COVER PAGE

Title: The Feasibility of Home-Based Measurement of Circadian Timing for Veterans with TBI and Insomnia (Home DLMO)

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**Subject Name:** _____ **Date:** _____

**Title of Study:** Feasibility of Home-Based Measurement of Circadian Timing in Veterans with TBI and Insomnia

**Principal Investigator:** [Redacted] **VAMC:** 554

**VA Investigator:** [Redacted] **COMIRB#** 22-2160

You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

**Key information:**

Your consent is being sought for participation in this research study. Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

Veterans who have experienced traumatic brain injury (TBI) often have trouble sleeping, which can delay recovery and reduce quality of life. The development of insomnia following TBI may be due to disruption of the rhythms in the body that are controlled by the body's internal clock. These are called circadian rhythms. One circadian rhythm that may be affected by a TBI is the time-of-day a person starts to feel tired and ready to fall asleep or wake up. Interventions exist that may help treat circadian-related insomnia, but these are rarely used in standard healthcare because it is difficult to measure circadian rhythms outside of specialized clinics or laboratories. This makes it hard to know if insomnia is caused by disrupted circadian rhythms or by other things.

This study will help us learn more about ways of measuring the timing of circadian rhythms in the homes of Veterans. We hope that these findings will be used to help provide Veterans with better access to identification and treatment of insomnia due to the disruption of circadian rhythms.

This research study is expected to take approximately 2 years. Your individual participation will take between 7-15 hours over the course of about 2 weeks. This will include a baseline eligibility screening, wearing an activity tracker for 8 days, completing short, daily sleep diaries each day, and collecting 7 hourly saliva samples for melatonin level measurements. You will be compensated for these procedures.

The study design does not offer any direct benefits to participants. It is designed for the researcher to learn more about ways of measuring circadian timing in the home, which may help future interventions designed to treat insomnia among Veterans with a history of TBI.

Any procedure has possible risks and discomforts. Discomforts you may experience while in this study include being asked to answer questions that make you feel uncomfortable or upset. You may feel frustrated or tired while completing the questionnaires. You may feel some physical discomfort when wearing the activity tracker due to rubbing or chafing. You may also experience temporary discomfort or tiredness while collecting saliva samples due to staying up 1 hour past your typical bedtime. There is a risk that people outside of the research team will see your research information. The study may include additional risks that are unknown at this time.

**Why is this study being done?**

This study plans to learn more about different ways of measuring circadian timing, or the body's internal clock, at home in order to help treat insomnia after traumatic brain injury (TBI).

You are being asked to be in this research study because you have a history of TBI and current sleep difficulties.

**Other people in this study**

Up to 86 people will be enrolled in the study.

**What happens if I join this study?**

If you join the study:

- At the Baseline assessment, we will determine if you are eligible to participate in the study. Time to complete Baseline procedures is estimated to take 2-4 hours. You will be compensated ($30) upon completion of baseline assessment. You will be asked to answer questions and complete surveys at the Rocky Mountain Regional VA Medical Center (RMR VAMC) or remotely on Microsoft Teams. The surveys will be presented on the CCTSI REDCap HIPAA-compliant web-based platform that is hosted by the University of Colorado Anschutz Medical Center (CU Anschutz). The topics of the questions will include personal history, physical and mental health, and sleep. You will also be asked if you have a caregiver and if they would be interested in providing additional information about your experience with our study. If they are, we will ask you for their contact information so that we may reach out and see if they would like to participate in our study.

- At the end of the Baseline assessment, we will introduce you to two ways of measuring circadian timing. The first involves an activity tracker that is worn on the wrist like a watch. This activity tracker records your movements and the amount of light to which you are exposed. We will show you how to put on this device and ask that you wear it for the next 8 days. We will also ask that you complete short, daily sleep diaries over the next week. The sleep diaries will be emailed to you each morning by the study team and completed using the CCTSI REDCap platform. These are

anticipated to take approximately 5 minutes each day. During the week of sleep diary collection, you will receive follow-up reminders (either by phone or email) if diary responses are not entered during the day. You will not need to make any other changes to your daily routine during this week. You will be compensated ($25) upon completion of this collection window.

