OREGON HEALTH & SCIENCE UNIVERSITY

MED. REC. NO. _____
NAME _____
BIRTHDATE _____

STUDY00023078

CLINICAL RESEARCH CONSENT AND AUTHORIZATION SUMMARY OF KEY INFORMATION ABOUT THIS STUDY

TITLE: Sleep Management And Recovery after Trauma in Kids (SMART-Kids): Melatonin Pilot Trial

PRINCIPAL INVESTIGATOR: Cydni Williams M.D., M.C.R (503) 494-5522

In this consent form "You" can mean you the adult participant, you the parent/guardian, or your child if the participant is a minor.

You are being asked to join a research study. This consent form contains important information to help you decide if you want to join the study or not.

PURPOSE: The purpose of the study is to learn about how melatonin and sleep education affect sleep wake disturbances after Traumatic Brain Injuries (TBI) in children. We are hoping to find out if the intervention is tolerated and whether it affects the quality of sleep.

DURATION: Your participation in the study will consist of surveys, a phone call and one study visit over one month. The visit will last up to one hour. We may ask to follow your health through the use of medical record review, surveys, and a follow up phone call or email during this month.

PROCEDURES: If you decide to take part in this study, you will get study drug (melatonin) or be assigned a placebo. You will be treated with usual care for TBI. Participants will also get additional sleep education in handouts. A placebo is a pill that looks like the study drug but has no real medicine in it. Half of the children in the study will receive melatonin. Of those children, some will receive 3mg and some will receive 5mg doses of melatonin based on body weight. We have designed the study so that you nor your care team will know which intervention you receive during the study.

You will be asked to have a number of tests and procedures. We will ask the parent/guardian to complete surveys about your health and sleep. We will ask you to take, the study drug before bedtime. We will ask you to wear an activity watch (Fitbit) to track your sleep.

CO1450

RISKS: The study drug may cause side effects like drowsiness, stomach upset, or vivid dreams. Wearing the activity watch may cause a rash or itchy skin. There is a risk of loss of confidentiality.

BENEFITS: You may or may not benefit from participating in this study. The increased focus on sleep through recruitment into the study may promote better sleep habits.

ALTERNATIVES: You may choose not to participate in this study, and may receive standard treatment. Or you may participate in another study if one is available. Standard care for TBI includes following up with your clinical care teams to treat any symptoms like sleep disturbances that can happen after injury.

This is a voluntary research study. You do not have to join the study. Even if you decide to join now, you can change your mind later. Please ask the Investigator if you have any questions about the study or about this consent form.

END OF CONSENT SUMMARY

OREGON HEALTH & SCIENCE UNIVERSITY

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STUDY00023078

Clinical Research Consent and Authorization Form

TITLE: Sleep Management And Recovery after Trauma in Kids (SMART-Kids): Melatonin Pilot Trial

PRINCIPAL INVESTIGATOR: Cydni Williams M.D., M.C.R (503) 494-5522

WHO IS PAYING FOR THE STUDY?: The National Heart, Lung, and Blood Institute (NHLBI)

DO ANY OF THE RESEARCHERS HAVE A CONFLICT OF INTEREST WITH THIS STUDY?:
No

WHY IS THIS STUDY BEING DONE?:
In this consent form "You" can mean you the adult participant, or you the parent/guardian, or your child if the participant is a minor.

You have been invited to be in this research study because you have had a traumatic brain injury (TBI). The purpose of this study is to learn about how the use of melatonin (the study drug) and sleep education affect sleep wake disturbances (problems with the quality, timing, and amount of sleep) in participants with TBI. Melatonin and sleep education may improve sleep quality, fatigue, and sleep efficiency.

The study drug is experimental. Melatonin is available as a dietary supplement over the counter, but is not FDA approved to treat sleep wake disturbances.

This study requires follow-up visits and will take about a month to complete.

Your identifiable information will not be stored and used for future research.

Up to 50 people will be enrolled in this study.

WHAT EXAMS, TESTS AND PROCEDURES ARE INVOLVED IN THIS STUDY?
Participants will receive clinical care and the usual follow up for TBI regardless of the intervention they are assigned to. There is currently no standard for treatment of sleep problems in the hospital after brain injury. Usual care for TBI includes referrals for clinical follow up with the Pediatric Critical Care and Neurotrauma Recovery Program, and/or referrals to other outpatient programs to address any symptoms like sleep disturbances that can happen after injury.

CO1450

If you agree to participate we will review your medical records.

