Title: Neuro-affective Response to Light in Depressed Adolescents and Young Adults

NCT Number: NCT05712772

Date: 11/20/2027

STUDY NAME:	Depression in Adults and Youth Light Study (DAYLight)
PROJECT DIRECTOR	**Adriane Soehner, PhD** Telephone: 412-246-6551 Email: soehneram2@upmc.edu
OTHER KEY TEAM MEMBERS:	Kathryn Roecklein, PhD; Henry Chase, PhD
SOURCE OF SUPPORT:	National Institute of Mental Health

KEY INFORMATION: You are being asked to take part in a research study. Research Studies include only people who choose to take part. The study team members will explain the study to you and will answer any questions you might have. You should take your time to make a decision.

- **Purpose of the research**: Light can have a profound impact on mood. We are conducting this study to learn more about how age and individual differences in retinal light sensitivity impact the effect of light on emotional brain function in adolescents and adults. We hope that our findings will help us understand how age, light, sleep, and brain function interact to impact mood, so that we can optimize light therapy treatments in depression.
- **Overview of study procedures**: This study has the following phases:
  - A baseline appointment for written informed consent, interview, and questionnaires
  - A 7-day home-based assessment of activity, light, sleep, mood, and behavior while keeping a stable sleep schedule
  - One approx. 7-hour visit to our lab at Western Psychiatric Hospital. The lab visit includes interviews, questionnaires, computer tasks, a brain scan, and pupillometry recordings.
  - Optional 14-days using bright light glasses in the morning and completing questionnaires
- **Who is being asked to participate in this research study?** You are being asked to participate because you expressed an interest in this study, and because the phone or web screening process suggested that you might qualify. We plan to enroll approximately 40 adolescents between 12-17 years-old and 40 young adults between 18-30 years-old. We plan to enroll males and females.

- **The most common risks** related to study procedures include emotional discomfort during the clinical interview; stress, fatigue and/or boredom when completing tasks during the lab visit or during the fMRI scan; discomfort from the loud noises of the fMRI scan; and the detection of a previously unrecognized psychiatric condition is possible.
- You will derive no direct benefit from participation in this study other than the knowledge that the information gained in this study may help others in the future.
- Your de-identified research information and may be shared with investigators conducting other research.

QUESTIONS ABOUT THE STUDY: If you have any questions about your rights as a research subject or wish to talk to someone other than the research team, please call the University of Pittsburgh Human Subjects Protection Advocate toll-free at 866-212-2668. You can contact the study investigator if either of you have any questions about the study, concerns, or complaints. Contact the Project Director, Dr. Soehner, or the project coordinator at sleepneuro@upmc.edu.

OVERVIEW OF STUDY PROCEDURES

Stage	Where	Duration	Purpose	Associated Activities
Initial Evaluation (Consent and eligibility screening)	Western Psychiatric Hospital or home (via Teams or Zoom)	3-4 hrs	To see if you are eligible for the study	• Sign consent • In-person or remote interviews • Questionnaires • Receive training to use the wrist activity monitor and smartphone-based sleep diary for use in the 7-day home-based sleep assessment
Home Monitoring (sleep/activity tracking)	At home	7-days	To track sleep, mood & behavior in daily life	• Wearing wrist activity and light monitor • Completing daily smartphone-based surveys
Lab Visit (Weds/Fri)	Western Psychiatric and UPMC Presbyterian Hospitals	~7 hrs	To assess brain and eye responsivity to light	• Overview of procedures • Complete saliva alcohol, urine drug, pregnancy tests • Questionnaires and computer tasks • Heart rate and activity tracking • Complete fMRI scan • Complete pupillometry
Optional Bright Light Protocol	At home	14 days	To see if bright light helps	• Wear bright light glasses in the morning for 20-30min after waking up, get up at the approx. the same time each day

			mood and sleep	• Complete brief daily online surveys • Complete questionnaires after 7 and 14 days of trying the bright light glasses

Initial Evaluation Visit (Eligibility Screening and consent visit)
This visit will take place at Western Psychiatric Hospital at the University of Pittsburgh or remotely via videoconference technology such as Teams or Zoom. This visit will take approximately 3-4 hours. During this visit, a member of the research team will interview you about your sleep, psychiatric history, drug and alcohol use, and other problems you may have experienced. You will also be asked to fill out several questionnaires about your sleep, mood, feelings, and medical history. A member of our research staff will be available to answer any questions you may have about these questionnaires. At the time of the interview, we will re-explain in detail both the interview process and the procedures involved for the rest of the study (also described below), and you will have an opportunity to ask any questions before getting started. If you are using a photosensitizing medication, we may also ask you to confirm with a physician that exposure to bright blue light will not cause an adverse reaction prior to proceeding in the study. Throughout this entire process, you will not have to answer any questions that make you uncomfortable. The interview portion of the visit will take about 1-2 hours.

If the screening interview suggests that you may have a psychiatric, substance use, or sleep disorder, this information will not be shared with you. The presence of such a disorder may make you ineligible for the study. Information about you will only be shared in the event there is a concern of harm to you or someone else. No other information about you will be shared unless we first receive your permission. Referral for treatment services may be provided upon your request.

If you qualify for the study at the end of the interview and wish to participate, we will schedule a time to complete the rest of the study. We will also provide you a wrist activity monitor and smartphone (unless you have your own) for use in the study. Finally, we will also review the lab visit procedures and set a sleep schedule for your home monitoring week.

If you request to do so, Visit 1 may be split into 2 separate sessions. You will receive a portion of the compensation for this visit after the first session, and the rest of the compensation after the second session.

Home Monitoring
For the week prior to your lab visit, you are asked to keep a regular sleep/wake schedule such that you go to bed within 30 min of a target time, arise within 30 min of a target time, and have approximately eight hours in bed each night. For example, if your target bedtime is 11 PM, try to go to bed between 10:45 PM and 11:15 PM. Adherence will be monitored through a daily sleep log and wearing an actigraph. The sleep log is a daily online survey that asks a set of questions (approx. 5 minutes). The activity monitor is a wristwatch-like device that tracks your activity level, which can be used to estimate

when you are asleep or awake. The activity monitor is water-resistant and can be worn continuously. If you do not maintain a regular sleep/wake schedule, you cannot enter the sleep lab for study and you will be rescheduled or excluded from further study.

If the Lab Visit occurs more than 1.5 months (~45 days) from the Initial Evaluation Visit, portions of the screening interview will be repeated to confirm continued eligibility.

Lab Visit

At the end of the 7 days of home monitoring, you will come into our research lab, located on the 13th floor of Western Psychiatric Hospital (WPH). You will be provided with regular snacks and meals throughout the lab visit.

