Title of research study: Clinical Sleep Educator, (CSE) Intervention

Investigator: ***Beth Mortonson, RPSGT, CCSH – Clinical Manager, RRMC Sleep Lab***

Sub-Investigator: ***John Ordal, MD – Asante Physician Partners – Pulmonary & Sleep***

Why am I being invited to take part in a research study?

We invite you to take part in a research study because we think that additional support from a Clinical Sleep Educator may help increase your chances of success with CPAP or PAP treatment.

What are the benefits of participating?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include getting used to PAP treatment faster. You may also find that with added support, the CSE may address any problems with mask fit or discomfort with pressures. Adhering to your CPAP and regularly using treatment may give you more energy during the day, improve your memory, your sleep, and lower your cardiovascular risk. Another benefit is to your bed partner, he/she will not have interrupted sleep due to your snoring.

What are my rights as a research subject?

- Someone will explain this research study to you, including:
  - The nature and purpose of the research study.
  - The procedures to be followed.
  - Any device to be used.
  - Any common or important discomforts and risks.
  - Any benefits you might expect.
  - Medical treatment, if any, that is available for complications.

Whether or not you take part is up to you

- You can choose without force, fraud, deceit, duress, coercion, or undue influence.
- You can choose not to take part.
- You can agree to take part now and later change your mind.
- Whatever you decide it will not be held against you.
- You can ask all the questions you want before you decide.
- If you agree to take part, you will be given a copy of this document.

How is this research funded?

This research is being funded by The Asante Foundation**,** also called the sponsor. Sponsors may change or be added. The Asante Rogue Regional Sleep Lab is being paid to conduct this study, but the study doctor and research staff have not received any direct income from the sponsor.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to Beth Mortonson, the principal investigator at the Asante Rogue Regional Sleep Lab (541) 789-4320.

For non-emergency issues you can call the Asante Rogue Regional Sleep Lab, at (541) 789-4320 and ask to speak with someone on the CSE research team**.** In the case of an emergency, dial 911 from any phone.

This research has been reviewed by the Institutional Review Board (IRB) of Southern Oregon.

You may talk to a IRB staff member at (541) 789-4626, 2825 East Barnett Road, Medford, OR 97504 for any of the following:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

Why is this research being done?

We are conducting this research to answer the question, "Does intervention by a clinical sleep educator (CSE), improve PAP adherence rates among patients newly diagnosed with obstructive sleep apnea?" The support given by a CSE is in addition to the standard of care you are currently receiving by seeing a sleep specialist provider at APP Pulmonary and Sleep Specialists.

Nationally, PAP adherence rates are low, typically at about 50%. We think that if a patient receives more education and support while starting PAP treatment, their chance of success may likely increase.

Risks or Discomforts

The risks associated with this study involve minimal risks such as a breach of confidentiality. In an effort to preserve confidentiality, both the investigator and the study sponsor have taken precautions to protect the data collected for this research. This study only involves additional education and support by a CSE.

How long will the research last?

We expect that you will be in this research study for 3.5 months. The entire research study will last approximately 12 to 18 months.

How many people will be studied?

We expect about 600 people in Rogue Valley area will be in this research study.

What happens if I say yes, I want to be in this research?

- After you receive your CPAP machine you will be scheduled for a 45-minute office visit with a Clinical Sleep Educator, (CSE).
- At the visit the CSE will answer any questions you have about your treatment; provide education about obstructive sleep apnea; discuss the effects of not using treatment on your body; and perform a mask fit to check for comfort. You will be able to try on a mask with the PAP pressure turned on to check for leakage.
- One week later you will receive a phone call from someone on the research team; he or she will ask about your experience with your new PAP treatment and what mask you are using.
- If you need additional help by visiting the CSE again, the research team member may schedule you for another visit at that time.
- Your CSE will write up a report and place it into your electronic medical record for your APP Provider to view.
- Kevin Ludwig, CRT, RPSGT, CCSH will conduct your CSE visit(s), he is a member of the research team.
- Each CSE visit will be scheduled at the Asante RRMC Sleep Lab.
- The study will be completed in approximately one year.
- The research we are conducting is the additional support by a CSE that you will receive.
- The current standard of care does not include CSE visit(s).
- You will still meet with your APP Provider for scheduled office visits even if you do not take part in this research project.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to let the CSE research team know if you are struggling with using CPAP treatment or are uncomfortable in any way from the use of it.

What happens if I do not want to be in this research?

You may decide not to take part in the research and it will not be held against you.

Instead of being in this research study, your choices may include:

- To continue to see your provider and DME company for support
- To attend a complimentary mask fitting at the RRMC Sleep lab

The important risks and possible benefits of these alternatives include:

- The risk would be less education and support regarding your new treatment.

