Subject Name: _____ **Last 4 SSN:**_____ **Date:** _____

Title of Study: SEdative-Hypnotic Deprescribing Assisted by a Technology-Driven Insomnia InterVEntion (SEDATIVE)

Principal Investigator: Adam Bramoweth, PhD **VAMC:** Pittsburgh (646)

LAY TITLE: Insomnia Treatment Using a Mobile App

KEY ELEMENTS: This is a research study, and your participation is voluntary. The purpose is to test two treatments that work together to reduce the use of sleep medications and improve sleep quality at the same time. The treatments are: (1) working with a Clinical Pharmacist to reduce sleep medication and (2) Cognitive Behavioral Therapy for Insomnia (behavioral change therapy) to reduce the amount of time it takes to fall asleep, reduce the amount of time spent awake in the middle of the night, and/or improve your sense of feeling rested upon awakening. Both treatments will be delivered, at the same time, through a mobile application on your personal device. The app is called COAST (Clinician Operated Assistive Sleep Technology). Both treatments (medication reduction and behavioral change for sleep) are available to Veterans at VA Pittsburgh Healthcare System (VAPHS), but they are not currently combined nor delivered through a mobile app.

If you choose to enroll in this study and use the COAST app, after the consent process, you will begin by downloading the app and then completing questionnaires and self-report measures about your sleep and health. A licensed Clinical Pharmacist will then work with you, through COAST, for up to 12 weeks on a personalized plan to reduce or eliminate your use of sleep medication. This plan can be paused or adjusted at any point, and you can report any symptoms, such as sleepiness, caused by medication withdrawal, through the app and the study team will respond within one business day. After the 12 weeks, if necessary and desired, you can continue your withdrawal plan with the provider who first prescribed your medication.

During the same 12 weeks, the COAST app will also lead you through Cognitive Behavioral Treatment for Insomnia (CBT-I), an evidence-based treatment. Each day, you will use the COAST app to record your sleep behaviors (e.g., bedtime, how long to fall asleep, number of awakenings, wake time). This information will allow for recommendations to be made to change and improve your sleep quality. Before you see the recommendations, they will be reviewed and approved by a Sleep Psychologist. Your assigned Sleep Psychologist may be located at VA Pittsburgh or VA Madison (Wisconsin).

There are risks to this study that are described later in this document. Some risks include increased sleepiness, anxiety, restlessness, irritability, and fatigue—all common when reducing sleep medications. The study team will work with you to minimize these symptoms (if present). You may directly benefit from participating in this study by learning how to avoid sleep medication while having your insomnia

symptoms reduced. This may include falling asleep faster, staying asleep longer, and/or feeling more rested when you wake up. However, we cannot guarantee these results. You may indirectly benefit because through your participation, as we will learn more about this combined treatment so that it may benefit Veterans like you with sleep problems in the future.

If you do not participate in this study, you may still seek treatments for insomnia like behavior therapy or medication. You may also talk with your provider about starting a step-by-step withdrawal from sleep medication.

If you are interested in learning more about this study, please continue reading below.

STUDY CONTACT INFORMATION: If you have a general question about this research study, or if you have any concerns or complaints related to this research study, you may call the Principal Investigator, Dr. Adam Bramoweth, at (412) 360-2806. For medication-related questions, please contact study Clinical Pharmacist and Co-Investigator, Dr. Amanda McQuillan, at (412) 360-3057.

If you experience any illness, injury, or other medical problem that you feel may be related to this study, please call Dr. Adam Bramoweth at (412) 360-2806. On after-hours or on weekends call 1-866-785-9015 and tell the operator that you are a research subject from the Pittsburgh VA in the study called "SEDATIVE" and need to speak with Dr. Adam Bramoweth. Then give the operator a phone number where you can be reached. The operator will get in touch with Dr. Bramoweth, or another person listed below who will call you back. In the case of a medical emergency contact your local emergency medical service or go to your local emergency room.

