LOMA LINDA UNIVERSITY

School of Behavioral Health

LOMA LINDA UNIVERSITY
CONSENT TO PARTICIPATE IN RESEARCH

Research Study Title: Understanding the Impact of Melatonin Use on Adolescent Functioning: A Pilot and Feasibility Trial of the Melatonin Adolescent Research Study (MARS)

Principal Investigators: Tori R. Van Dyk, PhD and Sunitha Nune, MD

Contact Information: tvandyk@llu.edu; (909) 558-7142

Parent Legal Name: _____

Child's Name: _____

Key Information for You to Consider

- **Voluntary Consent**. You and your child are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There will be no penalty or loss of benefits to which you or your child are otherwise entitled if you choose not to participate or discontinue participation.
- **Purpose**. The purpose of this research is to learn more about whether and how melatonin supplementation impacts adolescents' sleep, biological circadian rhythm, and daytime functioning.
- **Duration.** It is expected that participation will last 5-weeks during the academic year. Most of the study will be completed from home. Three (3) Friday evening office visits will be required at the end of weeks 1, 3, and 5. Office visits are expected to last for 2 to 3 hours. For those opting in, participation in the in-home saliva collection (to measure dim light melatonin) portion of the study will occur at the end of weeks 3 and 5, and will last 1 hour after your child's bedtime.
- **Procedures and Activities.** For week 1, your child will be asked to continue as normal when it comes to sleep and daytime activity. They will wear a special wristwatch called an "actigraph" that helps track sleep patterns. A daily questionnaire will be completed. For weeks 2 and 3, your child will take either a placebo or melatonin supplement every night. For weeks 4 and 5, your child will take the placebo or melatonin supplement they were not assigned in the previous two weeks. You and your child will attend office visits at the end of weeks 1, 3, and 5 and complete questionnaires regarding your child's sleep and daytime functioning. Weeks 3 and 5 will also include questionnaires on any negative side effects experienced while taking the supplement. If you and your child decide to participate in the in-home saliva collection portion of the study, your child will provide hourly saliva samples while

reclined starting at 5 hours before their typical bedtime and ending 1 hour after their typical bedtime. This will occur twice during the study.

- **Risks.** Potential negative side effects of melatonin supplementation, include headache, dizziness, drowsiness, and nausea. Though melatonin supplements appear to be safe for children for short-term use, it is possible that melatonin supplements could affect hormonal development, including puberty. However, we do not know for sure because of a lack of research. You may experience potential distress, discomfort, boredom, or frustration while completing questionnaires.
- **Benefits**. Your child could potentially experience benefits including: Societal benefits may include learning about how melatonin supplementation impacts adolescents' sleep, biological circadian rhythm, and daytime functioning.
- **Alternatives.** Participation is voluntary and the only alternative is to not participate.

We invite you and your child to participate in a research study being conducted at the Loma Linda University Psychological Research Center by the Departments of Psychology and Neurology at Loma Linda University.

Before you and your child volunteer to take part in this research, the study must be explained to you, and you must be given a chance to ask questions. You should discuss anything you do not understand with the research assistant before you agree to participate. If you choose to participate in the study, you must sign this consent form, which gives permission for you and your child to participate. You will be given a copy of this consent form to keep for your records. The nature of the study, its risks and potential benefits, and other important information are discussed below.

WHY ARE WE DOING THIS RESEARCH STUDY?

We are interested in learning more about whether and how melatonin supplementation impacts adolescents' sleep, biological circadian rhythm, and daytime functioning. Specifically, we will be studying the relationships between melatonin supplementation; sleep (i.e., sleep duration, sleep disturbance, fatigue, dim light melatonin onset); daytime functioning (i.e., mood, emotional regulation, behavior difficulties, physical activity); and any reported negative side effects. We hope that the results of this study will help us better understand the relationship of melatonin supplementation with these physical health, mental health, and social outcomes.

