DEPARTMENT OF VETERANS AFFAIRS
Medical Center
830 Chalkstone Avenue
Providence, RI 02908-4799

October 9, 2025

The ART Program
The VA ORD

To Whom It May Concern:

Enclosed please find the informed consent form for the completed clinical trial, IIR 19-048, *Post-Hospital Intervention for Veterans with Comorbid Bipolar and Substance Use Disorders* (**NCT04127604**). This version of the consent form was approved by the IRB on 12/04/2024.

Sincerely,

Jane Metrik, PhD
Co-Principal Investigator
Providence VA Medical Center
(401) 273-1000 Ext. 12024
Jane.Metrik@va.gov

Participant Name:_____ Date:_____

Title of Study: Post-Hospital Intervention for Veterans with Comorbid Mood and Substance Use Disorders (Veteran Participant Consent Form)

Principal Investigator: Jane Metrik, Ph.D. and Brandon Gaudiano, Ph.D. VA Facility: Providence 650

KEY SUMMARY INFORMATION ABOUT THE STUDY

You are being invited to take part in a research study that is being funded by the Department of Veterans Affairs Office of Research and Development. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. Taking part in this study is completely voluntary.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

This study is about a new treatment program for Veterans with mood disorders (bipolar spectrum, depressive, or schizoaffective disorders) and a history of substance use following a recent hospitalization, ER/crisis visit, or other care transition.By doing this study, we hope to learn if this new program can help Veterans successfully transition from a higher level of care to a lower level of care by improving symptoms related to their mood disorder and substance use, by reducing suicide thoughts and behaviors, and by helping Veterans take their medications as prescribed and keep better contact with their doctors. We will be testing whether this new program that provides additional monitoring and therapy sessions can better improve symptoms, compared with a different program that provides monitoring alone. Both study programs will be provided in addition to usual VA treatment.

Your participation in this research will begin following a qualifying clinical event (an inpatient admission, emergency department visit, urgent care visit, suicide/crisis hotline call, or discharge from a residential mental health or substance use treatment program) and will last for about 9 months. You will be asked to return to our research clinic at 3, 6, and 9 months after an initial, baseline, assessment so we can assess your progress. During those assessments you will answer questions about your mood, substance use, thoughts of death, and how well you function. These assessments will take about 2-3 hours each and you will be paid for completing them. After completing the baseline assessment to confirm your eligibility, you will be randomly assigned (50-50 chance, like a flip of a coin) to either your usual treatment plus the study keeping track of your symptoms or your usual treatment plus our study treatment program. Those who receive the usual treatment only will have brief reports summarizing their symptoms and progress sent to their health care providers at baseline, 3-, 6- and 9-months following study enrollment. In addition to these reports, those who receive our study treatment program also will receive 3 individual sessions,1 family meeting, and 11 follow-up phone calls or video sessions with a study therapist for 6 months following study enrollment. The individual meetings are about 1 hour each and the 11 phone or video sessions (based on preference) are about 15-30 minutes each.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

Regardless of which study program you receive, we hope that the study will help you keep track of your symptoms and help the doctors involved in your usual care by keeping them informed of your symptoms and safety. *For a complete description of benefits, refer to the 'Detailed Information about the Study' section.*

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

Providence VAHCS Institutional Review Board
Effective Date: December 4, 2024
Expiration Date: December 12, 2025

Some of the assessments concern sensitive information that you may find upsetting or uncomfortable. Another possible risk is loss of privacy. *For a complete description of risks, refer to the 'Detailed Information about the Study' section.*

Participating in this study does not restrict you from participating in any other treatments of your choice. Our study programs are designed to support and extend the other treatments you may already be receiving. *For a complete description of alternate treatment/procedures, refer to the 'Detailed Information about the Study' section.*

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The persons in charge of the study are study investigators Drs. Jane Metrik and Brandon Gaudiano of the Providence VA Medical Center. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, [redacted] contact information is: ([redacted]. [redacted] and [redacted] contact information is: [redacted].

