Permission to Take Part in a Human Research Study

Title of Research Study: Sleep quality monitoring of traumatic brain injury patients in the acute rehabilitation setting using wireless wearable sensors

Investigator: David Ripley, MD

Supported By: This research is supported by Shirley Ryan AbilityLab.

Key Information:
The first few pages of this document include a summary of this study to help you decide whether or not to participate. Detailed information is provided after the summary.

Why am I being asked to take part in this research study?
We are asking you to take part in this research study because you have a had a traumatic brian injury and are currently undergoing rehabilitation in a hospital setting.

What should I know about a research study?
- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?
The purpose of this research study is to investigate the relationship between sleep and behavior often displayed by traumatic brain injury patients. This study will investigate how sleep data, as recorded by wearable wireless monitors . The study will also investigate the relationship between total sleep time and a measure of attention.This study may benefit future traumatic brain injury patients by allowing us to understand how we can more accurately measure sleep in the inpatient rehabilitation setting.

How long will the research last and what will I need to do?
In this study you will be asked to wear a set of non-invasive wearable sensors to monitor your sleep quality. We expect that you will be in this research study for seven days.

More detailed information about the study procedures can be found under the section **What happens if I say "Yes, I want to be in this research"?**

Is there any way being in this study could be bad for me?
There are very few risks by participating in the study, and it is highly unlikely any significant risks will occur to anyone who is enrolled into the study, due to no devices being implanted and no drugs being administered. The main risks would be skin irritation from wearing wearable sensors. **"Is there any way being in this study could be bad for me? (Detailed Risks)"**

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Will being in this study help me any way?

There are likely no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include collection of information from this study will allow for improving sleeping habits in the inpatient rehabilitation setting.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled.

Your alternative to participating in this research study is to not participate.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

Whom can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, you can contact the Primary Investigator, David Ripley, at (312) 238-6875 or the lab manager, Lori McGee Koch, at (312) 238-2091 during business hours Monday to Friday, 9:00 a.m. to 5:00 p.m.

This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-9338 or irb@northwestern.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

How many people will be studied?

We expect about 40 people will be participating in this research.

What happens if I say "Yes, I want to be in this research"?

In this study we will ask you to answer some questionaires about your sleep quality, level of anxiety and if you are experiencing depression.

Sleep/Rest Assessment:
The Sleep/Rest Assessment will monitor patients during overnight sleep and during wakeful rest in their rooms. Sensors will measure vital signs and movement in the upper and lower limbs. We may ask you to wear these monitors for up to 3 days or for up to the duration of your inpatient stay. The sensors used to monitor your sleep will be placed on the skin using adhesive stickers that minimize friction, with additional support of medical dressings as needed. All sleep/rest assessments will be performed by a clinician or trained research staff.

We will also ask you to log your rest/activity quality using a log.

Karolinska Sleep Diary: Four items will be asked on this log (slept throughout, sleep restless, ease falling asleep, premature awakenings). This is to determine how well an individual slept throughout the night.

The Pittsburgh Sleep Quality Index (PSQI)*:* This self-rated 21 item questionnaire assesses individual sleep habits (bedtime, morning rising time, sleep-onset latency, and night sleep duration), insomnia, and medication use over a 1-month time interval.

The Berlin Questionnaire: These questions were designed to identify individualss who are likely to have sleep apnea. It asks about snoring behavior, wake time sleepiness or fatigue, and the presence of obesity or hypertension.

Post-traumatic Stress Disorder Checklist*:* To evaluate for symptoms of PTSD in our TBI population, we will use the Post-traumatic Stress Disorder Checklist (PCL) which assesses self-reported PTSD symptoms within the past 1 month.

The hospital anxiety and depression scale (HADS): It is a self-reported scale used to measure symptoms of depression and anxiety within the past one week.

The depression anxiety stress scales (DASS-21): It is a self-report scale assessing levels of depression, anxiety, and stress over the previous week.

Sleep Monitors:

These monitors are U.S. Food and Drug Administration (FDA) approved devices and include:

MC10 Biostamp nPoint: This monitor is in a silicone case and is worn by your chest. It measures electrical heart and muscle activity to show information about your heart rate throughout the night.

Actigraph: this monitor is worn on your wrist and collects similar information to the Actiwatch Spectrum, providing information about your physical activity and brightness of the room

This monitor is not approved by the FDA:

ANNE: this system is worn on your chest and finger to provide information about your breathing, oxygen levels, and temperature.