PRINCIPAL INVESTIGATOR:
Adam Bramoweth, PhD
VA Pittsburgh Healthcare System
Research Office Building, 151R
University Drive C
Pittsburgh, PA 15240
(412) 360-2806

Subject Name: _____ **Last 4 SSN:** _____ **Date:** _____

Title of Study: SEdative-Hypnotic Deprescribing Assisted by a Technology-Driven Insomnia InterVEntion (SEDATIVE)

Principal Investigator: Adam Bramoweth, PhD **VAMC:** Pittsburgh (646)

CO-INVESTIGATORS:

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(412) 360-2232

Megan Hamm, PhD
Department of Medicine
University of Pittsburgh School of Medicine
Pittsburgh, PA 15261
(412) 647-0280

James Lickel, PhD
William S. Middleton
Memorial Veterans' Hospital
2500 Overlook Terrace
Madison, WI 53705
(608) 256-1901 x17528

STUDY SPONSOR: VA Rehabilitation Research and Development

Additional information regarding the study sponsor can be provided upon request.

PURPOSE OF THE RESEARCH STUDY: The purpose of this research study is to test a mobile app called COAST (Clinician Operated Assistive Sleep Technology) to facilitate and deliver a combined treatment to reduce the use of sleep medications and improve sleep quality, through CBT-I, at the same time. The treatments delivered through the app will be by study team members: a Clinical Pharmacist and a Sleep Psychologist.

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You are being asked to participate in this research study because you are a Veteran who regularly uses sleep medications.

This study will enroll up to 50 Veterans at VAPHS.

This is a multi-site study. Only Veterans from VAPHS will be enrolled. However, one of the study Co-Investigators/Clinicians (Dr. Lickel) is located at the William S. Middleton Memorial Veterans' Hospital (Madison, WI) and will interact with Veterans from VAPHS.

A description of this clinical trial is available on http://www.ClinicalTrials.gov (search: NCT05027438), 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.

DESCRIPTION OF THE RESEARCH STUDY:

Location: This treatment will be delivered through the VA Pittsburgh Healthcare System, but study activities are remote via the mobile app (COAST).

Study Procedures:

Progress notes regarding your participation in this study will be placed within your VA medical record.

Baseline Assessment:

This process may take up to 1 to 2 hours. If you choose to sign this Informed Consent Document and participate in the study, you will first be guided through the process of downloading the app, called COAST, on your mobile device, and will undergo a brief training on how to use it. Training will include including instructions on how to access and navigate to the content areas, how to enter data for measures, how to use the sleep diary, and how to use the secure messaging. A user guide is also accessible on the app. If technical issues arise, you can inform the study team and your issues will be responded to rapidly by the Noctem team. After training on the COAST app, you will then answer a series of questionnaires and self-report measures on COAST about your sleep and health, and about the app itself (e.g., ease of use). Your responses to questionnaires and self-report measures throughout the study will be collected via the COAST app. Other data may be collected directly from you or your electronic health records and will be documented in the study database.

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Please note that, while we are measuring sleep and emotional disorders, this is a research study and is not the same as regular medical care. If we note any behaviors (e.g., suicidal/homicidal ideation, plan, intent) that place your or others at risk of harm, we will follow VAPHS guidelines to ensure your safety.

Treatment:

Following the Baseline Assessment, the treatments will be delivered through the COAST mobile app.

For the step-by-step medication withdrawal, the study's Clinical Pharmacist will first work with you over the phone or through telehealth to develop a personalized plan based on factors such as your type of medication, how long you have been taking it, and anxiety about the withdrawal. For up to twelve weeks, you will use the app to send the study team information about your medication use and sleep each day and will get feedback about when a change in dose and/or new medication is required.

At any point during treatment, the Clinical Pharmacist can pause or change this plan if you are struggling to adjust to it. You will report all medication withdrawal symptoms, such as fatigue and irritability, through the COAST app, and you will be responded to within the business day by a researcher involved in the study. If necessary, outside of business hours (M-F, 8:00am – 4:30pm EST) you can contact emergency services (e.g., 911 or your nearest Emergency Room).

For the behavioral sleep treatment, after you entered your sleep habits each day for about a week, the COAST app will use this information to generate recommendations about changes you can make to your behavior to improve your sleep in the long run. As noted above, all recommendations are reviewed and approved by the study Sleep Psychologist. For example, if you report that a stressful event has occurred in your life, the Sleep Psychologist may decide to slow or pause treatment. The study team can also respond rapidly to your reports, for example by sending you a secure text message through the app to follow-up. Your assigned Sleep Psychologist may be located at VA Pittsburgh or VA Madison (Wisconsin).