Lab visits will start in the morning, around 8:30am. We ask that you refrain from smoking and alcohol intake within 24 hours of entry into the lab and abstain from caffeine the day-of the lab visit. After arriving at our lab, you will be asked to complete a saliva alcohol test, urine drug screen, urine pregnancy test (post-menarchal females only) and questionnaires. If the result of the saliva alcohol, urine drug (except cannabis), or pregnancy test is positive, you may be ruled ineligible from the study. We will also collect your vitals, including blood pressure, heart rate, and temperature.

You will also be asked to return the wrist activity monitor. Your sleep will be reviewed to ensure adherence to the sleep schedule. If your sleep schedule deviates too far from the agreed-upon sleep schedule, you may be rescheduled or ruled ineligible from the study.

After completing drug/alcohol and sleep screening, you will be in dim light (5 lux) while completing questionnaires and interviews about mood, sleep, and alertness. Next, a brain scan (structural and functional magnetic resonance imaging) will take place in the at the Magnetic Resonance Imaging Research Center (MRRC). You will wear light blocking goggles while in transit from lab in WPH to the MRRC. The brain scan will last 1.5 hours. During the brain scan, you will be exposed to blue light, red light, or darkness while resting or while completing a computer task where you can win money. After the brain scan, you will return to WPH and sit in dim light for a brief interval while completing questionnaires. Finally, you will complete pupillometry to assess light sensitivity. The visit will end with a debrief session.

Throughout the protocol, you will be asked to complete research procedures, as described below. Please note that study results are not interpretable on an individual basis and will not be shared with participants, with one exception noted below.

- **Questionnaires, Computer, and Behavioral Tasks:** At various times throughout the lab visit, you will complete questionnaires, behavioral, computer-based tasks multiple times to measure your thinking, mood, movement, and alertness. You will have opportunities to take breaks.
- **Pupillometry:** Light is an important cue that sets our biological clock. We will measure your pupil response to light flashes to assess circadian photoreceptor sensitivity to light using a pupillometer. After adjusting to the dark, participants

watch (eye-safe) standardized red and blue wavelength light stimuli in a pupillometer.

- **Functional MRI:** Study staff will escort you to the Magnetic Resonance Research Center (MRRC) at UPMC Presbyterian for an fMRI scan. Before, during, and/or after the scan, you will complete tasks about winning money. The scan will last approximately 90 minutes. You will be familiarized with the MR scanning environment by a tour of the facilities. You will also be given the option of going in an MRI simulator (a plastic replica of the actual MRI scanner) in order to further familiarize yourself with the scanner. Prior to the scan, MRRC staff will verbally screen you about any metal in your body. For this visit, please avoid wearing clothing with metal pieces, such as zippers or underwire, so you are prepared for the scan. During the actual scan, you will be asked to perform tasks on a computer. While completing the tasks, we will record your brain activity using a procedure called functional magnetic resonance imaging (fMRI)—a technique that locates where certain functions occur in the brain. The fMRI scanner is FDA approved. As with traditional MRI, you will lie on a table that slides into the scanner's imaging space so brain images can be recorded for study. Because the noises produced by the scanner are loud and may cause discomfort, all participants must wear earplugs during the MRI scan; disposable earplugs will be provided for you. A staff member will be in constant contact with you throughout the procedure, and the scan can be stopped at any time should you be uncomfortable or are unable to tolerate the procedure. *Please note that the brain activity patterns collected with functional MRI are not interpretable on an individual basis, and can only be seen across large groups of participants. For this reason, information from your individual scan will not be shared with you. During the structural MRI, if the MRI technologist notices an adverse finding, the Principal Investigator will be notified, and the MRRC's medical director will review the scan. Any findings of medical significance found during the structural MRI will be shared with you, and forwarded to your personal physician if you provide written authorization to do so. These scans are conducted for research purposes and not medical purposes; scan results are not read by a neurologist, and findings of medical significance may not be detected.*

If portions of the study protocol are not completed, we may ask you back to the lab. If this happens, sleep monitoring and questionnaires will be repeated. Compensation will be $16 per hour..

Optional Bright Light Protocol

Morning bright light therapy can help mood, alertness, and sleep. In this optional part of our protocol, participants will use bright light glasses (Luminette 3, Lucimed SA, Villers-le-Bouillet, Belgium)
in the morning, every day, for 14 days. We are interested in learning whether bright light glasses are an easier alternative to a bright light box.





If you chose to complete this optional protocol, after orientation with a research team member at your lab visit, you will be asked to follow several procedures intended to help mood, sleep, and alertness on a daily basis. The procedures will include:

(1) maintaining a regular wake-up time (plus or minus 1hr, *including on weekends*)
(2) morning bright light (wearing bright light glasses for 20-30 minutes after getting up in the morning)
(3) a 2-minute daily survey to report wake up time, sleep quality, duration the glasses were worn, mood, and alertness.

After 7 days and 14 days, you will complete questionnaires about mood, alertness, and their experience wearing the bright light glasses. These questionnaires take < 10 minutes.

Possible risks, side effects, and discomforts of study

As with any experimental procedure, there may be adverse events or side effects that are currently unknown and certain of these unknown risks could be permanent, severe, or life-threatening. Those that are known are listed in the table below.

Procedure	**Expectancy of Risk**	**Measures taken**

Questionnaires, sleep diary, actiwatch, pupillometry, and psychological evaluation	Common: Becoming upset, bored, anxious, or embarrassed by the personal nature of the questions; detection of a previously unknown psychiatric problem; skin irritation due to Actiwatch, physical discomfort due to pupillometry	If the participation is too stressful for these reasons, you may discontinue your participation in the study, either temporarily or permanently; referral to a provider will be provided if indicated; participants can remove watch if skin is irritated
fMRI scan	Rare: Hearing discomfort, claustrophobia, metal in body attracted to the magnet. Lightheadedness when you first sit up after lying in the MRI machine. No known risk to females who are pregnant	You will be provided ear plugs, as well as the opportunity to enter the MRI simulator. Both our staff and the MR center staff will have asked screening questions about possible metal in your body.
Data collection throughout study	Rare: Breach of confidentiality—individuals outside of study team may learn of an individual's participation and data collected for the study about that individual Breach of confidentiality – text messaging and audio recording.	All data will be coded exclusively with study ID numbers. Only the people who need to know for research purposes will know your name. Identifiable data will only be available to study staff. Study materials will be stored in a locked cabinet in a locked office, and computer files will be password protected.
Bright light exposure	Common: Headache, eyestrain, nausea and agitation Rare: Mania (only in individuals with bipolar disorder)	Individuals with diagnosed bipolar disorder are not eligible for this study. Although most side effects resolve on their own, your teen may discontinue his/her participation in the study if side effects become too burdensome

Text Messaging

Over the course of the study, members of the study team may contact you via secure UPMC office phone lines, cell phones, or email accounts configured to utilize the available privacy and encryption settings. Communication may include information related to appointment scheduling or appointment reminders. You will also complete brief daily questionnaires using text messages or a website that are sent to a study database. Messages of this nature exchanged with the study messaging service or study staff may potentially contain sensitive and/or identifiable information.

