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Circadian Light Exposure Adjustment for Restfulness (CLEAR)

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Consent and Parental Permission to Participate in Research

Study Title: Circadian Light Exposure Adjustment for Restfulness (CLEAR)

Principal Investigator: Lauren Hartstein, PhD

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Sponsor and/or Funder: American Academy of Sleep Medicine, NIH National Heart, Lung, and Blood Institute

Certificate of Confidentiality: This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

If you are a parent of a child that is participating in this study, references to "you" and "your" throughout this document refer to both you and your child(ren).

Summary of the research

This is a consent form for participation in a research study. Your participation in this research study is voluntary. It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to ask questions before making your decision whether to participate.

In this study, we are testing three strategies (adjustment to home lighting, amber-tinted glasses, and clear glasses) to reduce children's evening light exposure in order to improve their sleep and the timing of their biological clock. This study takes place over approximately 5 weeks. After baseline assessments of your child's sleep timing, light exposure, cognition, and circadian rhythms, they will be randomly assigned to one of three interventions to reduce evening light

exposure for two weeks. After the two-week intervention period, we will repeat the baseline measures and interview you about your and your child's experiences with the intervention.

There are no direct benefits to you or your child from participating in this study, although you may learn about your child's sleep patterns and melatonin profile. There are some minimal risks if you and your child take part in this study. Some of the questions on the questionnaires may tap into sensitive areas, and there is a small risk of loss of confidentiality. An alternative to participating is that you can discuss other options for improving your child's sleep with their doctor.

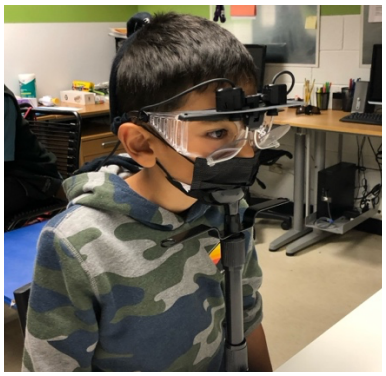
Why is this study being done?
Many young children are exposed to light in the evening hours before bedtime. Children's biological clocks are highly sensitive to evening light exposure, which can delay the timing of the clock and make it harder to fall asleep. The purpose of this study is to test two different strategies to reduce children's evening light exposure in order to improve sleep and circadian timing.

What will happen if I take part in this study?
This study will only be conducted during the academic school year (Sept – June). If you choose to take part in this study, we will use the information you have already provided in the online and phone surveys in the study. Additionally, our research team will provide you directions for completing several questionnaires online. These questionnaires ask about your child's sleep patterns and behaviors. They will take about 30 minutes to complete. You will also complete a form about your child's likes and dislikes to match games and rewards to the child's interests.

We will ask you to complete an optional media release to allow us to use photos or videos of your child participating in the study for lab publicity purposes and in academic presentations to illustrate the study methods (e.g., a picture of a child chewing on a cotton swab to illustrate the methods for collecting saliva samples). The photos/videos will never be published alongside study data. Signing the media release is not required, and you can still participate in the study if you do not want to sign it.

Throughout the study, your child will wear a "watch-like" wrist actigraph and you will complete daily diaries recording your child's sleep times.

During the first two weeks of the study, you and your child will make three brief visits (~1 hour each) to our lab to slowly introduce the procedures used to measure melatonin in saliva. During one of these visits, your child will also complete several iPad tasks measuring their reaction time and cognition. During another visit, we will also measure how your child's pupil size changes when he/she is exposed to two different lights. After sitting in a dimly lit room for 15 minutes, we will measure your child's pupil diameter for 30 seconds in dim lighting, then for 10 seconds as they briefly look at a light box, and then for a 40 second recovery in darkness. After 7 minutes, this procedure will be repeated with a different type of light. In order to take the measurements, your child will wear an eye-tracking device, which consists of 2 cameras and reflectors attached to a pair of glasses (pictured below).



On one evening, you and your child will come to the University of Arizona Center for Sleep, Circadian, and Neurosciences Research. Starting 3.5 hours before their average bedtime, your child will provide saliva samples every 20 or 30 minutes, continuing until 2h past bedtime (12 samples total). Your child gives saliva by "mouthing" a dry cotton roll for 1-2 minutes. These saliva samples allow us to measure levels of the hormone melatonin, which is related to the body's biological clock. Dr. Hartstein has performed over 75 of these assessments with preschool-aged children. The visit will take approximately 7 hours total.

