RUSH

CONSENT/AUTHORIZATION FOR PARTICIPATION IN A RESEARCH STUDY

Site Principal Investigator: Stephanie Crowley McWilliam, PhD
Department: Department of Psychiatry & Behavioral Sciences
Address and Contact Information: Biological Rhythms Research Laboratory
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312-563-4784

Protocol Title: Adolescent circadian misalignment: Mechanistic studies of sleep and light

Sponsor(s): National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH)

Name of Participant: _____

Note: If you are a parent, guardian or legal representative of a minor, the terms "you" or "your" refer to the research participant.

Key Information:

You are being invited to participate in a research study. Research studies answer important questions that might help change or improve the way we do things in the future.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

Taking part in this research study is voluntary. You do not have to participate in this study and may choose to leave the study at any time. If you decide not to participate in this study or leave the study at a later time, your health care, benefits, or relationship with Rush University Medical Center will not change or be affected.

The purpose of this study is to determine the effects of light on the timing of the body clock after adolescents have had different durations of sleep. In order to evaluate this relationship very carefully and completely, you will be asked to go to bed and get up on a schedule set by our lab, keep careful records of your sleep and daily activities, and spend about a week in our laboratory.

If you agree to participate in this study, your participation may last up to 2 weeks and you will be asked to complete a "home sleep week" and a "lab week." Throughout the study, you will wear a monitor on your wrist like a watch and a monitor around your neck like a necklace. You will not be allowed to have caffeine, nicotine, alcohol, or recreational drugs throughout the study.

You may be tested for COVID19 when you start the study, and COVID19 mitigation strategies (masking, hand-washing, social distancing, etc) will be followed as necessary even if you are vaccinated for COVID19.

During the home sleep week, you will sleep at home on a sleep schedule that requires you to be in bed trying to sleep for 10 hours. During the home sleep week, you will visit the lab at least once for a a "lab orientation day" (about 8 hours) where you will learn and practice some of the study tests, meet the other study participants (one or two) that you will be spending time with in the lab, meet the study staff, and read the data from your study equipment into our computer to review with you.

During the lab week, you will live in our lab for about a week. You will be assigned a sleep schedule that allows between 5.5 and 10 hours of sleep per night. You may be required to stay awake later than you usually do. You may also be required to wear sunglasses in the evening before you go to bed. You will be asked to provide saliva samples and you will sit in front of light boxes on three mornings while you are in the lab. You will also complete tasks on a computer and paper questionnaires every few days while in the lab.

For a detailed list of study procedures, please see the "*What are the activities you will be doing if you participate in this study?*" section of this consent form.

You will be paid for participating in the study, please see the "Will you be paid for your participation in this study?" section of this consent form.

There are risks to you for participating in this study. In this study, there is a small risk of developing a headache from sitting in front of the bright light boxes. There is a risk of loss of confidentiality if your medical information or your identity is obtained by someone other than the investigators, but precautions will be taken to prevent this from happening. If you become pregnant during the study, it is unknown whether the study procedures would harm the baby. You will be told of any new information that may affect your willingness to participate in this research.

You may not directly benefit from taking part in this study, but we hope that knowledge gained from this study may benefit others your age in the future. This is not a treatment study. Your only other option to participating in this study is not to participate.

Detailed Information: Please review the rest of this document for details about the above topics and additional information you should know before making a decision about whether or not you will participate in this study.

Why are you being invited to participate in this study?

You are being asked to participate in this study because you report good health and are between 14 and 17 years old.

How many participants will take part in this study?
Approximately 115 participants are expected to take part in this study.

What are the activities you will be doing if you participate in this study?
If you agree to be in this study, it will take 2 weeks to complete. During the first week, you will sleep at home ("home sleep week"). During the second week of the study, you will sleep and live in the lab ("lab week"). All procedures are being done for research purposes.

