

**INFORMATION AND CONSENT FORM AND AUTHORIZATION (PERMISSION) TO USE
AND DISCLOSE YOUR HEALTH INFORMATION FOR RESEARCH PURPOSES**

TITLE: A Randomized, Sleep Hygiene Controlled 6-Week Study To Compare the Efficacy of Four (CBT-I, FOA, Combined CBT-I and FOA and Sleep Hygiene) Different Behavioral Approaches for the Treatment of Adult Subjects with Insomnia

PROTOCOL: PSPC-17-01

SPONSOR: Puget Sound Psychiatry Center
10634 E. Riverside Drive, Suite 100
Bothell, WA. 98011
Tel: (425) 806-5021, Fax: (425) 486-3949

PRINCIPAL INVESTIGATOR: Max Hines, Ph.D.

RESEARCH SITE ADDRESS (ES):

Pacific Institute of Medical Sciences
10634 E. Riverside Drive, Suite 300
Bothell, WA 98011-3751

DAYTIME TELEPHONE NUMBER(S): 425-949-5779

24-HOUR CONTACT NUMBER(S): 425-223-2304

INTRODUCTION

You have been invited to participate in a research study. You do not have to participate if you do not want to. Before choosing to be part of this study, you need to understand why this research is being done and what it will involve for you.

This information and consent form describes the study and your role in it. Max Hines, Ph.D. has reviewed the study and has agreed to participate as an investigator (referred to in this form as the principle investigator). The study staff or principle investigator will answer any questions you have about this study or this information and consent form. You should read this document carefully and ask the study staff any questions you have regarding the information it contains. Please ask the study staff to explain any words or information that you do not clearly understand. Your questions should be answered clearly and to your satisfaction.

You may take home an unsigned copy of this information and consent form to think about or discuss the contents and its meaning for you as a study participant with family or friends before you make your decision.

Participating in a research study is not the same as receiving regular medical care. The purpose of regular medical care is to improve your health. The purpose of a research study is to gather information about a medical treatment. Being in this study does not replace your regular medical care, but you may have additional evaluations or changes in your treatments during the study.

If you do not take part in the study, you will not lose any benefits or medical care to which you are entitled. If you decide to participate, you are free to withdraw your consent at any time and without reason. If you decide to stop participating, you should tell the study staff immediately, even if between visits. The study staff may request you to come back for a safety follow up.

WHAT IS THIS STUDY ABOUT?

The purpose of this study is to measure and compare the effectiveness of four specific non-pharmaceutical treatment approaches. You must be an adult who meets the diagnostic criteria for Insomnia Disorder in order to take part in this study.

How Will We Determine If You Are Eligible?

Inclusion/Exclusion criteria to be assessed at Screening (Visit 1) and Every Visit (Visit 2, 3, 4, 5, 6, 7, 8, 9, 10 and 11)

Inclusion criteria: All potential participants must meet the following inclusion criteria.

- English speaking
- Age > 18 to 72 years
- Meet diagnostic criteria for Insomnia Disorder per DSM-5.
- Willing and able to sign Informed consent form
- Committed to following directions as prescribed by the study staff and to engage in behaviors designed to address sleep difficulty

Exclusion criteria: Participants who answer "yes" to any of the following will be excluded:

- Persons planning on moving away from the area in the next 3 months
- Females who are lactating or who are pregnant
- Night shift workers, and individuals who nap 3 or more times per week over the preceding month
- Consumption of caffeine beverages (i.e. tea, coffee, or cola) comprising usually more than 5 cups or glasses per day