DETAILED INFORMATION ABOUT THE STUDY

WHAT IS THE PURPOSE OF THIS STUDY?

By conducting this research project, we hope to learn how to better help Veterans with mood disorders and substance use problems transition successfully from a higher level of care to a lower level of care; with a higher level of care defined as any clinical encounter higher than the outpatient setting. To do this, we will be comparing the benefits of a new treatment program with a monitoring only program, when both are added to Veterans' usual care. We hope that this new treatment program will improve Veterans' symptoms and promote recovery.

HOW LONG WILL I BE IN THE STUDY?

This research study is expected to take approximately 5 years. Your individual participation in the project will take approximately 9 months.

WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?

If you decide to participate, you will complete the following procedures:

- First, you will complete a baseline assessment of your symptoms with a study research assistant, which includes an initial screening portion, to determine if you are eligible and a good fit for the study. If you are not a good fit based on this initial screening, you will not complete the rest of the baseline assessment. If you are deemed a good fit after the screening, you will complete the rest

of the baseline assessment. This decision about who can or cannot participate in this study includes specific characteristics that must be shared by all participants. The rest of the baseline assessment will include interviews (face-to-face) and questionnaires (paper/pencil or computer administered) given by the research assistant. This will take approximately 3 hours total to complete. If you are recruited from an inpatient unit and discharged before completing the assessment, you will be contacted by our research clinic at the Providence VA Medical Center to complete the interview within the first week after discharge. If you are not eligible for the study, you will just complete the interview portion.

- If you are eligible after the interview and continue in the study, you will complete additional follow-up assessments at 3, 6, and 9 months following the initial assessment to determine changes in your symptoms. These assessments will be done by the study research assistant and will include interviews and questionnaires, which will take about 2-3 hours each. You will return to our research clinic at Providence VA Medical Center to complete these assessments or will have the option of completing these confidential surveys remotely by mail, online using Brown University Qualtrics, or over the phone.

- If you elect to complete a study assessment online using Brown University Qualtrics, a research assistant will text and/or email you (if you give us your permission to do so) with a link specific to you that will direct you to the assessment survey. They will let you know when it is time to complete the survey. While none of the surveys that you fill out online will ask you for personally identifying information or collect your computer IP address, Brown University Qualtrics will record the date on which you submit a survey. The Brown Qualtrics survey questions can be accessed by anyone with access to your survey link; however, only study staff will be able to view the responses that you submit as part of the survey. For this reason, we ask that you keep all study communications confidential and complete the survey in private. If you decide that you do not want your survey submission date to be recorded or do not otherwise want to use Brown Qualtrics to fill out surveys, you will still have the option to complete the assessment by mail or by phone instead.

- At each follow-up in-person assessment, at months 3, 6, and 9, you may be asked by a research assistant to blow into a machine that will tell us whether you drank any alcohol before coming in. This will be decided at the discretion of the study investigators, Drs. Jane Metrik and Brandon Gaudiano, based on the clinical hospital guidelines at the time of your visit. If there is alcohol in your breath, we will have to re-schedule the interview. You will be evaluated by the researchers to determine if it is safe for you to leave (breathalyzer reading is less than 0.08 or if greater than 0.08, only in the company of a responsible adult) or if you need further medical evaluation in the Interim Care Clinic or the VA Emergency Department (if afterhours). If you are asked but you refuse to complete the breathalyzer, the researchers may not allow you to complete the assessment. Relevant urine screening information from your electronic health record will be used to assess recent substance use and, if you're able to become pregnant, rule out pregnancy. If you are pregnant, you will not be able to participate.

- You will receive an electronic pill cap that records opening and closings to take home following completion of the baseline assessment. You will return the pill cap at the 3, 6, and 9-month follow-up appointments or by mail following your 9-month follow-up appointment if you are unable to return it sooner so we can download the data (we will send you a postage paid envelope to

send the cap back in). The pill cap will be used to determine how you are taking your primary mood stabilizing medication (as noted by your doctor) throughout the duration of the study. At our research clinic, the information will be transmitted using a pill cap reader hooked to our computer, which will be uploaded to a secure server at the VA where the researchers can download the data. A research assistant will explain how to use the pill cap.

