University of Vermont Consent to Participate in Research

Title of Research Project:	Contingency Management to Improve Medication for Opioid Use Disorder Continuation After Discharge from the Emergency Department
Lead Investigator:	Eric A. Thrailkill, Ph.D.
Sites Where Research is Being Conducted:	University of Vermont Medical Center, Addiction Treatment Center (1 S. Prospect St.), Chittenden Clinic (San Remo Dr.)
Sponsor:	National Institute on General Medical Sciences

Introduction

You are being invited to take part in this research study because you have received a referral to outpatient services to continue a prescription for buprenorphine or methadone (we will refer to these as Medications for Opioid Use Disorder, or **MOUD**, for short). This study is being conducted by the University of Vermont at the UVM Medical Center.

Your participation in this research study is optional. We encourage you to ask questions and discuss the study with anybody you think can help you make this decision.

Key Information to Help You Decide Whether or Not This Study Is Right for You

The purpose of this research study is to determine whether delivering incentives for continuation of MOUD prescribed in the Emergency Department is effective and feasible. All participants will be prescribed buprenorphine or methadone in the Emergency Department and receive a referral to an outpatient treatment provider (Addiction Treatment Center or Chittenden Clinic) through STAR. All participants will receive services and medication from their outpatient treatment provider as described during the STAR referral. Participants will be assigned randomly (by chance) to one of two groups. Participants in Group A will complete a survey (Survey 1) in the Emergency Department today and then visit our lab in the University Health Center (1 S. Prospect) after 30 days to complete a second survey (Survey 2) and provide a urine sample. Participants in Group B will do all this and receive vouchers for attending the clinic and picking up their prescription. Total study duration is the 30 days after you leave the Emergency Department. The main risk of the study is related to accidental breach of confidentiality and we talk about this below.

The information above is only a brief summary of the study. If you are interested in learning more, it is important to read the following pages for additional detailed information about the study. If you decide to take part in the research, you will be asked to provide written consent at the end of this document.

Why Is This Research Study Being Conducted?

The purpose of this study is to learn about the feasibility of delivering incentives to support outpatient clinic attendance following MOUD prescribed in the Emergency Department. Prescriptions in the Emergency Department have increased access to MOUD, but only about half of those who receive prescriptions continue with the prescription at outpatient clinics following discharge from the Emergency Department. Incentives have proven effective for helping individuals engage with treatment in multiple settings. We want to understand whether providing incentives to support clinic attendance is feasible and can increase attendance more than standard care provided by the outpatient clinic.

How Many People Will Take Part In the Study?

Approximately 30 people are expected to complete the study.

What Is Involved In The Study?

What are we doing: If you agree to participate in this study, we will be checking that you are attending your outpatient clinic. We will do this by having a trained staff member look at your medical record. Specifically, we will be checking to see if you receive your MOUD prescription.

What are you doing: If you agree to participate in this study, you will be asked to do the following: First a computer program will randomly assign (by chance) you to one of two groups for the 30-day study**: Group A** or **Group B**. There is a one in two (50%) chance of being assigned to either Group A or Group B. These groups are described below:

- **Group A**: If you are assigned to Group A, you will receive standard care at the outpatient clinic (Addiction Treatment Center or Chittenden Clinic). You will receive standard buprenorphine or methadone maintenance treatment from your provider. The details of your treatment will be identical to anyone receiving a prescription for MOUD and referral outpatient treatment services through STAR.
- **Group B**: If you are assigned to Group B, you will receive standard care at the outpatient clinic (Addiction Treatment Center or Chittenden Clinic). You will receive standard buprenorphine or methadone maintenance treatment from your provider. During the study, you will receive financial incentives for coming to the clinic and picking up your prescriptions:
    - Attendance incentives. Following verification of receipt of medication, incentives ($15) will be added to a reloadable card that we distribute today. You can use this card anywhere that accepts payments from Visa.
    - The first time you pick up your prescription at the outpatient clinic (Addiction Treatment Center or Chittenden Clinic), you will receive $50. Each time you attend the clinic and pick up your prescription, additional incentives will be added to your card.
        - Addiction Treatment Center
            - Since 3-4 days may pass between buprenorphine doses, $15 will accumulate each day between visits to the clinic because you will only be paid when you pick up a prescription. For example, if your last visit was on Monday, you would receive $60 during your next visit on Friday (4 x $15 = $60). As long as you regularly attend the clinic to pick up your prescription, you will receive at least $15 per visit.
            - We will ask you to sign an additional form to acknowledge that our research collaborators at the Addiction Treatment Center will communicate whether you completed your medication appointment to

our study team at UVM. The Addiction Treatment Center is housed within the University of Vermont Medical Center.