- Participation in another trial for insomnia
- Persons unable to complete the study questionnaires and psychological tests
- Persons who are unable to participate for the entire duration of the study, or in the opinion of the investigators, are likely to be non-compliant with the obligations inherent in the trial participation
- Persons with severe anxiety or severe depression (BDI score of 29 or higher) or severe anxiety (BAI score of 36 or higher)
- Persons with untreated bipolar depression (must be on mood stabilizer, with medication considered stable and effective by both the person and the prescriber; must be medication compliant for at least 3 months)
- Presence of an untreated or unstable medical or psychiatric comorbid condition (e.g., major depressive disorder or psychotic disorder requiring admission within the last two years). (Persons using psychotropic medication, hypnotic or sedative medications may be included if they are on a stable dosage for the last two months prior to the study, if the dose remains stable throughout the study, and if the medication is judged to not interfere with the study outcomes.)
- Currently on medications known to produce insomnia (e.g., stimulants)
- Current alcohol or substance abuse/dependence disorder; if in question, must have an assessment or note from PCP or other qualified professional verifying no alcohol or substance abuse/dependence (must have >90 days of sobriety)
- Presence of other neurological disorders (e.g., multiple sclerosis, Parkinson's Disease)
- Persons with a history of epilepsy, seizures, or dementia
- Any significant, severe or unstable, acute or chronically progressive medical or surgical condition
- Serious head injury or stroke within the past year
- Diagnosed with another illness which has excessive daytime sleepiness as a feature of the disorder
- Sleep apnea (AHI >15) or previous diagnosis of Study participants who use a continuous positive airway pressure (CPAP) device for sleep apnea will be eligible for participation if they are below the apnea/hypopnea cutoff while using CPAP and agree to use the device during study participation.

If there is any reason for concern that you may be at risk or ineligible as per any of these criteria, the Research Coordinator will need to confer with the Principal Investigator before proceeding. After the Research Coordinator has conferred with the Principal Investigator, she will inform you of what will be needed in order to determine your eligibility. The Research Coordinator will also inform you that written approval from your Primary Care Physician or another qualified professional will be helpful in order to determine eligibility.

HOW LONG WILL I BE IN THIS STUDY?

It is expected that your study participation may last over a period of approximately 6 weekly sessions after screening and completion of the 1-week, 3-month, 6-month and 12-month follow-up assessment. You may need to attend unscheduled visits for safety or other reasons.

- Once you sign this consent form, you will be asked about any medication you may be currently taking for insomnia and its associated symptoms.
- You will have to come to the study center (11-12 times) during the study.
- The study staff will tell you when to come in for your study visits.
- You may need to attend unscheduled visits for safety or other reasons.
- You should ask the study staff how long your visits will last.

WHAT HAPPENS WHEN I COME IN FOR STUDY VISITS?

Before you start, the Principal Investigator or study staff will talk to you about the study. Once you sign this form, the Principal Investigator or study staff can begin the screening period to see if you qualify to be in the study. Below is a list of the scales and procedures that will be performed at each study visit.

Study Visit 1 (Screening) — This visit will take approximately 2-2.5 hours. At your first visit:

- The study will be reviewed with you, and your written consent will be obtained.
- You will be asked about your previous and current medication history.
- You will undergo clinical diagnostic interview that will determine your symptoms of insomnia or any other psychiatric disorders, and physical discomfort. You will also be asked if you have any thoughts/plans of hurting yourself or if you have in the past.
- You will complete a battery of questionnaires related to the study.
- It is recommended that patients abstain from alcohol consumption during the study.
- You are not allowed to initiate any other behavioral or non-pharmacological treatment prior to completion of the six-sessions.
- You are not allowed to initiate or change taking any sleep medications while enrolled in this study. You will cease taking all medications related to insomnia two weeks prior to Visit 2 (i.e., the first session).
- You are allowed to continue some ongoing counseling, for example couple counseling.
- You will be loaned an ActiWatch 2, which is a wrist-worn device that records data relevant to this clinical study. You will sign an agreement outlining your liability and responsibilities while in possession of the ActiWatch 2. In this agreement, you will confirm that the device is in satisfactory working condition at the time of inspection and that you accept financial responsibility in the amount of \$750.00 (USD) should the ActiWatch 2 be lost, stolen, or damaged while in your possession.
- You will be given a Weekly Sleep Log (WSL), which you will fill in each morning. The WSL consists of self-report data pertaining to your sleep.

