Participant Name: _____ Date:_____

Title of Study: **A Patient-Focused Approach to Insomnia Treatment for Women Veterans**

Principal Investigator: **Jennifer Martin, PhD** Contact number **818 891-7711 ext. 36066**

INTRODUCTION

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

Read the information below closely, and discuss it with family and friends if you wish. Ask one of the study staff if there is anything that is not clear or if you would like more details. Take your time to decide. If you do decide to take part, your signature on this consent form will show that you received all of the information below, and that you were able to discuss any questions and concerns you had with a member of the study team.

BACKGROUND AND PURPOSE

- The number of women Veterans receiving care in the VA is increasing. It is important for VA to offer treatments for sleep problems that are effective and preferred by women Veterans.
- The purpose of this study is to test two different insomnia treatment programs.
- You are being asked to participate in this study because you previously completed and returned the postal survey "How are Women Veteran's Sleeping?" and your answers indicated that you have symptoms of insomnia.
- A total of 400 women Veterans who returned the survey will be enrolled into this study.
- This study is funded by the VA and the principal investigator is Jennifer Martin, PhD of the VA Greater Los Angeles Healthcare System.

DURATION OF THE RESEARCH

This research study will be conducted for approximately four years. Your individual participation in the project will take approximately 3 months.

STUDY PROCEDURES

If you decide to take part in this study, this is what will happen after you sign this consent form:

Health and Sleep Evaluation

1. You will be asked questions about your health, medications and personal information, such as your marital status, number of children, and employment. This will take about 30 minutes.

SUBJECT'S IDENTIFICATION

2. You will be screened for sleep apnea with a monitoring device that you will wear for one night. This device is worn on your wrist and has four sensors: a 2 ½" plastic sensor worn on the index finger, a bandage-sized sensor worn on the ring finger, a nickel-sized sensor worn on the neck to detect snoring and a 2" sensor worn on the chest to detect body position. These sensors are painless and have a sticky pad on the side that is placed next to your skin. You will need to return the monitoring device to the Sleep Research office the next day.

3. When you return the sleep apnea monitor, you will be asked another set of questions about your mood, memory, stress, and quality of life. This will take about 90 minutes.

4. You will be asked to wear a sleep watch for 8 consecutive days. The sleep watch looks like a wrist watch and will measure when you are asleep and when you are awake.

5. You will fill-out a diary about your sleep each day that you wear the sleep watch. This will take about 1-2 minutes per day. You will return the sleep diary with the sleep watch.

6. When you return the sleep watch after 8 days, you will be asked questions about your sleep patterns and habits. It will take about 30 minutes to answer these questions.

Medical Record Review

If you volunteer to participate in this study, you are also agreeing to let the research staff review your VA medical records to obtain information about your:

- use of VA services (including insomnia treatments) over the past year
- diagnoses and treatment (including diagnoses and treatment related to mental health conditions and drug and alcohol abuse)
- current medications

After all of this information has been collected, it will be reviewed by the study doctors to determine if you meet the criteria for receiving the insomnia treatment program. If we find that you suffer from a condition that would make it difficult for you to participate in this study, you will be excluded from the study. We will inform you, and with your permission, your doctor of these findings.

Insomnia Treatment Program

If you are eligible to continue with the study, you will receive one of two insomnia treatment programs, Program A or Program B. Which treatment program you will receive will be determined randomly (like flipping a coin). You will attend 5 weekly sessions, each lasting 60 minutes, at the VA Sepulveda

Ambulatory Care Center. The content of each session will vary, but each one will focus on providing education and strategies to improve sleep and decrease concerns related to sleep. Neither program will include the use of sleeping medications. If you are currently using a sleeping medication, you will continue to follow your doctor's recommendations. The sessions will be led by Sleep Research staff who have been trained to teach this type of program. At the end of the program, we will ask you to complete questionnaires about your experience with the treatment program.

