PARENTAL CONSENT - CLINICAL BIOMEDICAL

Title of this Research Study
A SMART Design to Improve Sleep Disturbance in Adolescents with Neurodevelopmental Disorders

Invitation
You are invited to allow your child to take part in this research study. You have a copy of the following, which is meant to help you decide whether or not to allow your child to take part:

- Informed consent form
- "What Do I need to Know Before Being in a Research Study?"
- The Rights of Research Subjects

Why is your child being asked to be in this research study?
Your child is being asked to be in this study because your child is 10-18 years old with a diagnosis of Autism Spectrum Disorder and/or Attention Deficit Hyperactivity Disorder and may have problems with sleep.

What is the reason for doing this research study?
The purpose of this study is to compare the impact of a sequence of sleep interventions, based on participant treatment response, to optimize sleep health in adolescents with neurodevelopmental disorders (NDDs).

What will be done during this research study?
Your child must undergo a 2-month wash out period prior to participating in this clinical trial if he/she is already taking melatonin. Your child will be in this study for 9 weeks. There are three research visits.

At the first visit:

1. Your child will be randomly assigned to a sleep intervention treatment group (hereafter referred to as the sleep intervention) consisting of 4 weeks of melatonin or 4 weeks of The Bedtime Bank. Melatonin is a dietary supplement intended for use as a sleep aid. Your child will receive 3 mg of melatonin 30 minutes prior to bedtime if he/she is randomly selected and placed into the melatonin treatment group. The Bedtime Bank is a novel behavioral sleep intervention designed to promote a consistent bedtime routine and optimize sleep. Your child will follow and complete The Bedtime Bank and tracker each night if randomly selected and placed into The Bedtime Bank treatment group. You and your child will be trained on the

sleep intervention, and you will be given a participant training binder.

2. You and your child will be taught how to collect your child's saliva and urine (optional) to establish baseline melatonin levels and creatinine analysis. Saliva collection will begin three hours prior to habitual bedtime. Saliva will be collected every thirty minutes for a total of 7 samples. If participating in the optional urine collection, your child will need to collect his/her last evening void and first morning void for analysis.
3. You and your child will be taught how to record your child's sleep and wake time using a sleep diary.
4. You and your child will be taught how to attach and detach (e.g. bathing) the actigraph, which is an activity monitor that can track sleep.
5. You will be asked to complete:
    1. Demographic Questionnaire (~2-3 minutes)
6. Your child will be asked to complete:
    1. Cleveland Adolescent Sleepiness Questionnaire (~4-6 minutes)
    2. PROMIS Sleep Disturbance (questionnaire ~3-5 minutes)
    3. PROMIS Sleep Related Impairment (questionnaire ~3-5 minutes)

Baseline (1 week)

1. Your child will be asked to wear an actigraph for 1 week before starting the sleep intervention.
2. Your child will be asked to complete a daily sleep diary for 1 week, recording when he/she goes to bed and when he/she wakes up (~3-4 minutes per day).

First Stage (4 weeks)

1. Your child will begin the sleep intervention.
2. Your child will be asked to wear the actigraph activity monitor for 4 weeks.
3. Your child will be asked to complete a daily sleep diary for 4 weeks, recording when he/she goes to bed and when he/she wakes up (~3-4 minutes per day).

At the second visit:

1. You will be asked to complete:
    1. Abbreviated Acceptability Rating Profile (~5-7 minutes)
    2. Semi-structured Interview (regarding experience with sleep intervention; completed with adolescent if possible) (~10-12 minutes). Semi-structured interviews will be audio recorded.
2. Your child will be asked to complete:
    1. Cleveland Adolescent Sleepiness Questionnaire (~4-6 minutes)
    2. PROMIS Sleep Disturbance (questionnaire ~3-5 minutes)
    3. PROMIS Sleep Related Impairment (questionnaire ~3-5 minutes)