The recommendations to change your sleep behaviors will be based on Cognitive Behavioral Treatment for Insomnia and will include setting a sleep schedule, changing your thinking patterns, and learning relaxation techniques. Additional parts can be added as needed for nightmares and daytime fatigue. You will continue to use the COAST app to report your sleep each day during treatment (up to twelve weeks, if needed to withdraw from medication) as well as to report your psychological, emotional, and physical states and overall satisfaction with our sleep each week. In turn, the COAST app will continue to generate recommendations for you.

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The goal of this research study is all interactions with study clinicians will be done remotely, primarily using the COAST platform, but as needed by video telehealth or telephone. However, if you need to see a study clinician in-person, that visit will occur at VA Pittsburgh Healthcare System. For an in-person visit with a Sleep Psychologist you will see the Sleep Psychologist at VA Pittsburgh.

15 Veterans, during Treatment, will also be asked to be interviewed over the phone, or through video telehealth, about their experience with the COAST app and potential changes or new features that could improve it.

Post-treatment:

This process may take up to 1 to 2 hours. At the end of the treatment (12 weeks or sooner) you will complete another series of questionnaires on COAST about your sleep and health, and how easy to use the app has been for you. If you require further assistance in withdrawing from sleep medication at this time, you may also choose to continue this process with the VA provider who first prescribed it.

Follow-up:

About three months after you have completed treatment, you will again use the COAST app to complete a series of questionnaires about your sleep and health, and to enter a week of daily reports about your sleep habits.

Duration of Participation: Participation in this study, including the Baseline Assessment, Treatment, and Follow-Up may last approximately 5-6 months. Your participation in this study will end upon completion of all study procedures. You may withdraw from the study at any time without penalty; however, you may not be eligible for all study payments. If you choose to withdraw during treatment, you can still participate in the study assessments and be eligible for associated study payments.

Data Collection/Repository: Data will be collected as part of study procedures and used to accomplish study goals, such as, "Do insomnia symptoms and/or medications reduce after the intervention?" Collected data is stored on a secure study specific folder on the VAPHS server and your data will be de-identified so none of your personal/identifying information, like your name and date of birth, is linked to the data. In addition to this data being used for the current study, data will also be stored in the *VAPHS Research Repository (MIRECC)*. This repository allows other investigators, only with permission, to conduct additional research with your data that may benefit other Veterans and the delivery of

healthcare in VA. None of your identifying information will be stored in the repository and cannot be linked back to your identifying information—it will be anonymous. Data stored in the repository is optional—you will complete a separate form if you approve.

RISKS AND BENEFITS:

Risks Related to Medication Deprescribing: When reducing sleep medications, some common risks (withdrawal symptoms) may include increased sleepiness, anxiety, restlessness, irritability, and fatigue. These risks are the same as if you were reducing your sleep medication in a clinical setting at VAPHS. Through the COAST app, you will be able to report any of these symptoms as part of the daily sleep diary, or at any time they occur, and the study team will respond within one business day. Throughout the study, the study team will work with you to minimize these symptoms (if present).

Risks Related to Sleep: One of the primary risks involved is the potential for symptoms of insomnia to not improve or even worsen. There is the possibility of a decrease in sleep quantity and/or quality. However, these risks are a normal and expected part of decreasing sleep medication and/or participating in behavioral sleep interventions. Risks involved in participating in either of these interventions are similar to risks posed in a clinical setting. Both the Clinical Pharmacist and Sleep Psychologist will work with you throughout your treatment to adjust your medication and sleep habits as needed to minimize symptoms.

Psychological Risks: Other potential risks include emotional or psychological discomfort related to answering questions as part of the self-report questionnaires. You are encouraged to take breaks while completing the questionnaires in the app if you feel yourself becoming distressed. You may also take breaks if you become fatigued while answering the questionnaires. You can also refuse to answer any questions that make you uncomfortable and/or distressed and you can stop the interview/questionnaires at any time; however, this may result in your participation in the study ending.

