

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 “What is your relative stress level at this time?”

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.

Someone from the sleep lab staff is also available to you throughout the night. If you need assistance, you can contact him or her by phone. He or she can come to the room and help you with the equipment, if needed.

In the morning, the sensors are removed and you may leave the sleep lab. 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.

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:

- Follow the instructions of the polysomnography technologists and study staff
- Spend one night in the sleep lab
- Complete the questionnaires as instructed
- Ask questions as you think of them
- Tell 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

There is no monetary compensation for the sleep study. Participants will receive a small gift package, a copy of their 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:
