RESEARCH CONSENT FORM

Title: Sleep for Health Study

Protocol No.: 1990855

Sponsor: NIH

Researcher: Erin S. LeBlanc, MD, MPH

Study Contact: Erin S. LeBlanc

Daytime Phone Number: 503-335-2400

You are being invited to take part in a research study. A person who takes part in a research study is called a research subject, or research participant.

Study Summary

Why is this study being done?

We are inviting you to be in a research study called **Sleep for Health**. This is a clinical trial, a type of research study. Research is different from usual medical care. In usual medical care, the main goal is to find the treatment that is best for you as an individual. In a research study, the main goal is to gain knowledge to help patients in the future.

The **Sleep for Health** study includes a treatment program for insomnia. Some studies have shown that people who have sleeping problems are at higher risk of developing type 2 diabetes, a disease that occurs when your blood sugar is too high. We are testing whether improving sleep leads to lower blood sugar levels.

To do this study, we will work with about 300 people, 22 to 79 years of age, who have sleep problems and prediabetes. People with prediabetes have blood sugar levels that are higher than normal, but not yet high enough to be diagnosed as type 2 diabetes.

Which group will I be in?

If you agree to be in this research study, you will be assigned randomly (by chance), using a computer, to one of the study groups, either a **Sleep Treatment** or a **Patient Health Education** group. It is important to remember that we do not know if one group is better than the other group for lowering sugar levels. You should be willing to be in either group before you agree to be in this study. You will have an equal chance of being in either group.

What will happen in this study?

Visits**:** You'll visit the Kaiser Permanente Center for Health Research in North Portland three times for this study. The final visit will occur approximately 8 months after your first visit. You will have your height and weight measured and be asked to complete questionnaires about your health and mood during the visits.

Glucose tests: At each of the three visits, you will take an oral glucose tolerance test (OGTT), where you'll have a sugary drink. Then, researchers will take some blood to test how the drink affects your blood sugar. A glucose test is often used to test for type 2 diabetes.

Continuous Glucose Monitoring: Three times during the study (at each visit) someone will put a small sensor on your body to track your blood sugar levels. This sensor is called a continuous glucose monitor (CGM). A CGM is about the size of a large coin. It sticks to your skin with tape. It has a small "micro," flexible, plastic needle that gets put under your skin and stays there to track your blood sugar levels. It can be placed on your arm or stomach. Most people feel no pain while wearing it. Some people who have diabetes wear CGMs often, or even all the time. You don't need to change your day-to-day activities while you wear a CGM. You can take showers and swim with it on like you normally do. After 10 days, you will remove the CGM and mail it back to us.

Diet: Six times during the study you will be asked to log into a website to answer questions about what you ate and drank in the last 24 hours. This is called a dietary recall. Each dietary recall will take 20-40 minutes.

Activity Monitor: You will be asked to wear a special watch on your wrist for 10 days after every visit (3 times total). The watch will measure your activity level and sleep 24 hours for 10 days. The watch cannot tell *where* you are or *what* you are doing; it can only measure your amount of activity or sleep.

Do I have to be in this study?

No. You do not have to be in this research study, and you can quit at any time. If you decide not to be in the study, it will not affect your regular medical care or health benefits.

What are the benefits and risks of being in this study?

You may not directly benefit from being in this study. However, some people may experience an improvement in their insomnia and possibly improvements in blood glucose levels. Information we learn from this study may help people in the future who are at high risk for getting diabetes.

There is some risk to being in the study. A small number of people could have skin irritation from the CGM device. You could also feel sick or lightheaded from the glucose drink or get a bruise after the blood tests.

Why is this research being done?

The purpose of this research is to measure if a sleep treatment called Cognitive Behavioral Therapy for Insomnia (CBT-I) results in lower blood sugar levels in people who have prediabetes. People with prediabetes have blood sugar levels that are higher than normal, but

not yet high enough to be diagnosed as type 2 diabetes. Type 2 diabetes is a serious condition affecting about 1 in 10 people in the United States. Lifestyle changes, like healthy eating, exercise, and weight loss, can lower the chances of getting diabetes. But many people still get diabetes despite trying to change their lifestyle. CBT-I is known to help people with insomnia improve their sleep. But we do not yet know if CBT-I will help lower sugar levels. Using CBT-I to lower sugar levels is considered experimental. If CBT-I lowers sugar levels, it could help people with prediabetes and sleep problems reduce their risk of diabetes.