While our devices and accounts are secure, it should be noted that the calls, emails, and text messages that you send from your personal devices may not be encrypted or secure. Therefore, it is important to understand that your response may not be protected, and it is possible that it may be viewed by others. Depending on your cell phone carrier or email provider, even if you delete the message(s) from your device, your carrier/provider will retain those messages for an extended period of time. Additionally, depending on your specific device or carrier, copies of those messages may be stored on multiple devices and/or related cloud storage services. In the rare case where a message is intercepted during transit, only the question or answer will be revealed and never both. The texting service we use is compliant with privacy law (Health Insurance Portability and Accountability Act, HIPAA), and all messages from the texting service database are deleted immediately after processing. Others may view text conversations that are stored on your phone. You should delete messages from your phone if you are at all concerned about others reading them.

What are possible benefits from taking part in this study?
You will not directly benefit from participating in this research. Knowledge gained from this study may contribute to the scientific community and society at large may benefit from the information gained.

If I agree to take part in this research study, will I be told of any new risks that may be found during the course of the study?
You will be promptly notified if, during the conduct of this research study, any new information develops which may cause you to change your mind about continuing to participate.

Will I be paid if they take part in this research study?
Participants may earn up to $340 and light therapy glasses for completion of all main and optional study procedures. Compensation for main study procedures is up to $300, including the consent evaluation, home monitoring, and lab visit. Compensation for the optional study procedures is up to $40 plus bright light glasses. You will receive compensation for your time and effort for every post-screening component of the research study in which you participate.

All compensation is taxable income to the participant regardless of the amount. If a participant receives $2000 or more in a calendar year from one organization, that organization is required by law to file a Form 1099 – Miscellaneous with the IRS and provide a copy to the taxpayer. Individuals who do not provide a social security number may still participate in the research, but the IRS requires that 24% of the payment be sent by the institution to the IRS for 'backup withholding;' thus you would only receive 76% of the expected payment.

Study Component	Compensation
Consent &Initial Evaluation	**$30** **(If split: $10 after the first visit, $20 after the second visit)**
Home Monitoring	**Up to $60** • $3 per day for completing AM sleep log, PM sleep log, and wearing the activity watch ($3 x 7days = $21 total) • $2 per day for adhering to their sleep schedule ($4 x 7days = $28 total) • $11 bonus for complete sleep tracking and sleep schedule adherence
Lab Visit	**Up to $210** • $190 for completion of the full lab visit • Up to $20 in winnings for a computer task completed during the brain scan • Compensation for repeated portions of the protocol will be prorated on an hourly basis. Compensation will be $16 per hour.
Optional Bright Light Glasses	**Up to $40 and bright light glasses** • $1 per day for completing a daily morning survey plus a $6 complete data bonus ($1 x 14 days, plus $6 bonus = $20 total) • $10 for questionnaires at the end of 1 week • $10 for questionnaires at the end of 2 weeks

How will these payments be made?

UPMC utilizes electronic payment as a secure payment method to disburse research study compensation and/or expense reimbursements. You will be required to provide either an email address or a cell phone number that can receive a text message in order to receive the reimbursement(s). The study staff will discuss payment options with you and answer any questions you may have about the reimbursement(s). Payment through the University's approved payment system may involve electronic communication via text and/or email. Text and email messages may not be encrypted or secure during their transmission or storage and it is possible they could be intercepted and used by others not associated with this study. The study team will discuss the payment options with you.

Will I be charged for any portions of this research study?
Neither you nor your insurance provider will be charged for the costs performed only for the purposes of this research study. If we offer any treatment referrals as a result of the diagnostic interview, you or your insurance would be responsible for any costs associated with subsequent treatment. However, you are not obligated to pursue said treatment referrals.

Who will pay if I am injured as a result of taking part in this study?

If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation.

Who will know about my participation in this research study?
The research staff will keep all information obtained from this research as confidential (private) as possible. The University of Pittsburgh requires that all research records be kept for at least seven years after the study ends, and study data on minors must be retained until they at least turn 23. All paper records related to your involvement in this research study will be stored in a locked file cabinet. All computerized database records related to your involvement in this research study will be stored with password protection. Your identity on these records will be indicated by a case number rather than by your name, and the information linking these case numbers with your identity will be kept separate from the research records. Although every reasonable effort has been taken, confidentiality during Internet communication activities cannot be guaranteed and it is possible that additional information beyond that collected for research purposes may be captured and used by others not associated with this study. The information obtained in this study may be published in medical journals, but your identity will not be revealed. 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. This website can be searched at any time.

If the researchers learn that you or someone with whom you are involved with is in serious danger or harm, we will need to inform the appropriate agencies as required by Pennsylvania law. Likewise, if our evaluation determines that you are at imminent medical risk (e.g., active suicidal intentions), we will refer you to appropriate medical care.

Also, it is possible that we may use this information obtained from this study in other research studies examining the relationship between sleep, brain activity, mood, and behavior. We may also contact you in the future about other studies in which you may be interested in participating. Lastly, this information may be shared with other researchers here and at other research centers, but those researchers will never be provided with any personal identifiers that would allow them to learn your identity.

Who will have access to identifiable information related to my participation in this research study?

In addition to the investigators listed on the first page of this authorization (consent) form and their research staff, the following individuals will or may have access to identifiable information for the purpose of monitoring the appropriate conduct of this research study.

