Enhancing Access to Insomnia Care (EASI Care):
Implementing Brief Behavioral Treatment for Insomnia in Primary Care Mental Health Integration Clinics

NCT04350866

Informed Consent Form:
Phone Script for Verbal Consent of PCMHI Provider

8/11/2021

Date: ___ ___ / ___ ___ / ___ ___ ___ ___

Enhancing Access to Insomnia Care (EASI Care): Implementing Brief Behavioral Treatment for Insomnia in Primary Care Mental Health Integration Clinics

Verbal (Phone) Consent

Hello. My name is *[EASI Care team member name]* and I am a team member with the study: *Enhancing Access to Insomnia Care (EASI Care): Implementing Brief Behavioral Treatment for Insomnia in Primary Care Mental Health Integration Clinics*. Is *[participant's name]* there?
☐ **YES:** Continue below.
☐ **NO:** Leave a message with your name and number.

***OR** [if participant is returning a call]*

Hello, *[participant's name]*. First, I want to thank you for your interest in the study. This call is to review what participating in the study involves and answer any questions. Afterwards, if you are still interested and willing to participate, we can continue with the verbal consent process.

You should have an information sheet about the study. Did you have a chance to review it?
☐ **YES:** Continue below.
☐ **NO:** Let's review it together now.

Do you have any questions or concerns about the study?
☐ **YES:** Answer questions.
☐ **NO:** Continue below.

Are you still interested in being enrolled in the study and serving as a participant?
☐ **YES:** Continue below.
☐ **NO:** Thank you very much for your time. **STOP**

As indicated on the study information sheet, your participation involves three activities over the course of the study, across various phases (pre-implementation, implementation, post-implementation).
1. Brief surveys about utilization of implementation strategies (6x over 18-months)
2. Qualitative interviews by phone or via Microsoft Teams and audio-recorded (3x: once following training, once at the end of the implementation phase, and a final time at the end of the post-implementation phase)
3a. PCMHI provider – Quarterly mock BBTI sessions led by your site PI (5* times 18-36-months; site specific).*If you receive a passing competency score on three consecutive mock sessions, you may opt out of mock sessions until the mock session at the end of the implementation phase and the end of the post-implementation phase.
3b. Site PIs – Conduct quarterly mock BBTI sessions with PCMHI provider participants and monthly chart reviews

Your participation is voluntary, and you can withdraw at any time. You are not required to answer questions from the surveys and interviews. If you withdraw, any collected data will be retained by the study team. There is no expectation that you will receive aggregate or individual study results, although you may as determined by the study team. Identifiable information will be removed from the data collected and may be used in future studies by other investigators. All data for the current and potential future studies will be stored on a secure network drive at VA Pittsburgh Healthcare System and data will only be accessible by approved investigators and study staff.

Qualitative interviews will be recorded. At the time of the interview, if you consent to having the interview recorded, this response will be recorded, and the interview will proceed. However, if you do not give consent to audio-recording, the recording will be stopped, but the interview will still proceed.

This study is minimal risk. The information collected for this study will be kept confidential. Appropriate measures will be taken to ensure that your identity remains confidential. There are times when we might have to show your

records to others, for example, from the Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, the VA Central IRB, our local Research and Development Committee, and other study monitors may look at or copy portions of records that identify you.

You are not expected to directly benefit from participating and you will receive no payment for your participation.

Do you consent to participate in this study?
☐ **YES:** Thank you for agreeing to enroll in this study. Your site PI will be in contact with you about next steps.

☐ **NO:** Unfortunately, we cannot enroll anyone in this study without obtaining their informed consent. Thank you for your interest in the study. Please feel free to contact us at any time if you would like to be a part of the study in the future or if you have any further questions. **STOP**

PARTICIPANT CONSENTED TO STUDY: **YES** **NO** SITE: _____

NAME: _____

Only collect if consented to participate

VA EMAIL: _____ VA PHONE: _____

CONSENT OBTAINED BY: _____
Study Staff Name

DATE CONSENT OBTAINED: _____ _____ / _____ _____ / _____ _____ _____ _____

VA Central IRB Panel 1
Effective Date: August 11, 2021