Study Title: Bright Light Therapy for Treatment of Sleep Problems Following Mild Traumatic Brain Injury

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The University of Arizona Consent to Participate in Research

Study Title: Bright Light Therapy for Treatment of Sleep Problems Following Mild TBI

Principal Investigator: William D. "Scott" Killgore, Ph.D.

Sponsor: Department of Defense (DoD)

This is a consent form for research participation. It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.

You may or may not benefit as a result of participating in this study. Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious, depending on the nature of the research.

1. Why is this study being done?

Dr. William D. "Scott" Killgore and colleagues are conducting a research study funded by the Department of Defense. The study aims to understand the effectiveness of a six-week course of light exposure on cognitive functioning, mood, activity, and sleep in people that have suffered a mild traumatic brain injury (mTBI) or "concussion." The study also aims to understand the effectiveness of a single day course of light exposure on cognitive functioning, mood, and activity in healthy persons who have not had an mTBI or concussion.

mTBI:

During the course of the study, if you have had an mTBI, you will complete two cognitive testing sessions and magnetic resonance imaging (MRI) scans, which will occur 6 weeks apart. During the two testing and MRI scan sessions, you will undergo a series of tests of attention, concentration, memory, and other cognitive abilities, and will complete clinical measures to assess mood and post-concussion symptom severity. During the intervening 6-week period, you will use a light device to provide 30-minutes of light exposure each morning. Daily activity and sleep patterns will also be monitored throughout the study's duration by using self-report diaries, questionnaires, and a wrist worn activity monitor. You will have the option to continue this activity and sleep monitoring for 6 weeks after termination of the light exposure period to receive up to an additional $200.

In this study, we will use functional and structural brain imaging techniques such as functional magnetic resonance imaging (fMRI) and diffusion tensor imaging (DTI) to evaluate brain function and brain structure before and after the 6-week light exposure period. Identifying and mapping the brain systems before and after light exposure may help

researchers develop further insights into the relationship between concussion, light exposure, sleep, and brain function.

Healthy Participants:

You will complete a single cognitive testing session and magnetic resonance imaging (MRI) scan session. During the duration of this visit, we will measure heart rate using a heart rate monitor. This monitor is a mobile device placed in the middle of the lower chest region, and does not hurt. During this cognitive testing session, these participants will undergo a series of tests of attention, concentration, memory, and other cognitive abilities, and will complete clinical measures to assess mood. Following this, these participants will sit in a darkened room for 60 minutes of light exposure. Finally, you will undergo fMRI and DTI to evaluate brain function following the light exposure in addition to some final tests and questionnaires. Throughout this study visit, a saliva sample will be collected periodically from you for a total of three times. This is to measure melatonin levels, and does not hurt. During this visit, you will also wear an EEG headset. EEG stands for electroencephalography, and is used to measure electrical brain activity. This is done by placing a mobile device on your head and does not hurt or cause injury, although some people do have minor skin irritation.

Following this visit, you will be given an Actiwatch and instructed on its use until their follow-up visit at approximately 8:30 pm the same day. During the follow-up visit, you will return the Actiwatch, complete a final saliva collection, and have your heart rate measured one more time.

You have been deemed eligible to take part in this study because:

1) you are a healthy person between the ages of 18 and 50
2) or you have experienced a mild traumatic brain injury (mTBI) or concussion during the past 18 months, but no sooner than four weeks prior to the screening.

In order to decide whether you wish to be a part of this research study, you should know enough about its risks and benefits to make an informed decision. This consent form is intended to give you detailed information about the research project. A member of the research team will also discuss the procedures that are involved, any risks, and possible benefits of these procedures. Once you understand the study, you will be asked if you wish to participate. If so, you will be asked to sign this form.

2. How many people will take part in this study?

Approximately 40 individuals with mTBI between the ages of 18 and 50 will participate in this study. Fifty (50) healthy individuals between the ages of 18 and 50 will also participate in this study.

