Title of research study: Impact of Well-Timed vs. Mis-timed Sleep Extension on Adolescents' Dietary Intake (also called the Sleep Timing, Eating, and Activity Monitoring or *STEAM Study*)

Investigator:
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Contact Info:
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Funding: National Institutes of Health (R01 HL147915)

Key Information:

The following is a short summary of this study to help you decide whether to be a participant in it. More detailed information about the study is listed later in this form. This document does not replace the discussion you should have with the research team about this study including having any questions or concerns answered.

If you are a Parent/Guardian: You have the option of having your child or teen join this research study. This is a parental permission form. It explains this research study. If you decide that your child can be in this study, you will sign this form to show that you agree. If you sign this form, you will receive a signed copy for your records. When we say "you" in this form, we mean you or your child; "we" means the study doctor and other staff.

Reason for the study:

Many adolescents go to bed late and wake up early for school. We are only beginning to understand how that sleep schedule can affect them. We are interested in whether changing adolescents' sleep patterns affects their eating, physical activity, and how they feel. We are especially interested in the effects of changing both *how much* sleep adolescents get and *when* that sleep happens.

This study is limited to healthy 14-18-year-olds. Your child should not participate if he or she has been diagnosed with obesity, depression, bipolar disorder, psychosis, a neurological illness (e.g., epilepsy), intellectual disability, or ever had a head injury that knocked him or her out. Study staff will also ask about medications that affect sleep, eating, or activity. This study asks adolescents to change their sleeping habits. To help them succeed, we want youth who sleep in the same home during the summer, have freedom to go to bed early (perhaps as early as 9:30 pm) or to sleep late (as late as 10 am), do not snore often, and drink no more than "normal" amounts of caffeine (no more than 1 coffee or "energy drink" -- or 2 caffeinated sodas -- per day).

Procedures:

More details on procedures are provided below (under "Detailed Procedures"). Briefly, your child will be in the study for three weeks in a row. At the end of each week, we will have them and you come to an evening appointment at Children's. Your child will be with us for several hours during each appointment, but you'll be needed only at the

beginning and the end. During that time, we will be having your child fill out forms and relax in a darkened room watching movies and playing games. We will also collect saliva (spit) samples from them during those visits; later in this form you can tell us whether to use those samples only for checking melatonin levels or to also store them for later genetics analysis.

Your child will sleep at home during the study, keeping track of their sleep using a diary and "Sleep Watch" (looks like a wristwatch). We will ask your child to change their bedtimes and/or wake times for several nights in a row. Instructions will vary from 6 ½ to 9 ½ hours in bed per night, with the longer nights coming from either going to bed early or waking up late. They will also be keeping track of their daytime activity levels using a special Activity Belt, and we will be calling them on several occasions to do brief interviews about their eating over the previous day.

Risks to Participate:

Overall, this type of study is very safe. We will not give any medications and there will not be any needles or blood draws. Giving saliva (spit) samples does not hurt. On rare occasions, patients find the Sleep Watch or Activity Belt uncomfortable, or develop a rash from wearing it. If this happens to your child, they should stop wearing the device(s) and you should call us to see if there are other options. You and your child will also be filling out some forms that will ask questions about health, sleep, thoughts and behaviors. On rare occasions this can make people uncomfortable. You don't have to answer any questions you don't want to.

We expect that the amount of sleep that adolescents will get during the study will be like what teenagers often get during the school year on weeknights (for shorter nights) and weekends (for longer nights). Even so, the shorter nights may result in temporary daytime sleepiness, moodiness, headache, or problems paying attention or learning or recalling information. Your child should not drive, operate heavy machinery, or engage in jobs that require a high degree of coordination, balance, or attention (e.g., roofing) during the shorter sleep nights of the study. Short sleep can also affect a person's energy level during sports and exercise. During the study, we ask that your child pay attention to how his or her body feels during physical activity, and take breaks if he or she experiences chest pain or feels very out of breath, light-headed or dizzy. As you probably know from experience, all these effects go away once you get more sleep.

We will be asking your child to limit caffeinated beverages and to avoid naps during the study; this may be uncomfortable if he or she is accustomed to drinking a lot of caffeine or taking daytime naps. Your child may get tired or bored at times during the office visits. We will provide snacks and calm recreation options between activities.

Following the study sleep schedule and coming to Children's may be inconvenient. You will be compensated for your time and efforts (details below). As with any study, there

may be other risks that we do not know about yet; if we learn of any before or while you are in the study, we will be sure to let you know.

Benefits to Participate:

Being in this study may not help your child right now. Your child (and you) may learn more about how he or she acts and feels after changing sleep schedules. We expect that the results of the study will be helpful to others. For example, the findings will help us to better understand the effect of many adolescents' chronic lack of sleep on their health. This could affect public policies (e.g., school start times).

Other Options:

Participation in research is completely voluntary. Your decision to participate or not to participate will not affect the care you receive. You can choose not to participate.

Cost to Participate:

There is no cost to participate in this study.

