**Participant Name:** _____ **Date:** _____

**Study Title: Diagnosis and Treatment of Sleep Apnea in Women Veterans**

**Principal Investigator**: Jennifer Martin, PhD Phone: 818 891-7711 ext. 39311

## INTRODUCTION

You are being invited to take part in a research study at the VA Greater Los Angeles Healthcare System under the direction of Dr. Jennifer Martin, PhD and her research team. 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 to you and/or to the future population of individuals you represent.

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.

Your participation in this study is voluntary. 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 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.

## 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:
    1. to understand sleep disorders, including sleep apnea, in women Veterans and
    2. to test two different programs to help women Veterans with sleep apnea.

- You are being asked to participate in this study because you are a woman Veteran who has at least one risk factor for sleep apnea.
- A total of 300 women Veterans will be enrolled into this study.
- This study is funded by the VA. The principal investigator is Jennifer Martin, PhD of the VA Greater Los Angeles Healthcare System

## DURATION OF THE RESEARCH:

This study is expected to take up to 4 years to complete. The expected duration of your participation in this study is 12 months.

## STUDY PROCEDURES

Due to the COVID-19 pandemic, some or all research visits may occur using VA approved video telehealth platforms, like VA Video Connect. Study staff will help you use this system on your personal computer or smartphone. If the visits are in-person, you will be required to answer COVID-19 screening questions prior to each visit, wear a mask throughout the visit, and maintain social distancing.

If you decide to take part in this study, this is what will happen:

Health and Sleep Evaluation

Baseline Visit 1 (30 minutes):

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

2. You will be screened for sleep apnea. At the end of visit 1, you will be given a portable sleep apnea monitoring device to take home and 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 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.

Baseline Visit 2 (90 minutes):

1. You will be asked another set of questions about your mood, memory, stress, and quality of life.

2. You will be given a sleep watch to wear for 8 consecutive days. The sleep watch looks like a wrist watch and will measure when you are asleep and when you are awake. While you wear the sleep watch, you will be asked to keep a diary about your sleep each day. This will take about 1-2 minutes per day. You will return the sleep diary with the sleep watch.

Baseline Visit 3 (30 minutes):

1. When you return the sleep watch after 8 days, you will be asked questions about your sleep patterns and habits.

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 over the past year
- diagnoses and treatments (including diagnoses and treatments related to mental health conditions and drug and alcohol abuse)
- current medications

Review of screening results

The results of the sleep apnea screening test will be reviewed by physicians in the VA Sleep Disorders Center to determine if you have sleep apnea and will prescribe an appropriate treatment, if necessary. If you are diagnosed as having sleep apnea, you will be contacted by a physician or clinic staff member who will explain the results and will discuss treatment options with you. Information about your test results, diagnosis and prescribed treatment will be entered into your VA medical record. This is the usual process of care for all Veterans who have a sleep apnea screening test.

Final eligibility determination

Information collected from the health and sleep evaluation, the medical record review, and the results of your sleep apnea screening test will be reviewed by the research team to see if you are eligible for continuing in the study. To continue in the study, you must have sleep apnea and be prescribed a Positive Airway Pressure (PAP) device to treat your sleep apnea. The PAP is the recommended therapy for sleep apnea and is used throughout the VA to treat this condition. If you do not have sleep apnea, are not prescribed a PAP, or you suffer from another condition that would make it difficult for you to take part in study activities, you will be excluded from further participation. If this condition is a new finding, we will inform you, and with your permission, your doctor of these findings

Sleep Apnea Education Program

If you are eligible to continue in the study, you will receive one of two sleep apnea education programs, Program A or Program B. Which education program you receive will be determined randomly (like flipping a coin).

For both education programs, you will meet with a trained sleep specialist for 6 weekly sessions, each lasting 45 minutes. These sessions will take place at the VA West Los Angeles or Sepulveda campuses, or by computer using a VA approved video telehealth platform. The content of sessions in Program A and Program B will vary, but will focus on providing education about sleep and sleep apnea and will teach you strategies to improve your sleep. The education 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.

You will receive the Positive Airway Pressure (PAP) device prescribed by the Sleep Disorders Clinic during the education program and you will be encouraged to wear it while you sleep. A trained respiratory therapist will instruct you on the use of the PAP. The PAP device has a modem attached which transmits information about how the PAP is working. The study team will review the information transmitted from your PAP device at different times throughout the study.

You will be asked to answer a questionnaire at the beginning of session 1 and at the end of session 6. These questionnaires ask for your opinions about the education program.

Sleeping medications will not be prescribed as part of this research. If you are currently using a sleeping medication, you will continue to follow your doctor's recommendations.

Follow-up Evaluations

You will receive a follow-up evaluation at the end of the 6-week sleep education program (1 visit) and again after 3-months (2 visits). At each of these evaluations, you will be asked to repeat the questionnaires about your sleep, mood, stress, and quality of life. You will be asked to wear the sleep watch for 8 days and to complete a sleep diary. Research staff will again review your medical records for any changes in your health or medications.