- You will be randomly assigned to one of two different study treatment programs by a computer (50-50 chance, like the flip of a coin):

    - If you are randomly assigned to the **Safety Assessment Follow-up Evaluation (SAFE)**, you will complete your usual VA and non-VA community treatments with your doctors and health care providers. In addition, you will complete study assessments at baseline, 3, 6, and 9 months following study enrollment. Your doctors and regular VA and non-VA health care providers will receive a written report from research assistants based on your study assessments. Regular information about your mood and safety will let your doctor and health care providers help you stay safe and feel better as part of your usual care. The report will include things like thoughts of death, your mood, your use of drugs or alcohol, and whether your mental health is getting better or worse.

    - If you are randomly assigned to the **Integrated Treatment Adherence Program (ITAP)**, you also will complete your usual VA and non-VA community treatments with your doctors and health care providers. Also, you will complete study assessments at baseline, 3, 6, and 9 months following study enrollment and reports will be sent to your providers as described above. In addition to this, the ITAP treatment is designed to help you keep track of your symptoms and cope better with your illness. You will complete 3 individual sessions with a study therapist. The therapy sessions will begin following completion of the baseline assessment and be completed shortly after. With your permission, we also will invite a family member or significant other to participate in this program with you. You will discuss with your study therapist which family member to invite to participate with you beginning at the first session. You should select someone with whom you are comfortable discussing your symptoms, substance use, and thoughts of death as part of the program. At any time, you may withdraw your permission for the family member or significant other to participate in the study with you and their study participation will end. You will receive 1 family meeting with the study therapist after completing your individual sessions. The therapy sessions will take about 1 hour each. During this session, the study therapist will review your treatment goals and enlist the help of your family member or significant other in achieving your goals. If you do not have a family member or significant other to include, you can participate alone. Finally, you and your family member or significant other will receive 11 phone sessions over the 6 months following your enrollment in the study. You will have the option to complete the study sessions over the phone or by video via VA-approved VA Video Connect (VVC) or another VA-approved communication platform. VVC allows participants to virtually meet with the study team using encrypted video to ensure that the session is secure and private. You must provide your email address in order to access the VVC and you will need to enter your name to connect to the VVC. All study visits will still be completed as planned, but do not have to be completed in person. The therapist will contact you and

your family member or significant other separately to complete these sessions. During these sessions, the therapist will also ask questions to help track your substance use and mood symptoms, including thoughts about death. Your doctors and regular treatment providers at the VA will be alerted to the results of these phone assessments in your VA electronic medical chart. These sessions will last about 15-30 minutes each. All meetings and phone or video sessions are to help you feel better, check your progress from week to week, help you solve problems, and keep you safe. In the phone calls or video sessions with your chosen family member or significant other, the therapist will discuss ways they can assist you in your recovery process and support you in working toward your treatment goals. In summary, you will receive 3 individual sessions, 1 family meeting, and you and your family member or significant other each will receive 11 phone calls or video sessions (conducted separately) over 6 months. If you do not have a family member or significant other participating with you, you will receive 3 individual sessions and 11 phone calls or video sessions and will not receive the family meeting.

- The study team has explained that by signing this Informed Consent Document, you voluntarily and without separate compensation authorize voice recordings to be made of you by members of the study research team while you are participating in this study. We will audio-record the interview portions of the 4 study assessment visits, all therapy sessions, and all phone or video sessions. We will tell you whenever we plan to use an audio-recorder. Recordings will be carefully reviewed by supervising therapists and researchers to make sure that you are receiving the best service possible, and that research staff are following study procedures in the correct way and correctly recording information that you share with us. Recordings will be kept confidential and only our research team will be able to hear them. You may refuse audio-recording of interviews at any time and still participate in the study. The study team has also explained that you will not receive any royalty, fee or other compensation for such use. If you refuse to grant consent, there will be no effect on any VA benefits to which you may be entitled. You may at any time exercise the right to cease being recorded and may rescind your consent for up to a reasonable time before the voice recording is used. We will ask for you to indicate whether you give permission for audio-recording assessments at the end of this consent form.