- The second way of measuring circadian timing involves collecting 7 hourly saliva samples in small plastic tubes by drooling through a straw-like device. These saliva samples will be used to measure your melatonin levels, which is a hormone that your brain starts to release at night. During the Baseline assessment, we will show you how you can collect these saliva samples yourself in your home using a saliva collection kit that we will give you at the end of the session, along with a nightlight to be used during collection. We will also let you practice the saliva collection procedure and answer any questions that you have. We will then ask that you collect 7 saliva samples in your home during a specified time period after you have worn the activity tracker for one week. To do so, you will need to:
    - Avoid alcohol, caffeine, chocolate, pitted fruits and bananas the day you are scheduled to collect saliva samples.
    - On the day of collection, collect 1 saliva sample each hour, starting 5 hours before your typical bedtime and ending 1 hour after your typical bedtime.
    - Turn off or dim the lights and screens in your home during the saliva collection so that you are not exposed to light that will suppress your melatonin levels.
    - Store each saliva sample in your freezer inside of an insulated storage tube that we will provide you.
    - After the samples are frozen for a minimum of one day, drop the samples off at a nearby FedEx, where they will be shipped to the Salimetrics testing laboratory. We will provide you with all the shipping materials you need. You will be compensated ($30) for saliva collection.
- After you have shipped the saliva samples and returned the activity tracker in a provided return envelope, we will ask you to complete a brief interview on your experiences with the study that will take 15-30 minutes and be audio-recorded via Microsoft Teams. You will be compensated ($15) for completion of this interview.
- If you have a caregiver that elects to participate in this study, they will be asked to complete a brief interview to provide additional information about your experience with the study at this time. This will also be conducted and audio-recorded via Microsoft Teams and take approximately 15-30 minutes. They will be compensated ($15) for their interview feedback.

This research study is expected to take approximately 2 years. Your individual participation will take between 7-15 hours over the course of about 2 weeks.

**Collection, storage, shipping, and disposal of saliva samples**

The results from the saliva samples you collect will be used for future research purposes as part of this study. Saliva collection and initial storage will be performed by you in your own home. After collection, you will be asked to ship the samples via FedEx to the Salimetrics testing laboratory, neither of which is part of the VA, using provided shipping materials. The samples you send will be de-identified, meaning that they will not be labeled with any personal information that could be used to identify you. Instead, the samples will be labeled with a study number that the research team can use to link your results back to you. Only the research team will have access to the study number link. No one at FedEx or the Salimetrics laboratory will have access to this information or be able to link your saliva samples back to you.

Once the Salimetrics laboratory receives your saliva samples, they will store them on-site and use them to measure your melatonin levels at the times you collected each sample. After processing the saliva samples, the Salimetrics laboratory will send the results to the research team using an encrypted email. The only information that will be obtained from your saliva samples is the concentration of melatonin at each of the collection times. The Salimetrics laboratory will then dispose of your saliva samples using a biohazardous waste disposal company and send the research team a letter confirming that the samples have been appropriately destroyed. As such, your saliva samples will only be used for this study and will not be stored long-term or shared with other researchers outside of the research team. No genetic information will be collected from the saliva samples and no cells or other materials will be stored or immortalized.

The research team will not contact you or any of your family members regarding the results of the salivary melatonin testing. Your medical records will not be accessed as part of this study once the study is completed. If you choose to withdraw from the study prior to shipping the saliva samples, you may simply throw them away. If you choose to withdraw from the study after shipping the saliva samples, the research team will ask the Salimetrics laboratory to dispose of the samples without testing. However, if the samples have already been tested and the results have been collected, the research team will keep the results as part of the study records.

Neither the research team nor the researchers' institution (RMR VAMC) will receive real or potential commercial benefits as a part of the salivary melatonin testing.

**What are the possible discomforts or risks?**

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.

Discomforts you may experience while in this study include being asked to answer questions that make you feel uncomfortable or upset. You may feel frustrated or tired while completing the questionnaires. If this happens, you may pause or stop the study. You can also decline to answer any questions you do not feel comfortable answering. There are several safeguards built into the online survey to help monitor and manage this risk.

