

Fullpower Technologies, Inc.

Vitals 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

In this *Vitals* study, Fullpower Technologies Inc. is testing its under mattress contactless vital signs detection system. Vital signs include heart rate and respiration rate. The subject presence on the bed is also automatically detected. The under mattress system will be compared with vital signs data directly captured using ECG (Electrocardiogram) and respiration sensors. A technician will attach the ECG and respiration sensors to your body for the study. You will then be asked to lay down still in the bed while sensor data is being recorded. You may be asked to change sleeping positions (say, for example, from sleeping on back to sleeping on your left side) in the middle of the study.

The study may also involve other sensors. The sensors send signals to a computer. We will use this information to test our system. We will not store any information that can personally identify you, and we will keep all information confidential.

Duration of Study Involvement

Participation in the study should take about 1 hour of your time.

Procedure

If you agree to take part in this study, you will be first be asked to answer a set of questions. Examples of the questions are: “Do you wear a pacemaker or defibrillator device?” “Are you pregnant?”, “What are your age, weight and height?” and items on a “stress” questionnaire checklist such as experiencing the death of a family member, financial difficulties, and health and legal problems.

We then schedule an appointment at our test lab. You arrive at the test lab at the scheduled time.

The room where the test is done is a large office room with many beds and test setups. Only test administrators and test helpers will be in that room.

The test setup includes a video camera, so that the test administrator can later review the video to see the exact time for such actions as change of sleep position, etc.

One of the test administrators will place ECG sensors on your body using a mild adhesive, such as glue or tape. The test administrator will also hook you up with a nasal cannula to monitor your breathing. The sensors are connected by wires to a computer, but the wires are long enough to let you move normally for the test.

Once the test is completed, the sensors are removed, and you may leave the test lab. You can return to your usual activities immediately.

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, you are free to withdraw your consent, including your authorization regarding the use and disclosure of your health 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 vitals.study@fullpower.com or tell the test administrator if you are already at the test facility.

Possible Risks, Discomforts, and Inconveniences

Use of ECG leads and nasal Cannula is noninvasive and painless. Complications are rare. The most common side effect is skin irritation caused by the adhesive used to attach test sensors to your skin.

You might also find some of the questionnaire questions embarrassing.

Potential Benefits

There is no feedback to you from this short test. The test is intended to help us validate our systems.

Participant Responsibilities

As a participant, your responsibilities include:

- Following the instructions of the test technologists and study staff
- Spending about an hour in the test lab
- Completing 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 and to your satisfaction. If you decide not to participate, tell the study staff.

Confidentiality

Your identity will be kept confidential. Our research 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 vitals 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 parking.

Costs

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

Contact Information

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

Fullpower Technologies, Inc.
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, _____, (Patient/Guardian)

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

_____. (Name of Patient)

I understand that such photograph(s), audio recording(s) and/or video recordings may be used for study purposes to assist in evaluating the Fullpower under mattress system. 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 (patient or guardian)

Date

Relationship to Patient if Guardian:

General Liability Release of Claims

I, _____, for and in consideration of a small monetary compensation, 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:

It is understood and agreed that this payment and payment-in-kind is to be made and received in full immediately after the study 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)