Finally, you will choose 7 days during these two weeks to complete a media diary of your child's screen use. Completion of all daily diaries will take 10-15 minutes each day.

Your child will then be randomly assigned (like drawing names from a hat) to 1 of 3 two-week evening light reduction interventions:

Glasses (Amber-Tinted or Clear): Your child will wear a pair of child-sized glasses for 1 hour before bedtime every night for two weeks. The glasses are either amber-tinted or clear, and block certain wavelengths of light (pictured below). You will also complete a daily diary detailing when the glasses are worn.

Home Lighting Adjustment: We will come to your home and change some of the light bulbs to smart light bulbs, which will be set to automatically become dimmer and redder in the hour before your child's bedtime every night for two weeks.

For every 5 children in the study, 2 will be assigned to home lighting adjustment, 2 will be assigned to wear amber-tinted glasses, and 1 will be assigned to wear clear glasses.

After the two-week intervention period, your child will continue to wear the actigraph, and you will complete the diaries, for one additional week. You will complete the online questionnaires a second time and we will repeat the measurements of your child's cognition (iPad tasks) and salivary melatonin (in-lab evening). Finally, we will conduct a short interview (~30 minutes) with

you (can be scheduled via phone or zoom) to learn about your and your child's experience with the intervention.

How long will I be in this study?
The study will last for approximately 5 weeks.

How many people will take part in this study?
Approximately 60 children and 60 parents will take part in this study.

What benefits can I expect from being in this study?
There are no direct benefits to you or your child from participating in this study. You may learn about your child's sleep patterns and melatonin profile. Your child may enjoy participating in the study activities and receiving personalized attention from the research team. This study will represent the first to experimentally assess the impacts of a light-based intervention on sleep and circadian rhythms in young children and may make a significant contribution to the fields of behavioral sleep medicine and chronobiology. Our findings may represent a first step in developing circadian interventions to support sleep health in early childhood.

What risks, side effects or discomforts can I expect from being in the study?
There are some minimal risks if you and your child take part in this study. Some of the questions on the questionnaires may tap into sensitive areas, which could cause embarrassment or psychological discomfort. You can skip any question you do not feel comfortable answering.

The risks associated with your child wearing the actigraph are no greater than those associated with wearing a wristwatch. Standard procedures for collecting saliva samples with young children will be used. These procedures have been used with children as young as 18-months-old and do not pose any known risks.

It is possible that your child may express discomfort with the study activities. If your child is expressing discomfort with a study activity, the study team will pause the activity and give your child a break and discuss with you next steps. If you request it, we will try to have the child complete the study activity again. If your child still expresses discomfort, you will be able to determine whether to try to encourage your child to complete the activity. If they continue to express discomfort, then the study team will stop the study activity. We will never force a child to continue with a study activity against their will. You will remain with your child at all times during on campus visits and all research assistants have passed a comprehensive background check.

As with any research, there is the risk that your information could be disclosed to someone outside of the research team. However, we are very careful with the information we collect. The section below on confidentiality describes the ways we protect your and your child's information.

What other choices do I have if I do not take part in this study?
Your participation in this study is voluntary. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you, and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The University of Arizona. If you are a student or employee at the University of Arizona, your decision will not affect your grades or employment status.

When may participation in the study be stopped?
Because melatonin is a main measure of this study, your child may be removed from the study if it becomes evident during the training visits that they are not able to provide adequate saliva for samples. You may also be removed from the study for consistently failing to complete study activities (e.g., not wearing the actiwatch or completing the sleep diaries). You may also choose to end participation at any point. Any participant who does not complete the study will receive pro-rated compensation commensurate with the portions of the study already completed (see below).

What happens if I am injured because I took part in this study?
Although this study is low risk, side effects (injury) can happen in any research study. These effects may not be your fault, or the fault of the researcher involved. Known study risks have been described in this consent form.

However, side effects that are not currently known may happen and require care. If you think you have been injured as a result of taking part in this research study, tell the person in charge of the research study as soon as possible. The researcher's name and phone number are listed in the consent form.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

This, however, does not waive your rights in the event of negligence. If you suffer an injury from participating in this study, you should seek treatment. The University of Arizona has no funds set aside for the payment of treatment expenses for this study.

What are the costs of taking part in this study?
There are no anticipated additional costs for you to be in this study, except for your time.