Throughout the study, you will:
- Wear a wrist monitor, which looks like a wrist watch, for the entire study. It will record movements, and tell us when you are awake and when you are asleep.
- Wear a small photosensor (light sensor) around your neck like a necklace. It will measure light exposure. You must make sure it is not covered by your clothing.
- Be asked to not have caffeine, and not use nicotine, alcohol, or recreational drugs, like marijuana.
- Be asked to provide a urine sample at the beginning of the study for a drug/nicotine screen. You may also be randomly drug tested throughout the duration of the study. If the results are positive, you will not be able to continue in the study. We will not share the results with your parent(s)/legal guardian.
- May be asked to complete a test for COVID-19. This will require a small swab be inserted into both of your nostrils. If the results are positive, you will not be able to continue in the study.
- Be asked to follow the recommended COVID-19 mitigation strategies to reduce the risk of transmitting COVID-19 while you are in our laboratory even if you are vaccinated for COVID-19. These strategies include:
    - You and your parent/guardian will be required to complete a COVID-19 symptom screener before entering the lab. This is includes a touchless temperature check and some questions that ask you about how you are feeling, where you have traveled, whether you have been in contact with anyone who has been diagnosed with COVID-19, and whether you have been vaccinated.
    - Anytime you come to our lab, you (and your parent/guardian) must wear a mask that we will give to you. You will not be able to wear a cloth mask when you are in our lab.
    - If you are experiencing a fever, cough, runny nose, new rash, chills, muscle pain, sore throat, or new loss of taste or smell, then you must call our lab. You must not come to the lab.
    - If you have been in close contact with a person who has been diagnosed with COVID-19, then you must call the lab as soon as possible and you must not come to the lab.

During the Home Sleep Week (days 1-7), you will be required to:
- Follow a rigid (strict) sleep schedule, with bedtimes and wake times similar to your usual sleep schedule. You will be required to sleep at home in the dark for 10 hours each night. You will always have the same bedtime and same wake up time, even on the weekends. You must be lying in your bed in the dark trying to sleep during the sleep times. You may not read, use a computer or electronic device, watch television, listen to music, or use the

telephone during this scheduled sleep time. You will not be allowed to sleep at other times outside of your scheduled sleeping hours.

- Call the lab voice mail when you go to bed and after waking up every day. Because the study requires frequent phone contact, it is important that you have a phone to use while in the study.
- Record your sleep times and other events (such as medicine intake) that occur that day while sleeping at home. You may do this using an online form or on paper. If you are female, you will also record whether your menstrual period started or not.
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- Visit the lab to complete a "lab orientation day" to learn and practice some of the study tests (computerized and paper tests), learn how to give a saliva sample, meet the other study participants (one or two) that you will be spending time with in the lab, and meet the study staff. We will also read (download) your study equipment into our computer. This is another time to ask questions about the study if you have any, and for us to provide you with feedback and reminders. You will remain in the lab for about 8 hours this day. You will arrive in the morning or early afternoon and leave in the evening. This will usually occur on a Friday. Food and drink will be provided this day.
- Receive text message reminders on your cell phone for various study related tasks while you are sleeping at home. If you don't have a cell phone, we can lend you a cell phone with pre-loaded cards for texting. We are asking for your permission to contact you using a free text messaging service. We will show you how to stop these text message reminders if you no longer want to receive them. Please check one box below:

  ❑ Yes, it is OK to send me text messages during the study.
  ❑ No, it is not OK to send me text messages during the study.

  Parent Initial _____ Date_____

  Subject Initial _____ Date _____

During the <u>Lab Week</u> (days 8 – 14):

- You will remain in the lab the entire time.
- You will have your own private bedroom.
- Food and beverages will be provided during this time, but some foods that could interfere with the study (e.g., caffeine, bananas, and chocolate) will not be allowed.
- You will complete a <u>lazy boy session</u> on day 8. During a lazy boy session you will be asked to stay awake in dim red light in a lazy boy recliner chair for no more than 13 hours. You will provide a saliva sample (less than ½ teaspoon of saliva) every 30 minutes by rolling a small (1 x 4 cm) cylinder of dental cotton around in your mouth. You will provide no more than 25 saliva samples during the first lazy boy session. Your saliva will be tested at a later time to determine how much melatonin is in your body. This will tell us what time it is in your brain. During the lazy boy session, you can watch T.V. and movies that have been approved by your parent or legal guardian. To follow current public health guidelines, the recliners will be at least 6 feet apart from one another. As an added precaution, "sneeze guards" (see-through dividers) will be set up between each reclining chair. After the lazy boy session is over, you will sleep in our laboratory in your own private bedroom. We will tell

you when it is time to go to bed and when to wake up. We may ask you to take a nap the next day (day 9).

