Partners HealthCare System
Research Consent Form

Subject Identification

Certificate of Confidentiality Template
Version Date: January 2019

Protocol Title: Autonomic and fronto-cortical correlates of script-driven imagery of trauma-related nightmares compared with such imagery of index trauma in PTSD using ambulatory physiological and fNIRS recordings

Principal Investigator: Edward F. Pace-Schott, Ph.D.

Site Principal Investigator: N/A

Description of Subject Population: Adults with Posttraumatic Stress Disorder who experience frequent trauma-related nightmares.

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as "Partners."

If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

Key Information

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. Your decision won't change the medical care you get within Partners now or in the future.

The following key information is to help you decide whether or not to take part in this research study. We have included more details about the research in the Detailed Information section that follows the key information.

Why is this research study being done?

The purpose of this study is to determine whether the nightmares that persons like yourself experience following a traumatic experience can be used in a treatment for posttraumatic stress disorder (PTSD) called prolonged exposure therapy or PE. In PE, a patient repeatedly remembers their traumatic experience in the safety of a therapist's office and, by doing so, they become more used to this memory and learn react less to reminders of their trauma. PE is effective due to a well-known cognitive process called "fear extinction" which requires that the trauma memory and some of the emotions felt at the time be recalled vividly. Because in many cases the traumatic event occurred several months, years or even decades in the past, its memory can become changed or distorted. This study will test whether recalling more recently experienced trauma-related nightmares, rather than the memory of the event itself, might be more effective in creating extinction memories. To compare how effective memory of nightmares versus memory of the trauma itself will be during PE, we will use a technique called "script-driven imagery." During script-driven imagery, a patient will listen through headphones to an audio-recorded script of an experience that they have described in detail, read by another person, while their physiological reactions are monitored. These reactions are then compared to their reactions to other scripts describing other sorts of events.

Drs. Zhang and Strangman, investigators on this study, are inventors of the technology that is used in this study. The hospital owns this technology and therefore Drs. Zhang and Strangman and the hospital may benefit financially if this study shows that the technology is valuable. In accordance with Partners HealthCare's conflict of interest policies, the Partners Office for Interactions with Industry has reviewed Drs. Zhang and Strngman's financial interests in the company and determined that the interest creates no significant risk to the welfare of participants in this study or to the integrity of the research. If you want more information about this, please contact the Partners Office for Interactions with Industry at 857-282-2024 or PHSOIIRESEARCH@PARTNERS.ORG.

How long will you take part in this research study?

It will take you between three weeks and a month to complete all parts of this study.
During this time, we will ask you to make **seven (7)** study visits to **MGH's Charlestown Navy Yard.**

What will happen if you take part in this research study?

Overview of the study:

If you choose to take part in this study, we will ask you to sign this consent form before we do any study procedures. If you participate in this study, you will first undergo a psychiatric evaluation for PTSD and sleep disorders during which you will also audio record an account of your traumatic experience. These interviews will be carried out by the Principal Investigator and another PhD-level investigator using Healthcare Secure Zoom accounts that ensure full privacy protection. You can also request meetings with investigators using these same fully secure Zoom accounts at any time during the study. You will then spend 2 weeks monitoring your sleep with a diary, an audio recorder, a wrist motion detector and, on up to four nights (2 nights minimum), a home sleep recorder. During this time, you will also complete online questionnaires on the MGH fully secure REDCap system. These will be described below. Throughout this 2-week period, whenever you wake up from a nightmare, you will record a report of what you experienced during that nightmare into the audio-recorder. You will next come to Massachusetts General Hospital-East (MGH) to have a magnetic resonance image taken of your brain. Finally, you will come to MGH to complete two script driven imagery sessions on a single day. One of these will be a recorded script of imagery from your memory of the actual traumatic event and the other will be a recording of imagery that you have recorded from a nightmare related to this trauma. While you listen to these recording, electrodes on your body will record your physiological responses and we will also use a technique called near-infrared spectroscopy (NIRS) to measure your brain activity. The MRI that you completed will be used to place the NIRS recorders in the correct positions on your forehead. NIRS works by shining light through your skull and using the returning light to detect changes in blood volume and the amount of oxygen in the blood. We will examine the NIRS measurements collected while you listen to the nightmare and trauma scripts. For description of risks associated with NIRS, please see Risks of Near Infrared Spectroscopy (NIRS) section on page 10. Each of these procedures are described in greater detail in the section titled **"What will happen in this research study?"**

Why might you choose to take part in this study?

You will not benefit directly from taking part in this research study. What we learn by doing this study may help us improve a treatment for PTSD called Prolonged Exposure Therapy.

Why might you choose NOT to take part in this study?

Taking part in this research study has some risks and requirements that you should consider carefully. Important risks and possible discomforts to know about include:

- Emotional distress from recalling memories of the traumatic during the assessment interview and questionnaires as well as from the script-driven imagery sessions.