Study Visit 2 (Baseline)

At your second visit, the study staff administering your therapy will review the results of your prescreening interview and questionnaires responses from the first visit. Visit 2 will typically take place within approximately 2 weeks after Visit 1.

- You will be asked about how you are feeling.
- You will be asked about any medications you are taking.
- You will undergo clinical diagnostic interviews that will determine your diagnosis of insomnia.
- The study staff will follow a scripted protocol. The session is scripted so as to provide standardization, and the clinician will generally be reading the script.

Based on the results of your insomnia diagnosis and responses to the clinical diagnostic interview and questionnaires, the clinician administering your therapy will determine if you remain eligible to continue in the study.

If you and the clinician agree that you will continue with the study, you will be given a new Weekly Sleep Log (WSL) to complete for the upcoming week. You must bring this completed Weekly Sleep Log to the next session.

Study Visits 3, 4, 5, 6 and 7

As a participant, you will be expected to participate in five additional sessions scheduled weekly on the same day of the week and at the same time each week as was your first session with the clinician. It will be very important that you arrive on time for each of the sessions. If you miss one of the scheduled sessions for any reason, you must reschedule that session with your study staff for later that day or on the next day. If not, you will be discontinued from the study. The clinician may only be available at certain times, and you will be expected to make up for the session you missed. Only one such rescheduling is permitted.

At these visits, the clinician will follow five more session protocols for the specific therapy for which you are assigned. Each of these five sessions is scripted so as to provide standardization, and the clinician will generally be reading the script.

As part of your therapy, you will be required to continue keeping a Weekly Sleep Log (WSL) each morning to keep track of the time you went to bed, about how many minutes it took before you initially fell asleep, etc. The WSL consists of self-report data pertaining to your sleep. Each week you will be given a new WSL, which you will complete for the upcoming week until your next session. You **MUST** bring your WSL to each session. At the beginning of each session, the clinician will review the Weekly Sleep Log for completion. During sessions 2 — 6, you will also be asked to engage in specific behaviors designed to improve your sleep. The specific behaviors will depend on the approach to which you were randomly assigned. For example, the behaviors may involve adjusting your bedtime, improving your sleep hygiene, or using specific meditation strategies designed to help you relax your brain.

On the same day or the day after your sixth and final session, you will be expected to meet with the Research Coordinator to complete the post-therapy assessment (Visit 8). In addition, you will be expected to complete a 3-month (Visit 9), 6-month (Visit 10), and 12-month (Visit 11) follow up assessment conducted by the Research Coordinator. This will involve completion of a Weekly Sleep Log, an interview, and completion of questionnaires. As much as possible, the follow up assessments will be conducted by email and telephone. It will be important that you ensure that the Research Coordinator has your current email address and phone number, and that you inform the Research Coordinator of any change in either.

Study Visit 8 (Post-Therapy Follow-Up Assessment)

Visit 8 will be performed for all participants and includes the following:

- You will undergo clinical diagnostic interview that will determine your symptoms of insomnia.
- You will complete a battery of questionnaires related to the study.

Study Visit 9, 10 and 11

Visit 9, 10 and 11 will be performed for participants who have completed the therapy period. At this visit:

- You will complete a Weekly Sleep Log for the week prior to each follow up visit.
- You will undergo clinical diagnosis interview that will determine your diagnosis of insomnia and physical discomfort.
- You will complete a battery of questionnaires related to the study.

WHAT DO I NEED TO DO IF I DECIDE TO PARTICIPATE?

As a subject, you are responsible for following the study directions and those of your study staff and Principal Investigator. This includes returning to your study staff's office for all necessary study follow-up visits, reporting any changes in your medications (over-the-counter and prescription) and reporting any changes in how you feel to the study staff. If you experience any illness or discomfort in the study, you should notify your study staff. Your study staff will then evaluate you to determine if you should continue the study.

