Partners HealthCare System
Research Consent Form

Subject Identification

Version Date: December 2021

Protocol Title: Financial incentives for homeless smokers: A community-based RCT

Principal Investigator: Travis P. Baggett, MD, MPH

Site Principal Investigator:

Description of Subject Population: Adult (≥18 years old) patients at Boston Health Care for the Homeless Program who smoke 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.

Mass General Brigham HealthCare System is made up of Mass General Brigham hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Mass General Brigham system simply as "Mass General Brigham."

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

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. Your decision won't change the medical care you get within Mass General Brigham or Boston Health Care for the Homeless Program (BHCHP) now or in the future.

The following key information is to help you decide whether or not to take part in this research study. We have included more details about the research in the Detailed Information section that follows the key information.

IRB Protocol No: 2019P000034
IRB Expiration Date: 10/25/2024
Consent Form Valid Date: 11/1/2023
IRB Submission: CR3/AME30

Why is this research study being done?

In this research study we want to learn more about how to help people quit smoking and to see if the program that we created will help people be more successful with quitting smoking.

How long will you take part in this research study?

If you decide to join this research study, it will take you about **[6 months]** to complete the study. During this time, we will ask you to make **11** in-person check-in visits. We will meet you here at Jean Yawkey Clinic at 780 Albany Street for all future in-person visits. You will have the chance to earn money at each of these visits.

What will happen if you take part in this research study?

If you decide to join this research study, the following things will happen:

- We will ask you to answer survey questions
- We will ask you to do saliva tests to monitor your nicotine levels
- We will ask you to meet with a tobacco quit coach
- We will ask you to meet with a study clinician who may prescribe a medication to you to help you quit smoking called varenicline.
- We may ask you to complete an optional interview where you talk about your experience in the study.

Why might you choose to take part in this study?

We cannot promise any benefits to you from taking part in this research study. However, possible benefits of participating may include 5 free one-on-one coaching sessions, the chance to monitor your smoking levels by doing saliva tests and earning money for them, and a 12-week prescription for varenicline, a medication that helps you to stop smoking. These will hopefully help reduce your smoking, although we cannot promise that you will quit or experience other benefits. Even if you do not reduce your smoking, others who smoke may benefit in the future from what we learn in this study.

Why might you choose NOT to take part in this study?

Taking part in this research study has some risks and requirements that you should consider carefully.

Important risks and possible discomforts to know about include stress and physical discomfort from quitting smoking.

A detailed description of side effects, risks, and possible discomforts can be found later in this consent form in the section called "What are the risks and possible discomforts from being in this research study?"

Other things to consider are that most study visits will take place in-person here in this building at 780 Albany Street. We will take precautions to lower COVID-19 risk by limiting contact with study staff as much as possible.

What other treatments or procedures are available for your condition?

Other treatments or procedures that are available to treat smoking include getting nicotine replacement medication from your doctor or pharmacy, or by attending other stop smoking programs. You can also get medication, such as Varenicline and Bupropion, from your doctor.

If you have questions or concerns about this research study, whom can you call?

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

Dr. Travis Baggett is the person in charge of this research study. You can call him at 617-643-9314, Monday through Friday, from 8 a.m. to 4:30 p.m., or afterhours at 781-221-6565.

If you have questions about the scheduling of appointments or study visits, call Evangeline Kennedy at 617-306-2111.

If you want to speak with someone **not** directly involved in this research study, please contact the Mass General Brigham Human Research Committee office. 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 study to test a way of helping people quit smoking. If you choose to participate, you will be randomly assigned to 1 of 2 treatment groups by a computer program. The two groups are described in the section called "What will happen in this research study?"

This is a study that will help us see how many people in each of the two groups quit smoking. The results will help us figure out how to best help patients at Boston Health Care for the Homeless program quit smoking.

Who will take part in this research?

We are asking you to take part in this research study because you currently smoke cigarettes and stated you are interested in quitting. Up to 400 people will participate in this research study. All study visits will occur at a Boston Health Care for the Homeless Program clinic site.

This study is paid for by a grant from the National Institutes of Health (NIH).

What will happen in this research study?

If you choose to participate in this study, we will do a 35-minute survey today to collect some information from you about your smoking and other health issues. You will receive $25 for completing this survey. After that, a computer program will randomly assign you to Group 1 or Group 2. Neither you nor anyone else involved in this study can choose your study group. You will have a 1-in-2 (50%) chance of being assigned to Group 1 and a 1-in-2 chance of being assigned to Group 2.

No matter which group you are in, you will have the chance to receive:

A) Five sessions of tobacco coaching. You will be paid $15 for each coaching session you attend.

B) A prescription for the stop-smoking medication varenicline. In most cases, the prescription will be provided by our study clinician after a brief visit. In some cases, we may need to work with your primary care provider to get the prescription. Either way, we will assist

you with getting this medication filled either here at the pharmacy at 780 Albany Street or at an alternative pharmacy depending on available supply and/or preference. You may choose to take the medication for up to 3 months to help you quit smoking.