How many people will be in this study?

About 300 people will take part in this research.

How long will I be in this research?

You will be in this research for approximately 8 months. We will continue to monitor your electronic medical record until all participants have completed the study (approximately 3 to 5 years).

What happens next if I agree to take part in this research?

If you choose to be in the Sleep for Health study, we will ask you to sign this consent form before any study procedures are done.

Study visits: For your safety and the success of the study, it is important that you come to all three study visits and take part in all study procedures (see Table below).

During visit							In 10 days after visit			
Visit	**How long will the visit last?**	**Height**	**Weight**	**Oral glucose tolerance test**	**Answer some questions about health, habits, and mood**	**1 Diet Recall**	**Wear CGM continuously**	**Wear activity watch continuously**	**Daily Sleep diaries**	**1 Diet Recall**
Visit 1 (Week 0)	Around 3 hours	X	X	X	X	X	X	X	X	X
Visit 2 (Week 10)	Around 3 hours		X	X	X	X	X	X	X	X
Visit 3 (Week 32)	Around 3 hours		X	X	X	X	X	X	X	X

Communication: A member of the study team will call, email, or text you to remind you of your visits. Let your study team know how and when you want to be contacted.

Visit 1 –Screening/Baseline (Week 0):

Preparation: To make sure that the study tests are accurate, you must not have anything to eat or drink (other than water) for the 8 hours before your screening/baseline visit. This is called fasting.
At the visit, which will take place at the Kaiser Permanente Center for Health Research, the study team will:

- Measure your weight and height.
- Administer a 2-hour glucose test. A blood sample (about a tablespoon) will be taken. Then you will be given a sweet drink to drink in 5 - 10 minutes. If you like sugar, this part will be easy. If you don't, the drink might upset your stomach. Thirty minutes and two hours after you drink the sweet drink, additional blood samples (about a tablespoon at each time) will be drawn.
- Test your blood for glucose (sugar) and insulin, which measure how your body reacts to the sugar drink. The team will also test for hemoglobin A1c, which gives a measure of your average blood sugar level. The central laboratory that runs these tests will get your samples with a code number on them, so they won't know your name or other identifying information.
- Ask you questions about your health, sleep habits, mood, medications, dietary supplements, or other pills you may be taking, food cravings and your food intake in the previous 24 hours (called a dietary recall). See Table below:

Questionnaire	**Visit**	**Estimated time to complete**	**What is measured**
Demographics	1	5 minutes	Your age, sex, race and ethnicity, etc
Insomnia Severity Index	1,2,3	5 minutes	Sleep quality
Food Craving Inventory	1,2,3	5 minutes	Food cravings
Patient Health Questionnaire-9	1,2,3	3 minutes	Mood
Generalized Anxiety Disorder Scale	1,2,3	3 minutes	Anxiety
ASA24 Dietary recall	1,2,3 & 3 times outside of visits	20-40 minutes	Food & Drink in last 24 hours
Satisfaction with treatment	1, 2, 3	3 minutes	Satisfaction with treatments received outside of and as part of the study
COVID	1,2,3	3 minutes	COVID vaccination status and any recent COVID infection

- Place a continuous glucose monitor (CGM) sensor to measure your glucose levels. It will stay on for around 10 days before you remove it. A study team member will show you how to take it off safely. After you take it off, you'll either mail it back or drop it off at the clinic. If your CGM falls off, please call the study team. If it falls off in less than 5 days after you put it on, you'll need to return to the clinic so a member of the team can put

another one on. If it falls off after 5 or more days, you can call the study team, and then mail it back or drop it off.
- Give you an activity watch to wear around your wrist. The watch will measure your sleep and your activity level for 10 days after the visit. You will return the watch in the same envelope as the CGM. If we don't get enough data, you may be asked to re-wear the actigraphy watch.

In the 10 days after the visit, you will:

- Daily: Receive a link to a short questionnaire about your sleep, called a sleep diary. It will take about 5 minutes or less to complete. A new link will come each day for 10 days. We ask you to fill it out each morning about your sleep the night before.
- One time: Receive a link to log into a website to answer questions about what you ate and drank in the last 24 hours. This is called the ASA24 dietary recall. Each dietary recall will take 20-40 minutes to do. You will not know what day this link will be sent to you.