The treatment sessions you attend will be recorded for the purpose of making sure that study staff follow the protocol for each session. The recording will not be shared with anyone outside project staff.

Follow-up Evaluations

You will receive a follow-up evaluation at the end of the 6-week insomnia treatment program and again after 3-months. At each of these evaluations, you will be asked to repeat the questionnaires about your sleep, mood, stress, and quality of life. You will also be asked to wear the sleep watch for 8 days and to complete a sleep diary. Research staff will again review your medical records to see if there have been any changes in your health or medications.

All activities are being undertaken for research purposes only.

POSSIBLE RISKS OR DISCOMFORTS

You may experience the following risks and discomforts as a result of participating in this study:

Sleep monitoring: The known risks associated with wearing the sleep monitoring device are minimal. The sleep apnea sensors worn for one night and the sleep watch worn for 9 days may be annoying or uncomfortable for you. Rarely, they may cause skin irritation or an allergy. To minimize skin irritation, we provide wrist bands that are flexible and adjustable and we have limited the sleep apnea recording to only one night.

Questionnaires: You may feel uncomfortable answering questions about your health, mood, relationships or sleep habits. You can choose to skip any questions that make you feel uncomfortable.

Insomnia treatment program: You may find that coming to the 5 session insomnia treatment program is tiring or inconvenient. As you make adjustments to your sleep habits within the program, you may experience more daytime sleepiness at first. It will be important that you follow the instructions given by your program instructor if this occurs.

It is possible that there are other unforeseeable risks.

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POTENTIAL BENEFITS

We cannot promise that you will get any benefits from taking part in this research study. By attending the insomnia treatment program you may learn more about sleep and strategies to improve your sleep.

ALTERNATIVES TO PARTICIPATING IN THIS RESEARCH

You may choose not to participate in this study. If this is your decision, you can choose to receive treatment for insomnia from the VA or from a community provider. You can discuss these options with your primary care provider.

CONFIDENTIALITY

Taking part in this study will involve collecting private information about you. This information (data) will be protected in the following ways:

- We will ask you for your social security number in order to process your payment check and to access your VA medical record. If you do not wish to provide your social security number, you can still participate, but you cannot receive payment for your participation. Your Social Security Number will be stored in a locked file cabinet and only authorized Sleep Research staff will have access.
- You will be assigned an identification (ID) number and this ID number will be used instead of your name (or other identifiers) on all study records. All research records will be kept in locked file cabinets in locked offices and stored on password protected computers. Only authorized Sleep Research staff will have access to these records.
- Your information will be combined with data from other people taking part in the study. We will only write or talk about the combined data. Your individual answers will not be identified.
- We will not share your records or identify you unless we have to by law. There are times when we might have to show your records to other people. For example, someone 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 Greater Los Angeles IRB, our local Research and Development Committee, or other study monitors may look at or copy portions of records that identify you. This is to monitor the research project and to make sure it is in compliance with rules and regulations.

- In accordance with California law, confidentiality cannot be guaranteed if the investigator becomes aware that you may be a danger to yourself or to others, or becomes aware that child abuse or elder abuse is occurring.

COSTS TO PARTICIPANTS AND PAYMENT

Costs to Participants*:*

You will not be charged a co-payment for any visits, treatments or procedures that are part of this study. However, 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.

Payment Offered for Participation:

- You will be paid for completing the assessments before the insomnia treatment program. This will include $25 for completing the overnight sleep apnea monitoring, $75 for completing the questionnaires and $25 for wearing the sleep watch for 8 days.
- You will also be paid for completing the two follow-up assessments. This will include $25 for wearing the sleep watch for 8 days and $50 for completing the questionnaires.
- You will either be mailed a check or paid via electronic fund transfer (EFT) into your bank account approximately four (4) weeks after you complete the sleep evaluation, but it could take up to 2 months for processing. Note that your social security number (and bank account for EFT) is required to process payments. In addition, it is VA policy that the amount you receive from this study may be reported to the Internal Revenue Service (IRS) and may be considered taxable income.
- You will not receive payment if you do not return the sleep apnea monitor or the sleep watch.
- You will not receive payment for attending the five insomnia treatment program sessions, and you will not receive compensation for travel, even if you normally receive it when you come for clinical appointments.