Second Stage

1. Data pertaining to your childs sleep habits during the first stage (4 weeks) will be obtained from his/her actigraph activity monitor. If your child is determined to be responsive to his/her assigned sleep intervention, he/she will continue with an additional 4 weeks of the assigned sleep intervention to complete the second stage of treatment. If your child is determine to be non-responsive to his/her assigned sleep intervention, he/she will be randomly assigned to a new sleep intervention treatment group consisting of 4 weeks of melatonin, 4 weeks of The Bedtime Bank, or a combination of both melatonin and The Bedtime Bank.
2. Your child will be asked to wear the actigraph activity monitor for 4 weeks.
3. Your child will be asked to complete a daily sleep diary for 4 weeks, recording when you and your child go to bed and when you and your child wake up (~3-4 minutes per day).

At the third visit:

1. Your child will return his/her actigraph.
2. You will be asked to complete:
    1. Abbreviated Acceptability Rating Profile (~5-7 minutes)
    2. Semi-structured Interview (regarding experience with sleep intervention; completed with adolescent if possible) (~10-12 minutes). Semi-structured interviews will be audio recorded.
3. Your child will be asked to complete:
    1. Cleveland Adolescent Sleepiness Questionnaire (~4-6 minutes)
    2. PROMIS Sleep Disturbance (questionnaire ~3-5 minutes)
    3. PROMIS Sleep Related Impairment (questionnaire ~3-5 minutes)

What are the possible risks of being in this research study?

There are minimal risks associated with this study. Those risks are as follows:

Risk for collecting saliva: The risk of collection of saliva for melatonin analysis is minimal. To avoid any psychological stress regarding salivary specimen collection, you and your child will be provided with in-person instructions with return demonstration and written instructions, as well as the investigator's contact information if any questions should arise during sample collection.

Risk for collecting urine (optional): The risk of urine collection for melatonin and creatinine analysis is minimal. To avoid any psychological stress regarding urinary specimen collection, you and your child will be provided with in-person instructions with mock return demonstration and written instructions, as well as the investigator's

contact information if any questions should arise during sample collection.

Risk for completing questionnaires: There is the potential for psychological risk in that you and your child will be asked to identify concerns and answer questions regarding your childs sleep characteristics that may make you or your child feel uncomfortable. You and your child may take breaks during the completion of the questionnaires if needed.

Risk for wearing research device: Generally, the risk of wearing research devices is minimal. There is no contraindication to wearing an actigraph. It is possible that your child may find the actigraph uncomfortable to wear. If your child feels uncomfortable wearing the research device, he/she has the right to withdraw from the research at any time.

Risk for sleep interventions: The Bedtime Bank: There is the potential for psychological risk in that the you and your child will be asked to track your child's sleep characteristics that may make you or your child feel uncomfortable.

Melatonin: Generally, the risk of administering 3 mg of melatonin, 30 minutes before bedtime is minimal. Although of low incidence, side effects of melatonin in children may include: daytime sleepiness, headaches, dizziness, bedwetting, irritability, abdominal pain, and diarrhea.

What are the possible benefits to your child?
This study may have a positive effect on your child's sleep habits and may increase sleep time for your child.

Your child may not get any benefit from being in this research study.

What are the possible benefits to other people?
This study may lead to a better understanding of sleep in adolescents with Autism Spectrum Disorder and Attention Deficit Hyperactivity Disorder. The results of this study may be used in additional studies or applied in appropriate populations.

What are the alternatives to being in this research study?
Instead of being in this study, you can choose that your child not participate.

You can instead choose to speak to your primary health care provider or a health care provider who specializes in sleep regarding your child's sleep-related problems.

What will allowing your child to be in this research study cost you?

There is no cost to you for your child to be in this research study.

Will you or your child be paid for being in this research study?
Your child will be compensated with a gift card of $40, at each stage (Baseline, First Stage, Second Stage) for a total of $120. Your child may receive an additional $30 for participating in the baseline salivary measurement. Your child will be compensated an additional $10 if he/she chooses to participate in urinary melatonin collection. You and your child may receive a total possible compensation of $220.

Who is paying for this research?
This research is being paid for by grant funds from the National Institutes of Health (NIH). The Institution receives money from NIH to conduct this study.