As a participant in this research study, you are expected to:

- Ensure that you do not take part in any other research study until this research study is concluded.
 - You can participate in this research study at a single location only.
 - Participating in another study could affect the results of this study. Your participation in this research study will immediately end if you decide to enroll in another research study.
- Read this informed consent form and ask as many questions as needed. Follow the instructions of the study staff. Provide the study staff with a complete history of illnesses you have had and drugs you have taken in the past.
- Tell the study staff about any drugs (including prescriptions, over-the-counter drugs, or dietary supplements) you are taking or might take during your participation in the study.
- Refrain from taking any illegal substances during this study.
- Keep your study appointments. If you have to miss an appointment, please contact the study staff to reschedule as soon as possible and rescheduling new appointment occur on same or next day. If not then you will be discontinued from study.
- If you have to miss a second appointment then you will be automatically discontinued from study.
- If you have thoughts of suicide, please call 911 or crisis line?
- Then, please informed this study staff at your next appointment.

ARE THERE RISKS, DISCOMFORTS, OR INCONVENIENCES TO ME IF PARTICIPATE IN THIS STUDY?

Confidentiality Risks

Information about you will be handled in accordance with this consent and as confidentially as possible, but participating in the study may involve a loss of privacy and the potential for a breach in confidentiality. Study data will be physically and electronically secured. As with any use of electronic means to store data, there is a risk of breach of data security.

Unknown/Unforeseen Risks

You will be informed verbally and in writing of any new information, findings, or changes to the way the research will be performed that might influence your willingness to continue your participation in this study.

If you experience any side effects or research-related injury, contact the study staff or Principal Investigator immediately at the **phone number(s) listed on page one of this form.**

There may be risks to you while participating in this study. The risk of suicide is uncommon, but it is possible, if you have thoughts of suicide, please call 911 or crisis line?

Then, please inform study staff or Principal Investigator at your next appointment.

Women of Childbearing Potential

Pregnant and breastfeeding women are precluded from this study. It is a confounding variable and there are potential risks posed by sleep restriction. If you become pregnant while participating in this study, you will be withdrawn.

WILL I BE INFORMED OF NEW INFORMATION?

You will be told of any important new information that is learned during the course of this research study that might affect your condition or your willingness to continue participation in this study. You may be asked to sign a new informed consent form.

IS MY PARTICIPATION VOLUNTARY?

Your participation in this study is voluntary. You may decide not to participate without penalty or loss of benefits to which you are entitled.

CAN I LEAVE THE STUDY EARLY?

If you agree to participate in the study but then change your mind, you are free to withdraw your consent and stop your participation at any time without penalty or loss of benefits to which you are entitled.

Should you decide to end your participation in this study, you must notify your study staff or Principal Investigator that you wish to stop. It will be necessary for you to return to the study center for a final visit. During this study visit, the study staff will collect all study-related supplies. You may be asked to return to the study center after the final visit for safety assessments and follow up. If you choose to leave the study early, you will not be able to withdraw any data that was collected about you prior to leaving the study. This data will remain in the study.

CAN THE STUDY STAFF SHORTEN THE STUDY?

Your study staff or principle investigator may withdraw you from the study, and the study drug may be stopped, without your consent for one or more of the following reasons:

- You do not follow the instructions of the study staff, including failure to appear at your scheduled appointments.
- The Principal Investigator decides that continuing your participation could be harmful to you.
- The study is cancelled by the Sponsor, by the Investigative Site, by the IRB, by a governmental agency (like the FDA), or for any other reason.
- Unanticipated circumstances or other administrative reasons arise that require the study to stop.

All randomized patients who prematurely discontinue from the study prior to Visit 9, regardless of cause, should be seen for a final assessment. A one-week safety follow-up assessment will be performed after the Visit 9/Early Termination visit.

WILL BEING IN THIS STUDY HELP ME?

You may or may not receive any direct medical benefit from participating in this study.

Your participation in the study may benefit others with your disease or condition as a result of the knowledge gained from this research.

DO I HAVE ACCESS TO THE STUDY TREATMENT WHEN THE STUDY IS OVER? Following your completion of or early termination from the study (for any of the reasons described above), you will no longer have access to the study treatment. Following study completion or termination, you should discuss alternative therapies with the Principal Investigator.