- We normally will not share any information you tell us, as this helps to keep the privacy needed so we get honest answers. However, if you are found to have a life-threatening medical, mental or substance use disorder, the investigators will recommend that you receive a clinical evaluation, and you will be provided with information about local medical facilities and other resources. No other data or information about you will be shared with anyone unless we first receive your permission.
- Authorized representatives of the University of Pittsburgh Office of Research Protections may review your identifiable research information for the purpose of monitoring the appropriate conduct of this research study.
- Authorized representatives of the sponsor of this study, the National Institute of Mental Health may review and/or obtain identifiable information (which may include your identifiable medical information) related to your participation in this research study for the purpose of monitoring the accuracy and completeness of the research data. While the National Institute of Mental Health understands the importance of maintaining the confidentiality of your identifiable research and medical information, the University of Pittsburgh and UPMC cannot guarantee the confidentiality of this information after it has been obtained by the National Institute of Mental Health.
- Authorized representatives of the UPMC hospitals or other affiliated health care providers may have access to identifiable information (which may include your identifiable medical information) related to your participation in this research study for the purpose of (1) fulfilling orders, made by the investigators, for hospital and health care services (e.g., laboratory tests, diagnostic procedures) associated with research study participation; (2) addressing correct payment for tests and

procedures ordered by the investigators; and/or (3) for internal hospital operations (i.e. quality assurance).

- In unusual cases, the investigators may be required to release identifiable information related to your participation in this research study in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies. This means that if you report any active intent to harm yourselves or someone else, we are mandated to report that information for safety purposes.
- Members of the research team in Dr. Soehner's lab at the University of Pittsburgh may contact you in the future about other research opportunities being conducted within this lab.

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.

Your data and specimens used in this research study may contribute to a new discovery or treatment. In some instances, these discoveries or treatments may be of commercial value and may be sold, patented, or licensed by the investigators and the University of Pittsburgh for use in other research or the development of new products. You will not retain any property rights, nor will you share in any money that the investigators, the University of Pittsburgh, or their agents may realize.

Who will have access to non-identifiable information and data collected in this study?

Deidentified study data means that all personal information about you (such as name, address, birthdate, and phone number) is removed and replaced with a code number. De-identified data generated from this research study may be shared with other researchers, with University of Pittsburgh data repositories, and with federal repositories, such as the National Institute of Mental Health Data Archive (NDA). It is possible that you will participate in more than one research study that sends your deidentified data to a repository. Some of these repositories can connect your data from different research studies by matching the code number on your de-identified data from each study. This data matching helps researchers to count you only one time, without knowing who you are. After removing identifiers from any data collected, the de-identified data may be used for future research studies, shared with repositories, or shared with other investigators for future research studies without additional seeking informed consent from you.

For how long will the investigators be permitted to use and disclose identifiable information related to my participation in this research study?

The investigators may continue to use and disclose, for the purposes described above, identifiable information related to your participation in this research study indefinitely. University of Pittsburgh policy requires that all research records be kept for a period of at least 7 years following completion of the study.

Is my participation in this research study voluntary?

Yes! Your participation in this study is completely voluntary. You may refuse to take part in it, and you may stop your participation at any time, even after signing this form. Your decision will not affect your relationship with the University of Pittsburgh or the University of Pittsburgh Medical Center, current or future medical care at a UPMC hospital or affiliated health care provider, or current or future relationship with a health care insurance provider.

May I withdraw, at a future date, my consent for participation in this research study?

Yes. To do so, you must contact the Principal Investigator, whose name and contact information is listed on the first page of this consent form. If you withdraw from this study, we will retain the information we have collected prior to learning of your decision to withdraw consent.

If I agree to take part in this research study, can I be removed from the study without my consent?

You may be removed from this study by the investigators if you do not follow the instructions given to you by the investigator and research team. Investigators will withdraw you from the study if you cannot attend scheduled study visits or develop conditions that would exclude you from the study (e.g., suffering a head trauma, developing a psychiatric or sleep disorder, becoming pregnant). If you are able to complete most of the study but refuse some aspect of it (such as the MRI), we may continue with the rest of testing.

How can I get more information about this study?

If you have any further questions about this research study, you may contact the investigators listed at the beginning of this consent form. If you have any questions about your rights as a research participant, please contact the Human Subjects Protection Advocate at the University of Pittsburgh IRB Office (1-866-212-2668).

We would like to audio record portions of the study interview sessions. You and will know when audio recording is taking place. Audio recordings are used primarily for training and quality control purposes. **Do we have your permission to audio record your study interview sessions?**

Initial in the box of your choice.

☐ **Yes** ☐ **No**

Would you be willing to participate in an opt-in portion of the study that involves up to 14 days of using bright light glasses?

Morning bright light therapy can help mood, alertness, and sleep. In this optional part of our protocol, participants will use bright light glasses (Luminette 3, Lucimed SA, Villers-le-Bouillet, Belgium)
in the morning, every day, for 14 days. We are interested in learning whether bright light glasses are an easier alternative to a bright light box.





If you choose to complete this optional protocol, after orientation with a research team member at your lab visit, you will be asked to follow several procedures intended to help mood, sleep, and alertness on a daily basis. The procedures will include:

(1) maintaining a regular wake-up time (plus or minus 1hr, *including on weekends*)
(2) morning bright light (wearing bright light glasses for 20-30 minutes after getting up in the morning)
(3) a 2-minute daily survey to report wake up time, sleep quality, duration the glasses were worn, mood, and alertness.

After 7 days and 14 days, you will complete questionnaires about mood, alertness, and their experience wearing the bright light glasses. These questionnaires take < 10 minutes.

Initial in the box of your choice.

☐ **Yes** ☐ **No**

VOLUNTARY CONSENT

The above information has been explained to me, and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that my questions, concerns, or complaints be addressed by a listed investigator.

I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations in the event that the research team is unavailable.

_____

Participant's Name (Print)

_____

_____

Participant's Signature Date

CERTIFICATION OF INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____ _____

Printed Name of Person Obtaining Consent Role in Research Study

_____ _____

Person Obtaining Consent Signature Date

STUDY NAME:	Depression in Adults and Youth Light Study (DAYLight)
PROJECT DIRECTOR	**Adriane Soehner, PhD** Telephone: 412-246-6551 Email: soehneram2@upmc.edu
OTHER KEY TEAM MEMBERS:	Kathryn Roecklein, PhD; Henry Chase, PhD
SOURCE OF SUPPORT:	National Institute of Mental Health

KEY INFORMATION: Your child is being asked to take part in a research study. Research Studies include only people who choose to take part. The study team members will explain the study to you and your child and will answer any questions you might have. You and your child should take your time to make a decision.