What should you do if your child is injured or has a medical problem during this research study?
Your child's welfare is the main concern of every member of the research team. If he/she is injured or has a medical problem or some other kind of problem as a direct result of being in this study, you should immediately contact one of the people listed at the end of this consent form.

How will information about your child be protected?
Your child has rights regarding the protection and privacy of his/her medical information collected before and during this research. This medical information is called "protected health information" (PHI). PHI used in this study may include his/her medical record number, address, birth date, medical history, the results of physical exams, blood tests, x-rays as well as the results of other diagnostic medical or research procedures. Only the minimum amount of PHI will be collected for this research. Your child's research and medical records will be maintained in a secure manner.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. A Certificate of Confidentiality means that the researcher in most cases cannot reveal identifiable information about you to others without your permission. He or she can report things like potential child abuse or intent to harm self or others. He or she can report contagious diseases and can share information with agencies paying for the research or with the Food and Drug Administration. He or she can also share the information with other scientific researchers, as allowed by federal regulations protecting research subject. A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

Who will have access to information about your child?

By signing this consent form, you are allowing the research team to have access to your child's PHI. The research team includes the investigators listed on this consent form and other personnel involved in this specific study at the Institution.

Your child's PHI will be used only for the purpose(s) described in the section "What is the reason for doing this research study?"

You are also allowing the research team to share his/her PHI, as necessary, with other people or groups listed below:

- The UNMC Institutional Review Board (IRB)
- Institutional officials designated by the UNMC IRB
- Federal law requires that the subject's information may be shared with these groups:
    - The HHS Office of Human Research Protections (OHRP)
    - National Institutes of Health (NIH)

You are authorizing us to use and disclose your child's PHI for as long as the research study is being conducted. You may cancel your authorization for further collection of your child's PHI for use in this research at any time by contacting the principal investigator in writing. However, the PHI which is included in the research data obtained to date may still be used. If you cancel this authorization, your child will no longer be able to participate in this research.

How will results of the research be made available to you during and after the study is finished?

In most cases, the results of the research can be made available to you when the study is completed, and all the results are analyzed by the investigator or the sponsor of the research. The information from this study may be published in scientific journals or presented at scientific meetings, but your child's identity will be kept strictly confidential.

If you want the results of the study, contact the Principal Investigator at the phone number given at the end of this form or by writing to the Principal Investigator at the following address: 985330 Nebraska Medical Center - Omaha, NE 68198-5330.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify your child. At most, the website will include a summary of the results. You can search this website at any time.

What will happen if you decide not to give permission for your child to be in this research study?

You can decide not to give permission for your child to be in this research study. Deciding not to be in this research will not affect your child's medical care or his/her relationship with the investigator or the Institution. Your child's doctor will still take care of him/her. Your child will not lose any benefits to which he/she is entitled.

What will happen if you decide to stop your child's participation once it starts?

You can stop your child's participation in this research (withdraw) at any time by contacting the Principal Investigator or any of the research staff. Deciding to withdraw will otherwise not affect your child's care or relationship with the investigator or this institution. Your child will not lose any benefits to which he/she is entitled. Any research data obtained to date may still be used in the research.

Will you be given any important information during the study?

You will be informed promptly if the research team gets any new information during this research study that may affect whether you would want your child to continue being in the study.

What should you do if you have any questions about the study?

You have been given a copy of *"What Do I Need to Know Before Being in a Research Study?"* If you have any questions at any time about this study, you should contact the Principal Investigator or any of the study personnel listed on this consent form or any other documents that you have been given.

What are your child's rights as a research subject?