You and your child are being invited to participate in this study because your child is a healthy, typically developing adolescent with self-reported sleep difficulties. Results of this study will allow us to learn more about the potential benefits and risks of melatonin supplementation in a healthy, typically developing adolescent population. Approximately 73 subjects will be recruited to participate at LLU.

WHAT WILL HAPPEN IN THIS STUDY?

If you choose to participate, you and your child will be scheduled for a 5-week study participation period during the academic year. Before your participation period begins, our lab

will mail you all necessary study materials with directions. A research assistant will reach out to you and your child to confirm that you received all study materials and answer any last-minute questions you and your child may have.

For Week 1, your child will continue as normal when it comes to sleep and daytime activity. They will receive a small packet of materials and online links to daily questionnaires to complete and will wear a special wristwatch called an "actigraph" that helps track their sleep patterns without disrupting their sleep at home.

During weeks 2 and 3 your child will continue to sleep at their desired bedtime. They will also be asked to consume either a placebo or melatonin supplement an hour before their desired bedtime. A placebo is a harmless pill that has no effect on the body. The melatonin supplement and placebo come in pill form and can be taken with water. Whether your child receives the placebo or melatonin supplement first will be chosen at random by a random number generator. This study is also a double-blind study, meaning the melatonin or placebo will not be known to the participant or the researcher until the study has ended for all participants. During weeks 4 and 5 your child will take the placebo or melatonin supplement that they were not assigned in the previous two weeks an hour before their chosen bedtime. For weeks 2-5, your child will continue to fill out daily questionnaires.

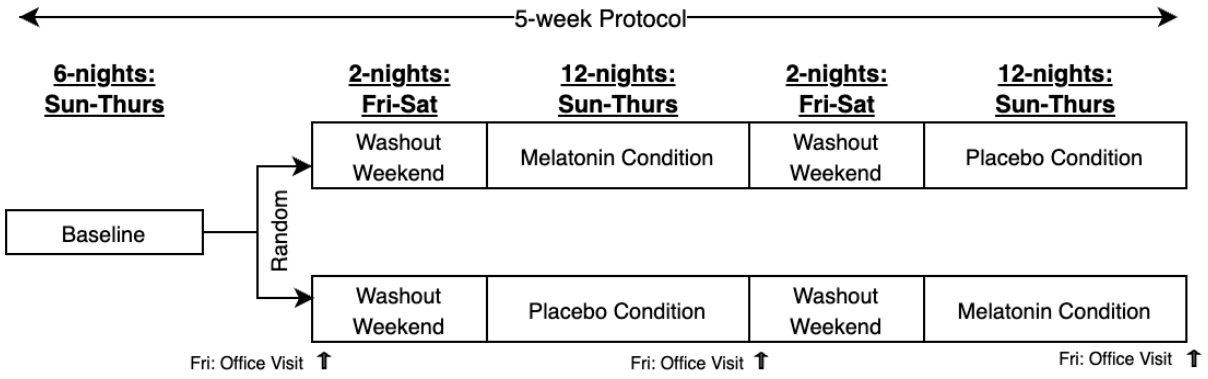
You and your child will attend office visits at the end of weeks 1, 3, and 5. Office visits will be held at Loma Linda University's research space on the Friday afternoon/evenings at the end of weeks 1, 3, and 5. At the first visit, you and your child will meet with a pediatric neurologist to confirm eligibility, as well as a research assistant to review information from the activity monitors. Both you and your child will fill out a series of questionnaires about your child's demographics, sleep, and daytime functioning. Your child will complete a brief cognitive assessment and will be screened for any mental health symptoms. You and your child will also have the opportunity to enroll in the dim light melatonin onset (DLMO) portion of the study at this time (see DLMO section below), as well as have the opportunity to ask any questions you may have about the details of the study. Your child will receive a total of $50 for initial participation (i.e., completion of week 1). We expect the first visit to last 2 to 3 hours.