C) Payments for doing saliva (spit) tests to monitor your nicotine levels. These tests are painless and easy to perform but must be done in person here at 780 Albany Street.

The only difference between Group 1 and Group 2 is how you get paid for the saliva tests:

- If you are assigned to **Group 1**, you will get $10 payments when you give a saliva sample, regardless of the result or whether you have been smoking.
- If you are assigned to **Group 2**, you will earn a payment *only* if the saliva test shows you have not been smoking. The first time this happens, you will receive $25. This amount will increase by $5 at each following visit that you have stayed quit, up to a maximum of $70. If the saliva test shows you have been smoking, you will not receive a payment.

Here are some other things that will happen for everyone in this research study, no matter which group you are assigned to be in:

- We will ask you attend an in-person group assignment visit where you will receive your study visit schedule and learn more about the group you are assigned to. You will also meet with the study clinician. You will get paid $10 for attending this visit.
- If the study clinician prescribes varenicline to you, we will ask you to attend 2 follow-up visits with the clinician (1 and 2 months from now). At these visits, the clinician will refill your prescription for another month if you want to continue taking varenicline.
- We will ask you to complete 25-minute surveys about your health and your smoking 3 and 6 months from now. During these survey visits, we will also collect a second saliva test that captures the exact amount of nicotine in your system. You will get $30 for each of these visits regardless of whether you have quit smoking.
- If you do not have a mobile phone of your own, we will provide you with a mobile phone and a 12-month talk and text plan at no cost to you to help us keep in touch with you throughout the study.

Some participants in each group may be asked to participate in 45-minute audio-recorded interviews about your experiences in the study 3 and 6 months from now. Audio recordings from these interviews will only be listened to by the research study staff or a professional transcriptionist (the person who will type what is in the recording). Once the information on the recording has been typed, we will erase the recording. Some things you tell us may be quoted in publications, but your name and any other information that could identify you will never be attached to anything you say. If you complete an interview, you will be paid $30 for your time.

A note 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. This will include what was discussed during visits with the study clinician and whether you were prescribed the medication varenicline. Please ask the study clinician if you have any questions about what information will be included in your medical record.

You can stop participating in the study at any time for any reason. You can also refuse to participate in any part of the study. If you choose to stop participating in the study, please call the study coordinator at 617-306-2111 and we will make sure that you do not receive any more contacts from the study.

How can you complete study activities safely?

During this study we may need to make changes to study visits and procedures to make sure everyone is safe during the COVID-19 (coronavirus) pandemic. We ask that you comply with any Boston Health Care for the Homeless Program's COVID-19 safety rules and procedures. If you feel sick or have tested positive for COVID-19 within 10 days before a study visit, please do not come in for study activities. When possible, we will limit how much time you meet with study staff in person or in the same space. This means you may complete study activities here at Jean Yawkey Place (780 Albany Street) or remotely using video conferencing or phone calls.

What do you need to know about video calls and phone calls?

Video visits will be completed using Zoom or Microsoft Teams. During these visits, study staff will set up the video call for you in advance in a private area. Some study visits can also be completed over the phone. Study staff will call your personal phone to complete the visit. The types of activities we may ask you to complete by video or telephone call include surveys, coaching sessions, visits with the study clinician, and/or interviews. The study clinician or the study leader, Dr. Travis Baggett, will be available during these remote visits to advise study staff or speak with you if needed.

As explained above, study staff will audio record the optional 45-minute interviews at months 3 and 6 if you choose to participate. Otherwise, we will not take any photographs or recordings of you during any other phone or video call appointments. We ask that you do not take screenshots, photographs, or recordings of any kind during any phone or video call appointments.

How will you be reminded about study visits?

We will send you text message reminders to your mobile/cell phone to help you remember when your study visits are. You can opt out of receiving these text messages. In some cases, we may

also call you to remind you of appointments. We can also provide you with appointment cards at the end of each study visit to remind you of the date and time of your next study visit.

Are there any risks to text messages?

Texting over mobile/cell phone 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.

What else do you need to know about texting?

- Text messages are not encrypted and therefore carry security risks. This research study and Mass General Brigham Healthcare are not responsible for any interception of messages sent through unencrypted text message communications.
- If you have your own phone, you will be responsible for all fees charged by your carrier's service plan for text messaging. This research study and Mass General Brigham Healthcare are not responsible for any increased charges, data usage against plan limits or changes to data fees from the research texts. If you have a study phone and plan, this research study and Mass General Brigham Healthcare are not responsible for any increased charges, data usage against plan limits, or changes to data fees from the research texts.
- Study staff will not respond to text messages. If you want to communicate with study staff, please call 617-306-2111.
- 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 receive text messages from staff associated with this research study at any time. You can do this in person or by replying "STOP" to study visit text message reminders.
- Your agreement applies to this research study only. Agreeing to other texts from Mass General Brigham Healthcare, such as appointment reminders, is a separate process. Opting out of other texts from Mass General Brigham Healthcare 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.

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?

