Department of Veterans Affairs	VA RESEARCH CONSENT FORM Social and Behavioral Research

Title of Study:	Improving Sleep Apnea Treatment Adherence after Brain Injury: A Feasibility Study		
Principal Investigator:	Marc A. Silva, PhD	VAMC:	Tampa-673

Informed Consent to Participate in Research: Social and Behavioral Research

University of South Florida, the IRB of record for the James A. Haley Veterans' Hospital
Information to Consider Before Taking Part in this Research Study

IRB Study # 000414741

Researchers at the James A. Haley Veterans' Hospital study many topics. Our goal is to find better ways to help treat patients. To do this, we need the help of people who agree to take part in a research study.

STUDY OVERVIEW:

1. **WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?**
   We are asking you to choose whether or not to volunteer for a research study (funded by the Department of Veterans Affairs) about a **counseling intervention for persons with TBI and Sleep Apnea**. This initial information is to give you key information to help you decide whether to participate. We have included detailed information after this information. Ask the research team questions. Taking part in this study is completely voluntary.

2. **WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?**
   The purpose of this study is to deliver a counseling intervention designed to enhance Positive Airway Pressure (PAP) therapy in persons with brain injury and Sleep Apnea, and then gather your feedback on the intervention. You will be asked to attend four counseling intervention sessions. The intervention was adapted from Motivational Interviewing (MI) and Cognitive Behavior Therapy (CBT), which are commonly used in persons without brain injury. We will gather your feedback on the intervention, such as what you liked did not like, and how you think the intervention can be improved for persons with brain injury.

   By doing this study, we hope to learn how to improve sleep apnea treatment in persons with TBI.

   This research study will occur over a 2-3 year time frame. Your individual participation in the project will be 6 sessions (today is the first session) over the course of 4-12 weeks.

Subject's Name: _____

Subject's Last 4 digits of SS# required: _____

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

To contribute to the testing and refinement of this counseling intervention for persons with brain injury.

For a complete description of benefits, refer to the Detailed Consent Section.

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

This study involves approximately 3 – 6 hours of your time.

For a complete description of risks, refer to the Detailed Section of the Consent and/or Appendix.

The alternative is to refrain from participation.

For a complete description of alternate treatment/procedures, refer to the Detailed Section of the Consent.

5. 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.

6. WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is **Dr. Marc Silva** of the James A. Haley Veterans' Hospital. This person is called the Principal Investigator. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his contact information is: Office: 813-972-2000 ext. 5613; Fax: 813-631-3057; snail mail: 13000 Bruce B. Downs Blvd, 116-B, Tampa, FL 33612.

After you read this form, you can:

- Take your time to think about the information that has been provided to you.
- Have a friend or family member go over the form with you.
- Talk it over with another health care provider.

It's up to you. If you choose to be in the study, then you can sign the form. If you do not want to take part in this study, you should not sign the form.

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DETAILED RESEARCH CONSENT SECTION

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to improve a counseling intervention that is designed to enhance use of PAP therapy in persons with Sleep Apnea who also have a history of TBI. The counseling intervention is based on Motivational Interviewing (MI) and Cognitive Behavior Therapy (CBT). MI and CBT are established intervention in persons without brain injury. However, these techniques have not been applied to persons with sleep apnea and a history of brain injury.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

About 19 people will take part in this study at James A. Haley Veterans' Hospital**.**

HOW LONG WILL I BE IN THE STUDY?

Your individual participation in the study will be 6 sessions. The timing of the sessions can occur over the course of 4-12 weeks, at your preference. It just depends on how soon or how far apart you would like the sessions to take place. Each session lasts between 30-60 minutes.