The two remaining office visits will also last 2 to 3 hours each. Our goal is to see how the placebo or melatonin supplement is affecting your child. Again, we will review information from the activity monitors with you and your child. Both you and your child will fill out a series of questionnaires about your child's sleep and daytime functioning, as well as any notable effects of the placebo or melatonin supplement. At the end of each office visit on weeks 3 and 5, your child will be compensated $100 for a total of $200 across both conditions (i.e., melatonin and placebo). The actigraph watch will be returned at the week 5 office visit.

<u>Dim Light Melatonin Onset (DLMO)</u>
Families will be invited on a first come, first serve basis to participate in the in-home dim light melatonin onset (DLMO) portion of the study. If you and your child are invited and choose to participate in the in-home DLMO portion of this study, the procedure will take place after each of the two office visits on weeks 3 and 5. DLMO is determined by analyzing the amount of

melatonin in saliva. To determine DLMO, your child will be asked to remain reclined in a dimly lit room at home and provide hourly saliva samples. Prior to at-home sample collection, your child will be screened for drugs and alcohol. Only youth with a clean screening may participate in the DLMO study. Your child will be instructed on how to passively drool into a container. They will also be provided an instruction booklet to take home at the end of the 2nd office visit. With your help, samples will be collected hourly starting 5 hours before their typical bedtime and ending 1 hour after their typical bedtime. A phone application will send you reminders with instructions when it is time to collect a sample. Each sample will be stored in your home freezer and brought to our lab the following day. At the end of each of the DLMO saliva collection procedures, your child will be compensated $50 dollars for a total of $100 across both collection time points.

All information collected via the questionnaires, actigraphy, and saliva will be entered into a secure database. Your information will be kept confidential and we will use identification numbers in place of your name and your child's name in the database to maintain confidentiality. A paper (hard-copy) document that links your child's name, birthdate, and their study identification number will be kept in a locked cabinet that is separate from other study data, in a secure location at the Department of Psychology. This linking information will be destroyed upon completion of the study.



WHAT ARE THE POSSIBLE RISKS OF BEING IN THIS STUDY?

We anticipate minimal risks with study participation. Potential negative side effects of melatonin supplementation include headache, dizziness, drowsiness, and nausea. Though melatonin supplements appear to be safe for children for short-term use, there are not many studies on children and melatonin. Additionally, there is not much information on long-term effects of melatonin use in children. Since melatonin is a hormone, it is possible that melatonin supplements could affect hormonal development, including puberty. You may also experience potential distress, discomfort, boredom, or frustration while completing questionnaires. We will provide a list of referrals and recommendations regarding sleep and mood problems for you and your child.

All records and research materials that identify you and your child will be held confidential. Any published document resulting from this study will not disclose your identity without your permission. Information identifying you and your child will only be available to study personnel on a need-to-know basis.

WHAT ARE THE POSSIBLE BENEFITS OF PARTICIPATING?

Previous research on children and adolescents noted improvements in daytime sleepiness, behavioral difficulties, social difficulties, late arrivals to school, and academic achievement following melatonin treatment; your child could potentially experience these benefits. Societal benefits may include a better understanding of whether and how melatonin supplementation impacts adolescents' sleep, biological circadian rhythm, and daytime functioning, which could inform future clinical recommendations and efforts to promote healthy sleep in this population.

WHAT ARE MY RIGHTS AS A SUBJECT?

You and your child's participation in this study in entirely voluntary. You and your child may refuse to participate or withdraw once the study has started. You and your child's decision whether or not to participate or terminate at any time will not affect your current or future medical care or standing with the researchers. You and your child do not give up any legal rights by participating in this study. If at any time you feel uncomfortable, you and your child may refuse to answer questions.

WHAT COSTS ARE INVOLVED?