- Chittenden Clinic
  - Since methadone is picked up more frequently, you will receive $15 for each daily pick up. If more than one day passes from one visit to the next, the $15 will accumulate over that day. As long as you regularly attend the clinic to pick up your prescription, you will receive at least $15 per visit.
  - We will ask you to sign an additional form to acknowledge that our research collaborators at the Chittenden Clinic/Howard Center will be communicating whether you completed your medication appointment to our study team at UVM.

- **All Participants.**
  - **Initial assessment**. If you choose to participate, you will complete a 10-min survey today before you leave the Emergency Department. You will receive $55 for completing the initial survey added to your study card.
  - **Follow-up assessment**. Participants in each group will also complete a 1-hr follow-up assessment at the end of the 30-day study period. This follow-up visit will take place at the University Health Center (UHC; 1 S Prospect St). The follow-up visit will include a urine sample and brief survey assess OUD symptom severity, other substance use and psychosocial functioning (similar to assessments you will complete at the intake visit in the Emergency Department). You will receive a $55 bonus for completing the 30-day follow-up assessment. You will be able to schedule your follow-up visit in a 10-day window following the end of the 30-day study period.
  - **A note on payment:** All participants will receive a Focus Blue Visa Card.
    - For those in Group A, the cards will be initially loaded with $55 to compensate for completing baseline assessments.
    - For those in Group B, the cards will be initially loaded with $70 ($55 for baseline assessment completion + $15 for MOUD dose received in the Emergency Department).
    - Payments require accessing and completing a brief payment acknowledgement form. This is done online. Our study team will contact you (your preference of text message/email/phone call) to notify you of a payment and deliver a link to complete the form on our website. This process takes about 2 minutes to complete.
    - If you lose access to a phone or device that connects to the internet, we will provide you with a study phone so that you do not miss any payments. If this occurs or is going to occur, please do not hesitate to contact us immediately. If you encounter circumstances that prevent you from access the online form or any other problems arise, please text/call/email the study staff at 802-656-2669 or eric.thrailkill@med.uvm.edu for support as soon as possible.
    - If the card is lost or damaged, please text/call/email the study staff at 802-656-2669 or eric.thrailkill@med.uvm.edu to arrange a replacement.

Future Use and/or Sharing

Identifiable private information collected from you during this study may be used for future research studies or shared with other researchers for future research. The identifiable private information may be used for future research on incentives and treatment adherence. If the

investigator distributes your information to other researchers or institutions, your information will be labeled with a research code and information that directly identifies you such as your name, address or social security number will not be shared. No additional consent will be requested for the future research use of information collected from you during this study.

What Are The Risks and Discomforts Of The Study?

The main risks of the study are related to a loss of confidentiality. Our staff will collect informaiton from your health records regarding certain medical care you recieve to see whether the prescription is filled and deliver incentives based on this. Your health records are protected by several privacy laws including the Health Insurance Portability and Accountablilty Act (HIPAA) and 42 C.F.R. Part 2 (see more information in Confidentiality section below). Staff will document this information by using a code that is unique to you. The code will replace any information that directly identifies you such as your name, address or social secuirty number. Information that identifies you will be kept separate from the coded data in a secure and restricted location. However, there is risk for an accidental breach of confidentiality. Additionally, although MOUD is standard care for treating opioid use disorder, participants who transition to MOUD may experience withdrawal symptoms (i.e., anxiety, depression, difficulty concentrating, hunger/weight gain, insomnia, irritability, and restlessness). Finally, if we think you intend to seriously harm yourself or others, we might alert proper authorities to maintain your safety.

What Are The Benefits of Participating In The Study?

You may not benefit directly from your participation in this study. However, you may experience a reduction in the problems that commonly occur with opioid use disorder. For example, participation in this study may increase your chances of stopping illicit opioid use and preventing long-term issues associated with opioid use disorder. You will also help us learn more about the best way to improve outpatient clinic attendance following discharge from the Emergency Department with a prescription for MOUD, which may benefit public health in general by reducing the adverse impacts of opioid use disorder.