Your PAP device contains an internal memory card (SD card) that stores information about the PAP. You will be asked to bring this SD card to the 3-month follow-up visit so we can transfer the information from the SD card into our computer database.

At 6-months, 9-months, and 12-months after you receive the PAP you may be contacted by telephone and asked questions about your use of the PAP. You may also be asked to mail the SD card to the research study office so we can transfer the information from the SD card into our computer database. The SD card will be mailed back to you each time.

After the 3-month follow-up you may request to receive the education program you did not receive during the main part of the study.

All activities are being undertaken for research purposes only.

## POSSIBLE RISKS OR DISCOMFORTS

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 unforeseeable (unexpected) risks also may occur.

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 devices are minimal. The sleep apnea sensors worn for one night and the sleep watch worn for 8 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, or sleep habits. You can choose to skip any questions that make you feel uncomfortable.

Sleep apnea education program: You may find that coming to the 6 education sessions 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.

## POTENTIAL BENEFITS

We cannot promise that you will get any benefits from taking part in this research study. By attending the sleep apnea education program you may learn more about sleep and strategies to improve your sleep. In addition, the information we get from this study might help us treat future patients.

## CONFIDENTIALITY

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

- We will ask you for your social security number 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.
- 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.
- Research records and payment forms will be kept in locked file cabinets in locked offices and stored on password protected computers. Access will be limited to authorized Sleep Research staff.
- The audio-recordings of the education sessions will not contain your name.
- Information about you will be combined with information from other people taking part in the study. We will write about the combined data we have gathered. Any talks or papers about this study will not identify you.
- We will not share your records or identify you unless we are legally required. 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.
- 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

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.

## PAYMENT OFFERED FOR PARTICIPATION

- In return for your time and inconvenience, you may be paid up to $250 and you may receive up to three $25 VA canteen vouchers.
- For the baseline health and sleep evaluation, you will receive $25 for completing the overnight sleep apnea monitoring, $50 for completing the questionnaires and $25 for wearing the sleep watch for 8 days.
- For the follow-up assessments you will receive $25 for wearing the sleep watch for 8 days and $50 for completing the questionnaires.
- You will not be paid for coming to the 6 education sessions.

- You will also receive a $25 VA canteen voucher if you mail the SD card to the study office at 6-months, 9-months, and 12-months.
- You will receive these payments even if you do not complete all parts of an assessment. However, if you do not complete any of the assessment, if you do not return the sleep monitoring devices, or if you withdraw from the study before a follow-up assessment, you will not receive payment.
- You will be mailed a check or paid via electronic fund transfer (EFT) into your bank account approximately four (4) weeks after the assessment, but it could take up to 2 months. 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.

## YOUR RIGHT TO TERMINATE PARTICIPATION

Your participation in this research is voluntary. You have the right to stop participating in the study at any time. If you withdraw from the study, it will not affect your relationship with the VA or the standard of care that you may receive here.

If you withdraw from the study, Dr. Martin can still use the information that was collected from you before you withdrew, but no further information will be collected, except from public records, such as survival data.

## RIGHT OF INVESTIGATOR TO TERMINATE YOUR PARTICIPATION

Dr. Martin has the right to end your participation in this study for the following reasons:

- you have a severe medical or psychiatric problem that prevents you from participating or requires referral for specialized treatment
- you do not follow the study procedures.

## PERSONS TO CONTACT ABOUT THIS STUDY

In the event that you have a question, complaint, or concern about the research, please contact Dr. Martin at (818) 891-7711 ext. 39311.

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 VA Greater Los Angeles 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 VA Greater Los Angeles IRB at 1-310-268-4437 if you have questions, complaints or concerns about the study, or if you would like to obtain information or offer input.

**FUTURE USE OF DATA AND RE-CONTACT**

With your permission, Dr. Martin and her research team may contact you after this study is completed to invite you to participate in future studies.

☐ Yes, I give my permission to be re-contacted for future research by Dr. Martin or a member of her research team.

_____ (subject's initials)

**USE OF PHOTOGRAPHY, VIDEO AND/OR AUDIO RECORDING**

One or more of the education sessions you attend might be audio-recorded. This recording will only be heard by Dr. Martin and project staff for the purpose of monitoring the quality of the education sessions and for training future staff. The recordings will not be transcribed and will not be shared with anyone outside project staff. Your full name will not be recorded on the session recordings to protect your identity. You do not have to agree to be recorded during the education sessions. Your refusal will not impact or affect your participation in other aspects of the research.

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Principal Investigator: Jennifer Martin, PhD

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## 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 be retained in the investigator's research records.

| **I agree to participate in this research study as has been explained in this document.** | | |
|---|---|---|
| _____<br>Participant's Name | _____<br>Participant's Signature | _____<br>Date |

| | | |
|---|---|---|
| _____<br>Name of person obtaining consent | _____<br>Signature of person obtaining consent | _____<br>Date |

## 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.