KEY INFORMATION FOR A STUDY TO EVALUATE A WIRELESS SENSOR AS A TOOL TO AID THE DIAGNOSIS OF SLEEP APNEA

TCH-110: A Multi Center, Single Arm, Quantitative Study Assessing Performance of TatchSleep Pro as a Tool to Aid in Sleep Apnea Diagnosis

This page is designed to give you key information to help you decide whether to participate in the program.

What is the study about and how long will it last?
The goal of this study is to determine how effective the TatchSleep Pro wireless sensor is at diagnosing sleep apnea. The study will last one (1) night and it will be conducted at the same time your overnight sleep study (polysomnography or PSG) is scheduled.

What are the key reasons you might choose to volunteer for this study?
You are being asked to participate in this study because you will need an overnight sleep study to find out if you have sleep apnea or to further evaluate your already diagnosed sleep apnea. The accuracy of the investigational device being tested in this study will be compared to the conventional devices currently used to diagnose patients with sleep disorders. You may indirectly benefit from the long-term results of this study, by contributing to the development of a more comfortable and less invasive wearable device for patients who need to undergo testing for sleep apnea.

What are the key reasons you might choose NOT to volunteer for this study?
You may decide that you do not want to participate in this study because you would rather have only the conventional diagnostic test done to you the night of your appointment, or because you would rather not answer personal and health questions as part of the study. Additionally, you may decide not to participate in the study because your medical records may become part of the research record which means that your medical records may be shared with the sponsor of this study and government agencies or other groups associated with the study. Finally, your sleep disorder symptoms will not improve by participating in this study. For a complete description of risks, refer to the Consent document below.

Do you have to take part in the study?
If you decide to take part in the study, it should be because you really want to volunteer. The device being tested will not improve your condition. If you choose not to volunteer in this study, you will not lose any services, benefits, rights or access to care you would normally have. You can withdraw at any time and for any reason.

What if you have questions, suggestions or concerns?
The person in charge of the study at **(Insert Study Site Name)** is **(Insert Name of Study Site Principal Coordinator)**. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study **(his/her)** contact information is: **(Insert Study Site Name, Address, Phone Number, and Email)**.

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact staff in the **(Insert Name of Overseeing IRB)** between **(Insert IRB Hours of Operation, Time Zone, Days of Operation, Phone Number, and Email)**.

(INSERT STUDY SITE)

DOCUMENTATION OF INFORMED CONSENT AND HIPAA AUTHORIZATION

Title: A Multi Center, Single Arm, Quantitative Study Assessing Performance of TatchSleep Pro as a Tool to Aid in Sleep Apnea Diagnosis

Protocol No.: TCH-110

Protocol Version: 1.1

Introduction

You are being asked to participate in a research study to test a wearable investigational device, called TatchSleep Pro, designed to help diagnose sleep disorders, such as sleep apnea. Your participation is voluntary -- it is up to you whether you would like to participate. It is fine to say "no" now or at any time after you have started the study. If you say "no," your decision will not affect any of your rights or benefits or your access to care.

The researcher in charge of this project is called the "Principal Investigator." **(His/Her)** name is **(Insert Title and Name of Principal Investigator)** at: **Office Address**: **(Insert Principal Investigator's Address)Telephone #: (Insert Principal Investigator's Phone Number)**
For questions about the research study, or if you believe you have an injury, contact the Principal Investigator or the IRB.

(Insert Name of Overseeing IRB) of **(Insert Study Site)** has approved this research study. The IRB # is in the stamp in the upper right-hand corner. If you have questions regarding your rights as a research subject you may contact the IRB office at **(Insert IRB Phone Number)**, by e-mail at **(Insert IRB Email)**, or by mail:

(Insert IRB Address)

The investigational device is provided by TATCH Inc., a sleep diagnostics device company based in New York. The study site will be paid by the Sponsor of the study.

Why is this study being done?