3. What will happen if I take part in this study?

mTBI:

This study requires four visits including an initial assessment, two testing/scanning sessions separated by six-weeks of daily light exposure treatment at home, and one visit during which you will return the wrist activity monitor and fill out a subject payment form.
During this first visit at the University of Arizona, you will have the procedures of the study fully explained. After providing written informed consent, you will then complete a brief clinical interview as well as several questionnaires about your personality, light exposure, and about the symptoms you have experienced since your mTBI. The first visit of the study will last about two hours. Your first visit is still considered part of the initial screening portion of the study and your responses to the assessment and questionnaires will be evaluated to determine your eligibility for subsequent portions of the study.

Your eligibility is dependent on a number of factors that are important for the validity of the study data. The Principal Investigator may decide not to schedule you for additional testing if the screening data do not meet the specific requirements of the study or if there is reason to believe that further continuation may not be in your best interest or in the best interest of the study. If you are not eligible for continuation, you will receive $25 for each hour you participated in the first visit, up to a maximum of $50 for the entire first visit.

At the conclusion of the first visit if you are considered eligible for the study, you will be fitted with a wrist activity monitor, which will be used to measure your waking and sleep patterns over the next few weeks. You will be required to wear this monitor at all times during the 7 weeks of the study, except during swimming. The wrist monitor should be worn at all other times, including showers. The only time it should be removed is if it is likely to be completely submerged under water or if it could be damaged during physical activities. In addition, you will complete a daily online sleep diary when you wake up in the morning. You will wear the wrist activity monitor and complete sleep diaries and scales starting the week prior to your baseline assessment/scanning session until the conclusion of the study.

Before you can participate in the remainder of the study visits, you must provide written documentation from a physician, nurse, coach, trainer, or other qualified health professional that documents that you sustained a mild head injury or concussion. This documentation must be provided before you can undergo subsequent testing and scanning.

When you return for your second visit at the University of Arizona, you will complete additional personality assessments, a comprehensive cognitive assessment battery, and several tests of motor functioning. During these tests, we will ask you to solve problems, remember lists of words, and complete other types of computerized mental tests. Throughout the duration of this visit, we will measure heart rate using a heart rate monitor. This monitor is a mobile device placed in the middle of the lower chest region, and does not hurt.

If you are a woman of childbearing age you will be required to take a urine pregnancy test prior to entering the scanner. You will then be escorted to the MRI. During this part of the study, you will spend approximately 1 hour in the MRI scanner. While in the scanner, you

will complete several experimental tasks. These tasks involve a spatial memory, attention, and reasoning tasks, which will involve pressing buttons on a keypad to match the numbers on a screen. We will also take some structural images of your brain, during which you will not need to do anything but rest quietly.

You will also complete multiple sleep latency tests (MSLT), each of which will be a half hour long. A multiple sleep latency test is a way to measure your brain activity while you take a nap. This will require you to be fitted with several electrodes (small metal cups with wires connected to a recording device) on your scalp and you will take a nap in a darkened quiet room. While you are napping, the electrodes will monitor your brain activity. At the conclusion of the assessment and scanning session, you will also be provided with a light exposure device and instructed about its proper use. During one of your assessments, a voice recording will be taken so the study team can make sure they captured your complete response; this will be deleted as soon as your response is verified the same day. This second visit should last approximately 9 hours.

For the following six weeks, you will use the light exposure device for **30-minutes** each morning **within two hours of awakening**, but **prior to 10:30 A.M. each and every day**. While undergoing light exposure, you can complete other activities, such as eating breakfast, completing your daily sleep diary, reading the paper, or even watching TV. A power usage meter will also be used in conjunction with the light device to measure compliance. Specifically, the power usage meter will be used to measure: times of the day during which the light device was used, duration of use, and intensity setting at which the light device was used.

You will be contacted by phone about once per week for a brief follow up to make sure that everything is progressing well and to answer any questions that arise. You will also receive daily email reminders and occasional phone calls reminding you to complete your sleep diary and use your light device. You will be asked to provide a preferred contact number and to return any phone messages you receive from study staff.