Your child has rights as a research subject. These rights have been explained in this consent form and in The Rights of Research Subjects that you have been given. If you have any questions concerning his/her rights or complaints about the research, you can contact any of the following:

- The investigator or other study personnel
- Institutional Review Board (IRB)
    - Telephone: (402) 559-6463.
    - Email: IRBORA@unmc.edu
    - Mail: UNMC Institutional Review Board, 987830 Nebraska Medical Center, Omaha, NE 68198-7830
- Research Subject Advocate
    - Telephone: (402) 559-6941
    - Email: unmcrsa@unmc.edu

Documentation of informed consent

You are freely making a decision whether to give permission for your child to be in this research study. Signing this form means that:

- You have read and understood this consent form.
- You have had the consent form explained to you.
- You have been given a copy of The Rights of Research Subjects
- You have had your questions answered.
- You have decided to permit your child to be in the research study.
- If you have any questions during the study, you have been directed to talk to one of the investigators listed below on this consent form.
- You will be given a signed and dated copy of this consent form to keep.

Signature of Parent/Guardian _____
Date _____

You are agreeing to be in this research study. You have had someone explain the study to you, and answer your questions.

Signature of Subject _____
Date _____

My signature certifies that all the elements of informed consent described on this consent form have been explained fully to the parent(s)/guardian(s) of the subject. In my judgment, the parent(s)/guardian(s) possesses the legal capacity to give informed consent for the subject to participate in this research and is voluntarily and knowingly giving informed consent.

Signature of Person obtaining consent _____
Date _____

Authorized Study Personnel
Principal
* Hanish, Alyson
phone: 402-559-6731
alt #: 402-559-6731
degree: PhD, MSN, RN

Data/Administrative Personnel
Stappert, Danielle
alt #: 402-559-6731

degree: BSN

Other Coordinator
* Klein, Abbey
phone: 402-559-6549
alt #: 402-559-6731
degree: BSN

What Do I Need To Know Before Being In A Research Study?

You have been invited to be in a **research study**. Research studies are also called "clinical trials" or "protocols." **Research** is an organized plan designed to get new knowledge about a disease or the normal function of the body. The people who are in the research are called **research subjects**. The **investigator** is the person who is running the research study. You will get information from the investigator and the research team, and then you will be asked to give your **consent** to be in the research.

This sheet will help you think of questions to ask the investigator or his/her staff. You should know all these answers before you decide about being in the research.

What is the **purpose** of the research? Why is the investigator doing the research?

What are the **risks** of the research? What bad things could happen?

What are the possible **benefits** of the research? How might this help me?

How is this research different than the care or treatment I would get if I wasn t in the research? Are there other treatments I could get?

Does **everyone** in this research study get the same treatment?

Will being in the research **cost** me anything extra?

Do I have to be in this research study? Will the doctor still take care of me if I say **no**?

Can I **stop** being in the research once I ve started? How?

Who will look at my **records**?

How do I reach the investigator if I have more **questions**?

Who do I call if I have questions about being a **research subject**?

Make sure all your questions are answered before you decide whether or not to be in this research.

Academic Research & Services Building 3000 / 987830 Nebraska Medical Center / Omaha NE 68198-7830
402-559-6463 / FAX 402-559-3300 / Email: irbora@unmc.edu / http://www.unmc.edu/irb

THE RIGHTS OF RESEARCH SUBJECTS
AS A RESEARCH SUBJECT YOU HAVE THE RIGHT

to be told everything you need to know about the research before you are asked to decide whether or not to take part in the research study. The research will be explained to you in a way that assures you understand enough to decide whether or not to take part.

to freely decide whether or not to take part in the research.

to decide not to be in the research, or to stop participating in the research at any time. This will not affect your medical care or your relationship with the investigator or the Nebraska Medical Center. Your doctor will still take care of you.

to ask questions about the research at any time. The investigator will answer your questions honestly and completely.

to know that your safety and welfare will always come first. The investigator will display the highest possible degree of skill and care throughout this research. Any risks or discomforts will be minimized as much as possible.

to privacy and confidentiality. The investigator will treat information about you carefully, and will respect your privacy.

... to keep all the legal rights you have now. You are not giving up any of your legal rights by taking part in this research study.

to be treated with dignity and respect at all times

The Institutional Review Board is responsible for assuring that your rights and welfare are protected. If you have any questions about your rights, contact the Institutional Review Board at (402) 559-6463.