

Fullpower Technologies, Inc.

Sleep Study Informed Consent Form

Your unique identifier is: _____

Please check one of the following:

_____ You are an adult participant in this study.

_____ You are the parent or guardian granting permission for a child in this study.

Print child's name here: _____

The following information applies to the adult participant or to the child or ward. If the participant is a child or ward, the use of "you" refers to "your child" or "your ward."

Are you participating in any other research studies? _____ Yes _____ No

Purpose of Study

A sleep study, or polysomnogram, is a test that records detailed information about how the body acts during sleep. This test is most often performed overnight. A technician attaches sensors to the participant's body, and the sensors keep track of a number of body functions, such as:

- Brain waves
- Breathing rate
- Eye movements
- Leg movements
- Heart rate and rhythm
- Blood oxygen level
- Snoring
- Jaw or chin movements

The study may also involve other sensors. The sensors send signals to a computer for storage and analysis. We use this information to refine our mathematical models and computer algorithms. We do not store any information that can personally identify the participant, and we keep all information confidential.

Duration of Study Involvement

Participation in the study should take about 8 to 10 hours of your time.

Procedure

If you agree to take part in this study, you will first be asked to complete a questionnaire. Examples of the questions are: “What are your age, weight and height?”, “How long does it take you to fall asleep?” and “Have you been told that you snore?”

We then schedule an appointment at our sleep lab. You arrive at the sleep lab in the evening for polysomnography and stay overnight. You may bring items you use for your bedtime routine, and you can sleep in your own nightclothes.

The room where polysomnography is done is similar to a hotel room, and it's dark and quiet during the test. You don't share the room with anyone else.

The room has a video camera, so the polysomnography technologist monitoring you can see what's happening in the room when the lights are out, and an audio system, so they can talk to you and hear you from their monitoring area outside the room.

After you get ready for bed, the technologist places sensors on your scalp, temples, chest and legs using a mild adhesive, such as glue or tape. The sensors are connected by wires to a computer, but the wires are long enough to let you move normally in bed. A small clip also is placed on your finger or ear to monitor the level of oxygen in your blood.

While you sleep, the computer monitors the recording of your brain waves, eye and leg movements, heart rate, breathing rate, etc. All of these measurements are recorded on a continuous graph.

If you need to get up at night, a quick connector allows you to disconnect the wires from the computer yourself, and reconnect them when you come back to bed.

In the morning, you simply remove the sensors and you may leave the sleep lab. There are washrooms and showers available. You can return to your usual activities after polysomnography.

Voluntary Participation

Your participation in this study is entirely voluntary. If you wish to participate in this study, you must sign this form. If you decide to participate and change your mind later, you are free to withdraw your consent, including your authorization regarding the use and disclosure of your information, and to discontinue participation at any time. If you decide to terminate your participation in this study, you should notify us at (831) 460–7070 or sleep.study@fullpower.com.

Possible Risks, Discomforts, and Inconveniences

Polysomnography is a noninvasive, painless test. Complications are rare. The most common side effect is skin irritation caused by the adhesive used to attach test sensors to your skin.

You may not fall asleep as easily or sleep as well in the sleep lab as you do at home. You might also find some of the questionnaire questions uncomfortable.

Note that this is an unattended study, meaning that you will be on your own after the technologist completes the sensor setup and verifies that the equipment works correctly. The sleep lab is located in a Class A business facility, with modern safety features. The building is not accessible to the general public at night. The door to your room is secured with a coded lock that only you and the sleep lab staff can open. The most common issue is a sensor probe becoming loose and not providing a strong signal. If this happens to you, chances are that the data collected will still be good enough to provide you with a meaningful report.

The sleep lab is located in a non-smoking facility. If smoking is part of your sleep time routine, you will need someone to escort you in and out of the building, and you won't be able to do so on your own after the technologist has left. You should make sure to tell the technologist if you need to smoke prior to your sleep study.

There are security guards on duty at night. You may hear them at times while they are patrolling the building.