Approximately 2 weeks after Visit 1:

- After you return your glucose sensor and actigraphy device, complete sleep diaries, and one dietary recall, you will be assigned randomly (by chance), using a computer, to one of the study groups, either a **Sleep Treatment** or a **Patient Education** group. To register for the programs, you will need to provide your email address to the University of Virginia who runs the programs. At the visit, you will be shown how to use both online programs.

Visit 2 – Week 13:

- This visit will be the same as the first visit except for:
- We will not measure your height
  We will ask about side effects from the study procedures or any new illness or medications since the previous visit

Visit 3 – Week 34:

- This visit will be the same as the second visit.

Which group will I be in?

If you agree to be in this research study, you will be assigned randomly (by chance), using a computer, to one of the study groups, either a **Sleep Treatment** or a **Patient Health Education** group. We do not know if one group is better than the other group for lowering your blood sugar. You should be willing to be in either group before you agree to be in this study. You will have an equal chance of being in either group.

What happens if I am in the Sleep Treatment group?

You will be sent a link to a web-based application that is run by the University of Virginia. You will need to enter your email address to set up an account so that you can access the sleep

treatment program. The online program uses cognitive behavioral therapy to change behaviors, thoughts, and habits that contribute to sleep problems. You will be asked to complete 6 "lessons." You will focus on one lesson each week and it takes 45 minutes to 1 hour to complete each. In the 2nd lesson, you will learn about the "sleep restriction" portion of the treatment. The goal is not to restrict sleep, but to reduce time spent in bed awake. It is a very important part of the therapy but may cause sleepiness when you first start restricting your time in bed. You will also be asked to answer questions about your sleep each day, which will take about 5 minutes. The full program will take 6 to 9 weeks to complete.

What happens if I am in the Patient Health Education group?

You will be sent a link to a web-based application that is run by the University of Virginia. You will need to enter your email address to set up an account so that you can access the patient health education program. There will be information about insomnia symptoms and some strategies to improve sleep. The materials can be accessed whenever you want over 6 to 9 weeks. You will not be asked to complete any additional questionnaires.

Will I receive results from the testing in this study?

- Your blood tests are being done for research purposes. Therefore, this study does not test your blood samples right away. If we detect test results that your medical provider needs to know about, we will let you and provider know. If you have concerns about your health at any point during the study, you should seek consultation with your doctor.
- You can receive your test results at the end of the study 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.
- It is possible that something called a hemoglobin variant might be found during our testing. A hemoglobin variant means that there is permanent change in the genetic code of hemoglobin, which transports oxygen in the blood. If such a variant is found, the study team will let you and your medical provider know. Your provider might refer you to a genetic counselor.
- When you have completed the study, we can give you a summary of your sleep, activity level, and diet as measured during the study if you request them.

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

If you take part in this research, you will have the following responsibilities:

- To notify the study staff as soon as possible if your doctor tells you that you have diabetes or if you are prescribed a prediabetes, diabetes, or weight loss medication (for any reason). If possible, you may be asked to come in early for a study visit before you start the new medication.

- To not participate if you have bipolar, schizophrenia or psychotic spectrum disorder, epilepsy, a high risk of falling, a serious medical illness that is not under stable treatment, moderate or severe obstructive sleep apnea, or parasomnia (meaning you seem to be alert, walking or talking or doing other activities but you are not aware of it or you have sleep terrors or sleep paralysis).
- To not join the study if you need to be particularly alert or cautious on the job (for example, if you are a healthcare/emergency services provider, long-distance driver, air traffic controller, operator of heavy machinery, or night shift worker).
- To avoid potentially dangerous tasks (like driving) if you have trouble staying awake during the sleep restriction portion of the program. If you can't avoid those tasks, you should stop following the sleep restriction part of the sleep program and tell this to the study researchers.
- To not join the study if you are trying to become pregnant.
- To let us know right away if you become pregnant during the study.
- To let us know if you are taking sleep medications. We will figure out if you can be in the study.

Could being in this research hurt me?

There is not much risk to being in this study. The things you are asked to do in this study are things that other people often do as part of their regular health care.

Possible risks include:

Related to insomnia interventions

- Increased sleepiness during the day in the early stages of treatment (uncommon and usually temporary).