- **Purpose of the research**: Light can have a profound impact on mood. We are conducting this study to learn more about how age and individual differences in retinal light sensitivity impact the effect of light on emotional brain function in adolescents and adults. We hope that our findings will help us understand how age, light, sleep, and brain function interact to impact mood, so that we can optimize light therapy treatments in depression.
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  - A baseline appointment for written informed consent, interview, and questionnaires
  - A 7-day home-based assessment of activity, light, sleep, mood, and behavior while keeping a stable sleep schedule
  - One approx. 7-hour visit to our lab at Western Psychiatric Hospital. The lab visit includes interviews, questionnaires, computer tasks, a brain scan, and pupillometry recordings.
  - Optional 14-days using bright light glasses in the morning and completing questionnaires.
- **Who is being asked to participate in this research study?** Your child is being asked to participate because you and your child expressed an interest in this study, and because the phone or web screening process suggested that your child might qualify. We plan to enroll approximately 40 adolescents between 12-17 years-old and 40 young adults between 18-30 years-old. We plan to enroll males and females.
- **The most common risks** related to study procedures include emotional discomfort during the clinical interview; stress, fatigue and/or boredom when completing tasks during the lab visit or during the fMRI scan; discomfort from the loud noises of the

fMRI scan; and the detection of a previously unrecognized psychiatric condition is possible.
- Your child will derive no direct benefit from participation in this study other than the knowledge that the information gained in this study may help others in the future.
- Your child's de-identified research information may be shared with investigators conducting other research.

QUESTIONS ABOUT THE STUDY: If you or your child have any questions about your rights as a research subject or wish to talk to someone other than the research team, please call the University of Pittsburgh Human Subjects Protection Advocate toll-free at 866-212-2668. You and your child can contact the study investigator if either of you have any questions about the study, concerns, or complaints. Contact the Project Director, Dr. Soehner, or the project coordinator at sleepneuro@upmc.edu

OVERVIEW OF STUDY PROCEDURES

Stage	Where	Duration	Purpose	Associated Activities
Initial Evaluation (Consent and eligibility screening)	Western Psychiatric Hospital or home (via Teams or Zoom)	3-4 hr	To see if your child is eligible for the study	• Sign consent • In-person or remote interviews • Questionnaires • Receive training to use the wrist activity monitor and smartphone-based sleep diary for use in the 7-day home-based sleep assessment
Home Monitoring (sleep/activity tracking)	At home	7-days	To track sleep, mood & behavior in daily life	• Wearing wrist activity and light monitor • Completing daily smartphone-based surveys
Lab Visit (Weds/Fri)	Western Psychiatric and UPMC Presbyterian Hospitals	~7 hr	To assess brain and eye responsivity to light	• Overview of procedures • Complete saliva alcohol, urine drug, pregnancy tests • Questionnaires and computer tasks • Heart rate and activity tracking • Complete fMRI scan • Complete pupillometry
Optional Bright Light Protocol	At home	14 days	To see if bright light helps mood and sleep	• Wear bright light glasses in the morning for 20-30min after waking up, get up at the approx. the same time each day • Complete brief daily online surveys • Complete questionnaires after 7 and 14 days of trying the bright light glasses

Initial Evaluation Visit (Eligibility screening and consent visit)

This visit will take place at Western Psychiatric Hospital at the University of Pittsburgh or remotely via videoconference technology such as Teams or Zoom. This visit will take approximately 3-4 hours. During this visit, a member of the research team will interview your child about their sleep, psychiatric history, drug and alcohol use, and other problems he/she may have experienced. Your child will be assessed for family history of mental health conditions, including immediate family members (parents, siblings). Your child will also be asked to fill out several questionnaires about their sleep, mood, feelings, and medical history. If your child is using a photosensitizing medication, we may ask participants to confirm with a physician that exposure to bright blue light will not cause an adverse reaction prior to proceeding in the study. You may also be asked to complete questionnaires about your child. A member of our research staff will be available to answer any questions your child may have about these questionnaires. At the time of the interview, we will re-explain in detail both the interview process and the procedures involved for the rest of the study (also described below), and you and your child will have an opportunity to ask any questions before getting started. Throughout this entire process, you or your child will not have to answer any questions that make you/them uncomfortable. The interview portion of the visit will take about 1-2 hours. Your child will complete the clinical interview and study surveys independently from you and you will not be privy to those results.

If the screening interview suggests that your child may have a psychiatric, substance use, or sleep disorder, this information will not be shared with you or your child. Information about your child will only be shared with you in the event there is a concern of harm to the child or someone else. No other information about your child will be shared with you unless we first receive your child's permission. Referral for treatment services may be provided upon your or your child's request. The presence of such a disorder may make your child ineligible for the study.

If your child qualifies for the study at the end of the interview and wishes to participate, we will schedule a time to complete the rest of the study. We will also provide your child a wrist activity monitor and smartphone (unless they have their own) for use in the study. Finally, we will also review the lab visit procedures and set a sleep schedule for your home monitoring week.

If you or your child request to do so, visit 1 may be split into 2 separate sessions. Your child will receive a portion of the compensation for this visit after the first session, and the rest of the compensation after the second session.

Home Monitoring

For the week prior to your lab visit, your child is asked to keep a regular sleep/wake schedule such that you go to bed within 30 min of a target time, arise within 30 min of a target time, and have approximately eight hours in bed each night. For example, if the target bedtime is 11 PM, try to go to bed between 10:45 PM and 11:15 PM. Adherence will be monitored through a daily sleep log and wearing an actigraph. The sleep log is a daily online survey that asks a set of questions (approx. 5 minutes). The activity monitor is a wristwatch-like device that tracks activity level, which can be used to estimate when

individuals are asleep or awake. The activity monitor is water-resistant and can be worn continuously. If you do not maintain a regular sleep/wake schedule, you and your child will be rescheduled or excluded from further study.

If the Lab Visit occurs more than 1.5 months (~45 days) from the Initial Evaluation Visit, portions of the screening interview will be repeated to confirm continued eligibility.

Lab Visit
At the end of the 7 days of home monitoring, your child will come into our research lab, located on the 13th floor of Western Psychiatric Hospital (WPH). Your child will be provided with regular snacks and meals throughout their lab visit.

Lab visits will start in the morning, around 8:30am. We ask that your child refrain from smoking and alcohol intake within 24 hours of entry into the lab and abstain from caffeine the day-of the lab visit. After arriving at our lab, they will be asked to complete a saliva alcohol test, urine drug screen, urine pregnancy test (post-menarchal females only) and questionnaires. If the result of the saliva alcohol, urine drug (except cannabis), or pregnancy test is positive, your child may be ruled ineligible from the study. We will also collect your vitals, including blood pressure, heart rate, and temperature.

Your child will also be asked to return their wrist activity monitor. Their sleep will be reviewed to ensure adherence to the sleep schedule. If their sleep schedule deviates too far from the agreed-upon sleep schedule, your child may be rescheduled or ruled ineligible from the study.