WHO WILL USE AND SHARE INFORMATION ABOUT MY BEING IN THIS STUDY? Your identity will be kept confidential and you will not be identified by name, address, social security number or other country-specific identifier, or telephone number, except as disclosure is required by law or as described in this informed consent form.

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity will not be disclosed in any of these meetings or publications.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

This study will utilize a Data Safety Monitoring Board (DSMB). The purpose of the DSMB is to review subject data to proactively monitor for trends in safety data observed during the trial. The DSMB will have the authority to review your study and related medical records.

Background and Purpose

Study interview information that identifies you by name will not be shared with the reviewing researchers or with the study sponsor..

Your data is protected through a secure system which controls access through encryption and password protection which prevents illegal access.

Voluntary Participation/Withdrawal

Taking part in this study is completely voluntary. If you decide not to take part or that you want to end your involvement before the end of the study, it will not affect your current or future relationship with your clinician any one associated with the Research Department or Puget Sound Psychiatric Center. If you decide to take part, you are free to withdraw at any time.

WILL I BE PAID FOR BEING IN THIS STUDY?

The treatment is provided at no cost to you. You will not be financially reimbursed.

WILL IT COST ANYTHING TO BE IN THIS STUDY?

It is not expected for there to be any costs to you for participating in this study. If you have any cost-related questions or concerns, please ask your study staff or Principal Investigator.

IS THE PRINCIPAL INVESTIGATOR PAID FOR CONDUCTING THIS STUDY?

The Principal Investigator is voluntarily completing this study with no financial reimbursement. Any further questions you might have about other financial arrangements the Principal Investigator or other study staff might have can be discussed with the Principal Investigator.

WHAT IF I GET HURT OR SICK WHILE I AM IN THE STUDY?

If you get hurt or sick while in this study, you should seek medical assistance from your regular providers. In addition, please inform study staff and/or Principal Investigator at your earliest convenience.

WHO CAN I TALK TO ABOUT THIS STUDY?

If you have questions now or in the future, please ask the Research Coordinator. Research Coordinator can be reached at rcapspc.org or 425-949-5779. If you have questions which research coordinator cannot answer fully, you can contact the principal researcher conducting this study.

If you have questions, concerns or complaints about the study or experience any research-related injury, contact:

Principal Investigator Name: Max Hines, PhD

Daytime phone #: 425-806-5021 or by email: maxa.pspc.org

24-hour Contact Number(s): ---- 425-223-2304

REGULAR DOCTOR OR SPECIALIST NOTIFICATION OPTION:

Please indicate below whether you want us to notify your regular doctor or specialist of your participation in this study.

Yes, I want the Principal Investigator or his representative to inform my regular doctor/specialist of my participation in this study:

Name of Doctor

Phone/Fax #

No, I do not want the Principal Investigator or his representative to inform my regular doctor/specialist of my participation in this study.

No, I do not have a regular doctor or specialist.

STATEMENT OF CONSENT

Do not sign this consent form unless you have had a chance to ask questions and have received answers to all of your questions. If you agree to participate in the study, please sign this document and you will receive a copy to take home with you.

Your signature indicates:

- that you have read and understood the above information
- that you have discussed this study with the person obtaining consent
- that you have had the opportunity to ask any questions you may have
- that all of your questions have been answered to your satisfaction
- that you have decided to participate voluntarily (of your free will) based on the information provided
- that a copy of this form has been given to you.

By signing this consent form, I have not given up any of the legal rights that I otherwise would have had prior to my participation in this research study.

Printed Name of Participant

Signature of Participant

Date (dd-MMM-yyyy)

The information about the study was described to the subject in language he/she understood.

Printed Name of Person Explaining Consent

Signature of Person Explaining Consent

Date (dd-MMM-yyyy)

Signature of Principal Investigator or Sub-Investigator

Date (dd-MMM-yyyy)

The information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject, and that informed consent was freely given by the subject.