- People who feel uncomfortable in confined spaces (claustrophobia) may feel uncomfortable in the narrow tube of the MRI.
- Mild scalp and skin irritation could occur at the location of electrodes placed on your body for the home sleep-recordings and NIRS-Scan sessions.

A detailed description of side effects, risks, and possible discomforts can be found later in this consent form in the section called "What are the risks and possible discomforts from being in this research study?"

Another thing to consider is **the multiple-visit commitment as well as travel to and from the Charlestown Navy Yard.**

What other treatments or procedures are available for your condition?

A number of different treatment options are available for treating PTSD and include several types of talk therapy (psychotherapy) and medications. We can assist you in locating clinicians and mental health facilities in your area that provide these forms of treatment.

On the first night of home sleep recording, we will screen for sleep disorders such as sleep apnea. This is not the equivalent of a clinical sleep evaluation which usually requires a sleep laboratory. However, if we believe we detect a sleep disorder, we will contact you and refer you to a sleep specialist for follow-up. If you have a primary care doctor, we can also contact your doctor (with your permission) and help get the right care for you.

If you have questions or concerns about this research study, whom can you call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Edward F. Pace-Schott, Ph.D. is the person in charge of this research study. You can call him at 508-523-4288 (24-hours a day, 7 days a week) with questions about this research study.

If you have questions about the scheduling of appointments or study visits, call **Augie Kram Mendelsohn** at **617-643-7374.**

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research
- Any pressure to take part in, or to continue in the research study

Detailed Information

Why is this research study being done?

The purpose of this study is to determine whether the nightmares that persons like yourself experience following a traumatic experience can be used in a treatment for posttraumatic stress disorder (PTSD) called prolonged exposure therapy or PE. In PE, a patient repeatedly remembers their traumatic experience in the safety of a therapist's office and, by doing so, they become more used to this memory and learn to react less to reminders of their trauma. PE is effective due to a well-known cognitive process called "fear extinction" which requires that the trauma memory and some of the emotions felt at the time be recalled vividly. Because in many cases the traumatic event occurred several months, years or even decades in the past, its memory can become changed or distorted. This study will test whether recalling more recently experienced trauma-related nightmares, rather than the memory of the event itself, might be more effective in creating extinction memories. To compare how effective memory of nightmares versus memory of the trauma itself will be during PE, we will use a technique called "script-driven imagery." During script-driven imagery, a participant listens through headphones to a audio-recorded script of an experience that they have described in detail, read by another person, while their physiological reactions are monitored. These reactions are then compared to their reactions to other scripts describing other sorts of events.

We are asking you to take part in this study because you have experienced a traumatic event and you have reported frequent nightmares concerning this event. We plan to enroll 50 people in this study at MGH. This study is supported by the National Institute of Mental Health (NIMH). Your scans, sleep recordings, MRI scans and other data will be used mainly to understand and compare how actual trauma memories and memories of the nightmares about these traumas are different. We will also determine whether memories of nightmares may be particularly useful for administering PE to patients with PTSD. The long-term goals of this research are to learn how to better understand, prevent, diagnose and treat posttraumatic stress disorder (PTSD). However, it is not possible to list every research

project for which the data that we collect from you may prove useful in the future. As we learn more, there may arise new types of research related to the fields of psychiatry and sleep medicine. In addition, new research questions, in which your data might be used, may become important in the coming years. Your data may also be used for research into other psychiatric conditions.

Who will take part in this research?

We are asking you to take part in this study because you have reported recurring nightmares about a traumatic event you experienced. About 50 people between the ages of 18 and 60 will take part in this research study at MGH's Charlestown Navy Yard. The National Institute of Mental Health (NIMH) is paying for this research study to be done.

What will happen in this research study?

Your first visit to MGH-East will be a single, approximately 1-hour visit during which you will:
- Sign the consent form
- Complete several questionnaires
- Take a urine test
- Write an account of the traumatic event(s) about which you have nightmares

Your second interaction with the lab will be an approximately 3-hour virtual interview process during which you will:
- Complete a psychiatric/psychological (mental health)
- Answer more questions and fill in details about the traumatic event(s)
- Complete a sleep disorder evaluation

But, to see how procedures may vary due to the COVID-19 pandemic please see page 9.

The mental health interview will be performed by an experienced researcher who will ask you about symptoms of mental disorders, your personality traits (for example, shyness), and your drug and medication use. There will also be questions about your life history, including any stressful or traumatic life events such as sexual abuse or physical violence.

You will then fill out some questionnaires, which will take about 15 minutes to complete. We hope that you will answer all the questions in the interviews and questionnaires, but you may skip over any questions that you choose not to answer. A different researcher will then carry out

the sleep disorders evaluation during which we will ask you about symptoms of the various sleep disorders and gather additional information concerning your nightmares.