After completing drug/alcohol and sleep screening, your child will be in dim light (5 lux) while completing questionnaires and interviews about mood, sleep, and alertness. Next, a brain scan (structural and functional magnetic resonance imaging) will take place in the at the Magnetic Resonance Imaging Research Center (MRRC). Your child will wear light blocking goggles while in transit from lab in WPH to the MRRC. The brain scan will last 1.5 hours. During the brain scan, your child will be exposed to blue light, red light, or darkness while resting or while completing a computer task where they can win money. After the brain scan, your child will return to WPH and sit in dim light for a brief interval while completing questionnaires. Finally, they will complete pupillometry to assess light sensitivity. The visit will end with a debrief session.

Throughout the protocol, your child will be asked to complete research procedures, as described below. Please note that study results are not interpretable on an individual basis and will not be shared with participants, with one exception noted below.

- **Questionnaires, Computer, and Behavioral Tasks:** At various times throughout the lab visit, your child will complete questionnaires, behavioral, computer-based tasks multiple times to measure their thinking, mood, movement, and alertness. Your child will have opportunities to take breaks.
- **Pupillometry:** Light is an important cue that sets our biological clock. We will measure your child's pupil response to light flashes to assess circadian photoreceptor sensitivity to light using a pupillometer. After adjusting to the dark,

participants watch (eye-safe) standardized red and blue wavelength light stimuli in a pupillometer.

- **Functional MRI:** Study staff will escort your child to the Magnetic Resonance Research Center (MRRC) at UPMC Presbyterian for an fMRI scan. Before, during, and/or after the scan, your child will complete tasks about winning money. The scan will last approximately 90 minutes. Your child will be familiarized with the MR scanning environment by a tour of the facilities. Your child will also be given the option of going in an MRI simulator (a plastic replica of the actual MRI scanner) in order to further familiarize them with the scanner. Prior to the scan, MRRC staff will verbally screen your child about any metal in their body. For this visit, please avoid wearing clothing with metal pieces, such as zippers or underwire, so you are prepared for the scan. During the actual scan, your child will be asked to perform tasks on a computer. While completing the tasks, we will record his or her brain activity using a procedure called functional magnetic resonance imaging (fMRI)—a technique that locates where certain functions occur in the brain. The fMRI scanner is FDA approved. As with traditional MRI, your child will lie on a table that slides into the scanner's imaging space so brain images can be recorded for study. Because the noises produced by the scanner are loud and may cause discomfort, all participants must wear earplugs during the MRI scan; disposable earplugs will be provided for your child. A staff member will be in constant contact with your child throughout the procedure, and the scan can be stopped at any time should your child be uncomfortable or is unable to tolerate the procedure. *Please note that the brain activity patterns collected with functional MRI are not interpretable on an individual basis and can only be seen across large groups of participants. For this reason, information from your child's individual scan will not be shared with you. During the structural MRI, if the MRI technologist notices an adverse finding, the Principal Investigator will be notified, and the MRRC's medical director will review the scan. Any findings of medical significance found during the structural MRI will be shared with you and forwarded to your child's personal physician if you provide written authorization to do so. These scans are conducted for research purposes and not medical purposes; scan results are not read by a neurologist, and findings of medical significance may not be detected.*

If portions of the study protocol are not completed, we may ask you and your child back to the lab. If this happens, sleep monitoring and questionnaires will be repeated. Compensation will be $16 per hour. .

Optional Bright Light Protocol
Morning bright light therapy can help mood, alertness, and sleep. In this optional part of our protocol, participants will use bright light glasses (Luminette 3, Lucimed SA, Villers-le-Bouillet, Belgium)

in the morning, every day, for 14 days. We are interested in learning whether bright light glasses are an easier alternative to a bright light box.





If your child chooses to complete this optional protocol, after orientation with a research team member at their lab visit, they will be asked to follow several procedures intended to help mood, sleep, and alertness on a daily basis. The procedures will include:

(1) maintaining a regular wake-up time (plus or minus 1hr, *including on weekends*)
(2) morning bright light (wearing bright light glasses for 20-30 minutes after getting up in the morning)
(3) a 2-minute daily survey to report wake up time, sleep quality, duration the glasses were worn, mood, and alertness.

After 7 days and 14 days, your child will complete questionnaires about mood, alertness, and their experience wearing the bright light glasses. These questionnaires take < 10 minutes.

Possible risks, side effects, and discomforts of study

As with any experimental procedure, there may be adverse events or side effects that are currently unknown and certain of these unknown risks could be permanent, severe, or life-threatening. Those that are known are listed in the table below.

Procedure	**Expectancy of Risk**	**Measures taken**
Questionnaires, sleep diary, actiwatch, pupillometry, and psychological evaluation	Common: Becoming upset, bored, anxious, or embarrassed by the personal nature of the questions; detection of a previously unknown psychiatric problem; skin irritation due to Actiwatch; physical discomfort due to pupillometry	If the participation is too stressful for these reasons, your child may discontinue their participation, either temporarily or permanently; referral to a provider will be provided if indicated; participants can remove watch if skin is irritated
fMRI scan	Rare: Hearing discomfort, claustrophobia, metal in body attracted to the magnet. Lightheadedness when your child first sits up after lying in the MRI machine. No known risk to females who are pregnant	Your child will be provided ear plugs, as well as the opportunity to enter the MRI simulator. Both our staff and the MR center staff will have asked screening questions about possible metal in your child's body.
Data collection throughout study	Rare: Breach of confidentiality—individuals outside of study team may learn of an individual's participation and data collected for the study about that individual Breach of confidentiality – text messaging and audio recording.	All data will be coded exclusively with study ID numbers. Only the people who need to know for research purposes will know your child's name. Identifiable data will only be available to study staff. Study materials will be stored in a locked cabinet in a locked office, and computer files will be password protected.
Bright light exposure	Common: Headache, eyestrain, nausea and agitation Rare: Mania (only in individuals with bipolar disorder)	Individuals with diagnosed bipolar disorder are not eligible for this study. Although most side effects resolve on their own, your teen may discontinue his/her participation in the study if side effects become too burdensome

Text Messaging
Over the course of the study, members of the study team may contact you and/or your child via secure UPMC office phone lines, cell phones, or email accounts configured to utilize the available privacy and encryption settings. Communication may include information related to appointment scheduling or appointment reminders. Your child will also complete brief daily questionnaires using text messages or a website that are sent to a study database. Messages of this nature exchanged with the study messaging service or study staff may potentially contain sensitive and/or identifiable information.