- In order for this project to be meaningful and have scientific value, we will make every effort to contact you with telephone, email, text message, and letter reminders and confirmations of the scheduled assessment sessions. At the initial baseline session, we will also ask you to provide us with the names of two friends or relatives whom we can contact in the event that your phone number or email address changes and we are not able to locate you. In addition to this, we will review your VA medical records for updated contact information. These individuals would be asked to provide your updated phone or email. We would not share any information with them that you have provided us.

- During all assessments, including the screening session, you may refuse to answer any question that you do not feel comfortable answering. You may stop your participation at any time. You will not have to tell the study staff your reasons for ending your participation. If your family member or significant other decides to exit the study or you would no longer like them to be a part of the study, you may still continue to participate. If you no longer want to receive the therapy sessions, you will still be able to complete the 3, 6, and 9-month follow-up assessments if you choose.

- This research study is a "blind" study, meaning that research assistants will not know which study treatment program you are randomly assigned to. Once informed of your study treatment program (ITAP vs. SAFE), do not disclose this information to any research staff other than your ITAP study therapist if assigned one. Additionally, if assigned to the ITAP program, do not disclose to staff whether or not you have any upcoming appointments with a study therapist.

- While participating in this research study, do not take part in any other research project without approval from the investigators. This is to protect you from possible injury from things such as extra blood drawing, extra X-rays, or potential drug interactions. Taking part in other research studies without first discussing it with the investigators of this study may invalidate the results of this study, as well as that of the other studies.

WHAT IS EXPECTED OF ME IF I TAKE PART IN THIS STUDY?

As a participant of the study, the following will be expected of you:

- Complete eligibility screening with study staff
- Schedule and attend four assessments, in-person or remotely: baseline, 3-month follow-up, 6-month follow-up, and 9-month follow-up
- Store your primary mood-stabilizing medication in the pill bottle provided by the study and return it to staff at every in-person visit, or if participating remotely, mail it back upon study completion
- If randomly assigned to the Integrated Treatment Adherence Program (ITAP), attend all phone/video or in-person meetings with a study therapist
- Contact study staff if you need to reschedule or have missed your appointment
- Do not tell study staff which treatment group you have been randomly assigned to
- Do not participate in other research projects without approval from the investigators first

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

Any procedure has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks or side effects listed. Rare, unknown, or unexpected risks also may occur.

1. Confidentiality and loss of privacy: Because we will be asking you questions about yourself, one possible risk is loss of privacy. However, we will minimize this risk by keeping all your information strictly confidential. Your information will only be available to our study research staff. All the forms you fill out, questions you answer, and recordings will be kept locked and identified only by a number. If you choose to complete this consent form via the DocuSign program or any follow-up study assessments online via the Brown University Qualtrics program, you will complete them in a web browser and they will be transmitted electronically over the internet in a secure manner. Your name, digital signature, date and time of digital signature, email address, and computer IP address are recorded by DocuSign. The date and time when you submit an assessment survey on Brown University Qualtrics is also recorded and collected as part of the survey data. Once downloaded to

the secure VA server, survey data will be permanently deleted from the Brown University Qualtrics server by the study team. If you choose to submit this consent form via email, you will be sending personal information over an unsecured network. Once received, your consent form will be downloaded to the secure VA server and the email will be deleted. The information from your electronic pill cap is encrypted and uploaded to secure servers, where only research staff may view and download the data. Your information will not be disclosed to advertisers or any other individuals that you do not authorize. The only exceptions to confidentiality are risk of harm to self or others, and suspicion of child or elder abuse or neglect. In these cases, study staff have a legal obligation to alert the appropriate state agency or police in order to protect study participants and vulnerable persons. These situations are also described in the section "How will my private information be protected?" on the following page. If you elect to complete study sessions and/or assessments remotely, we ask that you try to find a private space to help keep your sessions private and your responses to online surveys and other study communications as confidential as possible. However, it is still possible that others may overhear your sessions or see your responses or electronic communications.