At the completion of the 6 weeks of light treatment, you will return to the University of Arizona for another visit. At that time you will return the light exposure device. You will then complete more questionnaires and undergo cognitive assessments, functional and structural neuroimaging scans, and MSLT nap assessments, very similar to the ones you did during the prior visit. Throughout the duration of this visit, we will also measure your heart rate again using a heart rate monitor. This visit will take approximately 9 hours.

Optional Research Activity:

Optional research activity is part of this project. For an additional six weeks, you may continue to wear the wrist activity monitor and fill out the daily sleep diary to earn up to an additional $200. If you agree to participate in this optional part of the study, you must sign a separate consent form after week 6 of the study. You will then return to the University of

Arizona for a final visit, during which you will return the wrist activity monitor and fill out a subject payment form.

You will then return to the University of Arizona for a final visit, during which you will return the wrist activity monitor and fill out a subject payment form.

Healthy Participants:

This study requires a visit consisting of an initial assessment; a testing/scanning session, light exposure and three saliva collections followed by a follow-up visit the same day and a final saliva collection.

During the initial assessment at the University of Arizona, you will have the procedures of the study fully explained. After providing written informed consent, you will be asked to wear a heart rate monitor for the duration of this visit. You will then complete a brief clinical interview as well as several questionnaires about your mood and sleep habits, a comprehensive cognitive assessment battery, and several tests of motor functioning. During these tests, we will ask you to solve problems, remember lists of words, and complete other types of computerized mental tests.

Following this, we will collect a saliva sample through a small plastic tube placed in the lower part of the mouth. This is to measure melatonin levels, and does not hurt. Then, you will be asked to sit in a darkened room for 60 minutes of light exposure. During this time, you will wear an EEG headset so we can measure your brain activity, while you also complete several computerized tasks. After this session, a second saliva sample will be collected.

If you are a woman of childbearing age you will be required to take a urine pregnancy test prior to entering the scanner. You will then be escorted to the MRI scanner. During this part of the study, you will spend approximately 1 hour and 30 minutes in the MRI scanner. While in the scanner, you will complete several experimental tasks. These tasks involve a spatial memory, attention, and reasoning tasks, which will involve pressing buttons on a keypad to match the numbers on a screen. During one of the tasks, you will see brief presentations of negative images displaying graphic content that some people might find distressing. We will also take some structural images of your brain, during which you will not need to do anything but rest with your eyes closed. Next, we will collect a third saliva sample will be collected.

After the scanning session, you will complete a few final tasks. After this, we will collect a third melatonin sample. This study visit will take approximately 5 hours.

You will then be given an Actiwatch to wear until your follow-up visit at approximately 8:30 pm the same day and instructed on its use. At the follow-up appointment, a final saliva collection will be taken while having your heart rate measured and you will return the

Actiwatch. The follow-up visit will take about a half hour. Your total participation time should be about 5 and one half hours.

Magnetic Resonance Imaging (MRI) Procedures: All structural and functional MRI studies will be conducted at the University of Arizona Medical Center. You will be studied in a scanner that has a field strength of 3 Tesla. This field strength has been approved by the FDA for routine clinical use.

The magnetic resonance (MR) scanner looks like a large cylinder with a tube running down the center. You will be asked to lie down on your back on a foam-padded table and place your head into a special holder. The table will gently move so that your head and shoulders are part way inside the front opening of the scanner. Soft foam rubber pads may be placed on both sides of your head for comfort and to help keep your head from moving. Because the scanner contains a strong magnet, you will be asked to remove all metal objects from your body including, but not limited to; watches, rings, necklaces, bracelets, earrings and other body piercings, belts, loose change, wallet (with credit cards), items of clothing containing magnetic materials (for example, under wire bras, certain types of zippers), and shoes. These items will be secured in a safe place until your scan is completed. You will be able to remain in your street clothes.