The goal of this research study is to compare sleep data collected by the investigational device to the data collected by the polysomnogram (PSG) you will undergo when you come to the clinic to have your overnight sleep study done. A PSG is a painless, non-invasive overnight sleep study in which your brain waves, breathing patterns, body position, and heart rate are monitored and recorded. This test is done to find out if you have sleep apnea or to further evaluate your already diagnosed sleep apnea. This research study will assess the investigational device as a low-cost and user-friendly home sleep testing system for sleep apnea diagnosis.

The investigational device is not approved by the U.S. Food and Drug Administration (FDA), which means that it can only be used in research studies.

Why am I being asked to participate?

You are being asked to participate in this study because you are: (1) at least 21 years of age, (2) you have a physician referral for an overnight PSG test for sleep apnea diagnosis, and (3) you have expressed interest in participating in the study.

How many people will take part in the research study?

A maximum of 50 people will take part in this research study at approximately 3 study centers.

Will there be audio and/or video recording?

Yes, a black and white video of you with audio taken from above while you lay down on the bed where you will be sleeping will be recorded during your overnight sleep study. This is typically done as part of the standard setup of a PSG to rule out or confirm sleep disorders and to find out if the results are trustworthy. It may be possible to identify you in that video and your name, date of birth and/or medical record number may be associated with the PSG data that includes the video. In addition to the PSG recording, TatchSleep Pro may record audio to detect snoring symptoms as a tool for screening sleep apnea.

How long will I take part in this research?

The test with the study device will last one night only. We may ask you to come to **the site** to sign this informed consent form up to 7 days before your scheduled overnight sleep study (PSG). You will come to the **site** the day your PSG test is scheduled. You can end your participation at any time and for any reason. The Principal Investigator or TATCH, Inc. may recommend your withdrawal from the study at any time and for any reason.

What will happen if I participate in the study?

A polysomnography is an overnight test conducted to study sleep and to diagnose or rule out a variety of sleep disorders, including sleep apnea. During this test a sleep technician will monitor and record parameters such as your brain waves, breathing patterns, body position, and heart rate.

Once you are referred for a polysomnography test you will be asked about your interest in participating in a research study. We will discuss the study at length with you and answer all your questions. If you decide you would like to participate in the study, you will be asked to sign this informed consent form and given a signed copy to take home.

After you sign this informed consent form, a brief medical history will be collected including demographics (age, gender, race) and current medications. Your height and weight will be collected to calculate your Body Mass Index (BMI). Your skin type will be recorded to assess your reaction to sun exposure. Females of childbearing potential will be asked to do a urine dipstick pregnancy test to rule out possible pregnancy. Pregnant women are not allowed to participate in this study.

The night of your test, you will be required to wear 3 Tatch wearable sensors (investigational device), two patches and a pulse oximeter, in addition to the PSG device throughout the night. One patch will be placed over your torso, one on your abdomen. The pulse oximeter will be positioned on your finger.

You will not need to interact with the TatchSleep Pro. The sensors will be worn at the same time the PSG device is worn. When the participant completes the overnight PSG, a sleep technician will remove the patches and pulse oximeter and close the companion smartphone application.

A black and white video of you with audio taken from above while you lay down on the bed where you will be sleeping will be recorded during your overnight sleep study. This is typically done as part of the standard setup of a PSG to rule out or confirm sleep disorders and to find out if the results are trustworthy. It may be possible to identify you in that video and your name, date of birth and/or medical record number may be associated with the PSG data that includes the video. In addition to the PSG recording, TatchSleep Pro may record audio to detect snoring symptoms as a tool for screening sleep apnea.

Data from the patches and polysomnography will be shared with the sponsor for technical analysis.

Up to five days after the sleep study you will receive a follow-up phone call, text message, or email, to see how you are doing.

Information Banking (Future Use and Storage)

We will store information about you in a database “bank”, which is a library of information from many studies. This information can be linked to you. In the future, researchers can apply for permission to use the information for new studies to prevent, diagnose or treat disease. If you agree to the future use, some of your de-identified health information (not linked to you) may be placed into one or more scientific databases. These may include databases maintained by the federal government. Your information may be kept for a long time, perhaps longer than 50 years. You may remove your consent for future research at any time by contacting the Principal Investigator or the IRB office named on the first page of the consent. If you do, we will destroy the information in the bank but if the information was already shared with other researchers, we cannot get it back.

