



## **Consent Information Sheet**

**Study Title: Sleep for Health Study**

**Principal Investigator: Erin LeBlanc, MD, MPH**

**Study Contact: Erin LeBlanc, MD, MPH**

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*Note: This consent sheet is only for pre-screening study activities. This will be reviewed with the participant over the phone and the study staff will obtain and document verbal consent. If the participant qualifies for the main study, they will be asked to consent for those study activities separately.*

We are doing a research study about sleep treatment in people who have prediabetes. We are requesting you to participate because you have prediabetes and sleep problems.

We are doing this research to learn more about:

- Whether a sleep treatment called Cognitive Behavioral Therapy for Insomnia (CBT-I) results in lower blood sugar levels in people who have prediabetes.

### **What will I be asked to do?**

To see if you are eligible to join this study, we need to gather information about your sleep. To do that, we will ask you to complete a sleep diary each day for 10 days. Each morning you will receive a link to a short questionnaire about your sleep, called a sleep diary. It will ask you questions such as what time you went to bed, what time you woke up, and whether you woke up during the night. It will take about 5 minutes to complete. A new link will come each day for 10 days. The link to the survey can be sent by email, text, or both depending on what you prefer. We ask you to fill it out each morning about your sleep the night before. This survey is only for research purposes and would not become part of your medical record. You will receive up to \$10 depending on completing diaries in that 10-day period. You must complete at least 5 diaries to qualify for the next step and in order to receive any reimbursement.

If your sleep diaries show that your sleep difficulties meet our study entrance criteria, we then need to check your hemoglobin A1c. This is a test that measures the sugar levels in the blood over the last 3 months. We are doing the test for the purpose of our research study in order to see if you are eligible. The lab test can be done at the Center for Health Research on the Kaiser Interstate campus at a day and time that is convenient to you and there will be no extra charge for the test. We will give you a \$15 gift card for your time and effort in getting the lab test. The test is being done for research purposes and will not be part of the test results section in your medical record. However, if we detect results that your medical provider needs to know about, we will let you and your provider know. You can receive your A1c test result if you request them. We would send your lab tests to you via email and if you request it, we can encrypt the email, meaning that the information in the email would be converted into a secret code. To open and decode the email, you would need to create an account and enter an authorization code, which would come in a separate email.



If the hemoglobin A1c test indicates you are eligible for the Sleep for Health Study, we will then arrange for you to have a home sleep apnea test as part of the research study. This test will determine if you might have sleep apnea. In people with sleep apnea, breathing repeatedly stops and starts during sleep. You cannot be in this study if you have sleep apnea because the sleep treatment we are testing cannot be used in those with sleep apnea.

The home sleep apnea test will be one of two devices. The first, called Night Owl, is owned by a company called ResMed and the other is Circul+ ring, which is owned by a company called BodiMetrics. For both devices, we will give you the small measurement device and explain how to download the Night Owl or Circul app on your smart phone. You will need to enter your email address into the Night Owl app in order to create an account and complete the sleep apnea test. Before bedtime, you will follow directions on the app about how to either place the Night Owl device on your fingertip using an adhesive or wear the Circul ring. You will then synchronize the device to the Night Owl or Circul app. After you finish sleeping, the applications will upload the data for our team to review. You only need to wear the device for one night, however we will want you to keep the device in case additional nights might be needed (in case we need more information on your sleep). If you are given the Night Owl device and we give you the okay that no further testing is needed, you will just throw the device away. For the Circul ring, we will ask you to return it to us after we know that no further testing is needed. For your time and effort in doing this home sleep test, you will receive \$10.

This test is being done for research purposes and will not be part of the test results section in your medical record. However, if we detect results that your medical provider needs to know about, we will let you and your provider know. The test results could indicate that you may have sleep apnea and could suggest the need for additional sleep testing.

You can receive your sleep test result if you request them. As with the A1c result, we would send your results to you via email and if you request it, we can encrypt the email, meaning that the information in the email would be converted into a secret code. To open and decode the email, you would need to create an account and enter an authorization code, which would come in a separate email.

### **Are there any risks to participating in the study?**

The blood draw may cause temporary discomfort or bruising. There is a very rare chance of infection with a blood draw. The adhesive tape or ring could irritate your skin. If this happens, we would have you stop using the sleep measurement device. There is a small risk of loss of confidentiality.

### **Are there any benefits to participating in the study?**

This blood test will show your blood sugar levels. This information could be helpful for you because having high blood sugar levels can be bad for your health. This home sleep apnea test will show if you might have sleep apnea, which can be a serious sleep problem that impacts your overall health and may need to be treated.

### **Will I be paid for taking part in this research?**

You will be paid up to \$35 for doing these prescreening tests.

### **Do I have to be in the research study?**



No, you do not have to join this research study and you can withdraw at any time. Your participation is completely voluntary and your decision to participate or not will not affect your medical care or health benefits in any way.

### **Confidentiality and your Health Information**

Kaiser Permanente is committed to protecting your health information. State and Federal laws also protect your privacy. By agreeing to participate, you allow the study team to collect information about your A1c level and your sleep through the sleep diaries and home sleep apnea test. To protect your confidentiality, your information will be connected to a study ID (not your name). If we detect test results that your medical provider needs to know about, we will let you and provider know.

People and organizations involved in overseeing or auditing this study may also see or receive your information. These may include, for example, the Institutional Review Board (ethics review committee), the funder of the study, research collaborators, and the FDA or Office of Human Research Protection (federal agencies that oversee research).

We may publish the results of this research. However, we will not publish your name or any other identifying information.

If your data is used for future research or distributed to another investigator for future research without your consent, any information collected in this research that identifies you will be removed.

By agreeing to participate, you give permission to researchers at Kaiser Permanente to use and/or disclose (release) your sleep diary, A1c test, and home sleep apnea test results for the research described above. Once your information has been given to others, it may no longer be protected by state or federal privacy laws. It will be protected by other rules and agreements with the recipients. However, there is still a risk that a recipient could share your information without your permission. We would like your permission to keep your information “indefinitely.”

If you decide you want to stop sharing your health information for this study, you need to tell us in writing. You can tell us by writing to:

Erin LeBlanc, MD,  
Center for Health Research  
3800 N. Interstate Ave.  
Portland, OR, 97227

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When we receive your request, we will stop using and disclosing (releasing) your health information. We may continue to use information we collected before we received your request. If we have already disclosed (released) your information to someone else, we will probably not be able to get it back.

You do not have to allow the use and disclosure of your health information in the study, but if you do not, you cannot be in the study. If you choose not to participate, or if you decide to stop at any time, that will not affect your ability to receive health care at Kaiser Permanente or



insurance coverage.

If you have any questions about this study or feel you have been harmed by the study procedures, please contact Dr. LeBlanc at (503) 335-2400. If you have questions about your rights as a research subject, contact the Institutional Review Board (IRB) at (951) 739-6781. The Institutional Review Board (IRB) is a committee of scientific, nonscientific, and community members who review research studies to protect the rights and welfare of participants.

- By moving forward to the sleep diaries, lab test, and home sleep apnea test, you agree to let us use and share the information received from you during the testing in the ways described above.
- If you do not agree to this, we cannot include you in the study.

[SUBMIT/I CONSENT]