 mins/day	$20 (for returning with all refill pods)
4	Review ED week, bring in SREC pods, vital signs, coaching, short questionnaire, go home SREC pods	In-person visit; 40 minutes Daily reports 1-2 mins/day	$50 + $20 (compliance bonus) + $20 (for returning with all refill pods)
6	Bring in all SREC pods, brief check-in and coaching, go home with SREC pods, short questionnaire, pregnancy test, vital signs	In-person visit; 20 minutes Daily reports 1-2 mins/day	$20 (for returning with all refill pods)
8	Brief check-in to return SREC pods and coaching, vital signs, go home with SREC pods, short questionnaire	In-person visit; 20 minutes Daily reports 1-2 mins/day	$20 (for returning with all refill pods)
11	Brief check-in to return SREC pods and coaching, vital signs, go home with SREC pods, short questionnaire, pregnancy test	In-person visit; 20 minutes Daily reports 1-2 mins/day	$20 (for returning all pods)
14	End-of-treatment, return the SREC device and all SREC pods, complete questionnaire, vital signs, height and weight, daily use surveys end	In-person visit; 60 minutes	$20 + $20 (for returning the SREC device and all pods)
18	Brief follow-up questionnaire	Online or phone	$40 (for this questionnaire and at least 70% of the daily surveys)

Additional Payment Details:

The $50 payment for carrying the ED in weeks two and four requires that you successfully carry and interact with ED consistent with the training instructions for 7 days, complete the end-of-week interview and brief questionnaire, return a working device with appropriate amounts of interviews, and return the charger for the ED device. If you do not interact with the ED as instructed during training, you may be offered a second chance to carry the ED. If you do not wish to do it again, you will not be paid and you may be dropped from the rest of the study.

You will receive an additional $20 if you respond to at least 30 prompts (beeps) in the 7-day period and the number of prompts that you respond to is at least 80% of the total ED prompts. In other words, you must leave the device on during most of your waking hours and respond to most of the prompts, consistent with the training provided by study staff.

Finally, if you do not return the charger for the ED device, we will hold back $10 from your payment until the charger is returned to research staff.

The $20 payments in weeks 3, 4, 6, 8, 11, and 14 require that you return with **ALL** the SREC pods you were given at the previous visit regardless of whether or not they have been used (at week 14 you must also return the SREC device to receive the payment). Used pods will be collected by the research staff and the rest returned to you for use in the upcoming weeks. If you do not return with all the pods you were given at the previous visit, the $20 payment will not be made. If you forget to bring your pods back to a visit and are not paid, but at your next study visit return with all the cartridges you were given at both visits, you will receive both visit payments.

STUDY2017-0948
Effective: 11/23/2025
Expires: 11/22/2026
UIC Office for the Protection of Research Subjects

The $40 payment in week 18 will be made if you complete at least 70% of the daily use surveys sent between weeks 2 and 14 and you complete the final questionnaire. There will be 84 daily surveys (7 a week for 12 weeks); if you complete at least 58 of these short surveys, you will be eligible for the final $40 payment. The daily surveys can only be completed online by clicking on the link that is sent to you. Research staff cannot record your answers to these daily surveys by phone. The final questionnaire can be completed online from any computer, laptop, or tablet or by phone with our research staff.

Payment for study activities will be made by a check issued by the University and mailed to your home address. We will request two checks from UIC Accounts Payable: one after the week 4 visit and one after the week 18 follow-up questionnaire. Study staff will submit the check request within one week of these study visits. It may take between 4-6 weeks for UIC Accounts Payable to issue the payment. Payments are sent via USPS to your home address and the delivery time is outside of the control of the Switch to SREC staff and UIC.

Cumulative payments to you in a calendar year will exceed $200, therefore, it is the university's policy to obtain tax identification information from all participants as it may require reporting of these payments to the United States Internal Revenue Service (IRS) on Form 1099-MISC. Study staff will need to collect your social security number or Taxpayer Identification Number (TIN) using IRS forms W9 or W8-BEN. We will provide these documents to University Payables to issue your compensation and for tax reporting purposes to the United States Internal Revenue Service (IRS). If you are not a U.S. citizen, we may also need to collect copies of documents like your green card or visa (as applicable). Anything we collect is used only for tax reporting purposes and is kept strictly confidential. Payments made to nonresident aliens are subject to 30% federal and 4.95% state income tax rate withholding via TIN or Form 1042-S. If you refuse to provide the tax reporting information, you may still participate in the study; however, the University will follow IRS rules and will withhold 28% from your incentive payment.

Can I withdraw or be removed from the study?

Yes, you are free to withdraw your consent and discontinue participation at any time. We will ask that you return the SREC device and all pods you have been given before any final study payments will be made. You have the right to leave the study at any time without penalty. You may also be removed from the study for your safety or at the discretion of the research staff. You will be removed from the study if your urine pregnancy test indicates a pregnancy. In the event you withdraw or are asked to leave the study, you will only be compensated for the portions of the study that you have completed.

What if I am a UIC student?

You may choose not to participate or to stop your participation in this research at any time. This will not affect your class standing or grades at UIC. The investigator may also end your participation in the research. If this happens, your class standing or grades will not be affected. You will not be offered or receive any special consideration if you participate in this research.

What if I am a UIC employee?

Your participation in this research is in no way a part of your university duties, and your refusal to participate will not in any way affect your employment with the university, or the benefits, privileges, or opportunities associated with your employment at UIC. You will not be offered or receive any special consideration if you participate in this research.

STUDY2017-0948
Effective: 11/23/2025
Expires: 11/22/2026
UIC Office for the Protection of Research Subjects

Who should I contact if I have questions?
You can ask any questions you have now. If you have questions later, please contact your coach or any member of our research team. You can also contact the study director or the primary investigator.

- Study hotline at (312) 413-8824
- Dr. Kathleen Diviak, Study Director, kdiviak@uic.edu or (312) 996-2327
- Dr. Robin Mermelstein, Principal Investigator: robinm@uic.edu or (312) 996-1469

What are my rights as a research participant?
If you feel you have not been treated according to the descriptions in this form, or if you have any questions about your rights as a research participant, including questions, concerns, or complaints, or to offer input, you may call UIC's Office for the Protection of Research Subjects (OPRS) at (312) 996-1711 or 1-866-789-6215 (toll-free) or email OPRS at uicirb@uic.edu.

REMEMBER:
Your participation in this research is voluntary. Your decision whether to participate will not affect your current or future relations with the University. If you decide to participate, you are free to withdraw at any time without affecting that relationship.

Signature of Participant
I have read (or someone has read to me) the above information. I have discussed the procedures, risks, and benefits of the study with the research staff. I have been given an opportunity to ask questions and my questions have been answered to my satisfaction. I agree to participate in this research. I will be given a copy of this form for my records.

_____ _____
Signature Date

_____
Printed Name

Signature of Research Staff Who Conducted the Consent Process
I have discussed the purpose, procedures, risks, and benefits of this research study with the participant. I encouraged questions and answered all questions that were asked. The research participant demonstrated his/her understanding of the information I provided. He/she is aware that participation is voluntary and that he/she can stop participating at any time.

_____ _____
Signature of Person obtaining Consent Date (must be same date as the participant)

_____
Printed Name of Person Obtaining Consent