CGM:

- You might feel a small prick when the CGM is put on your body (common but temporary). Sometimes this prick can cause a small bruise, infection, bleeding, or pain (uncommon).
- The tape that holds the CGM in place might cause your skin to become itchy or irritated (uncommon). This will get better with removal of the tape.
- A sensor wire could break away and stay under the skin (very rare).

Glucose test:

- Drinking the sweet drink may upset your stomach (uncommon).
- Some people vomit or throw up because of the sweet drink (rare).
- People can pass out or faint because they must fast or not eat breakfast before the glucose test (rare).

Blood draw:

- Pain, redness, soreness, bruising, or infection may occur at the needle stick site (uncommon).

- Some people faint (rare).

Diagnosing diabetes:

- You might have to do extra things to take care of yourself after you are diagnosed with diabetes (common).
- If you are diagnosed with diabetes during the study, you might have emotional stress or feel badly (uncommon).

Questionnaire:

- Some people find some questions uncomfortable (uncommon, and you can skip any question you don't feel comfortable answering).

There is also the risk of an unexpected release of your health information. The chance that your information would be given to someone who is not allowed to use it is very small. We have several protections in place to safeguard your identity and health information. These are described below under "*What happens to the information collected for this research?*"

Will it cost me money to take part in this research?

You will not be billed for the costs of any services or procedures that are required by the study but are not considered part of your regular medical treatment.

Will being in this research benefit me?

We cannot promise any benefits to you or others from your taking part in this research. However, you might possibly learn ways to improve your sleep. Possible benefits to others include finding out that improving sleep can help with lowering blood sugar levels.

What other choices do I have besides taking part in this research?

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

- Talking to your medical provider about medications or other programs to help you sleep.
- Taking to your medical provider about medications or other programs to help lower your sugar levels.

What happens to the information collected for this research?

The information we collect about you for this study, which may include information from your medical record and data collected during the pre-screening process, will be used by and shared with individuals and organizations involved in conducting or overseeing this research. This is described more below under "Authorization."

We will communicate with your medical providers through your electronic medical record to let them know that you are in this study and that you will be wearing a CGM for research purposes only. Also, if we detect test results that your medical provider needs to know about, we will let you and provider know.

People overseeing the research may be allowed to review and copy information in your records related to this study. We may publish the results of this research. However, we will not publish your name or any other information that identifies you, such as your address.

State and federal privacy laws protect your health information. We will do our best to protect your privacy by using standard security measures as required by law. To protect your confidentiality:

- We will keep all of the information about you in strict confidence.
- We will use this information only for the purpose of this research study.
- We will use numbers instead of your name for identification.
- Whenever possible we will remove or separate information that identifies you (such as your name or address) from the rest of your health information in study records.
- We will store all study information about you on secure, password-protected computers and in secure areas.
- We will share study information only with authorized personnel who have been trained to protect sensitive information.

Still, there is a small chance your information could be released accidentally. And in certain situations, we would not be able to keep your information confidential. For example, state law requires us to report cases of child abuse, elder abuse, and certain diseases. We may also have to share your information in response to serious threats of harm to you or others.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, our researchers can refuse to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information for personnel of the US Government that is used in auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the FDA. A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. It also does not prevent the research team from disclosing information for public health reporting purposes.
A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

We are requesting your Authorization to Use/Disclose Protected Health Information. Why is this authorization required?

This authorization gives permission to researchers at Kaiser Permanente Center for Health Research to use and/or disclose (release) your health information for a research study called Sleep for Health.

The Privacy Rule requires that researchers obtain your written authorization to use and disclose (release) your Protected Health Information (PHI). By signing this authorization, you give permission for researchers at Kaiser Permanente Northwest to use and/or disclose (release) your individually identifiable health information for the purpose of the research study named above.

Do I have to give you access to my health information?

Giving access to your health information is voluntary. You get to choose. No matter what you decide, now or in the future, it will not affect your medical care. You can change your mind at any time in the future. However, if you choose not to give us access to your health information now, we will not be able to enroll you in the research study.

What kind of information will be collected?