Risk of Breach of Confidentiality: There is minimal risk of breach of confidentiality. Your protected health information will be stored securely, and your data will be linked to a unique ID number.

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Time Commitment Risks: By participating in this study, you may spend more time than usual completing self-report questionnaires and measures, such as a daily "sleep diary" and questionnaires about sleep and mood symptoms on a weekly basis during treatment.

Other Risks: Because there may be other risks associated with participating in multiple research studies at the same time, you must tell the research staff about any other studies you are currently participating in, both within and outside of the VA.

Benefits: You may benefit from participating in this study. Sleep medications have known unpleasant and/or dangerous side effects; direct benefits include reducing your use of sleep medication while learning behavioral change skills to improve insomnia symptoms and improve your sleep quality. You may indirectly benefit from this study. Indirect benefits include contributing to knowledge that can potentially improve the way insomnia is treated for Veterans and non-Veterans.

ALTERNATIVES TO PARTICIPATION: There may be other studies that you qualify for. Talk to your provider about such options. If you do not participate in this study, you may still seek treatment for insomnia, including Cognitive Behavioral Therapy for Insomnia. You may also talk with a provider about starting a step-by-step withdrawal from sleep medication. You may also choose not to seek treatment for insomnia or reduction of sleep medication.

NEW FINDINGS: You will be informed of any significant new findings during the course of the study, which may affect your willingness to continue to participate. After this study ends, however, there is no expectation that you will receive aggregate or individual study results.

INVESTIGATOR INITIATED WITHDRAWAL: The investigator(s) may stop your participation in this study without your consent for reasons such as: it will be in your best interest; you do not follow the study plan; or you experience a study-related injury. If the investigator stops your participation in the study during your step-by-step withdrawal from medication, the Clinical Pharmacist will work with the provider who first prescribed the medication to continue your withdrawal plan as appropriate, and you will be put under the care of the prescribing provider.

VOLUNTARY PARTICIPATION/RIGHT TO WITHDRAW: Your participation in this study is voluntary. You do not have to take part in this study, and your refusal to participate will involve no

penalty or loss of rights to which you are entitled. You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled. You may choose to withdraw from this study during treatment but continue to participate in the post-treatment and follow-up assessments.

Your doctor (i.e., Dr. Bramoweth) may also be involved as an investigator in this research study. As both your doctor and a research investigator, he is interested both in your medical care and the conduct of this research study. You are under no obligation to participate in this, or any other research study offered by your doctor. Before you agree to participate in this research study, or at any time during your participation in this study, you may discuss your care with another doctor who is not associated with this research study.

MEDICAL TREATMENT: In the event that you sustain injury or illness as a result of your participation in this VA approved research study, conducted under the supervision of one or more VA employees, all medical treatment (emergent as well as medical treatment beyond necessary emergent care) will be provided by the VA. Except in limited circumstances, the necessary medical care must be provided in VA medical facilities.

However, if such injury or illness occurred as a result of your failure to follow the instructions for this study, you may not be eligible for free care unless you have independent eligibility for such care under Federal Law.

FINANCIAL COMPENSATION: If you sustain an injury or illness as a result of participating in this research study, you may be eligible to receive monetary compensation for your damages pursuant to applicable Federal law. If you believe that you are injured as a result of participation in this study, please contact the Principal Investigator. If compensation is available the Principal Investigator will provide you with an explanation as to what that compensation consists of, or where you can obtain further information regarding it.

COST AND PAYMENTS: You or your insurance will not be charged for any costs related to the research. However, if you are receiving medical care and services from the VA that are not part of this study, and you are a Veteran described in Federal regulations as a "category 7" Veteran, you may be required to make co-payments for the care and services that are not required as part of this research study.

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Except in limited circumstances, payments issued through VA are generated by Electronic Funds Transfer (EFT). Therefore, in order to receive payment associated with your participation in this study, you must be willing to receive EFT and to provide banking information to VA, if that information has not already been provided. If you are not able to receive payment through EFT, the Direct Express Debit MasterCard may be issued. The Direct Express Debit MasterCard is a prepaid debit card. Please refer to the flyer that study personnel have provided for more information about which services may require a fee if using your Direct Express Debit MasterCard. In addition, due to limitations in the Financial Management System, payments made to you will generate Internal Revenue Service (IRS) Form 1099 regardless of amount. Payments will be reported to the IRS as income and your social security number will be used for this purpose.