If you feel too uncomfortable during the night, you can simply end the test early, remove the sensors and leave the sleep lab. In case of an emergency, you should call 9-1-1.

Potential Benefits

Polysomnography is widely recognized by the medical community as the gold standard to measure sleep objectively. Although this study should not be considered a substitute for a clinical evaluation, some feedback on your sleep patterns and sleepiness levels will be provided. A copy of the polysomnography report will also be available, which can be of great value for further discussion with your regular physician or a sleep specialist.

Participant Responsibilities

As a participant, your responsibilities include:

- Following the instructions of the polysomnography technologists and study staff
- Spending one night in the sleep lab
- Completing the questionnaires as instructed
- Asking questions as you think of them
- Telling us if you change your mind about staying in the study

Participant's Rights

You should not feel obligated to agree to participate. Your questions should be answered clearly, promptly and to your satisfaction. If you decide not to participate, tell the study staff.

Confidentiality

Your identity will be kept confidential. Our study results may be disclosed outside of Fullpower but only in aggregate, and no personally identifiable information will be disclosed. All information will be kept in a secure location and access will be limited to sleep study personnel.

Financial Considerations

Compensation

A small monetary compensation will be provided for your participation in the sleep study, as well as reimbursement for direct expenses such as overnight parking. You will also receive a copy of your polysomnography report, and any relevant notes and observations from the polysomnography technologists.

Costs

There is no cost to you for participating in this study.

Contact Information

Questions and comments can be sent via email to sleep.study@fullpower.com. Fullpower's corporate office contact information is as follows:

Fullpower Technologies, Inc.
Attention: Sleep Study Coordinator
1200 Pacific Avenue, Suite 300
Santa Cruz, CA 95060
(831) 460-7070

Signatures

Signing your name means you agree to be in this study and that you were given a copy of this consent form.

Signature of Adult Participant

Date

Signature of Parent or Guardian

Date

Permission to Record Audio and Video

I, _____, (Participant/Guardian)

hereby authorize Fullpower Technologies, Inc. or their representative to take photograph(s) and/or record audio and video of

_____. (Name of Participant)

I understand that such photograph(s), audio recording(s) and/or video recordings may be used for study purposes to assist in evaluating the participant's sleep. Fullpower Technologies, Inc. and its duly appointed representatives are hereby released without recourse from any liability arising from obtaining and using such photograph(s), audio recording(s) and/or video recordings.

Any recordings obtained during the course of the sleep study will remain confidential.

Signature (participant or guardian)

Date

Relationship to Participant if Guardian:

General Liability Release of Claims

I, _____, for and in consideration of a small monetary compensation, a copy of my polysomnography report and any relevant notes and observations from the polysomnography technologists, the receipt and sufficiency of which is hereby acknowledged, do hereby release and forever discharge Fullpower Technologies, Inc., their agents, employees, successors and assigns, and their respective personal representatives, affiliates, successors and assigns, and any and all persons, firms or corporations liable or who might be claimed to be liable, whether or not herein named, none of whom admit any liability to the undersigned, but all expressly denying liability, from any and all claims, demands, damages, actions, causes of action or suits of any kind or nature whatsoever, which I now have or may hereafter have, arising out of or in any way relating to any and all injuries and damages of any and every kind, to both person and property, and also any and all injuries and damages that may develop in the future, as a result of or in any way relating to the following:

Overnight Sleep Study (Polysomnography)

It is understood and agreed that this payment and payment-in-kind is to be made and received in full in approximately 4 to 6 weeks (or possibly longer in order to complete the analysis for the polysomnography report) and completes settlement and satisfaction of the causes of action, claims and demands mentioned herein; that this Release contains the entire agreement between the parties; and that the terms of this Agreement are contractual and not merely a recital. Furthermore, this Release shall be binding upon the undersigned, and his or her respective heirs, executors, administrators, personal representatives, successors and assigns. This Release shall be subject to and governed by the laws of the State of California.

This Release has been read and fully understood by the undersigned and has been explained to me.

EXECUTED this ____ day of _____, 20____.

Signed: _____ (Sign Here)