This is a randomized (like flipping a coin) study. Neither you nor the investigator can choose whether you get melatonin or the placebo. All participants will receive standard clinical care and follow up for TBI. Half of participants in this study will get the placebo. Taking melatonin is not

part of usual care for TBI. The other half will be given the study drug (melatonin). All participants will also receive a sleep education handout. You and the investigators will not know which pill or dose you are taking. The study is done this way because knowing whether you are getting the study drug can change the results of the study. If you start having serious side effects from the study drug, the investigators can find out what you are taking in order to help you. Please ask the investigator if you have any questions about this kind of study.

We will ask you to complete surveys to learn about your pre-injury health and sleep quality. These assessments will take 30 minutes at the time of enrollment. You will be asked to take the study drug or a placebo one hour before their usual bedtime each night for 30 days. We will provide a brief educational handout providing resources about sleep.

After one month, we will ask you to complete a study visit using surveys about health and sleep quality. These surveys ask about things like physical discomfort and function, mood and behaviors, falling and staying asleep, participation in activities and school. We will also ask you about using the study medication and your experience with the study. You will also return the study drug container with any remaining study drug. This visit will take up to an hour. We will try to coordinate this visit with other visits you need for medical care to the hospital. If you do not attend a visit for medical care at the hospital during the time frame of the study, we will contact you at the phone number or email address you provided so that you can choose to complete the study surveys by phone, mail, or electronic mail survey to help you complete the study visit.

Participants with TBI will be provided a Fitbit (activity device) to help us measure their activity and sleep level for one month after hospital discharge. This device is worn continuously (except when charging the battery) and collects information about vital signs (like heart rate), movement level, and sleep times that we use to measure how well and how long wearers are sleeping. We will program the device with a study number and set up an account with Fitbit that would collect information for the study. The Fitbit application on a mobile device or tablet will sync to the Fitbit device. For study purposes, we will also use a platform called Fitabase to allow us to collect your Fitbit data remotely by linking your Fitbit ap profile with Fitabase. OHSU does not own or manage Fitbit or its parent company Google, the Fitbit application, or Fitabase. When your information is released to these companies it may no longer be protected under federal or Oregon law. There is also a risk that this information could be used to identify you as a study participant. Using Fitbit and Fitabase requires that you agree to Fitbit and Small Steps Labs, LLC's policies about how they can use and share your information and what other information they can collect about you while you use their product. We do not control these policies, which can change at any time. You should read those policies before using Fitbit.

We will ask you to:

- Download the Fitbit app to your smartphone or tablet that can be used to sync with the Fitbit device weekly in order for us to collect your data remotely. You will use an email address of your choice to set up an account in the Fitbit app. Our study team will help you set up the account, but will not have access to your account.
- We will use a platform called Fitabase to collect and store your Fitbit data for the study period. Fitabase is owned and administered by Small Steps Labs LLC. In order to use this platform, we will share the mobile phone number you provided for the study with the Fitbit ap and with Fitabase to link to your account. You will be asked to accept the prompt from Fitabase to link your Fitbit account for the study period of 30days.
- Through this platform, we will also send weekly text messages to the mobile phone number you provided reminding you to sync your device and to communicate about the study. Text messages travel over unencrypted networks that OHSU does not own or control. You do not have to receive text messages to be in the study. You can opt out of receiving text messages at any time during the study by calling the study team at (503) 494-5522 or sending an email to willicyd@ohsu.edu.

- The Fitabase platform uses Twilio to send text messages and shares your mobile phone number with Twilio, Inc.
- No other identifying information will be stored on the Fitbit app or Fitabase platform, and your mobile phone number would not be shared or used for any other purposes.
- The study team highly recommends that you lock your phone. If your phone is not secure and you lose it – or it is stolen – the data on your mobile phone or device could be used by other individuals not authorized to view your data.
- Once our study team has collected data for the wearer for one month, you can keep the Fitbit device and we will transfer account ownership to your email address you provided. At that time, our study team would no longer have access to your data and only you would have access to the account settings.

In the future, your protected health information will not be given to researchers or the funder for other research studies.

WILL I RECEIVE RESULTS FROM THE PROCEDURES OF THIS STUDY?
The results of this research will not be made available to you because the research is still in an early phase and the reliability of the results is unknown.

WHAT RISKS CAN I EXPECT FROM TAKING PART IN THIS STUDY?:
There is a risk of side effects from taking melatonin. The rate of side effects in children related to melatonin overall is unknown. Studies using placebo medications also report similar side effects. Recent studies in children taking melatonin report the following side effects:

The most common side effects reported are:
- Stomach upset (nausea and or vomiting, diarrhea)
- Drowsiness or fatigue
- Headache
- Behavioral change or dysregulation

Other side effects reported less commonly are:
- Vivid dreams or nightmares
- Waking up at night
- Itchy skin, rash
- Appetite changes
- insomnia
- Bodily pain or aches
- Chest pain
- Enuresis or bedwetting
- Dizziness
- Tinnitus or ringing in the ears
- Feeling cold
- Allergic reactions (rash, difficulty breathing, swelling)

Melatonin may interact with other medications or supplements you are taking. Tell the investigator about all other medications and supplements you are currently taking.