While our devices and accounts are secure, it should be noted that the calls, emails, and text messages that your child sends from your personal devices may not be encrypted or secure. Therefore, it is important to understand that your child's response may not be protected, and it is possible that it may be viewed by others. Depending on your child's cell phone carrier or email provider, even if you delete the message(s) from your device, your child's carrier/provider will retain those messages for an extended period of time. Additionally, depending on your child's specific device or carrier, copies of those messages may be stored on multiple devices and/or related cloud storage services. In the rare case where a message is intercepted during transit, only the question or answer will be revealed and never both. The texting service we use is compliant with privacy law (Health Insurance Portability and Accountability Act, HIPAA), and all messages from the texting service database are deleted immediately after processing. Others may view text conversations that are stored on your child's phone. You and/or your child should delete messages from your child's phone if you are at all concerned about others reading them.

What are possible benefits from taking part in this study?
Your child will not directly benefit from participating in this research. Knowledge gained from this study may contribute to the scientific community and society at large may benefit from the information gained.

If my child agrees to take part in this research study, will I be told of any new risks that may be found during the course of the study?
Your child will be promptly notified if, during the conduct of this research study, any new information develops which may cause your child to change their mind about continuing to participate.

Will my child be paid if they take part in this research study?
Participants may earn up to $340 and light therapy glasses for completion of all main and optional study procedures. Compensation for main study procedures is up to $300, including the consent evaluation, home monitoring, and lab visit. Compensation for the optional study procedures is up to $40 plus bright light glasses. You will receive compensation for your time and effort for every post-screening component of the research study in which you participate.

All compensation is taxable income to the participant regardless of the amount. If a participant receives $2000 or more in a calendar year from one organization, that organization is required by law to file a Form 1099 – Miscellaneous with the IRS and provide a copy to the taxpayer. Individuals who do not provide a social security number may still participate in the research, but the IRS requires that 24% of the payment be sent by the institution to the IRS for 'backup withholding;' thus you would only receive 76% of the expected payment.

Study Component	Compensation
Consent & Initial Evaluation	**$30** **(If split: $10 after the first visit, $20 after the second visit)**
Home Monitoring	**Up to $60** • $3 per day for completing AM sleep log, PM sleep log, and wearing the activity watch ($3 x 7days = $21 total) • $2 per day for adhering to their sleep schedule ($4 x 7days = $28 total) • $11 bonus for complete sleep tracking and sleep schedule adherence
Lab Visit	**Up to $210** • $190 for completion of the full lab visit • Up to $20 in winnings for a computer task completed during the brain scan • Compensation for repeated portions of the protocol will be prorated on an hourly basis. Compensation will be $16 per hour.
Optional Bright Light Glasses	**Up to $40 and bright light glasses** • $1 per day for completing a daily morning survey plus a $6 complete data bonus ($1 x 14 days, plus $6 bonus = $20 total) • $10 for questionnaires at the end of 1 week • $10 for questionnaires at the end of 2 weeks

How will these payments be made?

UPMC utilizes electronic payment as a secure payment method to disburse research study compensation and/or expense reimbursements. You will be required to provide either an email address or a cell phone number that can receive a text message in order to receive the reimbursement(s). The study staff will discuss payment options with you and answer any questions you may have about the reimbursement(s).
Payment through the University's approved payment system may involve electronic communication via text and/or email. Text and email messages may not be encrypted or secure during their transmission or storage and it is possible they could be intercepted and used by others not associated with this study. The study team will discuss the payment options with you.

Will we be charged for any portions of this research study?
Neither you, your child, nor your insurance provider will be charged for the costs performed only for the purposes of this research study. If we offer any treatment referrals as a result of the diagnostic interview, you or your child's insurance would be responsible for any costs associated with subsequent treatment. However, you and your child are not obligated to pursue said treatment referrals.

Who will pay if my child is injured as a result of taking part in this study?

If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation.

Who will know about my child's participation in this research study?
The research staff will keep all information obtained from this research as confidential (private) as possible. The University of Pittsburgh requires that all research records be kept for at least seven years after the study ends, and study data on minors must be retained at least until they turn 23. All paper records related to your child's involvement in this research study will be stored in a locked file cabinet. All computerized database records related to your child's involvement in this research study will be stored with password protection. Your child's identity on these records will be indicated by a case number rather than by his or her name, and the information linking these case numbers with his or her identity will be kept separate from the research records. Although every reasonable effort has been taken, confidentiality during Internet communication activities cannot be guaranteed and it is possible that additional information beyond that collected for research purposes may be captured and used by others not associated with this study. The information obtained in this study may be published in medical journals, but your child's identity will not be revealed. 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. This website can be searched at any time.

If the researchers learn that your child or someone with whom he or she is involved is in serious danger or harm, we will need to inform the appropriate agencies as required by Pennsylvania law. Likewise, if our evaluation determines that your child is at imminent medical risk (e.g., active suicidal intentions), we will refer them to appropriate medical care.

Also, it is possible that we may use this information obtained from this study in other research studies examining the relationship between sleep, brain activity, mood, and behavior. We may also contact you in the future about other studies in which you or

your child may be interested in participating. Lastly, this information may be shared with other researchers here and at other research centers, but those researchers will never be provided with any personal identifiers that would allow them to learn your identity.

Who will have access to identifiable information related to my child's participation in this research study?

In addition to the investigators listed on the first page of this authorization (consent) form and their research staff, the following individuals will or may have access to identifiable information for the purpose of monitoring the appropriate conduct of this research study.

- We normally will not share with you any information your child tells us, as this helps to keep the privacy needed so we get honest answers. However, if your child is found to have a life-threatening medical, mental or substance use disorder, the investigators will recommend that your child receive a clinical evaluation, and you will be provided with information about local medical facilities and other resources. No other data or information about your child will be shared with you unless we first receive your child's permission.
- Authorized representatives of the UPMC hospitals or other affiliated health care providers may have access to identifiable information (which may include your identifiable medical information) related to your participation in this research study for the purpose of (1) fulfilling orders, made by the investigators, for hospital and health care services (e.g., laboratory tests, diagnostic procedures) associated with research study participation; (2) addressing correct payment for tests and procedures ordered by the investigators; and/or (3) for internal hospital operations (i.e. quality assurance).
- Authorized representatives of the University of Pittsburgh Office of Research Protections may review your child's identifiable research information for the purpose of monitoring the appropriate conduct of this research study.
- Authorized representatives of the sponsor of this study, the National Institute of Mental Health may review and/or obtain identifiable information (which may include your identifiable medical information) related to your participation in this research study for the purpose of monitoring the accuracy and completeness of the research data. While the National Institute of Mental Health understands the importance of maintaining the confidentiality of your identifiable research and medical information, the University of Pittsburgh and UPMC cannot guarantee the confidentiality of this information after it has been obtained by the National Institute of Mental Health.
- In unusual cases, the investigators may be required to release identifiable information related to you or your child's participation in this research study in response to an order from a court of law. If the investigators learn that you, your child, or someone with whom you or your child are involved is in danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies. This means that if you or your child report any active intent to harm yourselves or someone else, we are mandated to report that information for safety purposes.
- Members of the research team in Dr. Soehner's lab at the University of Pittsburgh may contact you in the future about other research opportunities being conducted within this lab.