2. Discomfort during study assessment: Some of the assessments concern sensitive information about you. Most people do not experience any discomfort during these assessments and find them to be helpful. However, it is possible that you may find some things we ask about to be upsetting and uncomfortable. You may also become aware of problems in your life during your participation. We will do our best to make sure that you are as comfortable as possible with any questions that we ask. You may refuse to answer any questions or if you wish to terminate the session, you will be able to do so. If you are selected for ITAP, you will be asked to find a person to participate with you and you will be asked to share information with your support person. You may find it hard to discuss personal problems with your support person. If you are feeling worse, we may ask your support person to give you extra help. We will always ask you before we share any information with your support person. If you decide you do not want to participate in the family meeting or would like to terminate your support person's participation in the study, you will be able to do so at any time.

3. Lack of symptom improvement or clinical deterioration: A risk of participating is that the program may not improve your symptoms. If we notice that you are feeling worse during the program, Dr. Metrik or Dr. Gaudiano will talk to you about your choices (e.g., different types of treatment available, etc.). We will only disclose information that is related to your mood or mental health. If you become distressed and need help, a study staff member will speak with you to determine what you may need. The study staff member then will put you in touch with your mental health care provider or will help you find a mental health provider.

4. Risk of bank account information or social security number being stolen or misused: There is a risk that your bank account information or social security number could be stolen and misused. Your bank account information and social security number are needed if you choose to get paid using electronic funds transfer (EFT). You can select another method of payment in the study to avoid providing this information to us. We will also minimize this risk by keeping all your information strictly confidential. All the forms you fill out will be kept locked.

5. Reports of impaired or abusive relationships: If you or your support person report significant impairment or conflict in the relationship, we will assess further and provide referrals for family or couples treatment if indicated.

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

Risks of the usual care you receive are not risks of this study. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

We do not know if you will get any benefits from taking part in this research study. Regardless of which study program you receive (ITAP or SAFE), we will be monitoring your symptoms and safety when you complete study assessments. We will provide feedback from these assessments to your regular doctors about how you are doing. If you receive ITAP, you may get additional benefit from speaking with a study therapist. In addition to potential personal benefit from the study treatments, your assessments and feedback will provide us with valuable information that will be used to help others with similar conditions in the future.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

This program is not intended to replace any of your regular care. We ask you to continue your treatment with your mental health providers. If you don't see any improvement in mood, or if you start to feel worse, you will be given information for other treatments. You may also withdraw from the study at any time. Your involvement in other mental health treatment is encouraged and we are happy to discuss additional treatment options.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Information collected for the purpose of this research study will be kept confidential as required by law. The results of this study may be published for scientific purposes, but you will not be personally identified in any reports or publications that may result from this study. Information about you is protected in the following ways. All information you provide for this study will be identified by a randomly assigned identification number only. A master list matching your personal information with your research number will be kept separate from your personal information. All study records will be kept in locked file cabinets in locked rooms and in password protected computer files that only the research team for this project can access. Audio recordings will be collected using a dedicated and encrypted electronic device that will be stored in a locked area or a microphone connected to a computer. Research staff will upload the audio files to a secure server following the session and then delete them from the recorder.

All answers that you give will be kept private. The confidentiality of the information you provide to us will be maintained in accordance with federal laws and the laws of the State of Rhode Island. Under the law, we must report to the state suspected cases of child or elder abuse. If you tell us you're planning to cause serious harm to yourself or others, we will share this information with clinical staff and/or the proper authorities. If you are at risk of harming yourself or others, we will let inpatient staff know. If you are an

outpatient, we will contact your VA outpatient clinician or family member with your permission, and/or notify the appropriate local police department if necessary. We will also contact the Providence VA Suicide Prevention Coordinator for follow-up. Per the Providence VA Medical Center policy, if you are under the influence of alcohol or drugs and threatening to leave against medical advice, the VA Police may be contacted and you may be put in protective custody until you are safe to leave.