You and your doctor should not expect to get information about the results of the research study or the results of your individual participation in the research study. The researchers involved in this study will study samples and information from many people. It could take many years before anyone knows whether the results have any meaning. There is a small chance that the researchers could find out something from the study that might be important to your health. If this happens, we may attempt to contact you to find out if you would like to learn more. However, even if we find something important to your health, we cannot guarantee that you will be contacted.

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

It is possible that quitting smoking will be stressful for you. The coach will try to help you with this. You may also feel uncomfortable because of nicotine withdrawal and cravings to smoke. Varenicline is designed to help with these symptoms.

The most common side effects of varenicline are nausea, constipation, gas, vomiting, and unusual dreams. In rare instances, people taking varenicline have reported psychiatric symptoms, including suicidal thoughts. We will be monitoring closely for any side effects you may have. If you have a serious side effect to varenicline, we will arrange for appropriate medical care to treat it. Another risk is the potential presence of a contaminant within varenicline that may increase the risk of cancer when people are exposed to high levels over a long period of time. The Food and Drug Administration (FDA) has set acceptable safe levels of this contaminant. All versions of the medication that are being distributed by pharmacies fall within these acceptable levels.

Because we will be collecting information related to your physical and mental health, there are risks to your privacy should this information be lost. We will make every effort to prevent this

from happening by storing all information we collect from you in a secure electronic database that only study staff has access to.

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

The coaching, smoking cessation medication, and other support you receive in this study may help you to quit smoking. However, it is possible that these treatments will not help you to quit smoking. Even if the treatments don't work for you, what we learn in this study could benefit other smokers at places like Boston Health Care for the Homeless Program.

What other treatments or procedures are available for your condition?

You do not have to take part in this research study. You may purchase nicotine patches, lozenges, and/or gum on your own, or you may get stop-smoking medications such as varenicline or bupropion as well as counseling through your regular health care provider. You can also get free telephone counseling from the Massachusetts Smokers' Helpline: 1-800-QUIT-NOW (1-800-784-8669).

Note: If you do decide to join this study, using nicotine replacement therapy (patch, gum, lozenge, inhaler or nasal spray) will interfere with the results of the saliva test that we ask you to complete. The saliva test may show that you are smoking even if you are not.

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 the 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.

If you drop out of the study, we will no longer contact you except to help arrange other follow up care, if needed. We will keep any data collected from you up until the point where you stopped participating.

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

Yes. You will be given a reloadable VISA debit card at the beginning of the study. Each time you are paid for a study visit, the money will be transferred immediately onto your debit card, which you will be able to use at any place that accepts VISA.

If the reloadable VISA debit card service is temporarily unable to load new payments or issue new cards, we will provide you with single-use gift cards matching the payment amount you are meant to receive for the visit you complete. If you complete a visit over the phone, you may choose to pick up the non-reloadable gift card in person or have it mailed to you.

How much money you earn will depend on which study group you are assigned to and how many study visits you attend.

No matter which group you are assigned to, you will receive $25 for completing a survey today, $10 for completing the clinician and group assignment visit, $15 for each coaching session you attend (5 total), and $30 each time you complete a survey and second saliva test for smoking at 3 and 6 months. This comes to a total of $170 if you complete all of those things.

As described above:

- If you are assigned to Group 1, you can also earn $10 for every saliva test you complete no matter what the result is.
- If you are assigned to Group 2, you could earn additional money for quitting smoking. The exact amount you earn will depend on whether you quit smoking and how long you stay quit. The minimum you can earn for a saliva test that shows you did not smoke is $25. The maximum you can earn for a saliva test that shows you did not smoke is $70. A detailed summary of possible payments will be provided to you at the group assignment visit if you are assigned to this group.

No matter what group you are assigned to, you will need to complete the saliva test on the date scheduled by study staff to get paid. If you show up before or after the scheduled date to complete the saliva test you will **NOT** get paid.

If you are selected to complete a 45-minute interview about your experience in the study, you will receive $30 for your time.

If there is no activity on your reloadable VISA debit card for one month, there may be a small fee deducted from the card value. There is no fee if the balance if zero. Please let study staff know as soon as possible if you lose any payment cards given to you.

If we provide you with a mobile phone because you do not have one of your own, then you may keep the phone at the end of the study if you still have it. However, the talk and text plan will be deactivated and you will have to cover the cost of future plans yourself. We will not replace the phone if you lose it.

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, like your tobacco coaching. If you choose to fill your prescription for varenicline, you may be responsible for a small copayment. If you are unable to make that copayment, we will assist you with accessing resources at Boston Health Care for the Homeless Program to receive the medication anyway. Although we do not anticipate this, 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?

If you are injured as a direct result of taking part in this research study, we will assist you in obtaining medical care to treat the injury. This means arranging for care at Boston Health Care for the Homeless Program or at a nearby acute care center for treatment of the injury.

The care provider may 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:

- 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 researchers within or outside Mass General Brigham, for use in other research as allowed by law.

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, the risks and benefits of texting, 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 identifiable information to be used and shared as described above.

_____	_____	_____
Subject	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.

_____	_____	_____
Study staff obtaining Consent	Date	Time (optional)