- On lab nights 9 and 10, you will be assigned a sleep duration that is between 5.5 and 10 hours long. You will be randomly assigned to a sleep duration group by chance (like a coin toss). You and the study doctor cannot choose your sleep duration group. You will have an equal chance of being assigned to one of the groups. We will tell you what sleep duration group you are in before you arrive. We will put you to bed at your usual time (like in the home sleep week) or we will put you to bed up to 4.5 hours later than your usual time. You will wake up at your usual time. Therefore, you may or may not get less sleep than you are used to.
- On lab nights 11, 12, and 13, you will have the same amount of time to sleep as nights 9 and 10 (between 5.5 and 10 hours). On these nights, however, your sleep schedule will move earlier each night by a few hours. When you wake up on the next day, you will sit in front of light boxes with fluorescent bulbs for 1.5 to 2.5 hours on each morning. The lights will produce bright light that is brighter than most indoor light, but not as bright as being outside on a cloudy day. Light boxes are safer than sunlight because they do not contain ultraviolet (UV) light. There are no known harmful effects from light of this intensity, but rarely people experience headaches.
- In the few hours before you go to bed each night in the lab, you may be required to wear sunglasses. The glasses we give you will block out different types of light from your eyes. We will provide the glasses to you and tell you the exact times that you need to wear them. You will begin wearing the glasses each evening close to your usual bedtime. You will be able to see a television, computer, or other screen while you are wearing the glasses. We will fit the glasses to your head and help you adjust the glasses to be as comfortable as possible.
- On lab day 14, you will complete a second lazy boy session. This lazy boy session is exactly like the one described above on day 8, except that it will be longer. The second lazy boy session will be no more than 16 hours. You will provide no more than 31 saliva samples. After the second lazy boy session is over, you will sleep in our laboratory in your own private bedroom. We will tell you when it is time to go to bed. You and the study doctor will agree on a good time for you to wake up the next morning and go home.
- You will complete performance tasks throughout the lab week. You may also be asked to complete some questionnaires that ask you how you are feeling every once and a while when you are in the lab.
- You will be required to wear a mask while you are in the lab except when you are providing a saliva sample, eating or drinking, and sleeping. We will provide you with a new mask each day. Staff will also be wearing a mask, face shield and gloves throughout the entire lab night.

Will you be contacted about participating in future research?
If you agree, we may contact you after your participation in this study about participating in future research. Please initial and date one of the following options:

_____ _____ Yes, I agree to be contacted about future research.
Initials Date

_____ _____ No, I do NOT agree to be contacted about future research.
Initials Date

What are the risks and discomforts of participating in this study?
Side effects, risks, and/or discomforts from participation in this study are minimal, but may include:

- Headache when sitting in front of the light boxes;
- Sleepiness or stronger emotions due to getting less sleep than usual in the lab;
- Feeling uncomfortable while you briefly undress and are examined for puberty staging by our pediatric physician.

There is no known risk to wearing an activity monitor or light sensor, or using cotton swabs to provide a small saliva sample. There may be other risks that may happen that we cannot predict.

While we are following all of the recommended COVID-19 safety precautions including screening all visitors, limiting contact between research staff and participants as much as possible, using personal protective equipment, and disinfecting touched surfaces/common shared areas between uses, there remains an inherent risk of infection.

What are the reproductive risks of participating in this study?
Women
If you become pregnant during the study, it is unknown whether the study procedures would harm the baby. You are responsible for using an effective birth control method such as birth control pills, barrier method (such as condoms or diaphragms), intrauterine device (IUD), hormone implants while you are taking part in this study. A pregnancy test will not be required. If you become pregnant, you must notify the study doctor immediately. We will not tell your parent or guardian if you become pregnant.

What if there is new information that may affect your decision to participate in this study?
During this study, you will be told about important findings (either good or bad), such as changes in the risks or benefits of participation in the study or new choices to participation that might cause you to change your mind about being in the study. If new information is shared with you, you may be asked to sign a revised consent form in order to continue participating in this study.

Can you leave or be removed from this study?
You have the right to leave a study at any time without penalty. For your safety, however, you should consider the study doctor's advice about how to leave this study. If you leave this study before the final study visit, the study doctor may ask you to complete the final steps. You may stop the study immediately, but must return the study equipment.

The researchers and sponsor also have the right to stop your participation in this study without your consent if:

- They believe it is in your best interests;
- You do not follow the instructions;
- The study is cancelled for any reason.

What about confidentiality of your medical information?

This authorization is voluntary. Rush University Medical Center and its affiliates ("Rush") will not withhold or refuse your treatment, payment, enrollment, or eligibility for benefits if you sign this authorization. You do not have to sign this authorization, but that means that you cannot be in the study or receive study-related treatment.

By signing this document, you voluntarily authorize (give permission to) Dr. Stephanie Crowley McWilliam, her study team, and other Rush personnel involved with the conduct and review of this study (which may include off-site personnel) to use or disclose (release) health information that identifies you for the study described in this document.