You may have some side effects we do not expect because we are still learning about taking melatonin for extended periods of time.

There is a small risk of discomfort from wearing the Fitbit activity watch. This could include rash, pain, and itchy skin. You can remove the Fitbit if you experience discomfort. You can still participate in other parts of the study if you choose to remove the Fitbit. To use your Fitbit data

for the study, it must be worn for the majority of the days in the study period, at least 5 of 7 days per week over the 30day study period.

WHAT ARE MY CHOICES IF I DECIDE NOT TO TAKE PART IN THIS STUDY?

You may choose not to be in this study. Standard care for TBI includes following up with clinical care teams to treat any symptoms from the injury such as sleep disturbances. Your participation in this study will not affect your access to these medical services.

The risks and benefits of the alternatives should be discussed with the study investigator or your or your child's usual provider. Melatonin is an over the counter supplement. You do not need to participate in the research study to receive the same treatment for sleep disturbances, if this is recommended by your medical provider.

WHO WILL SEE MY PERSONAL INFORMATION?

We will take steps to keep your personal information confidential, but we cannot guarantee total privacy. Although we have made efforts to protect your identity, there is a small risk of loss of confidentiality. We have taken steps to minimize this risk including programing Fitbit devices with coded study ID numbers and emails. All study related documents will also be coded with study ID numbers. Your mobile phone number will be shared with the Fitabase for the purposes of this study only. This platform is protected by an encrypted firewall. The remainder of your study data will be stored at OHSU and protected by an encrypted firewall. Only the Principal Investigator and study team at OHSU will have access to your other identifiable information that will be protected by the OHSU firewall.

We will create and collect health information about you as described in the WHY IS THIS STUDY BEING DONE? and the WHAT EXAMS, TESTS AND PROCEDURES ARE INVOLVED IN THIS STUDY? sections of this form. Health information is private and is protected under federal law and Oregon law. By agreeing to be in this study, you are giving permission (also called authorization) for us to use and disclose your health information as described in this form.

The investigators, study staff, and others at OHSU may use the information we collect and create about you in order to conduct and oversee this research study. We may release this information to others outside of OHSU who are involved in conducting or overseeing research, including

- The funder of this study, The National Heart, Lung, and Blood Institute (NHLBI), and the funder's representatives
- The Food and Drug Administration
- The Office for Human Research Protections, a federal agency that oversees research involving humans
- Google LLC, who provides the Fitbit system and/or another vendor who provides similar devices/services in support of this study
- Small Steps Labs LLC who provides the Fitabase software

Those listed above may also be permitted to review and copy your records, including your medical records.

We will not release information about you to others not listed above, unless required or permitted by law. We will not use your name or your identity for publication or publicity purposes, unless we have your special permission.

Under Oregon law, suspected child or elder abuse must be reported to appropriate authorities. When we send specimens or information outside of OHSU, they may no longer be protected under federal or Oregon law. In this case, your specimens or information could be used and re-released without your permission.

We may continue to use and disclose your information as described above indefinitely.

WILL ANY OF MY INFORMATION OR SAMPLES FROM THIS STUDY BE USED FOR ANY COMMERCIAL PROFIT

Information about you or obtained from you in this research may be used for commercial purposes, such as making a discovery that could, in the future, be patented or licensed to a company, which could result in a possible financial benefit to that company, OHSU, and its researchers. There are no plans to pay you if this happens. You will not have any property rights or ownership or financial interest in or arising from products or data that may result from your participation in this study. Further, you will have no responsibility or liability for any use that may be made of your samples or information.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

There will be no cost to you or your insurance company to participate in this study.

You will be paid 25$ for completing the baseline visit and $50 for completing 1 month follow up visit (total $75 for the study). You may receive payment via a debit card. There may be fees (for example, if the card is inactive for more than six months), which will be deducted from the balance on your card. Details on how to use the card and any fees are included in the separate card member agreement and FAQ sheet. We may request your social security number in order to process any payments for participation. We will also transfer Fitbit account settings to your preferred email address at the end of the study, and you can keep the device.

WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?:

If you believe you have been injured or harmed as a result of participating in this research and require treatment, contact Cydni Williams (503) 494-5522.

