Sleep Systems

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

STUDY TITLE: The Effect of Head Pitch and Roll Rotation Independent of Torso Position on the AHI in Positional Obstructive Sleep Apnea

PROTOCOL NUMBER: Apnea Guard – 1400

VERSION: 1.0

INVESTIGATORS: Dr. Stacia Sailer

STUDY CONTACTS: If you have any questions or should you wish to withdraw from the study at any time, you may contact the following individuals who are directly involved with this study:

Study Coordinator: Michael Lawee (617) 823-0921

This consent form may contain terms relating to sleep apnea or other terms and procedures that you might have specific questions about. Please ask the study doctor, or the study coordinator or study staff to explain information that you do not understand and answer your questions. An unsigned copy of this consent form is available to you to take home to think about your decision to participate or to discuss your decision to participate with family or friends. Please take your time making the decision whether or not to participate. It is important that you understand that no guarantees or promises can be made regarding the results of the study.

Your participation in this research study is entirely voluntary. Your decision to participate or not will not affect future care or therapy provided by your physician. Written, informed consent must be obtained from you prior to you entering this study. You will be given a complete and thorough review of this study as well as an explanation of the benefits and risks and or discomforts that may occur. You must sign this consent form before you can participate in the study.

You are being asked to participate in this study because you and your medical history indicate that you have been diagnosed with Obstructive Sleep Apnea that is affected by the position you sleep in.

Why is this research study being done? The purpose of this research study is to determine, during sleep, whether sleeping with your neck and head positioned on the left or the right, that is rotated from right to left or left to right while sleeping supine (on your back) will reduce the apnea-hypopnea index (AHI) that was calculated on a sleep study (polysomnogram) that you had done previously. Additionally, the sleep study that you completed previously had shown that the

majority of your sleep apnea occurred while sleeping on your back (positional obstructive sleep apnea). In other words, the question this research study wants to answer is if you sleep with your head in either the left or right position while also sleeping on your back, will your apnea (no breathing) or hypopnea (shallow breathing) get better or be eliminated. If you are on PAP (CPAP) therapy, sleeping in the position described above might provide the same relief without using your current PAP therapy. Researchers in sleep medicine have shown that apneas during sleep that occur primarily while sleeping supine (on the back) are distinct from apneas that occur in any sleeping position. Thus the distinction between the diagnosis of *Obstructive Sleep Apnea* and *Positional Obstructive Sleep Apnea.*

Qualification to participate in this study: In order to qualify for this study you must have had a previous diagnosis of obstructive sleep apnea with documentation that the majority of the apneas occurred while sleeping on your back. Additionally, you must be able to tolerate sleeping on your back while also rotating your neck from left to right and sleeping in either of these positions for an extended period of time. Additionally, you have to able to complete at least one overnight sleep study (polysomnogram) similar to the one you completed previously with an additional sensor attached to your forehead that measures your neck rotation while sleeping. If you cannot tolerate placement of the sensor on your forehead you will be disqualified from further participation. During the sleep study, the recording technologist (study staff) will periodically enter your sleep room and ask or help place your head and neck in positions from left to right. If you are unable to complete this while sleeping you will be disqualified from further participation in this study.

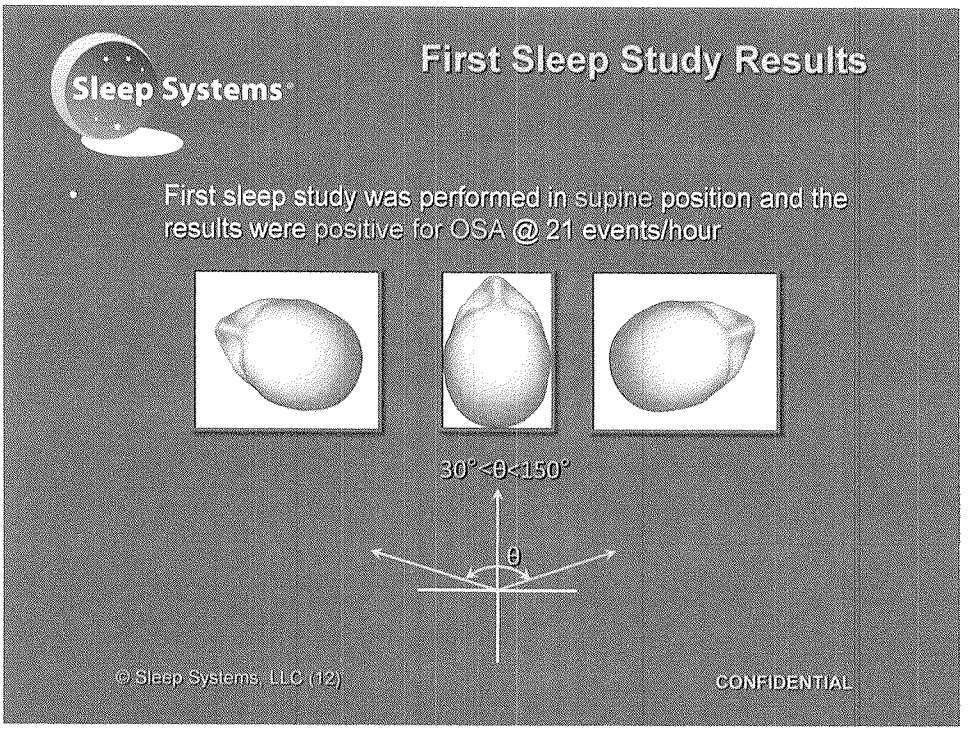
PROCEDURES: This study will require one screening visit and one overnight visit to the sleep center. The procedures explained in this document are considered research and would not be conducted if you were not participating in this study.