We will collect individually identifiable health information about you and your health for the purpose of this research. The following identifiable private information about you will be used and disclosed:

- Name
- Address
- Dates, including birth date
- Telephone numbers
- Electronic mail addresses
- Medical record number

This information may be obtained from:

- Screening procedures
- Study visits
- Your responses to study questionnaires
- Testing your blood
- Your electronic health chart
- A continuous glucose monitor (CGM)
- An actigraphy device which measures your sleep and activity level

We will be able to see all the information in your electronic health chart, but we will only collect the information we need for the research study.

We may collect sensitive information about you for this study, including:

- Mental health diagnosis or treatment information
- Alcohol or drug use, or substance use disorder diagnosis or treatment information

Notes from counselors or doctors in specialized clinics who treat mental health conditions or substance use disorders are usually private and not part of the chart. We will only be able to see these types of notes if they are part of your electronic health chart.

What is the purpose of the use or disclosure of my PHI?

Kaiser Permanente Center for Health Research will use your PHI, including your research and/or medical record, to conduct the study, monitor your health status, measure effects of the sleep interventions, and determine research results. In addition, others at Kaiser Permanente, for example, the Institutional Review Board that approved the study, and other representatives of Kaiser Permanente, may also review your research or medical chart, or both, to monitor the study.

Information from your research record and medical chart used and disclosed for the study may include, for example, laboratory and other tests, and observations made by your regular health care team and by the study team.

How will my health information be used or disclosed (released)?

KPNW researchers will use your health information to conduct the research study named above. Others at KPNW may access your health information to help coordinate or oversee the research. This may include employees of any of the organizations that make up KPNW:

- Kaiser Foundation Hospitals
- Kaiser Foundation Health Plan of the Northwest, Inc.
- Northwest Permanente Medical Group

We may disclose (release) the health information described above to others outside of KPNW who are involved in conducting or overseeing research, including:

- The study sponsor, which is NIDDK, which is part of the NIH
- The study monitor (a doctor unrelated to the study who oversees the study)
- Government oversight agencies, such as the Office for Human Research Protections or the Food and Drug Administration
- Kaiser Permanente program office or other Kaiser regions that monitor the research

Kaiser Permanente Center for Health Research staff may request records, such as information related to hospitalizations and care received outside of the Kaiser system, for eligibility, safety, and/or recruitment purposes. KPNW research staff may also disclose (release) the health information listed above to an outside provider to coordinate management of your care.

Your PHI may also be sent to persons outside of Kaiser Permanente Center for Health Research assisting with this study or to others as required by law.

How is my health information protected?

State and federal privacy laws protect your health information. We will do our best to protect your privacy by using standard security measures as required by law. We will also remove or

separate information that identifies you (such as your name or address) from the rest of your health information whenever possible. Everyone at Kaiser Permanente Center for Health Research with access to your information has received training in the protection of sensitive information.

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.

Will I have access to my information?

Some of the information collected and created in this study may be placed in your health record. After the study is done, you will only be able to access study information that was added to your health record. If you have questions about what study information you will be able to access, and when you can access it, ask the researchers.

When will this authorization expire?

This Authorization will not expire at the end of this research study.

What if I change my mind?

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, MPH
Kaiser Permanente Center for Health Research
3800 N. Interstate Avenue
Portland, OR 97227

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.

Will I get a copy of this authorization?

The researcher or staff person who is obtaining this authorization from you must give you a copy of this form after you sign it.

Who can answer my questions about this research?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed on the first page.

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at (951) 739-6781 or email KPINTERREGIONALIRB@kp.org if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

What if I am injured because of taking part in this research?

If you are injured or harmed by this study, Kaiser Permanente will provide necessary medical treatment as covered by your usual health benefits.

Kaiser Permanente and the sponsor do not offer any other financial compensation if you are injured or harmed as a result of participating in this research. However, you do not give up any of your legal rights by signing this form.

If you are on Medicare, and you are injured by being in this study, the sponsor must tell Medicare about any payments made to you, or any payments made for treatment of the injury. Your name, birth date, social security number, and the fact that you had been part of this study would be sent to Medicare.

Can I be removed from this research without my approval?

The researcher in charge of this research can remove you from this research without your approval. Possible reasons for removal include:

- It is in your best interest
- You have a side effect that requires stopping the research
- You need a treatment not allowed in this research
- The research is canceled by the FDA or the sponsor

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

What happens if I agree to be in this study, but I change my mind later?