We greatly appreciate your participation in our study. Participant payments to compensate you for your time and effort are as follows:

Baseline Assessment	$50
Post-Treatment Assessment	$50
3-month Follow-Up Assessment	$50

Additionally, if you are invited to participate in an interview after treatment about your experience with the app and choose to do so, you will receive $25.

RECORD RETENTION: Your research records will be retained in accordance with the Veterans Health Administration (VHA) Records Control Schedule, or longer, if required by other Federal regulations.

Confidentiality risks and precautions to decrease risk: Every effort will be made to make sure that the information about you obtained from this study will be kept strictly confidential. As private information is collected about you as part of this study, there is a risk to your privacy and confidentiality. The research staff will take every precaution to protect your identity and the confidentiality of the information collected about you.

We will protect your information with the use of a unique study ID (not your name or social security number). As part of your participation, certain identifying data will need to be collected by our study partner, Noctem Health, Inc., when using their mobile app, in particular your email address and your

mobile device IP address. We will not share your information with anyone who is not approved, unless required by law. While your study related data will be confidential, we still need to document your participation in your VA medical record as required by VA Pittsburgh Healthcare System policies.

If you are interviewed as part of study procedures, to further protect your identity on the audio recording, the interviewer will be instructed and will instruct you that names are not going to be used during the session. The recorder will be stored in a locked office or cabinet of the study team. Recordings will be downloaded to the secure study drive after completion of the interview. Recordings will be identified by your unique ID number. Recordings will be transcribed and coded for analysis/review by the study team.

You consent to the publication of the study results or release of the data when published, so long as the information about you is anonymous and/or disguised so that your identity will not be disclosed.

Future use: The information you provide may be used or distributed for future research studies without any additional informed consent. As noted above, your data will be stored in the VAPHS Research Repository (MIRECC).

REVOCATION: If you sign this form, you may change your mind and revoke or take back your permission at any time. You must do this in writing and must send your written request to the Principal Investigator for this study at the following address:

Adam Bramoweth, PhD
VA Pittsburgh Healthcare System (#646)
Research Office Building (151RU/MIRECC)
University Drive
Pittsburgh, PA 15240

If you revoke (take back) your permission, you will no longer be able to participate in this study but the benefits to which you are entitled will NOT be affected. If you revoke (take back) your permission, the research team may continue to use or disclose the information that it has already collected before you revoked (took back) your permission which the research team has relied upon for the research. Your written revocation is effective as soon as it is received by the study's Principal Investigator.

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EXPIRATION: Unless you revoke (take back) your permission, your authorization to allow us to use and/ or disclose your information will: Expire at the end of this research study. Any study information that has been placed into a repository to be used in future research will not expire.

RESEARCH SUBJECTS' RIGHTS: You have read or have had read to you all of the above. Dr. Adam Bramoweth or his authorized representative has explained the study to you and answered all of your questions. The risks, discomforts, and possible benefits of this research study, as well as alternative treatment choices, have been explained to you.

A description of the study has been provided to you, including an explanation of what this study is about, why it is being done, and the procedures involved. You have the right to ask questions related to this study or your participation in this study at any time. You should be giving your consent only under conditions in which you (or the person representing you) have sufficient opportunity to carefully consider whether or not to participate in this study. Your consent should not be given under conditions that pressure you or try to influence your decision in any way.

Your rights as a research subject have been explained to you, and you voluntarily consent to participate in this research study. You will receive a copy of this signed consent form.

If you have any questions about your rights as a participant in this study or wish to speak more about the study with someone not associated with the research study, you can call the Associate Chief of Staff for Research and Development at (412) 360-2394.

As long as the study is renewed as required by the IRB, your signature on this document is valid for the duration of the entire research study. Should any changes occur during the course of the study that may affect your willingness to participate, you will be notified.

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By signing this form, you agree to participate in this research study.

_____	_____	_____
Subject's Signature	Date	Time
_____	_____	_____
Investigator/Person Obtaining Consent	Researcher (Print)	Date

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