You may feel some physical discomfort when wearing the activity tracker due to rubbing or chafing. If this happens, you may remove the device. You may also experience temporary discomfort or tiredness while collecting saliva samples due to staying up 1 hour past your typical bedtime.

There is a risk that people outside of the research team will see your research information. We will do all we can to protect your information, but it cannot be guaranteed. A number of protections are in place to maintain the confidentiality of your records. Because saliva samples will not be shipped to the Salimetrics laboratory with any identifiable personal information and only tested for melatonin, we do not anticipate that a breach of confidentiality would lead to discrimination against you or your family in the areas of employment, insurability, social stigmatization, of psychological stress. There may be other risks the researchers have not thought of.

Every effort will be made to protect your privacy and confidentiality by storing records about you in password-protected or user-restricted files protected by the University of Colorado, Anschutz Medical Campus and VA electronic security systems. Your email address or telephone number may be stored on the secure CCTSI REDCap server at the UCD Anschutz Medical Campus.

Some things we cannot keep private. If you indicate that you are going to physically hurt yourself, we have to report that to a mental health provider or emergency services. If you indicate you are going to physically hurt someone else, we have to report this to local authorities, and/or a mental health provider.

The study may include risks that are unknown at this time.

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 the 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 the study?**

This study is designed for the researcher to learn more about ways of measuring circadian timing in the home, which may help future interventions designed to treat insomnia among Veterans with a history of TBI. It is not designed to directly benefit you.

This study is not designed to treat any illness or to improve your health. Also, there may be risks, as discussed in the section describing the discomforts or risks.

**Who is paying for this study?**

This research is being sponsored by the VA Rehabilitation Research and Development Service.

**Will I be paid for being in the study?**

You will be paid $30 for completing the Baseline assessment. You will be paid $25 for wearing the activity tracker and completing sleep diaries for a week. You will be paid $30 for collecting saliva samples in your home and dropping them off at FedEx for shipping. Finally, you will be paid $15 for the brief interview about your experiences after completing the study. The total amount possible to be paid to you is $100 if you complete all of the study procedures. This will occur in the form of a direct deposit EFT. The nightlight provided to you for collection procedures will also be yours to keep following study completion. If you leave the study early or if we have to take you out of the study, you will only be paid for the parts that you have completed.

It is important to know that payments from participation in a study are taxable income.

Your SSN will be collected and used to report this taxable income to the IRS.

**Will I have to pay for anything?**

There will be no cost to you for participation in this study. However, some Veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services provided by the VA that are not part of this study. If you decide to participate in this study, you cannot be charged nor your insurance billed for research-related interventions or procedures that are required by the protocol.

**Is my participation voluntary?**

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them.

**Can I be removed from this study?**

The study doctor may decide to stop your participation without your permission, if the study doctor thinks that being in the study may cause you harm, or for any other reason. Also, the sponsor may stop the study at any time.

**What happens if I am injured or hurt during the study?**

Every reasonable safety measure will be used to protect your well-being. The VA Eastern Colorado Health Care System (ECHCS) will provide necessary medical care and treatment for any injury that is a result of participation in this study for Veterans, in accordance with applicable federal regulations (38 CFR 17.85). Compensation for such an injury may be permitted by applicable federal laws and/or

regulations. The VA is not required to provide treatment for injuries in research studies if the injuries are caused by your non-compliance with study procedures.

You should inform your care provider(s) if you decide to participate in this research study. If you have questions about an injury related to the research, call [Redacted]. If your injury requires emergency medical attention, the Rocky Mountain Regional VA Medical Center Emergency Room can be reached at 303-399-8020 ext. 0.

**Who do I call if I have questions?**

The researcher carrying out this study at the VA is [Redacted]. You may ask any questions you have now. If you have any questions, concerns, or complaints later you may call [Redacted] at [Redacted]. You will be given a copy of this form to keep.

If you have questions regarding your rights as a research subject, concerns or complaints about this research study, please call the Colorado Multiple Institutional Review Board (COMIRB) office at 303-724-1055. This is the Board that is responsible for overseeing the safety of human participants in this study. If you want to verify that this study is approved or if you would like to obtain information or offer input, please contact the VA Research Office at 720-857-5094.

**Does this study involve genetic research? How will my genetic information be protected?**

This study does not involve genetic research.