What Other Options Are There?

You do not have to join this study. If you do not join, your care at the UVM Medical Center and/or Chittenden Clinic will not be affected. If you decide not to participate in the study or if you decide to withdraw from the study, you will still receive standard care consisting of MOUD prescription and referral to outpatient services.

Are There Any Costs?

All study visits and assessments will be in the Emergency Department or outpatient clinic (Addiction Treatment Center, Chittenden Clinic). If you choose to receive notifications about your incentive payments via text message, email or phone calls text messaging and data rates may apply depending on your mobile phone plan. There will be no additional cost to you for any aspect of this research study.

What Is the Compensation?

You will be compensated for your time completing assessments at the intake and follow-up visits. The total amount of compensation differs depending on which group you are assigned. Everyone will receive $55 for completing the intake questionnaire in the Emergency Department and $55 for completing the follow-up questionnaire at your outpatient clinic on day 30 (Addiction Treatment Center or Chittenden Clinic). Altogether, participants can earn up to $110 for completing the scheduled assessments. Participants randomly assigned to Group B may also

receive up to an additional $485 in incentives for outpatient clinic attendance for a total of up to $595.

You will be required to verify your name and address each time you receive a payment. You will also be requested to provide your social security number if the payment amount is equal to or greater than $100 or if the total payments from UVM are equal to or greater than $600 in a calendar year. If you are not a US Citizen or Permanent Resident Alien you will be required to complete additional paperwork including your immigration status for payment. This information will be strictly confidential and will be used for tax withholding and reporting purposes only and will allow the University to determine your US residency for federal income tax purposes.

Can You Withdraw or Be Withdrawn From This Study?

You may discontinue your participation in this study at any time. Leaving the study will not change your ability to receive standard medical care. The researcher may discontinue your participation in this study at any time. Your refusal to participate or early withdrawal from the study will not affect your future care at the UVM Medical Center or Chittenden Clinic/Howard Center.

If you choose to withdraw from the study, you may cancel permission for the use of your private health information. You should let the research team know that you are cancelling your permission. A member of the team will assist you in making your decision effective. The study will continue to use the self-reported private health information already collected for the study before you cancelled your permission, and you cannot get back information that was already shared with others.

What About Confidentiality of Your Health Information?

Your health information is being used for your participation in this research protocol. We need to know your past medical history to ensure that it is safe for you to participate and we need to collect ongoing health information once you have begun the research study to ensure your continued safety and to determine what effect the research project has had on your diagnosis.

The health information we are collecting is protected by several privacy laws including HIPAA and Part 2. Part 2 and HIPAA, protect any information about you that is collected by the UVMMC Addiction Treatment Center or the Chittenden Clinic/Howard Center related opioid use disorder. HIPAA protects all of the other information about you contained in your health records. We will do our best to protect and keep the information we collect from you confidential).

What health information will be used and disclosed for this study?

The health information we plan to collect for this study is listed below.

- Information that identifies you, such as your name, address, age, and sex
- Reports from hospital and clinic visits
- Laboratory and other test results
- Lists of medications you are taking
- Responses to health surveys and questionnaires
- Reports about drug and alcohol treatment, including records relating to treatment at a substance use treatment program

Who is disclosing your health information for this research study?

- The University of Vermont Medical Center
- Chittenden Clinic/Howard Center, if applicable.

Who will use your health information in this study?

Our research team will use your health information. We may also share it with those who assist with the conduct of the research or oversight of the activities for this study. The representatives from the institutions, organizations, and agencies are listed below.

- The University of Vermont and its Committees on Human Research
- Officials from agencies and organizations that provide accreditation and oversight of research
- The University of Vermont Medical Center and Chittenden Clinic/Howard Center, if applicable
- The sponsor of this study**,** the National Institute on General Medical Sciences
- Federal and state agencies that oversee or review research information, such as the U.S. Food and Drug Administration (FDA), the Department of Health and Human Services, the National Institutes of Health, and public health and safety authorities

The health information we are collecting is protected by several privacy laws including HIPAA and Part 2. Part 2 and HIPAA, protect any information about you that is collected by the UVMMC Addiction Treatment Center or the Chittenden Clinic/Howard Center related opioid use disorder. HIPAA protects all of the other information about you contained in your health records. We will do our best to protect and keep the information we collect from you confidential).