Will I be paid for taking part in this study?
Because this research requires time and effort, your family will receive $400 at the end of the study. This amount is pro-rated for completing each part of the study as follows:

Baseline:
Completing online surveys: $20
Actigraphy: $40
In-lab phase assessment: $80

Intervention:
$50/week for 2 weeks

Post-Intervention:
Completing online surveys: $20
Actigraphy: $40
In-lab phase assessment: $80
Completing qualitative interview: $20
Total: $400

Your child is also frequently rewarded with small “gifts”.

Any payment for participation in a research study is considered taxable income for you. If your payment for this research study or a combination of research studies is $600 or more for all or any dollar amount for undocumented noncitizens in a calendar year (January to December), you will receive the appropriate IRS Form for tax reporting purposes from the university. Please note, if you are an employee of UArizona, any compensation from a research study is considered taxable income.

For any compensation you receive, we are required to obtain identifiable information such as your name, address, and Social Security number for financial compliance purposes. Identifiable information collected for financial compliance purposes will not be linked to your research data.

Will my data or specimens be stored for future research?
Your data will be stored indefinitely (without your name or any identifiable information) for future research. Your data will be stored at the University of Arizona and in the National Sleep Research Resource repository. No specimens will be stored for future research.

Will my specimens be sold for commercial profits?
Your specimens will not be sold for commercial profits.

Will I hear back on any results that directly impact me?
You will have the opportunity to review your child’s actigraphy and melatonin data with the researchers after completion of the study and melatonin assays. You will not receive any other clinically relevant results discovered about your child and/or the general population.

Will Whole Genome Sequencing be done with my specimen?
Whole genome sequencing will not be done with your child’s samples.

Will my study-related information be shared, disclosed, and kept confidential?
Efforts will be made to limit the use and disclosure of your personal information, including research study records, only to people who have a need to review this information. We cannot promise complete secrecy. The information from this research may be published for scientific purposes; however, your identity will not be given out. Your information may be shared or disclosed with others to conduct the study, to comply with regulations, and to help ensure that the study has been done correctly. These other groups may include:

- Office for Human Research Protections or other federal, state, or international regulatory agencies
- The University of Arizona (UA) and the UA Institutional Review Board
- The sponsor and/or funder supporting the study, their agents or study monitors

Signed consent forms will be kept in a locked room in the Sleep and Development Laboratory along with your child’s assigned identification number. All data will be maintained on encrypted, password-protected computers. All questionnaire data will be obtained and initially stored using REDCAP, the University of Arizona’s secure web-based application that supports data capture. Copies of raw data from the questionnaires will later be downloaded and stored on our secure laboratory server, which can only be accessed via our password protected computers. All

collected data will be in association with each subject's identification number and not personal identifiers. The list connecting your name to this identification number will be kept in an encrypted and password protected file. Only the research team will have access to the file. When the study is completed and the data has been analyzed, the list will be destroyed.

Your child's saliva samples will be labeled with the identification number and sent to an external lab, where they will be tested for melatonin levels. The samples will be destroyed after being tested.

There are three exceptions to this confidentiality:

1. *If we see or are told information that makes us reasonably suspect that a child or at-risk adult is being or has been abused, mistreated, or neglected, we will immediately report that information to the county department of social services or a local law enforcement agency.*
2. *If we learn of a serious threat of imminent physical violence against a person, we will report that information to the appropriate legal authorities and make reasonable and timely efforts to notify the potential victim.*
3. *This confidentiality does not include information we may learn about future criminal conduct.*

Who can answer my questions about this study?
For questions about your rights as a participant in this study, or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Human Subjects Protection Program Director at 520-626-8630 or online at https://research.arizona.edu/compliance/human-subjects-protection-program.

If you are injured as a result of participating in this study or for questions about a study-related injury, general questions, concerns, or complaints about the study you may contact Dr. Lauren Hartstein at 520-621-1360 or via email at laurenhartstein@arizona.edu.

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.

Signing the consent form
I have read (or someone has read to me) this form, and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study. I am not giving up any legal rights by signing this form. I will be given a signed copy of this form**.**

Printed name of subject	**Signature of subject**	**Date**

Printed name of person authorized to consent for subject (when applicable)	Signature of person authorized to consent for subject (when applicable)	Date

Relationship to the subject

Name of child

Investigator/Research Staff

I have explained the research to the participant or the participant's representative before requesting the signature(s) above. There are no blanks in this document. A signed copy of this form has been given to the participant or to the participant's representative.

Printed name of person obtaining consent	Signature of person obtaining consent	Date