Records will be maintained in accordance with the Department of Veteran Affairs Records Control Schedule 10-1. Your research records and the information within them will not be used for any purpose other than that which is described in the study as approved by the IRB.

The identifiers might be removed from the identifiable private information about you and that, after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the you or your Legally Authorized Representative (LAR).

We will include clinically relevant information about your study participation in your medical record. This is required for participation in the study.

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.

While this study is being conducted, you will not have access to your research related health records. This will not affect your VA healthcare including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

Health Insurance Portability and Accountability Act (HIPAA)

There are rules to protect your private information. Federal laws and the federal medical or HIPAA Privacy Rule also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by these laws and the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. Other information such as HIV status, drug, alcohol or STD treatment, genetic test results or mental health treatment may be viewed or collected, if necessary or if there are interviews or surveys where you, as the research subject, provide that information to the research team.

The research team may also need to disclose or share your information to others as part of the research and study progress. Others may include the following: Food and Drug Administration (FDA), Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), the Government Accountability Office (GAO; Sponsors; Contractors, Affiliates as appropriate), the VA Institutional Review Board, and the local VA medical facility Human Research Protections Program.

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or the HIPAA Privacy Rule regulations and may be subject to re-disclosure by the recipient.

While this study is being conducted you will have access to your research related health records.

This will not affect your VA healthcare, including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you can ask a member of the research team to give you a form to revoke your authorization in writing. Your written request will be valid when the research team receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, Dr. Jane Metrik, Dr. Brandon Gaudiano, and their research team can continue to use information about you which the research team has relied upon for the research and that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

You or your insurance will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

COMPENSATION OFFERED FOR PARTICIPATION.

You will receive compensation from a member of the research team for doing the individual baseline assessment visit and for each individual in-person, phone, or video follow up assessment at 3, 6, and 9 months. If you complete the screening portion of the baseline assessment but are found ineligible for the study, you will receive $10 instead of the full payment of $40 for the entire baseline assessment ($10 for screening + $30 for the assessment). After completing each assessment visit, you will have the option to be compensated using either electronic funds transfer (EFT) or gift cards. You will be paid $40 for the baseline assessment, $35 for the 3-month follow-up assessment and $10 for the returned pill cap at the 3-month follow-up, $40 for the 6-month follow-up assessment and $10 for the returned pill cap at the 6-month follow-up, and $45 for the 9-month follow-up assessment and $10 for the returned pill cap at the 9-month follow-up. If you elect to participate remotely, instead of being paid $10 for returning your pill cap at each follow-up assessment, you will have the option to receive the appropriate compensation of up to $30 total if you return your pill cap by mail following your 9-month follow-up appointment. In addition, if you complete all four assessment sessions, you will be given a $10 bonus. The total compensation that you

can receive for completing all study assessments including returning all pill caps is $200. You will receive the compensation after each completed assessment. If you withdraw from the study before the end, you will not receive the remaining compensation. If you choose to stop participating before you complete all assessments in a session, you will receive only a partial payment of $15 for that session.

Additionally, to receive funds by EFT, you will have to provide your bank account number, bank routing number, and social security number on the form provided, so the funds can be sent directly to your bank account. This usually takes less than a week after we have asked the funds to be sent to you. When using EFT, all payments will be reported directly to the Internal Revenue Service. Payments may also be disclosed to others listed on the account and any unpaid debts/liens on the account may affect the deposited funds. You may also be issued an Internal Revenue Service Form 1099-MISC for the payment/s you receive in this study, which would require us to share your social security number with the VA Research Service, as they will be issuing the payments.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

The VA has the authority to provide medical treatment to participants (veterans and non- veterans) injured by participation in a VA research study. If you are injured as a result of being in this study, the VA will provide the necessary medical treatment in accordance with applicable federal regulations (38 CFR 17.85). If you want to make a legal claim against the VA or anyone who works for the VA, special laws may apply. The Federal Tort Claims Act (28 U.S.C. 1346(b), 2671-2680) is a federal law that c controls when and how a person can bring a claim against the U.S. Government. If you sign this document, you are not giving up your right to make a legal claim against the United States.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call the numbers below.