The study is expected to run over the course of 2-3 years.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

You will be asked to complete questionnaires on sleep symptoms, such as fatigue, sleepiness, and how your sleep symptoms are affecting your quality of life. We will also ask about your brain injury history (such as how it occurred and how old you were) and complete a brief cognitive test. Then, you will meet with a therapist for the counseling interventions, which will take place at the James A. Haley Veterans' Hospital and/or remotely via tele-health platforms. After each counseling session, you will be asked to complete a brief questionnaire about the session. The counseling sessions will be recorded using digital audio recorders with encryption or web-conference recorder and reviewed to make sure the intervention is consistent with MI and CBT. Basically, it is a quality check.

Following the last counseling session, you will be interviewed by someone other than the therapist to gather information from you about what you thought of the intervention. We want to know what was helpful, what was not helpful, what you liked, what you did not like, and how you think the intervention could be improved for persons with sleep apnea who also have a history of brain injury. These post-

intervention interviews will be de-identified and transcribed by a VA-approved vendor. We will also review some of your medical records to fill in gaps about your sleep apnea and brain injury history (such as results from tests you may have had).

A study visit is one you have with study staff. There are 6 total sessions (today is the first one). You will need to come for 6 study visits. Most study visits will take about 30-60 minutes. You do not need to do anything different from your normal routine prior to the first study visit. Here is a summary of the study visits and the activities associated with each:

Visit	Activity	Study Team Member	Estimated Time
1	1. Review and sign (a) informed consent form; (b) permission to review your medical records form; and (c) permission to record counseling sessions form 2. Complete questionnaires on sleep symptoms and brain injury history; complete brief cognitive testing	Project Manager or Research Assistant	30-60 minutes
2	1. Receive counseling intervention session 1 2. Complete questionnaire on your experience of the session	Study therapist	30-60 minutes
3	1. Receive counseling intervention session 2 2. Complete questionnaire on your experience of the session	Study therapist	30-60 minutes
4	1. Receive counseling intervention session 3 2. Complete questionnaire on your experience of the session	Study therapist	30-60 minutes
5	1. Receive counseling intervention session 4 2. Complete questionnaire on your experience of the session 3. Complete questionnaires on sleep symptoms	Study therapist	30-75 minutes
6	1. Participate in interview on your experiences of the four counseling sessions	Project Manager or Research Assistant	30-60 minutes

During the study visits, you will be asked:

- During the counseling sessions, to discuss your thoughts and feelings about managing your sleep apnea, and to discuss the pros and cons of treating your sleep apnea
- Before the first counseling session and after the last counseling session, to complete questionnaires about your sleep symptoms. You may skip any questions that you prefer not to answer.

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Recordings of the counseling sessions will be stored on a secure folder behind the VA firewall at the James A. Haley Veterans' Hospital. The recordings will be kept for the duration of the study. Your recording will be identified using a unique ID number that will be assigned to you for this study – it will not contain your name, social security number, or other identifiers. Only members of the research team and VA-approved vendor have access to these recordings.

For the purposes of the study, we ask the following of you:

- Keep your study appointments.
- If you miss an appointment, please contact the investigator or research staff to reschedule as soon as you know you will miss the appointment. The principal investigator can be contacted at 813-972-2000 extension 5613 or 813-537-9445.
- Complete your questionnaires as instructed. You may skip any item you prefer not to answer.
- Ask questions as you think of them.
- Send you appointment reminders via mail, text, and/or electronically (email) through Azure Rights Management System (Azure RMS)

A description of this clinical trial is available on www.ClinicalTrials.gov. This website will not include information that can identify you. At most, the website (which you can search at any time) will summarize study results: https://clinicaltrials.gov/ct2/show/NCT04221009?term=NCT04221009&rank=1

If you would like to receive a summary of the results of this study, please provide your mailing address, below. Results will be summarized in aggregate form, which means findings will be presented for the overall group. No participants will be specifically identified.

