

Morning Light Treatment for Traumatic Stress: the Role of Amygdala Reactivity

NCT04117347

Date of IRB Approval: 12/15/2022

UNIVERSITY OF MICHIGAN CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title:

Morning Light Treatment for Traumatic Stress: The Role of Amygdala Reactivity

Agency sponsoring the study:

National Institute of Mental Health (NIMH)
Department of Psychiatry

Names, degrees, and affiliations of the principal investigator and study coordinator:

Principal Investigators: Helen Burgess, PhD – Department of Psychiatry, University of Michigan *and*
Allyson Zalta, PhD – Department of Psychological Science, University of California at Irvine

Study Coordinator: Muneer Rizvydeen, Department of Psychiatry, University of Michigan

1.1 Key Study Information

You may be eligible to take part in a research study. This form contains information that will help you decide whether to join the study. Take the time to carefully review this information. Talk to us about the study and ask any questions you have. You may also wish to talk to your family, friends, or doctors about joining this study. If you decide to join the study, you will be asked to sign this form before you can start study-related activities. Before you do, be sure you understand what the research study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about different conditions and how to treat them. You should consider the reasons why you might want to join a research study, or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of treating your condition. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to scheduled visits at the study site in Ann Arbor or elsewhere. This may require you to arrange travel, change work schedules, find child care, or make other plans. In your decision to participate in this study, consider all of these matters carefully.

This research study is looking at whether morning light treatment can change how the brain responds to potentially stressful pictures. We are testing a type of light glasses (ReTimer) to see if they can reduce stress symptoms. While the ReTimer glasses are commercially available, this use is considered investigational. We are doing this study to learn more about how the brain works, and to try and find new and inexpensive treatments for traumatic stress. Being in this study requires that you come to Ann Arbor 7 times over 5 weeks, and that you complete the light treatment and study logs at home. Information about your overall health and fMRI scans of your brain will be collected for this study.

Additionally, you must not drink alcohol for the 24 hours before any study visit and refrain from using recreational drugs, including marijuana, during the entire study.

This is a randomized study. This means you are assigned to a study group based on chance. We use a computerized process like a coin-flip to determine your study group. We do this so we can compare the different light treatments.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may include the burden associated with completing the study activities, and the chance that you might experience some emotional or mental distress at having to share personal details of your trauma. More detailed information will be provided later in this document.

This study may offer some benefit to you. You might notice a change in how you feel or in the traumatic stress symptoms you experience. On the other hand, you might not experience any benefit. This study will help others in the future by increasing our knowledge about how the brain responds to light treatment. More information will be provided later in this document.

We expect the amount of time you will participate in the study will be 5 weeks.

You can decide not to be in this study. Alternatives to joining this study include talking to your doctor about other treatment options or investigating other studies.

Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues in Section 2 of this document.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

The purpose of this study is to see how morning light treatment affects brain function in people with traumatic stress.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

Adults between the ages of 18-60 years who have experienced a trauma, and who report distressing symptoms are potentially eligible to be in this study.

There are a couple of main reasons why you might not be eligible for this study: if you are pregnant or breastfeeding, or if you have a history of epilepsy or eye surgery or disease (like cataracts or glaucoma). Also, because this study involves having a functional MRI, you cannot be in this study if you have metal in your body (for example, shrapnel or metalwork fragments, artificial joint, artificial heart valve, etc.) or cannot tolerate being in a small space.

3.2 How many people are expected to take part in this study?

About 66 people are expected to take part in this study.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

During this 5-week study you will come to Ann Arbor 7-8 times. Some of the visits will include having to drive between our research lab and the fMRI lab on the Michigan campus which are a 10-minute drive from each other. If you do not have access to timely public transportation and do not have access to a car or rides with friends and family, we may offer you the option of a free taxi cab service to help you get to the lab visits and back home after the lab visits.

WEEK 1	WEEK 2	WEEK 3	WEEK 4	WEEK 5
<ul style="list-style-type: none"> Visit 1 - answer questions about medical history and see how you do in a mock scanner. Visit 2 –answer questions about your traumatic stress Pick up study materials Start wearing wrist monitor 	<ul style="list-style-type: none"> Visit 3 w/extra drive fMRI scan Questionnaires Start treatment Wrist monitor 	<ul style="list-style-type: none"> Visit 4 check-in Questionnaires Wrist monitor Keep up with treatment 	<ul style="list-style-type: none"> Visit 5 check-in Questionnaires Keep up with treatment Wrist monitor 	<ul style="list-style-type: none"> Visit 6 check-in Questionnaires Wrist monitor Finish treatment Visit 7 w/extra drive fMRI scan Questionnaires