DURING THE DAY:

[redacted] at [redacted] or [redacted] at [redacted]. If Dr. Metrik or Dr. Gaudiano are not immediately available, call the Interim Care Clinic at (401) 273-7100 ext. 13400.

AFTER HOURS:

Providence VA Medical Center at (401) 273-7100 ext. 0; ask for the psychiatrist on call._____

Emergency and ongoing medical treatment will be provided as needed.

You can also call the VA National Suicide prevention hotline at 1-800-273-TALK (8255).

DO I HAVE TO TAKE PART IN THE STUDY?

You are free to decide whether to participate in this study or not. 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. If you are employed by the VA, your refusal to participate will in no way influence your employment, ratings, subsequent recommendations, or academic progress. If you withdraw from the study before the end, you will not receive the remaining study compensation. Even if you revoke (take back) this consent and authorization, VA researchers may still use or share health information about you that they already have obtained prior to you withdrawal when doing so is necessary to maintain the integrity or reliability of the current research; no additional information can be collected further, except for public records, such as survival data.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

You may be terminated from the study if you do not complete study procedures, or you develop problems that would make it difficult or unsafe for our research staff to work with you. If Dr. Metrik and Dr. Gaudiano decide that you should withdraw from the study, they or another study investigator will meet with you to discuss alternative treatment options. If you are terminated early, you will continue to be followed for all remaining assessments.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

If you have further questions or complaints about this project or about research-related matters, please contact [redacted] or [redacted].

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the Institutional Review Board (IRB) at the Providence VA Medical Center. This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the Research Administration at (401) 457-3066 or the Providence VA Healthcare System Patient Advocate at 401-457-3093 if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

You will be told of any significant new findings that come to light over the course of this study and that may relate to your wanting to stay in the study.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr. Jane Metrik, Dr. Brandon Gaudiano or their delegated research study staff has explained the research study to me. I have been told of the risks or discomforts and possible benefits of the study. I have been

told of other choices of treatment available to me. I have been given the chance to ask questions and obtain answers.

By signing this document below, I voluntarily consent to participate in this study and authorize the use and disclosure of my health information for this study. I also confirm that I have read this consent, or it has been read to me. I will receive a copy of this consent after I sign it.

I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name (printed)	_____ Participant's Signature	_____ Date

ADDITIONAL CONSENT – AUDIO RECORDING

I agree to have my assessment(s), therapy sessions, and telephone calls audio recorded. This will be used for research and training purposes only. I can withdraw my permission at any time and this recording (and any copies) will be destroyed.

_____
Participant's Name (printed)

_____ _____
Signature Date

ADDITIONAL CONSENT – RELEASE OF INFORMATION

I voluntarily provide my permission for research staff to release as needed information pertaining to my participation in the ITAP Study to the individual(s) indicated below. I understand that this is optional and not a requirement for participation in the study, and that I can withdraw my permission at any time.

Please select the individuals you agree to having study information shared with:

☐ SO/support person (if randomized to the ITAP condition) ☐ No one outside of my treatment providers

_____
Participant's Name (printed)

Participant Name:_____ Date:_____

Title of Study: Post-Hospital Intervention for Veterans with Comorbid Mood and Substance Use Disorders (Veteran Participant Consent Form)

Principal Investigator: Jane Metrik, Ph.D. and Brandon Gaudiano, Ph.D. VA Facility: Providence 650

_____ _____

Signature Date

Providence VAHCS Institutional Review Board
Effective Date: December 4, 2024
Expiration Date: December 12, 2025