You can choose not to participate in the bank and still be part of the main study and this will not affect your treatment at this facility.

INITIAL ONE (1) OF THE FOLLOWING OPTIONS
_____ I consent to have my information used for future research studies.
_____ I do NOT consent to have my information used for future research studies. Information about me will be kept as long as required by regulations and institutional policy, but will not be used for future studies.

INITIAL YOUR CHOICE BELOW
_____ I consent to be contacted in the future to learn about:
    _____ New research protocols that I may wish to join.
    _____ General information about research findings.
_____ I do not want to be contacted at all.

Will I be paid for being in this research study?

You will receive a $50 Amazon gift card only after the completion of the overnight study.

Some researchers may develop tests, treatments or products that are worth money. You will not receive payment of any kind for the information you share with the study team if any tests, treatments, products or other things of value result from this research.

Will it cost me anything to participate in this study?

Taking part in this study will not cost you anything. You and/or your insurance company will have to pay for any costs that are part of your regular medical care.

What will happen if I am injured because I took part in this study?

If you are injured as a result of this research, only immediate, essential, short-term medical treatment as determined by the participating hospital, will be available for the injury without charge to you personally. The sponsor will cover the reasonable medical expenses required for the diagnosis, care and treatment of the research related injury or illness as long as it is a direct result of the device or procedures required by the study. The sponsor will not cover any medical treatment that you would have received if you were not participating in this study (standard medical care) or any treatment for any injury or illness that is part of your normal disease progression or a pre-existing condition. The sponsor will not offer to cover the cost of medical care if the illness or injury is the fault of the study site personnel or third parties or the result of your own actions or inactions, such as your failure to follow the informed consent document, the directions of your study doctor or the treatment regimen for any pre-existing condition or events.

- No monetary compensation will be offered.
- No other payment will be made for expenses such as lost wages, discomfort and disability.
- You are not waiving any of your legal rights by signing this informed consent document.

Immediately report any discomforts, problems or injuries you experience during the course of your participation in the study to the Principal Investigator named on the first page of the consent.

What else do I have to do?

- You must tell the research study doctor about any past and present diseases, medications or allergies you are aware of.
- You must follow the sleep technician's instructions during the overnight sleep study.
- If you do not feel well at any time during the overnight sleep study, let the sleep technician know, call your doctor or the research study doctor immediately.
- ***It is important that you report all symptoms, reactions and other complaints about the investigational device to the research study doctor.***

Confidentiality

The researchers and study staff follow federal and state laws to protect your privacy. This part of the consent form tells you what information about you may be used and shared in the research

described in this form. You do not have to sign this form but, if you do not, you may not participate in the research.

The health information that we may use or disclose for the research described in this form includes information from your entire medical record, such as your name, phone number, email, medical diagnoses, dates, test results, social security number, medical record numbers, etc. In addition, the researchers may wish to review information pertaining to your substance abuse and/or psychiatric treatment records. By law, you must specifically authorize access to these specific records in addition to your standard medical records:

☐ Yes, I authorize the use and disclosure of my information pertaining to substance abuse treatment.
Initial: _____ Date: _____

☐ Yes, I authorize the use and disclosure of my information pertaining to psychiatric treatment.
Initial: _____ Date: _____

Your information and research records will be kept confidential. Your study information will be kept as long as they are useful for the research described in this form.

The only people who can see your research records are:

- Researchers and other individuals who work with the researchers
- The Sponsor (Tatch, Inc), its representatives and consultants who are helping conduct this study and/or paying for the care you may receive as a result of participation in this study;
- Groups that review research such as central reviewers, Institutional Review Boards, the Office for Human Research Protections, the US Food and Drug Administration, data coordinating centers, and domestic and foreign agencies that regulate research.