Printed Name of Witness (if applicable)

Signature of Witness (if applicable)

Date (dd-MMM-yyyy)

*Impartial Witness: If the subject cannot read, the signature of an Impartial Witness is needed.

An impartial witness is:

- a person who is independent of the trial,
- who cannot be unfairly influenced by people involved with the trial,
- who attends the informed consent process, and
- who reads the informed consent form and any other written information supplied to the subject.

SCHEDULE OF EVALUATIONS: Study PSPC-17-01											
	Screening	Randomized, Open label, sleep Hygiene Controlled 6 Week study						EOT/ET (1 week F/U)	Safety Follow up Period		
Visit #	I	(BV)/ 2	3	4	5	6	7	8	9	10	II
Study Day Weeks/Months	up to 14 days	1W	2W	3W	4W	5W	6W	7W	3M	6M	12M
Informed consent	X										
Review of Histories	X										
Medication History Concomitant Medications	x										
Inclusion/Exclusion	x	X	a	x	x	x	X	X	X	N	X
Randomization Assessment		X									
Questionnaire and inventories	X										
[SI]								X	x		
BDI	X							X	x	X	X
BAI	X							x	x	X	X
SRSM	X	X	x	x	x	x	X	X	x	X	X
WSL								X	x	X	X
CGI-I	X	X	x	x	x	x	X	X	x	X	
CGI-S	X	X	x	x	x	x	X	X	x	x	X
Q-LES	X							X			
DSM-5 diagnostic interview										X	
C-SSRS	X	X	x	a	a	a	X		a		X

Beck Depression Inventory (BDI); Beck Anxiety Inventory (BAI), Insomnia Severity Index (ISI); Self Report Sleep Measures (SRSM); Weekly Sleep Log (WSL); Clinical Global Impression - Improvement (CGI-I); Clinical Global Impression — Severity scale (CGI-S) Quality of Life Enjoyment and Satisfaction (Q-LES); End of Treatment (EOT)/Early Termination (One week F/U): (ET) Columbia suicide severity rating scale (C-SSRS); Baseline Visit (BV)

**AUTHORIZATION (PERMISSION) TO USE AND DISCLOSE YOUR
HEALTH INFORMATION FOR RESEARCH PURPOSES**

Purpose of this Form

State and federal privacy laws protect the privacy of your health information. Under the law, health information that includes identifiable patient information may not be used for research purposes unless you give written permission in advance. You do not have to sign this Authorization. If you do not sign this Authorization, you will not be allowed to participate in this research study. Your decision not to sign this Authorization will not affect any other treatment, healthcare, enrollment in health plans or eligibility for benefits.

Your health information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What health information will be obtained, used or disclosed?

Health information related to this study may be used or disclosed in connection with this research study. Health information shall mean information contained in your medical or other healthcare records. Health information may include, protected health information that can identify you. For example, it may include but not be limited to your name, mailing/email address, phone number, birthdate, medical record number and social security number. Health information collected in connection with this research study may also be found in the following:

- Progress notes
- Personal questions
- Health and medication questions
- Vital sign measurement
- History and Physical exam
- Questionnaires
- All research related information and study data

Who may use and disclose your health information?

The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Principal Investigator
- Puget Sound Psychiatry Center (Sponsor)
- Research study staff

Who may receive or use the information?

The parties listed in the above section may disclose your health information to the following persons and organizations in connection with this research study:

- Sponsor and/or its representatives, including affiliates, agents and contractors ("Sponsor");
- Institutional Review Boards (IRB) who oversee this research study
- The Office for Human Research Protections in the US Department of Health and Human Services;
- Federal and regulatory authorities (e.g. United States Food and Drug Administration-FDA, Health Canada, etc.), including those outside of the United States.
- Data Safety Monitoring Board

What is the purpose of this research study and how will my health information be utilized in the study?

The purpose of this research is to compare the efficacy of four behavioral, non-pharmaceutical treatments for adults with insomnia.