We will then have you provide a urine sample for a drug toxicology screen that can detect recreational drugs such as marijuana, opiates, amphetamines, barbiturates, benzodiazepines, PCP, and cocaine. A positive test for these substances will exclude you from the study. The results of the urine drug test will not become part of your medical record. These test results will, however, remain part of your confidential study record.

After we review your interview and questionnaire responses, and urine screen, we will let you know if you qualify for the second part of the study. If you do qualify and wish to continue, you will continue with the study as described below. If you do not qualify or do not wish to continue, you will receive payment for completing your first visit according to the payment schedule below.

You will then dictate an account of the traumatic experience about which you have nightmares. We will audio record this account in order to prepare the script of your trauma memory. The psychologist who conducted your psychiatric interview may ask you some additional details of your experience in order to ensure we have obtained enough information to create this script. You may take as long as you wish to complete your account and you are entirely free to stop at any point that you feel uncomfortable or upset.

Lastly, if you are continuing in the study, we will schedule you for a two week period during which you will keep sleep diaries, wear an activity monitor, audio-record descriptions of any nightmares that awaken you, and complete four overnight home sleep recordings (polysomnography). Each of these activities is described in detail below. At the end of these two weeks, we will schedule you to come to MGH for your two script driven imagery sessions. Please also note that use of alcohol and recreational drugs is prohibited throughout your participation in the study

Sleep diaries
Sleep diaries are filled out in the evening before going to bed and in the morning when waking up and take no more than 5-10 minutes total. Questions in the evening concern prior daytime activities such as exercise, caffeine intake, naps and the time you begin trying to go to sleep. Questions in the morning portions ask what time you woke for the day, how long you think it took you to go to sleep and how many times you woke up. It will also ask you to rate your quality of sleep and how you feel waking up. It will also ask you to describe your dreams and nightmares. (This information will be used to create the nightmare script.)

Wrist actigraph
An actigraph is a small device that looks like a watch that you wear on your wrist. It monitors your movement, giving us a general idea of when you are asleep and when you are awake. It also has a button that you press when you go to bed and wake up. It is worn continuously, and you can wear it in the shower, when exercising, etc. If you need to remove it for a special circumstance (for example, some team sports don't allow anything on wrists), we ask that you record in your diary the times you take it off and put it back on.

Home sleep recording (polysomnography)
During two to four nights of these two weeks, you will undergo home-based polysomnography. You will come to MGH on the evening before each of these recordings to have electrodes attached to your head and torso. The recording device and its wires are worn in a pouch on your chest and most individuals easily adjust to wearing these. Polysomnography records brainwaves, eye movements and muscle movements in order to measure stages of sleep. To prepare you for polysomnography we will apply electrodes to your scalp, on the temples near your eyes, behind your ears and on your chin and on your torso (to record heart rate). On your first night of polysomnography, we will screen you for sleep disorders. On just this first night, you will also have a sensor placed under your nostrils, electrodes placed on your shins, two belts placed around your torso and a small clip attached to one of your fingers. We will provide you with instructions on how to place these additional sensors in your home before you go to bed. On the remaining 3 polysomnography nights, you will only have the electrodes attached to your face, scalp and torso and we will attach all of them in the laboratory. If you come to MGH by public transportation to have your sleep recording electrodes attached, we will send you home by taxi. You will be asked to keep these electrodes on while you have a normal night's sleep. You will remove these electrodes when you wake up the next morning. All of the materials used to attach electrodes come off readily in the shower. We will arrange a mutually convenient location the following morning to pick up the sleep recording materials.

Audio-recording nightmares
Whenever you wake up from a nightmare, you will record a report into the audio-recorder of what you experienced during that nightmare in as much detail as you can remember. You will have to turn on the recording device, start recording, and stop recording. You can add any details that you wish to the nightmare report when you wake up for the day.

MRI scanning
You will also come to MGH for an MRI scanning session during which we will obtain a picture of your brain that we will use to position the fNIRS sensors on your head for your script driven imagery sessions. The MRI scanner is a very large machine with an opening like a tunnel in the center. The tunnel is a little bit wider than your body. This procedure does not use any ionizing radiation, like x-rays do. MRI uses radio waves and magnetic fields to make pictures of the

inside of the body. You will lie down on your back on a narrow table that will slide you into the center of the MRI scanner. You will lie quietly inside the machine. A large plastic cylinder with holes in it (called a coil) will surround your head. You will hear knocking and beeping sounds during the scanning. These sounds mean that the scanner is working. We will give you earplugs to muffle the sound and protect your hearing. You must lie quite still during the scanning procedure, but we will be able to speak to you while you are in the scanner. We will also be able to hear you. Women who can become pregnant must have a urine pregnancy test immediately before the MRI scanning session. Pregnant women cannot take part in this study. Persons with any metallic objects in or on their body cannot be scanned and we will ask you several times, in detail, about any such objects. The scanner is an enclosed space, with the top and sides of the tunnel being very close to your face and body. If you have ever felt claustrophobic (fearful of closed-in spaces), tell us before the scanning starts. We will help you if you become uncomfortable and can stop the scanning any time, if you ask.