Payment:

Altogether you and your child could receive up to $510 for the costs, inconvenience, and time associated with the research study. It breaks down this way: $100 at the office visit at the end of the first week of the study, $150 at the second office visit, and $200 at the third office visit, plus $10 for each of six dietary-recall phone interviews. These amounts assume that you complete all parts of the study and that you provide your own transportation. If you leave the study early, the reimbursement will cover only the part you did. Also, if we need to pay for transportation, we will deduct that cost.

You will receive payment for this study in the form of a reloadable debit card (Clincard). We will give you a handout that will explain how to use the card. Because you are being paid for your participation, Cincinnati Children's is required by the Internal Revenue Service (IRS) to collect and use your (your child's) social security number (SSN) or taxpayer identification number (TIN) to track the amount of money that we pay. You will need to complete a Federal W-9 form for this income tax reporting. This form requires you or your child's Social Security number. This form will be given to the Cincinnati Children's business office. It will not be kept as part of your study chart. If you move during the study, you will need to complete another W-9 with an updated address.

Additional Study Information:

The following is more detailed information about this study in addition to the Key Information.

If I have Questions or would like to know about:

Who to talk to for…	**You can call …**	**At …**
• Emergencies • General study questions • Research-related injuries • Any research concerns or complaints	**Primary Investigator** Dean Beebe, Ph.D.	Phone: 513-636-3489
• Emergencies • General study questions • Research-related injuries • Any research concerns or complaints	**Lead Study Coordinator** Catharine Whitacre	Phone: 513-636-5360
• Your child's rights as a research participant	**Institutional Review Board** This is a group of scientists and community members who make sure research meets legal and ethical standards.	Phone: 513-636-8039

Detailed Procedures:

We expect about 200 youth and their caregivers will start this study (about 50 each summer for four summers). Details of each step in the study are below.

Week 1 (Nights 1-6): Just before you start the study, we will send a package to your home with the Sleep Watch, Activity Belt, Sleep Diary, and study forms in it. Your child will wear the Sleep Watch and Activity Belt and fill out the Sleep Diary for the 7 days (6 nights) before your first office visit. This first week focuses on getting adolescents on a consistent sleep schedule that allows 8 hours in bed every night. The exact times in bed will depend on whether your child is a "morning lark" or "night owl." Morning larks prefer earlier bedtimes and wake times than many teens. Night owls prefer later bedtimes and wake times. During this first week of the study, morning larks will go to bed no later than 11 pm and rise by 7 am. Night owls will go to bed no earlier than 12:30 am and rise no earlier than 8:30 am.

Office Visit 1 (Evening/Night 7): You and your child will come to Cincinnati Children's. This visit will start around 6 pm for morning larks and 7:30 for night owls. We will double-check that your

child is eligible and safe to participate. We will also review the prior week's sleep with you and your child, and provide sleep instructions for the next week. Your child will then spend the next several hours with us in dim lighting filling out forms and engaging in calm recreational activities (e.g., movies); every 30 minutes they will swish cotton balls in their mouths and then spit them into a tube to give us saliva (spit) samples. You don't have to stay for that part, but we will need you to come back at the end (by 1 am if your child is a morning lark; 2:30 if your child is a night owl). Coming back at that time may be the hardest part of the study for you, but we cannot allow adolescents under age 18 to leave without you or another adult that you have designated.

Week 2 (Nights 8-13): This will start with your child getting four nights of short sleep (6 ½ hours in bed, around 12:30 am – 7 am) and then two nights back on the same schedule as week 1. As during the first week, your child will wear sleep and activity monitors. In addition, they will get 15-minute phone calls on three days of the short sleep period to ask what they ate the previous day.

Office Visit 2 (Evening/Night 14): This will be very similar to the first office visit. We will need both you and your child to review the prior week's sleep and get sleep instructions for the next week. You can then leave while your child spends the evening with us filling out forms, engaging in calm activities, and providing saliva samples. As before, we will need you or an adult that you designate to pick up your child at the end, in the early morning hours.

Week 3 (Nights 15-20): Your child will start with one more night on the same schedule as the first week. The next five nights will involve spending extra time in bed (9 ½ hours per night). To do that, your child will either be asked to go to bed earlier (9:30 pm – 7 am) or wake up later (12:30 am – 10 am). Which schedule is used will be determined at random (like flipping a coin); it may or may not line up with your child's preference. Again, your child will wear sleep and activity monitors and get 15-minute phone calls on three days of the longer sleep period.

Office Visit 3 (Evening/Night 21): This will be very similar to the other office visits, except that we will not provide any more sleep instructions. We will still need you and your child at the very beginning to review the previous week's sleep. You can then leave while your child spends the evening with us doing the same things as the other office visits. As before, we will need you or an adult that you designate to pick up your child at the end, in the early morning hours.

Optional Saving of Saliva Samples for Later Study:

Your child's saliva samples will be used to test melatonin levels, which tell us when his or her body is preparing for sleep. If you choose, we can also freeze some samples and save them for later study of how genes relate to sleep and sleep timing. That way, we can learn even more from this study. If you choose for us to do that, we will not be able to provide information back to you on any genetic tests because we will remove any information that identifies you. Not only would the person doing the tests not know who gave which sample, we may not have that information either. It is your choice whether to have samples saved for genetic tests. If either you or your child says no, we will not do it, and they can still stay in the regular (non-genetic) part of the study.