Responsibilities and Expectations for Research Procedures

- 1) *Research visits* – you will come to our research lab 7-8 times. The first two visits are to confirm your eligibility and collect baseline information. The activities associated with Visit 2 can be split over two days. These two visits would need to occur within one month of one another. Other visits are to check-in with you about side effects and to download information from your ReTimer glasses. These visits are about 1 hour or less. And finally, some visits are to measure how the treatment is affecting you by doing a functional MRI (fMRI) and have you answer questions about your mood and symptoms. These visits will require that you drive between our research lab and the fMRI lab, and will typically last about 5-6 hours. If you can't drive we may offer you a free taxi cab service to help you make these lab visits. If it's not possible to do your fMRI and research lab visit on the same day, the fMRI visit can occur on a different day as long as it's within 7 days of your visit to our lab.
- 2) *Assessment of your trauma symptoms and mood* – you will meet with one of our study clinicians who will ask you questions about your traumatic stress and any symptoms you might experience. You will also fill out some questionnaires asking you other questions related to your history and experiences.
- 3) *Vision tests*: We will test how well you can see and for color blindness using eye charts similar to those used in optometrists' offices. We will only do this once, at the screening visit.
- 4) *Videotaping* – some of the assessments will be videotaped. This is to make sure that the clinicians are administering the assessments the way they are supposed to.
- 5) *Wrist activity monitor and daily logs* – you will wear a wrist-watch like device that monitors motion and light. You will wear it all the time for the entire 5 weeks, even when you are sleeping or showering. It tells us when you are asleep and when you are awake. Additionally, to help us understand your wrist monitor information, you are asked to write down your bed time and wake up times, any medications you took, and the times when you did the light treatment every day.
- 6) *Functional MRI* – we will measure your brain activity using a special MRI that looks at how blood flows between brain areas during different activities before and after treatment. This involves you lying still, on your back, in a tube and looking at different pictures of faces or images. The faces show different emotions like fear or happiness, and the images are things that are associated with negative feelings (e.g. person crying), positive feelings (e.g. flowers or puppies), and neutral feelings (e.g. blow dryer). Some of the images may be shocking, including some violent images. You will be shown some sample images at your first lab visit to help you decide if you want to participate. We are measuring how your brain responds to the pictures. You will have opportunities to move your hands and feet in between scans. We ask that you keep your head still for the whole scanning session.
- 7) *Light treatment* – you will be trained on how to use the ReTimer glasses for your light treatment. You will be asked to wear the glasses for either 15, 30 or 60 minutes a day starting right after you wake up in the morning. You will do this for the last 4 weeks of the study.
- 8) *Alcohol and drug use* – you should not drink alcohol for 24 hours before you come to the lab for a research visit. You will take a breathalyzer test at each visit. If you test positive for alcohol use, you may be dropped from the study. You must also not take any recreational or street drugs, including marijuana, during the entire study period (all 5 weeks). We will test your urine at different times during the study. If you test positive for drug use, you will be dropped from the study. All information related to alcohol and drug use will be kept confidential.

4.2 How much of my time will be needed to take part in this study?

You will be in this study for 5 weeks.

4.3 When will my participation in the study be over?

Your participation ends after the 7th and final study visit at the end of week 5.

4.4 What will happen with my information used in this study?

Your research information will be entered into the National Institute of Mental Health's Database for Clinical Trials related to Mental Illness (NDCT). The NDCT is a data repository that is part of the National Data Archive. It allows researchers studying mental health to collect and share de-identified information with each other. The information we share will not contain anything that personally identifies you.

During and after the study we will send de-identified information from the study to the NDCT. Other researchers nationwide can apply to use your de-identified study information for other studies without additional informed consent from you. These researchers must have approved access before getting the data. You may not benefit directly from allowing your information to be shared with the NDCT. The information provided to the repository may help researchers find better treatments and outcomes. The National Institute of Mental Health reports to Congress and on its website the different studies that are being done using the NDCT database.

You may decide now or later that you do not want to share your study information with the NDCT. If so, please contact us and we will tell the NDCT to stop sharing it; however, we cannot take back information that was shared before you changed your mind. More information about the NDCT is available online at <https://nda.nih.gov/>.

With appropriate permissions, your collected information may also be shared with other researchers, here, around the world, and with companies.

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

- Some of the questions ask for information about your trauma and related symptoms, and this might be uncomfortable for you. You can skip any question that makes you feel too uncomfortable.
- Overall, the risk level of the fMRI is minimal. But there are still some things that you should know about it:
 - The images you see while in the scanner are intended to elicit emotional feelings from you. These images may cause distress (feelings like anxiousness or sadness) or may be triggering (make you think of past traumatic experiences). The feelings you experience as a result of these images may be mild or may be intense. We expect that the discomfort associated with these images will be temporary and are unlikely to continue beyond completion of the study procedures. You can stop the test at any time if these feelings become more than you want to deal with. If you are distressed at the end of the task, please tell the study staff.