If you decide to leave this study, contact the research team. You can withdraw from the study at any time. If you leave the study, information collected while you were in the study will not be removed from our records. We will still look at your medical records or chart after you decide to stop being in the study. If you do not want us to look at your medical records or chart anymore, please tell your study team.

Will I be paid for taking part in this research?

For taking part in this research, you may be paid up to a total of $365. Your compensation will be broken down as follows:

	Baseline	10-week	32-week	Completion bonus	**TOTAL**
Visit	$35	$35	$35	$30	$135
Actigraphy and CGM returned	$30	$30	$30	$30	$120
Sleep diaries completed	$5 to $15 depending on how many completed	$5 to $15 depending on how many completed	$5 to $15 depending on how many completed	$10	$55
ASA-24 completed	$15	$15	$15	$10	$55
OVERALL TOTAL IF ALL ACTIVITIES COMPLETED: $365					

Federal tax law requires that you report your research payments when you file your taxes. If your total payments from KP Northwest exceed $600 per year, KP Northwest will report these payments to the Internal Revenue Service (IRS) and you will receive a 1099-MISC form from us. This form tells the IRS that payment was made to you, but it does not name the study or studies in which you participated. You will be asked to provide your Social Security Number for tax reporting purposes if you were to receive more than $600 per year. This information is stored confidentially and separate from research data.

Optional Parts of the Study:

The rest of this document includes detailed information about parts of the study that you can choose to do or not do.

Future optional research:

- You can choose whether the study team can contact you about future studies you might be able to join.
- You can choose whether the study team can contact you about future information for this study, such as sharing study results.
- You can choose whether to store your blood samples for future research in the Sleep for Health Repository. Not all of the samples may be used up during this study, so we are asking if the leftover parts might be kept for future research.

You do not have to do the optional parts of the study. If you choose not to do one, more, or any optional parts of the study, you can still be in the main Sleep for Health study.

What is the Sleep for Health Repository?

We are asking to store any leftover blood sample permanently in the Sleep for Health Repository. A “repository” is simply a place where things are stored. These collections are

helpful and are used in health-related research in the future, after the current study is completed. These samples will be stored permanently and may be used in the future for research related to prediabetes, diabetes, sleep, or metabolic diseases. Information that identifies you will be removed from data or specimens collected in this research and could be used for future research without your consent. At the end of this form, we will ask if we can store your blood specimen for future research. You can opt out of this storage and still take part in this study.

How is my privacy protected?

The Repository does a lot of things to protect your privacy. Before the researchers in this study send samples and information collected from you to the Repository, the data and each sample will be given a code number. Your name and all personal information that might tell someone who you are, such as address, social security number, and date of birth, will be removed. The Repository will not be able to give out your name, or other information that identifies you. However, the Repository and scientists will have some data about you, such as age, sex, diagnosis, race, and results of this study.

Are there risks and benefits of participating in the optional parts of the study?

It is likely you will not receive any direct benefit for participating in these optional studies. Samples and information collected from you might benefit the future health of others. You and your medical provider will not know what happens to your samples and information or what results other studies show about your samples and information. Research on your samples and information might be written about for a medical paper. If that happens, your name any other information that could tell someone who you are will not be in the paper.

What to do if you change your mind?

If you agree to take part in one or more of the optional parts of this study, you can change your mind at any time. If you change your mind, you should tell your study team or study investigator. If you change your mind, the study team will not send any more of your samples to the repository at the end of the study. You can still be part of Sleep for Health even if you decide now or later to not do the optional parts of this study. Samples already sent to the repository up until the time that you withdraw may be kept and used.

Do you agree to be contacted about future studies you might be able to join?

__Yes __No

Do you agree to be contacted about future information for this study? For example, at the end of the study, the researchers will share the overall study results.

__Yes __No

Do you agree that your leftover blood samples can be sent to the repository for future research?

__Yes __No

Statement of Consent and Authorization:

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

Your signature also confirm that you have read this Authorization describing how your health information will be used, have had a chance to ask questions about the use of your health information, and have received answers to your questions.

By signing this form, you agree to share your health information as described above. The document can be printed or saved after signing. <We will use the e-consent framework in REDCAP to complete the consent portion and will request participants complete the following fields:

- First Name
- Last Name
- E-Signature
- Date >