During the study, Dr. Stephanie Crowley McWilliam and her study team will collect Protected Health Information (PHI) about you for the purposes of this research. PHI is your health information that includes your medical history and new information obtained as a result of this study. Some of this information will come from your medical record.

The health information that Rush may use or disclose for this research includes:

- Melatonin levels in your saliva;
- Sleep/wake (activity) patterns measured from the wrist monitor;
- Light/dark patterns measured from the light sensor necklace;
- Your puberty stage.

Dr. Stephanie Crowley McWilliam's study team may share your health information and the results of your study-related procedures and tests with people outside of Rush who assist with the conduct and review of this study. The persons who receive your health information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, but only if permitted by the laws governing them. Your health information described above may be used or disclosed to:

- Researchers at SolidPhase, Inc who will analyze your coded saliva samples for melatonin (they will only receive your code name, not your real name);
- Katherine Sharkey, MD of the Warren Alpert School of Medicine at Brown University who will monitor study safety and the progress we are making on data collection;
- The study Sponsor, *National Heart, Lung and Blood Institute (NHLBI)*, and its representatives;
- Monitoring agencies such as the Food and Drug Administration (FDA), the National Institutes of Health (NIH) and the Rush Institutional Review Board (IRB).
- Researchers at LabCorp, Inc. will analyze your nasal swab sample for SARS-CoV-2 (the virus that causes COVID19).

While you participate in the study you will have access to your medical record, but Dr. Stephanie Crowley McWilliam is not required to release to your study information that is not part of your medical record. Rush is required by law to protect your health information, and study records that identify you will be kept confidential. The results of study tests/procedures performed as part of this study may become part of your medical record. Any study information in your medical record will be kept indefinitely. Your identity will not be revealed on any report, publication, or at scientific meetings. Audio recordings from performance tests will be stored on our password protected server until the data are verified and data analysis is complete at which point the audio files will be deleted.

You have a right to inspect and copy the information to be disclosed with this authorization and you may obtain a copy of the information by contacting the office listed above.

If you no longer want to be in the study and do not want your future health information to be used, you may change your mind and revoke (take back) this authorization at any time by writing to Dr. Stephanie Crowley McWilliam at 1645 W Jackson Blvd, Suite 425 Chicago IL 60612. If the authorization is revoked, you will no longer be allowed to participate in the study and previously authorized individuals/entities may still use or disclose health information that they have already obtained about you as necessary to maintain the integrity or reliability of the current study.

This authorization is valid for the entirety of this research study. It will expire upon completion of the study or if you revoke (take back) the authorization.

If you withdraw from this study, the data already collected from you may not be removed from the study records. The study doctor and/or study team may ask you whether they can continue to collect follow-up data on you. If follow-up information will be requested, you will be asked to sign a separate consent form before this information can be collected.

Records of participation in this study will be maintained and kept confidential as required by law. You will be given a special code name so that all of your data is linked to a code name and not your real name.

The Rush Institutional Review Board (IRB) will have access to your files as they pertain to this research study. The IRB is a special committee that reviews new and ongoing human research studies to check that the rules and regulations are followed regarding the protection of the rights and welfare of human participants.

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.

Certificate of Confidentiality

To help us protect you and the information we will be collecting from you, this study has obtained a Certificate of Confidentiality by the U.S. government. This Certificate means that researchers cannot be forced, even by courts or the police, to disclose any information about you.

The Certificate does not stop you from disclosing, or agreeing in writing to allow researchers to disclose, information about you. For example, if you would like an employer or insurer to know something about you that is documented in this study, you can write and sign a statement telling the researchers it is okay to give your employer or insurance company information.

For the protection of your privacy, this research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). The researchers may not disclose or use any information, documents, or specimens that could identify you in any civil, criminal, administrative, legislative, or other legal proceeding, unless you consent to it. Information, documents, or specimens protected by this Certificate may be disclosed to someone who is not connected with the research:

(1) If there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases);
(2) If you consent to the disclosure, including for your medical treatment;
(3) If it is used for other scientific research in a way that is allowed by the federal regulations that protect research participants;
(4) For the purpose of auditing or program evaluation by the government or funding agency.

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. Please contact the investigator for more information on how to provide this consent.

If you disclose actual or suspected abuse, neglect, or exploitation of a child, or disabled or elderly adult, the researcher or any member of the study staff must, and will, report this to Child Protective Services (such as the Department of Family and Human Services), Adult Protective Services, and/or the nearest law enforcement agency.

What are the costs to participate in this study?

There are no costs to you for participating in this research.

Will you be paid for your participation in this study?