**How will my private information be protected?**

1. Taking part in this study will involve collecting private information about you. We will keep all research records that contain your identifiable health information confidential to the extent allowed by law. Records about you will be kept in locked filing cabinets in a locked room or on computers protected with passwords. The primary investigator, as well as approved and trained study personnel, will have access to the electronic documents.

2. Your data will be coded using assigned study IDs. Participants will be identified by a unique study ID assigned at enrollment.

3. Any and all paper AND electronic documentation containing confidential, personally identifiable information, protected health information, and any other sensitive information will be disposed/destroyed according to current VA regulations at the time of disposal/destruction of documentation. Research files will be maintained, stored, and destroyed in accordance with the Record Control Schedule (RCS-10-1) approved by the Archivist of the United States.

4. If results of this study are reported in medical journals or at meetings, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent. Your private information will be maintained according to this medical center's requirements.

5. Your medical and research records will be maintained according to this medical center's requirements. There is a possibility that the Office for Human Research Protections (OHRP), Food and Drug Administration (FDA), VA Office of Inspector General (OIG), Veterans Health Administration (VHA), DoD, other oversight agencies including the Office of Research Oversight (ORO), the Research Compliance Officer, Institutional Review Board members or other research staff may have access to your research and/or medical records or may inspect the records. Every effort will be made to keep information about you both private and confidential. Codes (not your name and social security number) will be used for all reports generated, to help maintain your confidentiality.

6. Some things we cannot keep private: If you give us any information about child abuse or neglect, we have to report that to state social services.

7. Some things we cannot keep private: If you tell us you are going to physically hurt yourself or someone else, we have to report that to the state police or other medical agencies.

8. To learn more about your background, mental health, and the healthcare you receive, we will collect information regarding physical and mental health symptoms, VA appointments, and service connection from your medical record.

We will include information about your study participation in your medical record.

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 Information Portability and Accountability Act (HIPAA)

### Who will see my research information?

There are rules to protect your private health information. Federal and state laws and the federal medical law, known as the 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 the HIPAA 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. They may also collect other information including your name, address, date of birth, and information from your medical records such as medical history, or mental health treatment.

The research team may also need to disclose your health information and the information it collects to others as part of the study progress. Others may include:

- Federal agencies such as the Food and Drug Administration (FDA), the General Accountability Office (GAO), the Office of the Inspector General, Office for Human Research

Protections (OHRP), and the VA Office of Research Oversight (ORO) that protect research subjects like you, may also copy portions of records about you.

- People at the Colorado Multiple Institution Review Board
- The investigator and research team for this study
- The sponsor, study monitors, or agents for the sponsor
- Officials at the institution where the research is being conducted, and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research
- Our local VA Research and Development Committee
- University of Colorado Anschutz Medical Campus
- Salimetrics testing laboratory, for processing the collected saliva samples

I understand that by signing this consent form, a copy of limited data about me, restricted to ***all research data*** that is collected as part of this specific VA research study, will be stored at either the Rocky Mountain Regional VA Medical Center (RMR VAMC), secure RMR VAMC local servers, the REDCap database at the VA Information Research Center (VIReC), or the REDCap database at the University of Colorado Anschutz Medical Campus (CU Anschutz). This data will be used solely for the purposes defined in this consent form and for this specific study. Data collected about me for this study placed in one of these databases will not be accessed or used for any other study or purposes and will only be accessed by VA-credentialed personnel. The VIReC and CU Anschutz REDCap Databases are highly secure, nationally utilized data management systems that are housed within highly secure environments.

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

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility, or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office 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, [Redacted] and his research team can continue to use information about you 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.

Specific title 38 USC 7332 protected information (drug abuse and alcohol abuse) will also be collected for the purpose of this study.

**Agreement to be in this study**

I have read this form, or it has been read to me. A member of the research team has explained the study to me. I have been told about 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 form below, I voluntarily consent to participate in this study and authorize the use and disclosure of my health information for this study. I will receive a copy of this consent after I sign it. A copy of this consent form will be placed in my medical record.

Subject's Signature: _____ Date: _____

Print name: _____

Consent form explained by: _____ Date: _____

Print name: _____