_____ No, I do not want a summary of the results mailed to me.
(Initials)

_____ Yes, I would like a summary of the results mailed to me. Send to the following address:
(Initials)

_____
Street Address Apt/Unit #

_____
City State Zip

_____

Subject's Name: _____

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Photographs, audiotaping, or videotaping

By signing this Informed Consent Document, you voluntarily and without separate compensation authorize pictures and/or voice recording(s) to be made of you by the research team while you are participating in this study. The said picture, video, and/or voice recording is intended for the following purposes: Review of counseling intervention sessions and post-intervention interview for quality control (to ensure the sessions follow the principles of MI and CBT).

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 filmed, photographed or recorded, and may rescind your consent for up to a reasonable time before the picture, video or voice recording is used.**

If study personnel deem that you are at risk for harming yourself or someone else, they will:

- Stay with you until you can be 'handed off' to appropriate medical staff (such as a physician, psychiatrist, psychologist, or psychiatric nurse).
- If you are an outpatient, this will involve taking you to the Emergency Room for evaluation.
- If you are an inpatient, this will involve calling your primary treatment team and/or escorting you to such providers.

All study personnel who work directly with research participants will be given the names and phone numbers of the patient's medical care team. After the patient has been 'handed off' to the appropriate staff, the study PI will be alerted."

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.

The potential risks associated with this study are minimal. The activities and procedures of this study are non-invasive. Thus, risk of physical harm is unlikely. It is possible that emotional discomfort may occur while participating in the brief cognitive test, or completing symptom questionnaires, or when discussing your health and sleep apnea treatment. In the event of emotional discomfort, you may choose to

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discontinue the activity. Also, we can notify your current health care treatment providers or refer you to a physician or psychologist if you want us to. We do not anticipate any financial or legal risk associated with this study. It is possible that there risks that are unknown to us.

COMPENSATION

You will be compensated $100 via gift card(s) over the course of the study as follows: ($25 for completion of pre-intervention questionnaires, $25 for completion of post-intervention questionnaires, and $50 upon completion of the post-intervention qualitative interview).

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

By participating in this study, there is potential that study findings will lead to improvement in the management of sleep apnea in persons with brain injury. Your input is important to us, and the information we gather from you will be used to refine the intervention. We cannot promise any direct benefit to you by participating. While there may be no direct/personal benefits to you from your taking part in this research study, the information we get from this study might help others with brain injury and sleep apnea.

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

Participation in this research study is entirely voluntary. In other words, you may choose not to participate in this study.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Describe the procedures used to maintain the confidentiality of the records and data pertaining to the participant, how the participant's privacy will be protected, and who may inspect the records.

Your identity will not be attached to the data collected for this study. Data collection forms will not contain your name, social security number, or other personal identifiers, except for date of birth which is used to calculate your age at various points in time (e.g., at injury, at time of sleep apnea diagnosis, at time of study participation). After completion of the study, all identifiers (i.e., date of birth) will be removed. After that removal, the information could be used for future research studies or distributed to

Subject's Name: _____

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another investigator for future research studies without additional informed consent from you or your legally authorized representative.

We will include information about your study participation in your medical record. We will communicate with your health care providers for appointment scheduling purposes.

Health Information Portability and Accountability Act (HIPAA)

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 your medical history, test results, and sleep apnea 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. For example, we will disclose you name to clinic staff involved in your health care to facilitate scheduling appointments. Others may include the Institutional Review Board, Food and Drug Administration Office (FDA), Office of Human Research Protections (OHRP), VA Office of Research Oversight (ORO), and the Government Accountability Office (GAO).

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 Principal Investigator of the study at this facility.

Principal Investigator: Dr. Marc A. Silva
James A. Haley Veterans' Hospital 116-B
13000 Bruce B. Downs Blvd.
Tampa, FL 33612-4745

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You can also ask a member of the research team to give you a form to revoke the authorization. The study team will contact the Release of Information Office. 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. 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.**

Recordings of the study sessions will be used for quality control. That is, the recording will be reviewed to ensure the counseling intervention sessions follow the principles of MI and CBT. Only IRB-approved study team members have access to these recordings.

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

It will not cost you anything to take part in this study.

You 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.