You are expected to provide your own transportation to and from office visits. Office visits, including meetings with a board-certified neurologist, and all procedure-related materials (e.g., melatonin, placebo, questionnaires, flyers) will be provided at no charge.

IS THERE COMPENSATION FOR PARTICIPATING IN THE STUDY?

Adolescent participants in this study can earn up to $350 for participation. Adolescent participants will receive $50 for completion of the baseline office visit following week 1, $100 for completion of the 2nd office visit following week 3, $50 for completion of the 1st condition DLMO procedure following week 3, $100 for completion of the 3rd office visit following week 5, and $50 for completion of the 2nd condition DLMO procedure following week 5. In order to receive payment, you will be asked to provide your child's home address and/or your child's social security number.

WHAT WILL HAPPEN IF YOU/ YOUR CHILD DECIDED NOT TO CONTINUE THIS STUDY?

Participation in this study is voluntary. You or your child may refuse to take part in or stop taking part in this study at any time. Your decision to participate or not participate will in no way impact your care or the services provided at Loma Linda University Health.

HOW WILL THE INFORMATION COLLECTED BE KEPT CONFIDENTIAL?

Information collected for this study will be kept confidential to the extent allowed by law. Information pertaining to you and your child will be recorded using a unique ID number and will not be associated directly with identifying information such as your name. Information will be

collected electronically unless you would prefer to complete paper measures. All electronic data will be stored on a secure server without identifying information in password protected files. Paper files will be stored in a locked cabinet, in a locked office, within a secured building.

The master list relating your study ID number, name, and date of birth will be available only to authorized personnel on the research team conducting this project. The master-list (hard-copy) document will be kept in a locked cabinet within the PI's locked lab, separate from other study data. This master list will be destroyed upon study completion.

Information from the current study may be presented in aggregate form publicly for scholarly purposes (e.g., journal articles, research presentations, professional posters, etc.). To protect the confidentiality of study participants, neither you, nor your child's identity will be revealed in such presentations. The researchers will disclose voluntarily, and without your consent, information that would identify you or your child as a participant in the research project under the circumstances of suspected abuse and/or neglect of the child. In cases where there is evidence or suspicion of abuse or neglect, a report will be filed with Child Protective Services, as required by law.

WILL THERE BE ANY FURTHER FOLLOW UP?
Currently, there is not planned follow-up; however, with your permission below, you may be contacted by phone, email, and/or mail about participation in a follow-up study.

Initial one of the choices below;

___ I agree to allow the researchers to contact me in the future in the case of a follow-up study.

___ I do not want the researchers to contact me in the future in the case of a follow-up study.

WHO DO I CONTACT REGARDING QUESTIONS ABOUT THIS RESEARCH PROJECT?
The principal investigator, Tori Van Dyk, Ph.D., can be reached by telephone at (909) 558-7142. Please contact the investigator if you have any concerns or complaints about the research. To talk to someone other than the research staff, please contact Loma Linda University Patient Relations at (877) 558-6248 or call (909) 558-4647 or email patientrelations@llu.edu for information and assistance with complaints or concerns about your rights in this study.

SUBJECT'S STATEMENT OF CONSENT
- I have read the contents of the consent form and have listened to the verbal explanation given by the investigator.
- My questions concerning this study have been answered to my satisfaction. This protocol has been explained to my child at a level that they can comprehend and I give permission for my child to participate in the study.
- Signing this consent document does not waive my rights nor does it release the investigators, institution or sponsors from their responsibilities.
- I hereby give voluntary consent to participate in this study.

I understand I will be given a copy of this consent form after signing it.

Signature of Subject (Parent/Guardian)	Printed Name of Subject
Date	

Relationship to child:_____

Signature of Subject (12 years or older)	Printed Name of Subject (12 years or older)
Date	

INVESTIGATOR'S STATEMENT

I have reviewed the contents of this consent form with the person signing above. I have explained potential risks and benefits of the study.

Signature of Investigator	Printed Name of Investigator
Date	