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 your child 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 and your child 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 your child harming himself/herself) 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 or your child's information from being used for other research if allowed by federal regulations.

Researchers may release information about your child 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 child's involvement in this research. It also does not prevent you or your child from having access to your own information.

Your child's data and specimens used in this research study may contribute to a new discovery or treatment. In some instances, these discoveries or treatments may be of commercial value and may be sold, patented, or licensed by the investigators and the University of Pittsburgh for use in other research or the development of new products. You and your child will not retain any property rights nor will you or your child share in any money that the investigators, the University of Pittsburgh, or their agents may realize.

Who will have access to non-identifiable information and data collected in this study?

Deidentified study data means that all personal information about you and your child (such as name, address, birthdate, and phone number) is removed and replaced with a code number. De-identified data generated from this research study may be shared with other researchers, with University of Pittsburgh data repositories, and with federal repositories, such as the National Institute of Mental Health Data Archive (NDA). It is possible that your child will participate in more than one research study that sends deidentified data to a repository. Some of these repositories can connect your child's data from different research studies by matching the code number on your child's de-identified data from each study. This data matching helps researchers to count your child only one time, without knowing who your child is. After removing identifiers from any data collected, the de-identified data may be used for future research studies,

shared with repositories, or shared with other investigators for future research studies without additional seeking informed consent from your child or from you.

For how long will the investigators be permitted to use and disclose identifiable information related to my participation in this research study?
The investigators may continue to use and disclose, for the purposes described above, identifiable information related to your or your child's participation in this research study indefinitely. University of Pittsburgh policy requires that all research records be kept for a period of at least 7 years following completion of the study, or until the child is at least 23.

Is my child's participation in this research study voluntary?
Yes! Your child's participation in this study is completely voluntary. Your child may refuse to take part in it, and he or she may stop his or her participation at any time, even after signing this form. Your child's decision will not affect his or her relationship with the University of Pittsburgh or the University of Pittsburgh Medical Center, current or future medical care at a UPMC hospital or affiliated health care provider, or current or future relationship with a health care insurance provider.

May I withdraw, at a future date, my consent for my child's participation in this research study?
Yes. To do so, you or your child must contact the Principal Investigator, whose name and contact information is listed on the first page of this consent form. If your child withdraws from this study, we will retain the information we have collected prior to learning of his or her decision to withdraw consent.

If I agree for my child to take part in this research study, can he or she be removed from the study without my consent?
Your child may be removed from this study by the investigators if he/she do not follow the instructions given to him/her by the investigator and research team. Investigators will withdraw your child from the study if he/she cannot attend scheduled study visits or develops conditions that would exclude him/her from the study (e.g., suffering a head trauma, developing a psychiatric or sleep disorder, becoming pregnant). If your child is able to complete most of the study but refuses some aspect of it (such as the MRI), we may continue with the rest of testing.

How can I get more information about this study?
If you or your child have any further questions about this research study, you or your child may contact the investigators listed at the beginning of this consent form. If you or your child have any questions about your child's rights as a research participant, please contact the Human Subjects Protection Advocate at the University of Pittsburgh IRB Office (1-866-212-2668).

We would like to audio record portions of the study interview sessions. You and your child will know when audio recording is taking place. Audio recordings are used primarily for training and quality control purposes. **Do we have your permission to audio record your study interview sessions?**

PARENT initial in the box of your choice.

☐ **Yes** ☐ **No**

CHILD initial in the box of your choice.

☐ **Yes** ☐ **No**

Would your child be willing to participate in an opt-in portion of the study that involves up to 14 days of using bright light glasses?





If your child chooses to complete this optional protocol, after orientation with a research team member at their lab visit, they will be asked to follow several procedures intended to help mood, sleep, and alertness on a daily basis. The procedures will include:

(1) maintaining a regular wake-up time (plus or minus 1hr, *including on weekends*)
(2) morning bright light (wearing bright light glasses for 20-30 minutes after getting up in the morning)
(3) a 2-minute daily survey to report wake up time, sleep quality, duration the glasses were worn, mood, and alertness.

After 7 days and 14 days, your child will complete questionnaires about mood, alertness, and their experience wearing the bright light glasses. These questionnaires take < 10 minutes.

PARENT initial in the box of your choice.

☐ **Yes** ☐ **No**

CHILD initial in the box of your choice.

☐ **Yes** ☐ **No**

VOLUNTARY CONSENT

The above information has been explained to me and my child, and all of my current questions have been answered. I understand that my child and I are encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given. I understand that my child or I may always request that my questions, concerns, or complaints be addressed by a listed investigator.

I understand that my child or I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations in the event that the research team is unavailable.

_____

Printed Name of Child-Participant

PARENTAL CERTIFICATION

As a minor (age less than 18 years), the above-named child is not permitted to participate in this research study without my consent. Therefore, **by signing this form, I give my consent for his/her participation in this research study**. A copy of the consent form will be given to me.

_____ _____

Parent's Name (Print) Relationship to Child-Participant

_____ _____

Parent's Signature Date

CHILD ASSENT

This research has been explained to me, and I agree to participate.

_____ _____

Signature of Child- Participant Date

CERTIFICATION OF INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____

_____ Printed Name of Person Obtaining Consent Role in Research Study

_____

_____

Person Obtaining Consent Signature Date

CONSENT FOR CONTINUED PARTICIPATION

I understand that I am currently participating in a research study. I further understand that consent for my participation in this research study was initially obtained from my parent because I was a minor at the time that this initial consent was requested. I have now turned 18 years old, and I am able to provide direct consent for continued participation in this research study.

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any aspect of this research study during the course of this study, and that such future questions, concerns or complaints will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that my questions, concerns, or complaints be addressed by a listed investigator. I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations in the event that the research team is unavailable. By signing this form, I agree to participate in this research study.

By signing below, I agree to continue my participation in this research study. A copy of this consent form will be given to me.

_____

_____

Participant's Signature Date

CERTIFICATION of INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____ _____

Printed Name of Person Obtaining Consent Role in Research Study

_____ _____

Signature of Person Obtaining Consent Date