During the scanning procedure you will hear a number of different sounds. Some of these sounds are loud and are part of the normal operation of the scanner. These noises vary with the type of scan being performed. During the structural and functional MRI scans, you may hear sounds like a hammer hitting a piece of wood, repetitive buzzing noises, and a long series of loud beeps. In particular, the noises during the Diffusion Tensor Imaging (DTI) scan are louder and you may feel a slight vibration. Some scans are silent. These sounds, or combinations of them, may be repeated several times. Because many of the scans are loud, you will be provided with earplugs to minimize the sounds.

The longest continuous period during the scan may be up to 20 minutes and you will not be given breaks during these continuous periods. You are free to talk during the preparation time for the scan, but you should not talk during the actual scanning process. During scans, you should try to remain as still as possible. The entire time that you will be in the scanner will be about 1 hour. When your session is over, the technician will move you out of the scanner and assist you from the table.

Some people feel slightly cramped inside the scanner, so it is important to inform the study staff if you have any concerns about the procedure or if you feel you may be claustrophobic. The technician will be able to see and hear you at all times and you are free to end the procedure at any time. You will be given an emergency squeeze ball to end the scan if you experience any concerns or discomforts.

Randomization and Blinding:

- There will be two different groups of healthy participants enrolled into this study. Both groups will go through all of the same study procedures but will each be exposed to different wavelengths (colors) of light in order to test their effects on the brain. You will not be told what group you have been assigned to, and your study coordinator will not know which group you are in either. This will help determine how the light exposure affects the brain.
- The light color given to you will be decided by a randomization procedure, which means it will be chosen by chance, like the flip of a coin. No matter what condition you are assigned to you will be monitored for adverse events, and will receive the same compensation.

4. How long will I be in the study?

mTBI:

Overall it will take you about 7 weeks to complete this research study, and will require you to come to the University of Arizona Medical Center for three study visits. If you choose to participate in the optional 6-week follow-up portion of the study, you will be involved in this study for a total of about 13 weeks.

Healthy Participants:

You will be in the study for a single day over two visits taking approximately 5.5 hours total.

5. Can I stop being in the study?

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

The Principal Investigator may also remove you from the study if it is in your best interest and/or at his discretion in order to best serve the interests of the study and/or protect the integrity of study data.

6. What risks, side effects or discomforts can I expect from being in the study?

Participation in this study may involve some risks or discomforts, which are described below.

During the study visits, you may be asked some questions during the brief clinical interview and on the questionnaires that deal with personal or emotional matters. These questions might cause psychological discomfort. You may refuse to answer any questions that make you uncomfortable. If you reveal during these sessions that you are currently or have recently had thoughts of self-harm or suicide, a qualified psychiatrist will be paged and appropriate follow-

up care will be ensured. Results of the clinical evaluation will be kept in a locked cabinet and identified using only your unique study identification number.

Unlike X-rays or CAT scans, magnetic resonance (MR) technology does not use ionizing radiation. Instead, it uses strong magnetic fields and radio waves to collect the images and data. With appropriate precautions, there are no known hazards or risks associated with MR techniques. Significant risks may exist for people with:

- Certain dental work, such as braces or permanent retainers
- Cardiac pacemakers
- Metal clips on blood vessels (also called stents)
- Artificial heart valves
- Artificial arms, hands, legs, etc.
- Brain stimulator devices
- Implanted drug pumps
- Ear implants
- Eye implants or known metal fragments in eyes
- Exposure to shrapnel or metal filings (wounded in military combat, sheet metal workers, welders, and others)
- Other metallic surgical hardware in vital areas
- Certain tattoos with metallic ink (please tell us if you have a tattoo)
- Certain transdermal (skin) patches such as NicoDerm (nicotine for tobacco dependence), Transderm Scop (scopolamine for motion sickness), or Ortho Evra (birth control)

If you are unsure whether you have any of these items in your body, you should know that most would have been placed or implanted as part of a surgical or dental procedure. So, trying to remember any past operations may help you remember. Our policies for MRI may be stricter than those in clinical settings, since even some devices made of materials considered "MRI-safe" can still pose some risk or may distort the MRI image, so we do not allow such materials into the scanner. You will be asked whether you have any devices such as those listed above or history of exposure to shrapnel or metal filings, and, if so, you may not be able to participate in this study.