Screening visit: You will be asked to come to the sleep center for an initial screening visit to determine eligibility and discussion of the consent form and asked if you have any questions about this study. Before signing the consent form you should understand all the procedures, the duration of the additional overnight visit and potential risks and benefits of enrolling in the study. You are free to choose not to enter the study and this will not affect your current medical treatment in any way. Once you sign the consent form, a member of the study staff will ask about your medical history and if on PAP (CPAP) therapy, your compliance with the prescribed therapy. You then be asked to undergo the following procedures:

- Medical History: Your Medical History will be collected along with a history of your PAP usage at night. Based on your medical history the Research Technologist might determine that you will need to have an interview with the Study Physician. If so the Study Physician will interview you during the screening visit.

- Pulse oximetry and Heart Rate: A small clip will be placed on your finger to measure the amount of oxygen in your blood and your resting heart rate.
- Weight, and height will be measured and BMI calculated.
- You will be asked to lie on your back and rotate your head and neck in different positions from right to left to simulate the positions during the overnight position.
- You will complete a few paper based questionnaires.
- The Research Technologist will discuss with you the overnight sleep study.
- You will be scheduled for the overnight visit

Overnight Sleep Study: You will be scheduled to come for an overnight sleep study (polysomnogram) at the sleep center. You will be asked to complete a questionnaire about your sleeping habits. Before being asked to start your sleep time you will be fitted with the standard sleep study (polysomnogram) montage (application of electrodes to your body), similar to your previous sleep study. Additionally a sensor patch will be attached to your forehead and secured by a physiological adhesive tape. This patch is essential to the research study and will record your neck and head position while sleeping. This sensor patch is not part of the standard acceptable montage that is currently approved by the American Academy of Sleep Medicine (AASM). Following the application of electrodes, sensor patch, and specific calibrations to the recording device you will be asked to go to bed at your assigned sleep room. You may request to "settle down" and "relax" by watching Television or reading but at some predetermined time the research technologist will ask that you turn of lights (Lights Off) and go to sleep. The Research Technologist will monitor your sleep, breathing, EKG and leg movements at a separate monitoring station and determine the stage of sleep (depth of sleep) and the number of apneas (no breathing) and hypopneas (shallow breathing) that you are experiencing and correlate these events with your sleeping position as determined by the forehead patch and other position sensors within the standard montage. Once the Research Technologists has determined the "existence of Positional Obstructive Sleep Apnea", he/she will enter your assigned sleep room and position your head to the right using pillows or other "foam wedge" pillows to stabilize the neck in the right position. The Research Technologist will continue to monitor your sleep in this position and following a specified recording time will enter your assigned sleep room and rotate your neck and head from right left in specific amounts corresponding to the degrees of rotation as required by the study protocol. Entry to your room shall be intermittent throughout the night. Following each rotation, the Research Technologist will monitor the recorded sleep study to determine if the Apnea (no breathing) and hypopnea (shallow breathing) has decreased or is eliminated. The illustration below will you help you understand the position that the Research Technologist will apply. If you do not understand the illustration please ask the study staff to explain further:



RISKS AND DISCOMFORTS: Potential adverse effects of monitoring sleep studies are minimal. Allergic reaction to electrode placement has been reported but the frequency of these reports is not known. If you do experience an allergic reaction to either the placement of electrodes or the sensor patch to the forehead report this to the Research Technologist, after which the study and recording will be terminated. Additionally you may request to stop this overnight visit at any time during the recording time. The Research Technologist will be available and present through the overnight visit.

BENEFITS: There may or may not be direct medical benefit to you for your participation in this study. The information developed in this study may help other people with Positional Obstructive Sleep Apnea.

COSTS: The study forehead sensor, physician fees, tests and overnight sleep study (polysomnogram) will be provided at no cost to you. You or your insurance provider will be responsible for costs directly related to the treatment of your underlying medical conditions.

COMPENSATION FOR PARTICIPATION: You will be compensated for your time and travel expenses related to study participation up to $450.00 for completion of the study. If you do not complete the entire study, you will be compensated for each completed visit as follows:

- Screening Visit: $50.00

- Overnight Sleep Study (polysomnogram): $400.00
  (Based on 10 hours of overnight participation)

Payment will be made at the completion of the study by check mailed to the address you provide. If you should chose to terminate the overnight portion of the study prior to its completion, you will be compensated for the hours you have participated.