- There is a minor risk of discomfort or anxiety from being in the confined space of the MRI scanner. We will provide pads and blankets to make you as comfortable as possible. You will be able to talk to us throughout the study, and you will be able let us know right away if you want to stop the study and get out of the scanner.
 - The MRI scanner makes loud, vibrating noises. You will wear foam earplugs to reduce the loud noises made by the scanner and prevent any hearing damage.
 - Some studies, like this one, have the potential to cause "peripheral nerve stimulation" (PNS). PNS is a light touching sensation on the skin surface, lasting only for a few seconds. It may cause mild discomfort, but is not harmful to you. The MRI machine is operated within FDA guidelines so the potential for inducing PNS is low.
 - Sometimes, subjects report a temporary, slight dizziness, lightheadedness or nausea during or immediately after the scanning session. If you feel dizzy or light-headed, we will have you get up slowly from the scanner.
 - Because the strong electromagnetic fields can move metal objects and cause heating, there is a risk that loose objects (jewelry, keys) outside your body could be pulled towards you by the magnetic field, possibly hitting you and causing injury. There is also a risk that the magnetic fields could move a metal fragment in your body, interfere with an implanted device, such as a pacemaker or neurostimulator, or cause metal (including foil-backed medication patches) on or in your body to heat up, causing you harm. We keep the environment around the MRI scanner completely free of loose metal objects that could be moved by the magnetic field, and we will make sure that you have no metal on your body that could be affected by the MRI scanner. We will also ask you questions and have you complete an MRI screening form to make sure that you have no metal inside your body that would cause you harm during the MRI scan. This includes a urine pregnancy test at each fMRI scan for women. You cannot be in the study if this test is positive.
 - There is the potential that a magnetic resonance image may reveal an abnormality that is already in your head or brain, such as a cyst or tumor. Many such abnormalities are not clinically significant, but you may need or want to investigate them further. Such a finding might require additional studies, and maybe even treatment, which would not be paid for by the investigators, the sponsor, or the University of Michigan. However, you should also know that your scan images will not be routinely examined by a specialist trained to make medical diagnoses. Any abnormalities that you may currently have may not be noticed in the images obtained in this experiment. If you have any current health concerns, you should consult your doctor.
- The light treatment may shift your body clock so you might experience symptoms like jet-lag or having traveled across a time zone. These usually include things like sleepiness, feeling tired, headache and upset stomach. Eyestrain and agitation can also occur. These symptoms are usually mild and go away within a day or two.
 - Additionally, there may be a risk of loss to confidentiality or privacy. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

Overall, this study is described as “no more than minimal risk” which means that the risks are not any greater than those you experience as part of a routine doctor’s appointment. We have described the most common and major risks for this study. As with any research study, there may be other risks that we don’t know about or don’t expect.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

Please let us know if you have an injury or illness as a direct result of being in this study. Also follow up with your regular doctor. We will check-in with you each week for any side effects related to the light treatment.

5.3 If I take part in this study, can I also participate in other studies?

You should not take part in more than one study without approval from us and the researchers involved in the other study. Being in more than one research study at the same time, or even at different times, may increase the risks to you, and may also affect the results of the studies.

5.4 How could I benefit if I take part in this study? How could others benefit?

There is a chance that you might experience a decrease in your trauma-related stress. On the other hand, you might not notice any personal benefits from being in this study. The information we learn today will help future individuals with traumatic stress.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, we will tell you if we learn any new important information that may change your mind about staying in the study. If we share new information with you after you have joined the study, it is possible that you will be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?

You can decide not to be in this study, or you may choose to talk to your doctor about other treatment options for traumatic stress.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?

You can leave the study at any time without penalty to you. You will not lose any benefits owed to you if you leave the study early. If you choose to tell us why you are leaving the study, we will record this information in the study record. Please contact us if you decide to leave the study early (see Section 10 "Contact Information").

7.2 Could there be any harm to me if I decide to leave the study before it is finished?

No, nothing bad will happen to you if you decide to leave the study early. If you noticed an improvement in your traumatic stress symptoms, you might notice that these return to your pre-study levels.

7.3 Could the researchers take me out of the study even if I want to continue to participate?

Yes. There are many reasons why we may need to end your participation in the study. Some examples are:

- Positive breathalyzer or drug test
- We believe that it is not in your best interest to stay in the study
- You become ineligible to participate

- You start a treatment that is not allowed while you are taking part in the study
- You do not follow study instructions
- The study is suspended or canceled

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

There is no cost to you for being in this study. All equipment and research procedures are paid for by the study. By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?