Once your health information is shared outside of the University of Vermont Medical Center, we cannot guarantee that these laws will continue to apply. As a result, your health information could be further disclosed for other purposes. The confidentiality of your health information cannot be guaranteed if you agree it may be used in this study.

How long will your health information be used for this research?

Your permission to use your health information will not end unless you withdraw your permission. During this study, you will not have access to study data. You may ask for your data once study activities are complete. You have a right to receive a copy of the information in your medical record at any time.

What if you decide not to give permission for research use of your health information?

If you decide not to allow the use and disclosure of your health information, you may not take part in this study. Your decision will have no effect on your current or future medical care.

If you choose to stop taking part in this study in the future, you may cancel permission for the use of your health information. You should let the research team know that you are cancelling your permission. A member of the research team will assist you in making your decision effective. The study will continue to use the health information already collected for the study before you cancelled your permission, and you cannot get back information that was already shared with others.

Who can answer your questions about the use and disclosure of your health information?

If you have questions or concerns about the use and disclosure of your health information, you should ask a member of the study team at 802-656-1641 or the Privacy Officer at The University of Vermont Medical Center, Inc, at (802) 847-2667.

Safeguarding Your Private Information

The information that you give us in this study will be confidential. To protect your confidentiality, we will keep your records locked in a secure location or password-protected file on a secure server hosted by the University of Vermont Medical Center. However, there is certain information that we must report for legal or ethical reasons, such as child abuse, elder abuse, or intent to harm yourself or others. When the research is completed, our research team may save coded study records for use in future research done by myself or others without additional consent. We will retain this study information for at least three years after the study is over. The same measures described above will be taken to protect confidentiality of this study data. If results of this study are published or presented, individual names and other personally identifiable information will not be used.

The sponsor (National Institute on General Medical Sciences) or their appointed designees as well as the UVM Institutional Review Board and regulatory authorities will be granted direct access to your original research records for verification of research procedures and/or data.
If your record is used or disseminated for government purposes, it will be done under conditions that will protect your privacy to the fullest extent possible consistent with laws relating to public disclosure of information and the law-enforcement responsibilities of the agency.

Any communications through email and social media are not considered private or secure. Though we are taking precautions to protect your privacy, you should be aware that information sent electronically through these methods could be read by a third party.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate does not stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate does stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also does not prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

To protect your confidentiality, we will save all study data securely; paper documents filed in a locked secure location and digital information in password-protected files on a secure server. Only study staff with credentials specific to the University of Vermont Medical Center electronic health record data safety protocols and Addiction Treatment Center or Chittenden Clinic/Howard Center electronic health record data safety protocols will access identifiable information (Please note that you may be asked to sign a separate release form for the Addiction Treatment Center or the Chittenden Clinic). Other study staff will have access to anonymized data only.

The results of this study may eventually be published, and information may be exchanged between medical investigators, but patient confidentiality will be maintained.

If your record is used or disseminated for government purposes, it will be done under conditions that will protect your privacy to the fullest extent possible consistent with laws relating to public disclosure of information and the law-enforcement responsibilities of the agency.

The study sponsor requires sharing of study data. Any data shared will have all identifying information removed (e.g., names, addresses, dates). Your name and other identifying information will be replaced with a code that cannot be connected to your name.

Clinical Trials Registration

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.

Contact Information

You may contact Dr. Eric A. Thrailkill, the Investigator in charge of this study, at 802-656-2669 for more information about this study. If you have any questions about your rights as a participant in a research project or for more information on how to proceed should you believe that you have been injured as a result of your participation in this study you should contact the Director of the Research Protections Office at the University of Vermont at 802-656-5040.

Voluntary Consent

You have received and read or were read a summary of this research study. Should you have any further questions about the research, you may contact the person conducting the study at the address and telephone number given below. Your participation is voluntary, and you may refuse to participate or withdraw at any time without penalty or prejudice to your present and/or future care.

You agree to participate in this study, and you understand that you will receive a copy of this form.

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Signature of Participant Date

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Name of Participant Printed

_____

Signature of Principal Investigator or Designee Date

_____

Name of Principal Investigator or Designee Printed

Name of Principal Investigator: Eric A. Thrailkill, Ph.D.
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