All patient rooms at the Shirley Ryan AbilityLab have the capability to be equipped with video and audio recording devices. This recording is automatically started during data collection sessions as this is a part of the standard of care in the current hospital room you are staying in. In this study, we would check the consistency of the data collected with the sensors with the video that is being recorded in the room. The recordings that are used for safety in the standard of care will also be utilized solely during data analysis, as previously mentioned. Recordings will only be used by the trained research staff involved in the study.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to:

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Participate in all scheduled sessions of sleep monitoring, answer the questionaires and notify the research team of any changes in your health.

What happens if I say "Yes", but I change my mind later?

You can leave the research at any time and it will not be held against you.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment.

Information collected prior to the study discontinuation by a participant may still be used by the research team.

If you agree, this data will be handled the same as research data.

Detailed Risks: Is there any way being in this study could be bad for me?

There is a risk of irritation to the skin from wearing the sensors. This risk will be reduced by minimized by excluding people who have a known allergy and discontinued use if skin irritation occurs.

In addition to these risks, this research may hurt you in ways that are unknown.

Will it cost me anything to participate in this research study?

Taking part in this research study will not lead to any costs to you.

Will being in this study help me in any way?

There will likely be no direct benefit by participating in this research study. The long-term goal of this research is to improve the ability to measure sleep quality in stroke and look at the impact of sleep quality during the inpatient stay. This benefit could lead to better treatments in the future.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health (NIH). The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings; for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you. You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

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The sponsor, monitors, auditors, the IRB, the Northwestern University Office for Research Integrity, the US Office of Research Integrity (ORI), the US Office for the Protection of Human Research Protections (OHRP), and the US Food and Drug Administration (FDA) may be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

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.

Data Sharing

De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include a medical event or complication that may alter the inclusion/exclusion criteria, or which limits the patient from safely completing the remainder of the study, or at the discretion of the PI.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What else do I need to know?

The hospital [university, researchers] will not pay for medical care required because of a bad outcome resulting from your participation in this research study. This does not keep you from seeking to be paid back for care required because of a bad outcome.
If you have an injury or illness from the study device, or the procedures required for this study, the reasonable medical expenses required to treat such injury or illness may be paid for by the study sponsor.

The coverage for such injury or illness is only available if the Northwestern University principal investigator and study sponsor, if applicable, have decided that the injury/illness is directly related to the study drug, device, or procedures and is not the result of a pre-existing condition or the normal progression of your disease, or because you have not followed the directions of the study doctor. If your insurance is billed, you may be required to pay deductibles and co-payments that apply. You should check with your insurance company about any such payments.

HIPAA Authorization

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that

can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes:

- Results of physical examinations
- Medical history
- Lab tests, or certain health information indicating or relating to a particular condition as well diaries and questionnaires
- Records about study devices

The following clinical providers may give the researchers information about you: all current and previous health care providers, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH).

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or affiliates): the Northwestern University Institutional Review Board Office and Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or University policy [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

The following entities may receive your health information:

- Authorized members of the Northwestern University and the Shirley Ryan AbilityLab workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board.
- Clinical affiliates, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), Northwestern Lake Forest Hospital (NLFH), and the Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's). Your participation in this clinical trial may be tracked in an electronic database and may be seen by investigators running other trials that you are enrolled in and by your healthcare providers.
- Clinical affiliates, including but not limited to Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH), for purposes including, but not limited to, the affiliate's provision of care to you and/or the affiliate's scheduling of appointments and/or billing activities.
- Other University research centers and University contractors who are also working on the study
- Study monitors and auditors who make sure that the study is being done properly
- Samsung, who is sponsoring the study, and that company's contractors and partners.
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).

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Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

Unless you revoke your consent, it will not expire.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

PI's Name: David Ripley
Institution: Shirley Ryan AbilityLab
Department: Physical Medicine and Rehabilitation
Address: 355 E. Erie Street, Chicago, IL

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

A copy of this signed consent document, information about this study, and the results of any test or procedure done may be included in your medical records and may be seen by your insurance company.

Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

I agree	I disagree	
_____	_____	The researcher may audio or video record me to aid with data analysis. The researcher will not share these recordings with anyone outside of the immediate study team.
_____	_____	The researcher may audio or video record me for use in scholarly presentations or publications. My identity may be shared as part of this activity, although the researcher will attempt to limit such identification. I understand the risks associated with such identification.
_____	_____	The researcher may contact me in the future to see whether I am interested in participating in other research studies by the Principal Investigator of this study.

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Signature Block for Capable Adult:

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent

Signature Block for Adult Unable to Consent:

Your signature documents your permission for the named participant to take part in this research.

_____
Printed Name of Participant

_____ _____
Signature of Legally Authorized Representative Date

_____ _____
Printed Name of Legally Authorized Representative Date

_____ _____
Signature of Person Obtaining Consent Date

_____ _____
Printed Name of Person Obtaining Consent Date