You are eligible for up to \$1210 if you finish all parts of the study. To be eligible for payment you must complete the study activities as described in Section 4.

- Visit 1 - \$20 + \$10 to \$30 travel allowance
- Visit 2 – up to \$60 travel allowance, \$10 to \$30 for each day if you do the Visit 2 research activities over 2 days
- Visit 3 – \$225 + \$10 to \$30 travel allowance
- Visit 4 - \$75 + \$10 to \$30 travel allowance
- Visit 5 - \$175 + \$10 to \$30 travel allowance
- Visit 6 - \$75 + \$10 to \$30 travel allowance
- Visit 7 - \$225 + \$175 bonus for finishing study + \$10 to \$30 travel allowance

Travel allowance amount will be pre-determined based on the location from which you are traveling to the lab. We will offer a minimum of \$10 for each visit and an additional \$1 per mile traveled, up to a maximum of \$30 per visit. We can only pay travel allowances for the visits where you come to the research lab at the Rachel Upjohn Building. If you need to do your functional MRI on a different day, which may occasionally occur if the functional MRI laboratory is not available on some days, we cannot give you a travel allowance for those visits.

8.3 Who could profit or financially benefit from the study results?

It is not expected that we or the University of Michigan will benefit financially from the study results. Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

9.1 How will the researchers protect my information?

Day-to-day, we will keep your information in a secure environment and label everything with a study code instead of your name or other identifier. Paper files will be kept in locked filing cabinets, and electronic and video files will be stored behind UMICH firewalls, and in restricted access databases.

While the videos will be stored at University of Michigan, they will be accessed and viewed by our research study colleague at another institution (University of California at Irvine).

Additionally, this research study has applied for a Certificate of Confidentiality from the National Institutes of Health. We, the researchers with this Certificate, may not disclose or use information, documents that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information or documents protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by National Institute of Mental Health which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as child abuse and neglect, or harm to self or others.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by US law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives us your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)

- Mental health care records (except for psychotherapy notes which are not kept with your medical records)
- All records related to your condition, treatment you have received, and your response to treatment
- Demographic information
- Personal identifiers

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.

We might need to share this information with other people or organizations, including:

- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- The National Institute of Mental Health, or safety monitors or committees, may need the information to make sure the study is done safely and properly, learn more about side effects of light treatment, or analyze the results of the study.
- We may need to use the information to create a databank of information about traumatic stress or its treatment.
- If you receive payment of \$600 or more for taking part in this study, the University of Michigan accounting department will collect your name, address, social security number, payment amount, and related information. For tax reporting purposes this information must be sent to the Internal Revenue Service (IRS).
- Federal or State law may require us to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over or if I leave the study before it is finished?

As a rule, we will keep your study information even after the study is over. As described in Section 4.4, your de-identified information is also shared with the National Database for Clinical Trials Related to Mental Illness (NDCT). Once the study is over we will delete any of the information pieces that identify you. We do this for several reasons:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. This information would not include your name, social security number, or anything else that could let others know who you are.
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at <http://www.uofmhealth.org/patient+and+visitor+guide/hipaa>.

9.4 When does my permission to use my PHI expire?

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by calling us (see Section 10 "Contact Information"). If you withdraw your permission, you may no longer be eligible to participate in this study.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Helen Burgess, PhD

Mailing Address: University of Michigan Department of Psychiatry, Rachel Upjohn Building
4250 Plymouth Road
Ann Arbor, MI 48109
Telephone: 734-936-4833

Study Coordinator: Muneer Rizvydeen

Mailing Address: University of Michigan Department of Psychiatry, Rachel Upjohn Building
4250 Plymouth Road
Ann Arbor, MI 48109
Telephone: 734-764-1320

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies, include the appropriate [calling codes](#).)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.

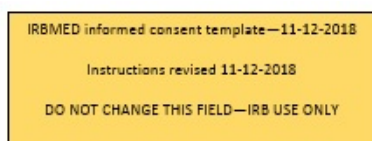
When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem.

This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:



- This "Consent to be Part of a Research Study" document.

12. SIGNATURES

Sig-A

Consent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-B

Consent to video/audio recording solely for purposes of this research

This study involves video and/or audio recording of the clinical assessments. These recordings will be accessed by the co-Principal Investigator at the University of California at Irvine. If you do not agree to be recorded, you CAN STILL take part in the study.

_____ Yes, I agree to be video/audio recorded and allow access to all study team members who require it for completion of their study responsibilities.

_____ No, I do not agree to be video/audio recorded, or allow access to all study team members.

Print Legal Name: _____

Signature: _____

Sig-G

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____