MEDICAL TREATMENT AND COMPENSATION FOR INJURY

Every reasonable safety measure will be used to protect your well-being. If you experience any of the study-related risks or discomforts or if you are injured in some other way as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury was due to your not following the study procedures. If you should have a medical concern or get hurt or sick as a result of taking part in this study, you should seek medical treatment as needed, and report this to Dr. Martin at (818) 895-9311.

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You do not give up any of your legal rights and you do not release the VA from any liability by signing this form.

PARTICIPATION IS VOLUNTARY

It is up to you to decide whether or not to take part in this study. If you decide to take part you may still withdraw at any time. If you do not wish to be in this study or leave the study early, you will not lose any benefits to which you are entitled. If you don't take part, you can still receive all usual care that is available to you. Your decision not to take part will not affect the relationship you have with your doctor or other staff, and it will not affect the usual care that you receive as a patient.

If you decide to withdraw from the study, the information that has already been collected from you will still be included in the study findings. However, no further information will be collected from your medical record.

RIGHT OF INVESTIGATOR TO TERMINATE PARTICIPATION

Dr. Martin has the right to end your participation in this study. If we discover that you have medical or psychiatric symptoms that might interfere with your participation, if you do not return the sleep monitoring devices on time, or if you do not keep your appointments with the Sleep Research staff, your participation will be terminated.

FUTURE USE OF DATA AND RE-CONTACT

With your permission, the information that we collect from you during this study (your data) will be kept for use in future studies by Dr. Martin and/or her research team. These data will be stored in locked filing cabinets in locked rooms and only Dr. Martin and/or her research team will have access to the data. Please check the box to indicate whether you agree or do not agree to have your data stored for use in future studies.

☐ I agree to have my data stored for future use by Dr. Martin and her research team.
☐ I do not want my data stored for future use by Dr. Martin and her research team.

With your permission, we may contact you after this study is completed to invite you to participate in future studies. Please check the box to indicate whether you agree or do not agree to be contacted for future studies.

☐ I agree to be contacted for future studies by Dr. Martin and her research team.
☐ I do not want to be contacted for future studies by Dr. Martin and her research team.

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PERSONS TO CONTACT ABOUT THIS STUDY

In the event that you have a question about the research or experience a research related injury or adverse reaction, please immediately contact one of the investigators on this study: Dr. Martin at 818-891-7711 ext. 36066.

You may contact the Human Research Protection Administrator at 310-268-3080 if you have any concerns regarding the following:

- the legitimacy of this study (whether it is a VA approved study);
- your rights as a research subject;
- how to express complaints regarding this research study; or
- what will happen in the event of a research-related injury;

You may also contact the Associate Chief of Staff for Research and Development for the VAGLAHS at the VA Greater Los Angeles Healthcare System, 11301 Wilshire Blvd, Mail Code 151, Los Angeles, CA 90073. The telephone number is 310-268-4437.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr./Mr./Ms_____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.

You voluntarily consent to participate in 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. A copy of this signed consent will also be put in your medical record if applicable.

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

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RIGHTS OF HUMAN SUBJECTS IN MEDICAL EXPERIMENTS

Any person who is requested to consent to participate as a subject in a research study involving a medical experiment or who is requested to consent on behalf of another has the right to:

1. Be informed of the nature and purpose of the experiment.

2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.

3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.

4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.

6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

7. Be given an opportunity to ask any questions concerning the experiment or the procedure involved.

8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.

9. Be given a copy of any signed and dated written consent form used in relation to the experiment.

10. Be given an opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

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