You will be paid $975 after successful completion of this study. Successful completion includes: 1) you wear the study equipment (wrist monitor and/or light sensor) correctly, fully complete the daily sleep and event records, and leave daily telephone messages during the home sleep part of the study; 2) you come to the lab appointments so that we can look at your daily records, activity monitor data, and light sensor data; 3) you complete the lab orientation day; and 4) you complete the lab week. Your check will be processed after all your forms are received and all of your equipment (wrist monitor and light sensor) is returned. Your check will arrive by mail within 4 weeks of completion of the study.

We will pay for parking in our attached garage when you come to our laboratory.

We will deduct $5 from your final payment for each missed phone call and each missed morning

or bedtime sleep log during the home sleep part of the study.

Unless you complete the entire study, we cannot use your data. Therefore, if you leave the study, you will be paid $10 for each day completed. If we have to drop you from the study because you did not follow the rules (such as you take the activity monitor off your wrist, you are late for the lab week, you fail a drug/nicotine/alcohol screen, you leave during the lab week, or you have incomplete daily records), then you will be paid $10 per day completed. If we have to drop you for reasons that are not your fault (such as equipment failure), then you will be paid $20 per day completed. If you are dropped from the study, you will not lose money for missed phone calls.

We must report your payment to the Internal Revenue Service. We will collect your social security number at the beginning of the study for reporting purposes.

What if you are injured as a result of your participation in this study?
If you get ill or injured from being in the study, Rush University Medical Center will help you get medical treatment. You should let the study doctor know right away that you are ill or injured. If you believe you have become ill or injured from this study, you should contact Dr. Stephanie Crowley McWilliam at telephone number 312-563-4783.

You should let any health care provider who treats you know that you are in this study. If you do seek medical treatment, please take a copy of this document with you because it may help the doctors where you seek treatment to treat you. It will also provide the doctors where you seek treatment with information they may need if they want to contact your study doctor.

You or your health insurance plan will be billed. No money has been set aside to pay the costs of this treatment. Health insurance plans may or may not cover costs of research-related injury or illness. You should check with your insurance company before deciding to participate in this research study. Costs not covered by insurance could be substantial.

Rush University Medical Center has no program for financial compensation or other forms of compensation for injuries which you may incur as a result of participation in this study.

By signing this form, you are not giving up any legal rights to seek compensation of injury.

Who can you contact for more information about this study?
Questions are encouraged. If there are any questions about this research study or if you experience a research related injury, please contact the staff at the Biological Rhythms Research Lab at 312-942-9991 or the study director, Dr. Stephanie Crowley at 312-563-4783 or email the study team at sleep_study_2@rush.edu.

Who can you contact if you have concerns about your rights as a study participant?
Questions about the rights of research participants may be addressed to the Rush University Medical Center Office of Research Affairs at 1-800-876-0772.

What are your rights as a study participant?
Taking part in this study is voluntary. If you choose not to participate in this study or to leave the

study at any time, your health care, benefits or relationship at Rush University Medical Center will not change or be affected.

If you choose to leave this study and you do not want any of your information to be used, you must inform Dr. Stephanie Crowley McWilliam in writing at the address on the first page. Dr. Stephanie Crowley McWilliam may still use your information that was collected prior to your written notice.

SIGNATURE BY THE PARTICIPANT AND THE PARTICIPANT'S LEGAL REPRESENTATIVE:

By signing below, you are consenting to participate in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily to you by the study staff. You do not waive any of your legal rights by signing this consent form. You will be given a signed copy of this consent.

Name of Participant	Signature of Participant	Date of Signature

Minor Assent	Date of Signature

Parent, Guardian or Legal Representative's Signature	Date of Signature

SIGNATURE BY THE INVESTIGATOR/INDIVIDUAL OBTAINING CONSENT:

I attest that all the elements of informed consent described in this consent document have been discussed fully in non-technical terms with the participant and the participant's legally authorized representative. I further attest that all questions asked by the participant and the participant's legal representative were answered to the best of my knowledge.

Signature of Individual Obtaining Consent	Date of Signature

SIGNATURE BY WITNESS/INTERPRETER:

I observed the signing of this consent document and attest that, to the best of my knowledge, the person signing the consent form is the participant and the participant's legally authorized representative and the person signing the form has done so voluntarily.

Name of Witness/Interpreter

Signature of Witness/Interpreter	Date of Signature

SIGNATURE OF THE PRINCIPAL INVESTIGATOR:

I attest that I am aware of the enrollment of this subject in the study discussed in this consent document.

Signature of the Principal Investigator	Date of Signature