

Consent and Authorization Document

Research Study Title: A Randomized Trial of Continuous Positive Airway Pressure (CPAP) for Sleep Apnea in Pregnancy (SLEEP)

You are invited to take part in a home sleep test (a screening visit) to see if you are eligible to take part in a research study. This study is voluntary and it is up to you to decide whether or not you want to participate.

If you agree to be screened for this study, you will need to sign this consent form. This process is known as informed consent. Please tell the study doctor or study staff if you are taking part in another research study. This consent form may contain words that you do not understand. Please ask the study staff to explain any words or information that you do not clearly understand.

The purpose of the home sleep test is to find women with sleep apnea. Sleep apnea is when you have one or more pauses in breathing or shallow breaths while you sleep. Studies have shown that women with sleep apnea have an increased risk of high blood pressure and diabetes during pregnancy. If the test shows that you have sleep apnea in the mild to moderate range you will be eligible for a research study to find out whether a treatment with CPAP (continuous positive airway pressure) reduces the chance of getting high or increasing blood pressure and other problems associated with being pregnant.

If you agree to complete the home sleep assessment, you will wear a simple sleep monitor on one night during your pregnancy, between 16 weeks and 21 weeks. The monitor has one soft elastic belt that you will wear around your chest while you sleep. You will tape a small, plastic sensor to your index (or pointer) finger. Additionally, you will have small, plastic tubing placed below your nose and around your ears that you will also tape in place. The monitor records information about your breathing, how fast your heart is beating, and how well your body is getting oxygen while you are sleeping.

We will schedule a time for you to return the sleep monitor. When you come in we will download the data from the sleep monitor. Within 30 minutes we will determine if you have sleep apnea and if you are eligible for the treatment trial. If you are eligible, then we will go over a separate consent form about the trial. We will also show you the CPAP machine and ask you to try on a mask and practice breathing. You will be able to see what the machine and mask looks like and feels like so that you can decide if you want to enroll.

You may be asked to redo the home sleep test if we do not get a good recording. To get a good recording, the monitor will need to be worn as instructed and good quality data from the sensors needs to be available for a minimum of 4 hours of sleep.

The adhesives and sensors of the home sleep test may cause minor discomfort or local skin irritation. If you feel that anything you are wearing is too uncomfortable, you can take it off at any time. You should not have any long lasting or serious discomfort from wearing these items. There are no other known risks to you or your unborn baby from using the sleep monitor.

This screening may not benefit you directly. You will be notified of the results of the sleep assessment, and if eligible will be offered enrollment in our treatment trial.

The alternative is not to participate in the screening.

If you have questions, complaints or concerns about this study, you can contact <<contact name>> at <<phone number>>. If you think you may have been injured from being in this study, please call <<PI name>> at <<phone number>>. <<PI name>> or one of his colleagues can be reached at this number 24-hours a day.

Institutional Review Board: Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.

Research Participant Advocate: You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu.

You are free to withdraw your consent and stop taking part in this research study at any time without giving a reason. Refusal to take part or the decision to withdraw from the study will involve no penalty or loss of benefits to which you are otherwise entitled. Your refusal will not affect your legal rights or quality of health care that you will receive at this hospital.

There will be no cost to you to take part in the research study. All study-related equipment and procedures will be provided at no cost to you or your insurance company. The costs of your standard medical care will be billed to you or your insurance company in the usual manner.

You will be paid \$10 for bringing the device back in and \$40 for successfully completing the sleep assessment and returning it by 21 weeks and 6 days. If you return it on time, but it is not a successful recording you will be offered to take it home again for a retest. In the rare situation where an assessment shows that you have a severe breathing or heart rate problem while you sleep, you and your health care provider will be notified. If you return the device after 21 weeks and 6 days, you will be paid \$10 for the return of the device but your sleep results will not be downloaded for analysis.

Funding for these assessments has been provided by two funding agencies. These are the <<funding agency 1>> and the <<funding agency 2>>.

During the course of the study, we may find new information that could be important to you. This includes information that may cause you to change your mind about being part of the study. We will notify you if any significant new information becomes available which may affect your health, safety, or willingness to continue in this study.

AUTHORIZATION FOR USE OF YOUR PROTECTED HEALTH INFORMATION

Signing this document means you allow us, the researchers in this study, and others working with us to use some information about your health for this research study.

This is the information we will use and disclose in our research records:

- Demographic and identifying information like name, address, telephone number and email address;
- Related medical information about you like medical record number, previous pregnancies, height, weight and whether you drink or smoke plus information about your sleep patterns;
- All tests and procedures that will be done in the study.

How we will protect and share your information:

- We will do everything we can to keep your information private but we cannot guarantee this. Study information will be kept in a secured manner and electronic records will be password protected. Study information may be stored with other information in your medical record. Other doctors, nurses, and third parties (like insurance companies) may be able to see this information as part of the regular treatment, payment, and health care operations of the hospital. We may also need to disclose information if required by law.
- **This** research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the NIH or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it

- A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.
- If we lose track of you, study staff may collect information from the internet including social network sites in order to find your contact information.
- The information collected for this research study will be entered into an electronic database at the data coordinating center, <<name of data coordinating center>>. The database has information from all of the participants. Your information in the database will only be used for statistical analysis and may appear in scientific publications but will not identify you. The information sent to the data coordinating center does not include your name, address, social security number, hospital number, date of birth or any other personal identifiers. Instead, the data center will use a unique code for each person consisting of a number and the first letter of your first name. The key to the code linking the data and samples to you will be kept here in a locked file. Only the research study staff employed for this study at this hospital will have access to the key to the code.

- **In** order to conduct this study and make sure it is conducted as described in this form, the research records may be used and reviewed by others who are working with us on this research:
 - Members of the research team and University of Utah Health
 - The University of Utah Institutional Review Board (IRB), which reviews research involving people to make sure the study protects your rights
 - Other local hospital(s) that we are working with: <<name of hospital>>
 - The United States Food and Drug Administration (FDA) and/or the Office for Human Research Protections (OHRP).
 - The <<funding agency 1>> which sponsors this study, including persons or organizations working with the sponsors, such as the data coordinating center, <<name of data coordinating center>>.
- Some de-identified data regarding your home sleep test results will be stored on a secure network managed by <<manufacturer name>>, the manufacturer of the sleep monitor. <<Name of institution>>, will also have access to this de-identified data.
- **If** we share your identifying information with groups outside of University of Utah Health, they may not be required to follow the same federal privacy laws that we follow. They may also share your information again with others not described in this form.
- **If** you do not want us to use information about your health, you should not be part of this research. If you choose not to participate, you can still receive health care services at the University of Utah Health.

What if I decide to Not Participate after I sign the Consent and Authorization Form?

- **You** can tell us anytime that you do not want to be in this study and do not want us to use your health information. You can also tell us in writing. If you change your mind, we will not be able to collect new information about you, and you will be withdrawn from the research study. However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research.

This authorization does not have an expiration date.

Please **INITIAL** the appropriate statement to indicate whether or not you give permission for future contact.

YES _____ I give permission to be contacted in the future for research purposes.
(Please initial)

NO _____ I do not give permission to be contacted in the future for research purposes.
(Please initial)

CONSENT

I confirm that I have read this consent and authorization document and have had the opportunity to ask questions. I will be given a signed copy of the consent and authorization form to keep. **I agree to take part in this research study and authorize you to use and disclose health information about me for this study, as you have explained in this document.**



Participant's Name

Participant's Signature

Date

Name of Person Obtaining Authorization and Consent

Signature of Person Obtaining Authorization and Consent

Date