Significant risks can also arise if certain materials (many types of metal objects) are brought into the scanning area, as they can be pulled into the magnet at great speed. Such items can cause serious injury if they hit you. Therefore, these types of items are not permitted in the scanning area. You will not be allowed to bring anything with you into the scanning room.

The MR exams are painless, and except for pulsating sounds, you will not be aware that scanning is taking place.

Your scan is scheduled to take place on a 3T scanner. You should know that those scanners are approved by the FDA for routine clinical studies in children or adults. Although there are no known risks from these scans, there could be adverse effects that are delayed or very mild, such that they have not yet been recognized. Most people experience no ill effects from these scans, but some people do report claustrophobia (fear of being in enclosed small spaces), dizziness, mild nausea, headaches, and a metallic taste in their mouth, double vision, or the sensation of flashing lights. These symptoms, if present, disappear shortly after leaving the scanner.

In rare cases, a very slight, uncomfortable tingling of the back is induced in some people undergoing certain types of scans. If you experience this sensation, you are asked to report this immediately so the scan can be changed to avoid this. Although these precautions will avoid all known risks associated with MRI, this procedure may involve risks to you that are currently unforeseeable.

The sounds that you hear inside the scanner are the normal operating sounds the scanner makes while it takes pictures of your brain. While they may be annoying, their intensity is not harmful to your hearing. However, you will be given a pair of earplugs to wear to muffle the sounds. You also may be asked to wear a set of headphones, which further reduces the noise level and permits the technician to speak to you.

The light exposure device used in the present study (i.e., Philips goLITE) has no significant known harmful effects. However, the light device is not recommended for individuals who use photosynthesizing medications, who have had cataract surgery, or who have pre-existing eye conditions, or bipolar disorder. Exact or similar forms of this device have been used for treatment of seasonal affective disorder (SAD) and jet lag. This product has undergone extensive safety testing based on U.S. and international standards for safety of light devices. You will be instructed on how to properly use the device, especially regarding the importance of **not staring directly at the LEDs**.

NOTE: DO <u>NOT</u> STARE DIRECTLY AT THE LIGHTS ON THE LED PANEL. IT IS SUFFICIENT THAT THE LIGHT REACHES YOUR EYES DIRECTLY FROM THE SIDE.

Although the light device is safe to use, we want to minimize unnecessary direct exposure to the bright light to reduce the possibility of discomfort or persistent visual symptoms. Therefore, **DO <u>NOT</u> STARE DIRECTLY AT THE LIGHTS ON THE LED PANEL.** Although looking directly at the LEDs for brief periods is not known to be harmful to your vision, it is unnecessary and may lead to glare, eyestrain, or other irritating visual sensations that can be easily avoided by keeping the panel at an angle in your peripheral vision. It is sufficient that the light reaches your eyes indirectly from the side. Looking directly at the LEDs does not provide any additional benefit. Prolonged staring at the LEDs could lead to significant eye irritation, lingering afterimages, or other symptoms such as headaches. Although the light emissions of the device are well within safe limits and no problems have

ever been reported, we want to minimize any risks. While extremely unlikely, it is possible that prolonged continuous staring at the LEDs could lead to more severe changes in vision such as photoretinitis, a condition that is most commonly associated with looking for too long at very bright light sources such as snow on a bright sunny. Such a condition could lead to temporary or long-term vision problems. Thus, to minimize your risk, **DO NOT STARE DIRECTLY AT THE LIGHTS ON THE LED PANEL.** As individuals may differ in sensitivity to light, you may experience eye fatigue or irritation while using the light exposure device. If you notice any unusual sensations or discomforts, you are advised to discontinue use and to contact the principal investigator immediately.