FOR EMPLOYEES :

For Employees of Sleep Systems, LLC and Mass Lung & Allergy, PC:

Your participation in this study is voluntary. You are free to withdraw your consent and discontinue participation in this study at any time without prejudice or penalty. Your decision to participate or not participate in this study will in no way affect your continued employment or your relationship with individuals who may have an interest in this study.

_____initials

(Please note you will be participating in this study on your own time; not during regular working hours.)

ALTERNATIVE PROCEDURES: You may choose not to participate in this study. You should talk about other treatment options with your doctor. Make sure that you understand all your choices before you decide to take part in the study.

CONFIDENTIALITY STATEMENT: All documents and information pertaining to this research study will be kept confidential in accordance with all applicable federal, state, and local laws and regulations. You understand that medical records and data generated by the study may be reviewed by New England Independent Review Board (NEIRB), the Office for Human Research Protections (OHRP), the study sponsor, and Sleep Systems, LLC. You understand that the results of this study may be published. If any data is published, you will not be identified by name.

COMPENSATION FOR INJURY: You understand that if you sustain an injury as a result of participation in this study, only physician fees and medical expenses not covered by my medical and hospital coverage or other third party coverage will be paid at no cost to you by Sleep Systems, LLC. You understand that financial compensation for such injuries is not available. You understand that you have not waived any of the legal rights that you would otherwise have as a participant in an investigational study.

VOLUNTARY PARTICIPATION STATEMENT: Your participation in this study is entirely voluntary. Refusal to participate will involve no penalty or loss of benefits to you. Your participation in this

study may be stopped at any time by the study doctor, study coordinator or sponsor without your consent.

INSTITUTIONAL CONTACT: If you have any questions concerning your rights as a research subject, you are asked to contact New England Independent Review Board, 197 First Avenue, Suite 250, Needham, MA., 02494. T: 617-243-3924

CONSENT:

My signature below indicates that I have read this entire consent form, and that all known risks and benefits have been explained to my satisfaction. All of my questions about the study and my participation in it have been answered. I am fully aware that I may call the phone numbers provided to me in this consent form to ask any further questions that I may have regarding my participation with this research. I agree to keep all information associated with my participation confidential. I voluntarily agree to participate in this investigational engineering study.

I understand that signed and dated copy of thos consent form will be given to me .

By signing this consent form, I have not waived any of the legal rights that I otherwise would have as a participant in this evaluation.

_____

Printed name of Participant

_____ _____

Participant's signature Date

_____ _____

Printed Name of Person Conducting the Informed Consent Discussion

Position

_____ _____

Signature of Person Conducting the Date

AUTHORIZATION FOR USE AND DISCLOSURE OF INFORMATION FOR RESEARCH PURPOSES:

I, _____, hereby authorize the sleep center site conducting this research study to use the following protected health information and to disclose the following protected health information to Sleep Systems, LLC, located at 12 Curtis Road, Tyngsboro, MA 01879.

The information to be used and disclosed includes:

- My birth date, gender, height, weight and BMI
- My medical condition and history
- My dates, types and results of treatment, laboratory tests, and diagnostic tests associated with this research study.
- My dates and type of physiologic monitoring and clinical information obtained during monitoring associated with this research study, including the sleep study (polysomnogram) I completed during my overnight stay and compliance data retrieved from my PAP therapy device.
- My dates and description of complications and side-effects associated with this research study.

This protected health information will be used or disclosed for the following purposes:

- To screen and properly select patients for enrollment into this research study and subsequent phases to this particular study.
- To monitor and assess safety of the subjects during the course of the research study.
- To assess the success of testing during the course of the research study.
- To determine and evaluate outcomes of the research study and adjust subsequent phases of the research study based on collected data of Phase 1 (current protocol).
- Submission of this data as part of peer reviewed publications or as an abstract at specific meetings associated with obstructive sleep apnea

I understand that I have the right to revoke this authorization, by sending written notification to the site contact person identified above, as indicated. *If I revoke my authorization, I will not be able to stay in this study nor will I be able to screen for subsequent phases of this research study.*

I understand that information used or disclosed pursuant to this authorization will not be further disclosed by the recipient (Sleep Systems, LLC, Tyngsboro, MA.) with my express written consent, except to the FDA, as required by federal law and the Department of Health and Human Services (DHHS) agencies. If the results of this study are made public, information that identifies me will not be used.

I understand there is a risk that my information will be given to others without my permission.

I understand that I have the right to:

- Inspect or copy the Protected Health Information to be used or disclosed as permitted under federal law. I will not be able to inspect and copy such Protected Health Information while the clinical research is taking place because I know that the goals of the clinical research might be affected by my review of my medical records. I understand that my right to access and copy Protected Health Information will be reinstated at the completion of the research.
- Refuse to sign this authorization.

I understand that the Study Coordinator and the Study Staff at the sleep center conducting this study will refuse to provide any research-related treatment or discontinue the Procedures listed above (screening visit and overnight visit) to me if I refuse to sign this authorization. This refusal to sign will prevent me from participating in the research study.

This authorization has no set expiration date and shall be in force indefinitely.

AUTHORIZATION SIGNATIRE:

I have been given the information about the use and disclosure of my health information for this research study. My questions have been answered.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

_____ _____

Signature of Participant Date