What happens if I say yes, but I change my mind later?

You can leave the research at any time and it will not be held against you.

If you decide to leave the research, you will receive less education and support. If you decide to leave the research, contact the investigator so that the investigator can remove you from the study.

If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

What happens to the information collected for the research?

Efforts will be made to limit use or disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information include the Southern Oregon Institutional Review Board. The Southern Oregon University IRB may have access to the final, de-identified data collected for the study.

If you agree to participate in this research study, a signed copy of this consent document will be filed in your electronic medical record (EMR).

Confidentiality

Your data will be confidential. The records collected during this study will be kept private. We will not include any information that will make it possible to identify you. Research records will be kept in a locked file, a secure hard drive, and only the researchers will have access to your records.

Authorization to use and disclose health Information

This section of the Informed Consent governs how your health information will be used and shared. By signing this form, you are giving your permission (consent) to the uses and disclosures stated in this Authorization. You do not have to sign this form. If you do not sign it, you will not be able to be in the study, but it will have no other effect on the medical care you receive.

What information about you can be used or shared?

The health information that may be used or shared is:

- All information collected during this study;
- Information in your medical records that is relevant to the study.

When you see the phrase "health information" in this form, it means all of the information listed above.

Who may use and share information about you?

As part of the study, your health information will be kept by the research investigator, your provider(s), and the study staff. When you see the word "Researchers" in this form, it refers to all of these people. You agree to permit your health care providers to disclose health information in your medical records to the Researchers. You also agree to permit your Providers to disclose your health information as required by law and to representatives of government organizations, review boards, and other persons who are required to watch over the safety and effectiveness of medical products and therapies and the conduct of research.

What can the Researchers do with your health information?

The Researchers can:

- Use and share your health information to conduct the study and evaluate the results;
- Use and share your health information to meet the reporting requirements of government agencies;
- Use and share your health information to prepare publications or presentations on this study (but no publication about the study will reveal your identity without a different specific, written permission from you);
- Use and share your health information as required by law.
- Disclose your health information to the groups listed in the next section of this form.

What can the research team do with your health information?

After your health information has been disclosed to the investigator, the investigator may use and share it, in the United States or throughout the world, for any of the following purposes:

- To conduct, monitor, and/or audit the study, and to confirm the research results;
- To prepare publications or presentations (but no publication about the study will reveal your identity without a different specific, written permission from you);
- As required by law.

Can I decide not to allow the use and sharing of my health information?

Yes. You do not have to sign this form. However, if you do not sign this form, then you cannot participate in the study.

Can I take back (revoke) my permissions given by signing this form?

Yes. At any time you can change your mind about allowing your health information to be used or shared by telling your research team or provider in writing. If you change your mind, you will be taken out of the study and no further health information about you will be gathered for the study. However, the health information gathered before you notified your research team or provider that you changed your mind may be used or shared by the Researchers and Sponsor as provided in this Informed Consent. If you think it is likely that you will change your mind, please do not sign this form.

Is my health information always protected?

After the researchers have shared your health information with others permitted by this Informed Consent, including the Sponsor, federal laws may not protect the health information from being shared again.

Can I see my research information?

You may not be able to see your research information while the study is going on, unless the information is also being used for your health care. There may be other limitations on access to medical information unrelated to this study. Once the study is over, you can ask your study provider to see any research information that is maintained by the research team. However, you may not be given access to research records that are not part of your medical record.

Can I be removed from the research without my OK?

The research investigator can remove you from the research study without your approval. Possible reasons for removal include

- If the patient has received additional outside support and no longer fits inclusion criteria for the research study.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What else do I need to know?

There is no charge for you to participate in this study. Neither you nor your insurance carrier will be charged for your taking part in the research. All costs associated with the study will be paid by the sponsor/department.

Only the costs of research will be paid by the study**,** they include one or two 45 minute office visits with a CSE and follow-up support over the telephone.

Research-Related Injury

In the event you become injured or become ill as a result of participation in this study, you or your insurance will be billed in the usual manner for the costs of treatment, assessments, procedures, and medications for such injury or illness. Since the risks of participating in the study are minimal, we do not anticipate any research-related injuries

You will not be compensated for taking part in this study.

Are there other research opportunities?

If you are interested in being contacted for future research, please provide your phone number and/or email. <u>This is completely optional.</u>

_____(initials) Yes, I am willing to be contacted for future research opportunities. My phone number and/email is: (_____) _____ - _____. Email: _____.

Do not write below this line. For IRB stamp and version date only.

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

Do not write below this line. For IRB stamp and version date only.