The purposes of these uses and disclosures are to (1) conduct the study and (2) make sure the study is being done correctly. The information covered under this form may no longer be protected by federal privacy laws (such as HIPAA) once disclosed, and those persons who receive your health information may share your information with others without your additional permission. All of these groups have been asked to keep your information confidential.

Medical information collected during the research, such as test results, may be entered into your electronic medical record and will be available to clinicians and other staff who provide care to you.

Information about your participation in this study will be entered into your Electronic Medical Record (EMR). Once placed in your EMR, the information will be available to all of your providers who participate in the EMR system. The purpose of this entry is to provide research information that has the potential to impact your medical care.

To maintain the integrity of this research study, you generally will not have access to your research-related personal health information. If it is necessary for your care, your research-related health information will be provided to you or your physician.

Are there any times you would not keep my data confidential?
If you give us information that you may hurt yourself or someone else we may disclose this information to other healthcare specialists or the authorities in an attempt to avoid any injury or death to you or others.

Are there any risks to me?

Risks of using the TATCH investigational device:

You may experience some slight discomfort wearing the TatchSleep Pro patch or pulse oximeter throughout the night. It is possible that patients with sensitive skin may experience mild skin irritation due to the patch adhesive. You will be clearly instructed that you are allowed to remove the patches if you experience skin irritation or significant discomfort at any point.

Potential TatchSleep Pro side effects:

- Skin irritation
- Discomfort while/after wearing the patches

There is a small risk that the TatchSleep Pro system will not function as anticipated during the study causing partial recording of the study night which might make your data unusable. These technologies are still evolving, and they may experience glitches or malfunctions.

Your sleep disorder symptoms will not improve by participating in this study and there may be other minor risks that are not known at this point.

Polysomnography (PSG) Risks
Polysomnography is painless and noninvasive, so it's relatively free of risks. You may experience slight skin irritation from the adhesive that attaches the electrodes to your skin.

Privacy
A risk of taking part in this study is the possibility of a loss of confidentiality or privacy. Loss of privacy means having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The study team plans to protect your privacy – see the Confidentiality section above for details.

New Findings
If we learn any significant new findings during the study that might influence your decision to participate, we will contact you and explain them.

Unknown Risks
We have described all the risks we know. However, because this is an investigational device, there is a possibility that you will have a reaction that we do not know about yet and is not expected. If we learn about other risks, we will let you know what they are so that you can decide whether or not you want to continue in the study.

Are there possible benefits to me?

You may or may not receive personal, direct benefit from taking part in this study. You may indirectly benefit from the long-term results of this research, which may advance knowledge in the field of using wearable devices to create a more comfortable and less invasive experience for patients who need to undergo testing for sleep apnea.

What choices do I have other than participating in this study?

You can refuse to participate in the study. If you decide not to participate, the medical care providers at this facility will still give you all of the standard care that is appropriate for you.

Are there any consequences to me if I decide to stop participating in this study?

No. If you decide to take part, you are free to stop participating at any time. This will not affect your care and you will continue to be treated at this facility. However, some of the information may have already been entered into the study and that will not be removed. The researchers and TATCH Inc. may continue to use and share the information they have already collected.

To revoke (take back) your consent and authorization, you must contact the Principal Investigator or Study Coordinator. After your withdrawal from the study is confirmed, the study team will stop collecting new information about you unless additional follow ups are necessary due to ongoing adverse events. If you take back your consent and authorization, you will not be allowed to continue participating in this study.

Can the study team end my participation early?

We will not let you participate in the study if any of the following happens: 1) you do not follow the study requirements or instructions, 2) if there are any safety concerns while you are participating in the study, or 3) if TATCH Inc. or the Principal Investigator end your participation in the study or the study stops earlier than expected.

CONSENT TO PARTICIPATE

I have read the consent form and I understand that it is up to me whether or not I participate. I know enough about the purpose, methods, risks and benefits of the research study to decide that I want to take part in it. I understand that I am not waiving any of my legal rights by signing this informed consent document. I will be given a signed copy of this consent form.

Printed name of participant	Signature of participant	Date	Time

Printed name of the person conducting the consent process	Signature	Date	Time