There are no anticipated risks associated with saliva collection. These samples will be collected via a small plastic tube placed in the lower part of your mouth. These samples will be labeled with your unique study ID number only and will be kept in the research suite only accessible to authorized study personnel.

There is the possibility of some irritation to the skin from the EEG/EKG leads. This can be alleviated using lotion or cream.

Every effort will be made to protect the confidentiality of your study data and personal information. Your name and identifying information will never be associated with your study data. Instead you will be assigned a unique study ID. Despite these efforts, there is always the possibility, however unlikely, that confidentiality could be breached. In rare cases of emergency or in cases where it is possible that harm may come to yourself or others, confidentiality cannot be ensured.

Certificate of Confidentiality:

We will do everything we can to keep others from learning about your participation in this study. To further help us protect your privacy, we have obtained a Certificate of Confidentiality from the United States Department of Health and Human Services (DHHS).

With this Certificate, we cannot be forced (for example by court order or subpoena) to disclose information that may identify you in any federal, state, local, civil, criminal, legislative, administrative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except to prevent serious harm to you or others, and as explained below.

A Certificate of Confidentiality does not prevent you, or a member of your family, from voluntarily releasing information about yourself, or your involvement in this study.

If an insurer or employer learns about your participation, and obtains your consent to receive research information, then we may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy.

Disclosure will be necessary, however, upon request of DHHS for the purpose of audit or evaluation, and is limited only to DHHS employees involved in the review.

We will in all cases, take the necessary action, including reporting to authorities, to prevent serious harm to yourself, children, or others. For example, in the case of child abuse or neglect, suicide, domestic abuse, etc. Please note that the Certificate of Confidentiality does not represent an endorsement of the research study by the Department of Health and Human Services or the National Institutes of Health.

7. What benefits can I expect from being in the study?

This research is not intended to provide any direct benefit to you. A potential benefit to society is a better scientific understanding of effects of light exposure on cognition and sleep patterns following a concussion. Such information may improve the ability to treat sleep disorders and cognitive performance among patients with mTBI.

The diagnostic assessment and heart rate measures may reveal previously unidentified psychiatric and/or cardiac abnormalities you didn't know you had. If any abnormalities are identified, you will be provided with information about the finding and encouraged to follow up with your primary care physician. Please note that we are not providing psychiatric, neuroradiological, or other clinical services; only that we will let you know in the event that the study team notices anything abnormal. We are unable to assume responsibility or offer compensation for related medical costs that you make as a result of being informed of an abnormal finding.

There may be instances in which an abnormality exists but is not identified in our analyses. Our team is not trained in clinically diagnosing issues pertaining to abnormalities found in the collected data. Further, our data analyses are not intended to treat, diagnose, or replace the expertise of a medical doctor or a medical diagnosis. Thus, you should not rely on our analyses to reveal abnormalities in your data, and our lab claims no responsibility for abnormalities that go undetected during your participation in any research related activities.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law. Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies
- The University of Arizona Institutional Review Board or Office of Responsible Research Practices
- The sponsor supporting the study, their agents or study monitors

10. What are the costs of taking part in this study?

There are no anticipated costs for you to be in this study. You are expected to find your own transportation to and from the University of Arizona, but please speak with the study coordinator if any issues arise related to transportation.

11. Will I be paid for taking part in this study?

mTBI:

You will receive $1,000 for completion of the first three study visits (including the first screening visit), continuous use of the actigraph, daily completion of the sleep diaries and full adherence to the daily light exposure treatment. This payment is also intended to cover all transportation expenses to and from the hospital as well as any food that you will need to purchase during the study visits.

You may choose to participate in an additional 6-week follow-up period during which you would continue to use the wrist-worn activity monitor and complete daily sleep diaries. This period would conclude with an additional (fourth) visit to the lab to return the Actiwatch. You would receive $200 in additional compensation for full completion of all activities during this follow-up period.