PLEASE WRITE YOUR INITIALS FOR YOUR CHOICE:

_____YES, I consent for my child's saliva samples to be saved for future studies of sleep and genetics.

_____NO, I do not consent to saving my child's saliva samples for future genetic studies. Use those samples only for testing melatonin as part of the current study.

Change of Mind/Study Withdrawal:

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

The person in charge of the research study or the sponsor can remove your child from the study without your approval. Possible reasons include if the study investigator thinks it is in your child's best medical interest, if the study ends early, or if new information becomes available that changes the potential risks or benefits of the study. We will tell you about any new information that may affect your child's health, welfare, or choice to stay in the research.

Privacy:

We take your privacy very seriously. Efforts will be made to limit the use and disclosure of your child's personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete privacy. Organizations that may inspect and copy your information include the IRB (Cincinnati Children's Ethics Board) and other representatives of this organization.

To protect your privacy in this research study:

- All non-electronic research information will be kept in locked cabinets at Children's.
- All electronic records will be stored on computers that are protected with passwords.
- Individual data will not be available to anyone not directly associated with the research studies without your written consent.
- All information will be coded by a subject number that is unique to this study (not name, medical record number, or social security number). The master list of subject names and numbers will be kept locked in a separate file in Dr. Beebe's office, and will be destroyed at the end of the study.

A copy of this consent form will be included in your child's medical record, and you will receive a copy of the form for your records. Your child also will be listed in the CCHMC computer system as a research subject.

Although we are not asking about this for our study, if your child happens to tell us about any serious medical or emotional issues they are having, our job is to keep them

safe. We will tell you, as a parent or legal guardian, and give you contact information for providers here at CCHMC who can help.

Return of results:

The tools we will use are research-based. They do not yield information that can be used clinically. As such, you will not get individualized results. However, if you have concerns about how your teen is doing, Dr. Beebe will be available to discuss those concerns and to help you figure out the best next steps (e.g., a clinical evaluation).

AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION FOR RESEARCH

To be in this research study you must also give your permission (or authorization) to use and disclose (or share) your child's "protected health information" (called PHI for short).

What protected health information will be used and shared during this study?

Cincinnati Children's Hospital Medical Center (Cincinnati Children's) will use and share your child's PHI as part of this study. This PHI will come from:

- Your child's Cincinnati Children's medical records
- Your child's research records

The types of information that will be used and shared from these records include:

- Diagnoses and medications
- Reports and notes from clinical and research observations
- If applicable, information concerning HIV testing or the treatment of AIDS or AIDS-related conditions, drug or alcohol abuse, drug-related conditions, alcoholism, and/or psychiatric/psychological conditions (but not psychotherapy notes).

Who will share, receive and/or use your protected health information in this study?

- Staff at all the research study sites (including Cincinnati Children's)
- Personnel who provide services to you as part of this study
- Other individuals and organizations that need to use your PHI in connection with the research, including people at the sponsor and organizations that the sponsor may use to oversee or conduct the study.
- The members of the Cincinnati Children's Institutional Review Board and staff of the Office of Research Compliance and Regulatory Affairs.

How will you know that your PHI is not misused?

People that receive your child's PHI as part of the research are generally limited in how they can use your child's PHI. In addition, most people who receive your child's PHI are also required by federal privacy laws to protect your child's PHI. However, some people that may receive your child's PHI may not be required to protect it and may share the information with others without your permission, if permitted by the laws that apply to them.

Can you change your mind?

You may choose to withdraw your permission at any time. A withdrawal of your permission to use and share your child's PHI would also include a withdrawal from participation in the research study. If you wish to withdraw your permission to use and share your child's PHI you need to notify the study doctor, listed on the first page of this document, in writing. Your request will be effective immediately and no new PHI about your child will be used or shared. The only exceptions are (1) any use or sharing of PHI that has already occurred or was in process prior to you withdrawing your permission and (2) any use or sharing that is needed to maintain the integrity of the research.

Will this permission expire?

Your permission will expire at the end of the study.

Will your child's other medical care be impacted?

By signing this document, you agree to participate in this research study and give permission to Cincinnati Children's to use and share your child's PHI for the purpose of this research study. If you refuse to sign this document your child will not be able to participate in the study. However, your child's rights concerning treatment not related to this study, payment for services, enrollment in a health plan or eligibility of benefits will not be affected.

SIGNATURES

The research team has discussed this study with you and answered all of your questions. Like any research, the researchers cannot predict exactly what will happen. Once you have had enough time to consider whether your child should participate in this research, you will document your permission by signature below. You will receive a copy of this signed document for your records.

_____
Printed Name of Research Participant

_____ _____
Signature of **Parent** or Legally Authorized Representative indicating assent* Date

_____
* If signed by a legally authorized representative, a description of such representative's authority must be provided

_____ _____
Signature of **Study Staff** Obtaining Consent Date