If you are injured or harmed by the study drug or study procedures, you will be treated. OHSU and the NHLBI do not offer any financial compensation or payment for the cost of treatment if you are injured or harmed as a result of participating in this research. Therefore, any medical treatment you need may be billed to you or your insurance. However, you are not prevented from seeking to collect compensation for injury related to negligence on the part of those involved in the research. Oregon law (Oregon Tort Claims Act (ORS 30.260 through 30.300)) may limit the dollar amount that you may recover from OHSU or its caregivers and researchers for a claim relating to care or research at OHSU, and the time you have to bring a claim.
If you have questions on this subject, please call the OHSU Research Integrity Office at (503) 494-7887.

This federally funded study also does not have the ability to provide compensation for research-related injury. If you are injured or become ill from taking part in this study, it is important to tell your study doctor. Emergency treatment may be available but you or your insurance company will be charged for this treatment.

WHERE CAN I GET MORE INFORMATION?

If you have any questions, concerns, or complaints regarding this study now or in the future, contact Cydni Williams (503) 494-5522.

This research has been approved and is overseen by an Institutional Review Board (“IRB”), a committee that protects the rights and welfare of research participants. You may talk to the IRB at (503) 494-7887 or irb@ohsu.edu if:

- Your questions, concerns, or complaints are not being answered by 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 more information or provide input about this research.

You may also submit a report to the OHSU Integrity Hotline online at https://secure.ethicspoint.com/domain/media/en/gui/18915/index.html or by calling toll-free (877) 733-8313 (anonymous and available 24 hours a day, 7 days a week).

WHAT ARE MY RESPONSIBILITIES IN THIS STUDY?
We will ask you to complete surveys, and to take the study drug before bed. We will ask you to wear a Fitbit device to track their sleep.

DO I HAVE TO TAKE PART IN THIS STUDY?
Your participation in this study is voluntary. You do not have to join this or any research study. You do not have to allow the use and disclosure of your health information in the study, but if you do not, you cannot be in the study.

Your health care provider may be one of the investigators of this research study and, as an investigator, is interested in both your clinical welfare and in the conduct of this study. Before entering this study or at any time during the research, you may ask for a second opinion about your care from another doctor who is in no way involved in this project. You do not have to be in any research study offered by your physician.

IF I DECIDE TO TAKE PART IN THIS STUDY, CAN I STOP LATER?
If you do join the study and later change your mind, you have the right to quit at any time. This includes the right to withdraw your authorization to use and disclose your health information. If you choose not to join this study, or if you withdraw early from any or all parts of the study, there will be no penalty or loss of benefits to which you are otherwise entitled, including being able to receive health care services or insurance coverage for services. Talk to the investigator if you want to withdraw from the study.

If you no longer want your health information to be used and disclosed as described in this form, you must send a written request or email stating that you are revoking your authorization to:

Cydni Williams M.D., M.C.R
707 SW Gaines St
CDRC-P
Portland, OR 97239
willicyd@ohsu.edu

Your request will be effective as of the date we receive it. However, health information collected before your request is received may continue to be used and disclosed to the extent that we have already acted based on your authorization.

If you want to stop participating in the study we may ask you to complete final surveys on your child's sleep and health.

If in the future you decide you no longer want to participate in this research, we will remove your name and any other identifiers from your information, but the material will not be destroyed and we will continue to use it for research.
You may be removed from the study if the investigator or funder stops the study, you become pregnant, you develop serious side effects, you do not follow study instructions.

We will give you any new information during the course of this research study that might change the way you feel about being in the study.

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.

You have to option to receive text messages for this study. Please initial by your choice:

_____Yes, I consent to receive text messages and understand the OHSU cannot guarantee they will be confidential.

_____No, I do not want to receive text messages

SIGNATURES:
Your signature below indicates that you have read this entire form and that you agree to be in this study.

We will give you a copy of this signed form.

Child Printed Name	Child Signature (only if 15-17 years old)	Date

Parent/Guardian/Adult Printed Name	Parent/Guardian/Adult Signature	Date

Person Obtaining Consent Printed Name	Person Obtaining Consent Signature	Date

USE OF AN INTERPRETER

Complete if the participant is not fluent in English and an interpreter was used to obtain consent. **Participants who do not read or understand English** must not sign this full consent form, but instead **sign the short form** translated into their native language. **This consent form should be signed by the investigator and interpreter only**. If the interpreter is affiliated with the study team, the signature of an impartial witness is also required.

Print name of interpreter: _____

Signature of interpreter: _____ Date: _____

An oral translation of this document was administered to the participant in _____ (state language) by an individual proficient in English and _____ (state language).

If applicable:

Print name of impartial witness: _____

Signature of impartial witness: _____Date: _____

See the attached short form for documentation.