If you choose to withdraw from the study prematurely or are disqualified for any reason, you will be compensated at a rate of $25/hour for the time you were undergoing scanning and testing, according to the following schedule:

- Discontinuation during or following the initial visit, you will be paid $25 per hour up to a maximum of $50 for completing the initial clinical interview and questionnaires.
- Discontinuation before the end of the second visit (i.e., first testing and scanning session): $25/hour, up to a maximum of $250 total, following return of all study-related equipment.
- Discontinuation any time during the 6-week light exposure period: $275 maximum total payment, following return of all study-related equipment.
- Discontinuation during but before the end of the third visit: $275 plus $25/hour during the third visit, up to a maximum total payment of $475, following return of all study-related equipment.
- Completion of study procedures up to the end of the third visit and return of all study equipment: $900.

- Completion of all study procedures up to the end of the third visit, return of all study equipment, and evidence that all at-home study procedures were followed (i.e., regular compliance with the use of wrist activity monitors, full completion of sleep diaries, regular usage of light exposure device as instructed and monitored through the WattsUp? Pro® power usage meter): $1,000. If you fail to return the Actiwatch and/or Light Device, you will receive no compensation.

If you choose to participate in the 6-week follow-up period after the initial 7 weeks:

- Discontinuation at any time during the 6-week period post light exposure: $1,000 plus $33.33/week for each week of participation after the end of the third visit.
- Completion of all study procedures for the entire duration of the study (13 weeks), including return of all study equipment within 10 days and evidence that all at-home procedures were followed (i.e., regular compliance with the use of the wrist activity monitor, regular completion of sleep diaries): $1,200. If you fail to return the Actiwatch and/or Light Device, you will receive no compensation.

Payment cannot be rendered until all study-related equipment has been returned.

By law, payments to you may be considered taxable income.

Healthy Participants:

You will receive maximum compensation of $200 total for completion of all study activities including the assessment, light exposure, brain imaging scans, saliva collection, the follow-up visit and return of the Actiwatch. This amount is also intended to cover any and all of your transportation expenses to and from the hospital.

If you choose to withdraw from the study prematurely, you will be compensated at a rate of $8.05/hour for the time you were undergoing scanning and testing (up to a maximum of $40.00). You will be given a bonus of $160.00 for completing the follow-up visit and returning the Actiwatch. Your total maximum compensation is $200. If you do not return for the follow-up visit, or fail to return the Actiwatch, you will receive no compensation.

12. What happens if I am injured because I took part in this study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the next section of this consent form.

If you suffer an injury from participating in this study, you should seek treatment. The University of Arizona has no funds set aside for the payment of treatment expenses for this study.

13. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

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

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

You have the right to get a copy of your study data as it pertains to this study by contacting Dr. Killgore with the information provided on this form. Please note that you may only get such information after the research is concluded and the primary findings have been published.

An Institutional Review Board responsible for human subjects research at The University of Arizona reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

14. Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact Dr. William Killgore at the University of Arizona Department of Psychiatry at (301) 760-0765.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Human Subjects Protection Program at 520-626-6721 or online at http://rgw.arizona.edu/compliance/human-subjects-protection-program.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact Dr. William Killgore at the University of Arizona Department of Psychiatry at (301) 760-0765 or Mike Miller at (520) 626-8573. If they cannot be reached, you may contact the Department of Psychiatry at (520) 626-6255.

Signing the consent form

I have read (or someone has read to me) this form, and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this signed form**.**

May we have your permission to contact you again by phone in about 1-year to ask you a few follow-up questions related to this study?

☐ *Yes*

☐ *No*

Would you be willing and interested to allow us to contact you about future studies for which you might be eligible*?*

☐ *Yes*

☐ *No*

Printed name of subject	**Signature of subject**
	AM/PM
	Date and time
Printed name of person authorized to consent for subject (when applicable)	**Signature of person authorized to consent for subject (when applicable)**
	AM/PM
Relationship to the subject	**Date and time**

Investigator/Research Staff

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

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM
	Date and time