Your information about you and your health, and information that may identify you is being collected for the purposes of the research study. The Principal Investigator and research staff will use your information to analyze and publish the results of the research study.

Regulatory authorities and the IRB may also review and copy your information to make sure that the research study is done properly or for other purposes required by law.

The results of this research study may also be presented at scientific or medical meetings or published in scientific journals. Your identity will not be disclosed in any of these meetings or publications.

Your information may also be used along with the medical information of others to make and keep a research database. The database will be used for follow-up or future research and/or statistical purposes regarding medical conditions such as yours.

Do I have to sign this authorization form?

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study and you will not be able to receive any research-related treatment.

Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I cancel my permission or withdraw from the research study later?

You are free to withdraw or cancel your permission regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any cancellation or withdrawal, your health information will no longer be used or disclosed in the research study, except to the extent that the law allows us to continue using your information (e.g. information necessary to maintain the integrity or reliability of the research). Any revocation will not be effective to the extent that we have already taken an action in reliance on your authorization. If you wish to cancel or withdraw your permission for the research use or disclosure of your health information in this research study, you must provide written notice to: the Principal Investigator at the address listed on page 1 of this form.

If you cancel or withdraw (or stop participating) from the research study and cancel and withdraw this Authorization, no new information will be collected for the research study purposes unless the information concerns an adverse event (a bad effect) related to the research study. If an adverse event occurs, your entire medical record may be reviewed. All information that has already been collected for research study purposes, and any new information about an adverse event related to the study, will be sent to the study sponsor.

Your information may be subject to re-disclosure by the recipients described above. If those recipients are not required by law to protect the privacy of the information, it would thus no longer be protected by this authorization or by law.

When will my authorization expire?

If you do not withdraw this Authorization, it will remain in effect until December 31, 2020.

Approve

Will access to my medical record be limited during the research study?

To maintain the scientific integrity of this research study, you may not have access to any health information developed as part of this study until the study is completed. If it is necessary for your care, your health information will be provided to you or your doctor.

AUTHORIZATION

The study site is required by law to protect your health information. By signing this document, you authorize the study site to use and/or disclose (release) your health information for this research study. Those persons who receive your health information may not be required by federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them. You acknowledge that you have received a copy of this form.

Printed Name of Participant

Signature of Participant

Date (dd-MMM-yyyy)

Printed Name of Person Obtaining Authorization

Signature of Person Obtaining Authorization

Date (dd-MMM-yyyy)

The information in the authorization and any other written information was accurately explained to, and apparently understood by, the subject, and that informed consent was freely given by the subject.

Printed Name of Witness (if applicable)

Signature of Witness (if applicable)

Date (dd-MMM-yyyy)

~~Impartial Witness. If the subject cannot read, the signature of an Impartial Witness is needed. An~~

impartial witness is:

- a person who is independent of the trial,
- who cannot be unfairly influenced by people involved with the trial,
- who attends the informed consent process, and
- who reads the informed consent form and any other written information supplied to the subject.

The information about the study was described to the subject in language he/she understood.

Signature of Principal Investigator
or Sub-Investigator

Date

The information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject, and that informed consent was freely given by the subject.

Printed Name of Witness (if applicable)

Signature of Witness (if applicable)

Date

*Impartial Witness: If the subject cannot read, the signature of an Impartial Witness is needed.

An impartial witness is:

- a person who is independent of the trial,

Approve

- who cannot be unfairly influenced by people involved with the trial,
 - who attends the informed consent process, and
- who reads the informed consent form and any other written information supplied to the subject.

Approve

Addendum A:

In light COVID-19 Global Pandemic, the subject visits will be held via Tele-Health.

Confidentiality and record-keeping for the insomnia study trail (Protocol number PSPC-17-01) will stay the same.

The investigator will ensure the appropriate conduct of the trail through Tele-Health.

The subject consents to participate through Tele-Health.

Name and Signature of the Participant:

Date (DD/MM/YYYY)

Signature of the Principal Investigator-Sub investigator:

Date (DD/MM/YYYY)