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

You are participating in a research project approved by a Research & Development Committee and conducted under the supervision of one or more VA employees. Every reasonable safety measure will be used to protect your well-being. If you are injured because of your participation as a research subject in this research study, the VA medical facility will provide you with necessary medical treatment.

If you need emergency care:

- **Go to your nearest hospital or emergency room right away. Call 911 or for help.**
- It is important that you tell the doctors at the hospital or emergency room that you are participating in a research study. If possible, take a copy of this consent form with you when you go.
- Call the person in charge of this study as soon as you can. They will need to know that you are hurt or ill. Call Dr. Marc Silva at (813) 972-2000 extension 5613.

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If you need emergency care in a private hospital, have a friend or family member contact the VA immediately at (877) 881-7618 or 813-903-4275 option 2 and your study doctor so that they can coordinate care with a private hospital. If an eligible veteran requires admission to a non-VA hospital as a result of an emergency, the Department of Veterans Affairs will not be responsible for the cost incurred unless the Department of Veterans Affairs is involved immediately.

If it is not an emergency, and you get hurt or begin to feel bad: Go to your regular doctor. Tell your doctor that you are taking part in this study. If you can, take a copy of this consent form with you.

If you believe you have a medical concern related to this study, or have been hurt or became sick because of something that is done during the study, you should call the person listed below immediately.

DURING THE DAY: Dr. Marc A. Silva
(813) 972-2000 ext. 5613

AFTER HOURS: Physical Medicine and Rehabilitation (PMRS) on call physician
(813) 972-2000
Veterans Crisis Line
(800) 273-8255 Press 1

Emergency and ongoing medical treatment will be provided as needed.

Compensation for Research-Related Injuries

Financial compensation for research-related injuries, lost wages, discomfort or disability may be available. You do not give up any of your legal rights and you do not release the VA from any liability by signing this form.

DO I HAVE TO TAKE PART IN THE STUDY?

Participation is voluntary. If you do not want to take part in the study, there will be no penalty or loss of benefits to which you are otherwise entitled. If you are a VA employee or a student, refusal to take part in the study will in no way influence your employment, ratings, subsequent recommendations, or academic progress as applicable. Also, you may discontinue taking part at any time without any penalty or loss of benefits. We do not anticipate any consequences if you decide to withdraw from the study. If you do withdraw, data already collected prior to your withdrawal may continue to be available to the investigator, but no further information will be collected, except from public records, such as survival data.

_____

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RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

Even if you want to stay in the study, there may be reasons we will need to take you out of it. You may be taken out of this study if:

- We find out it is not safe for you to stay in the study. For example, your health may worsen, or we may find that the procedure might harm you.
- You stop coming to your study visits as scheduled.
- You have expressed that you intend to harm yourself.

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

If you have questions, concerns, or complaints about this study, you can contact the study PI, Dr. Marc Silva, at 813-972-2000 ext. 5613, or 813-537-9445.

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). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the USF IRB at (813) 974-5638 or contact the USF IRB by email at RSCH-IRB@usf.edu if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

If you would like to contact someone independent of the research study, or cannot reach the research staff, you may contact the James A. Haley Veterans' Hospital Research Compliance Officer at 813-903-4274.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

As stated above, if you would like to receive a summary of the results of this study, we will send the summary the address you provided to us. Results will be summarized in aggregate form, which means findings will be presented for the overall group. No participants will be specifically identified.

FUTURE USE OF DATA AND RE-CONTACT

Data will be retained as a de-identified dataset after conclusion of this study. That is, there will be no personally identifying information in the retained dataset. The dataset will be stored as a password protected document on a VA server behind the VA firewall. The data will be available to IRB-approved research investigators.

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AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr./Mr./Ms. _____ (person obtaining informed consent) has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

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

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

Signature of Person Obtaining Informed Consent/Research Authorization		
_____ Name	_____ Signature	_____ Date

Subject's Name: _____

Subject's Last 4 digits of SS# required: _____