Script-Driven Imagery
Your visit to MGH-East for script-driven imagery sessions will last for 4-5 hours over one entire afternoon. It will consist of two 1-h sessions with one hour between them. During the script-driven imagery procedure, you will be seated in a comfortable armchair and we will place electrodes on your palm, face and torso. You will first be asked to sit quietly for 5 min then you will listen to eleven 30-second pre-recorded scripts through headphones. Some of these scripts will describe personal experiences you have told us about, including the traumatic event you experienced or the nightmare that you recorded at home. Other scripts will describe situation or events in which you were not personally involved. You will be instructed to listen carefully during the playing of each script, and upon its conclusion to imagine as vividly as possible the experience that was presented until you hear a tone signal. You will then relax for a few minutes, rate how you felt on several scales and then rest again. You will then start to listen to the next script. You will then spend one hour watching a nature video. After this hour, you will complete a second session with eleven scripts. After this second session, we will make sure you are not upset, and we will explain the study to you.

During this study we may need to make changes to study visits and procedures to comply with public health efforts to address COVID- 19 (coronavirus). We may need to adjust the study visit schedule, where you sign the consent form, number of home sleep studies, whether or not an MRI is performed, and/or research procedures as a result of study site restrictions on research visits. We may conduct study visits remotely until the restrictions are lifted. Remote visits will be conducted by Zoom or telephone. During these visits, someone from the study staff will contact you by using Zoom or telephone and conduct the following types of research activities: Pre-Screening Interview, Psychiatric/psychological (mental health) evaluation, Sleep Disorders Evaluation.

Study staff will provide you information on how to access the video conferencing platform. We will launch the video conferencing in a private and secure area. To protect your privacy we ask that you do not take screenshots, photographs, or recordings of any kind with any electronic equipment.

We would like to remind you that a video meeting is similar to us visiting you at home. We may learn more about your home and the people living with you than we would during a visit at the hospital. For example, we may learn information from you that must be reported to public health or public safety authorities. We are required by law to report known or suspected child or elder abuse. If we make such report, the public health and safety authorities can use the information as they see fit and may end up sharing it with other government agencies. Please ask the research staff if you have any questions about this prior to your video visit.

How may we use and share your samples and health information for other research?

Data from this study will be submitted to the NIMH Data Archive, an informatics system run by the National Institute of Mental Health that allows researchers to review and use data from this study for their own research. With an easier way to share, researchers hope to learn new and important things more quickly than before.

- During and after the study, the researchers will send information about your health and behavior to the NIMH Data Archive. However, before they send it, they will remove information such as your name, address, and phone number, and replace that information with a code number. As part of your participation in the study, a unique subject number will be assigned to you that will allow researchers to see if you have been involved in more than one research study or database for patients who have had traumatic experiences. If you have participated in more than one study or database, this unique subject number will help connect information across studies. This subject number will also allow your de-identified data to be combined with data from other research studies to increase the likelihood of meaningful analysis. Only this subject number and not your personal identifiable information will be accessible to other investigators. This unique subject number may make it possible for a study doctor who used this unique subject number in another study that you took part in to identify you. Other researchers nationwide can then file an application with the National Institute of Mental Health to obtain access to your study data for research purposes. Experts at the National Institute of Mental Health who know how to protect health and science information will look at every request carefully to minimize risks to your privacy.

- You may not benefit directly from allowing your information to be shared with the NIMH Data Archive. The information provided to RDoCdb might help researchers around the world treat others so that they have better outcomes, however, RDoCdb will not be able to contact you individually about specific studies.

- You may decide now or later that you do not want to share your information using the NIMH Data Archive. If so, contact the researchers who conducted this study, and they will tell the NIMH Data Archive, which can stop sharing the research information immediately. However, the NIMH Data Archive cannot take back information that was shared before you changed your mind. If you would like more information about the NIMH Data Archive, it is available on-line at https://nda.nih.gov.

At the completion of this research study, we would like to store and be able to use and share your identifiable samples and health information with researchers at Partners for other research related to **PTSD and sleep disturbances**. If we share your samples and/or health information with other researchers outside of Partners, we will label the samples and information with a code instead of your name or other directly identifying information. The key to the code connects your name or other identifiers to your sample and/or information. We will keep the code in password-protected computers and all physical information tying your code to your personal information in locked cabinets inside locked offices.

Because these samples and/or health information are identifiable, we are asking your permission to store, use and share them for other research. You can still take part in the research study whether or not you give permission for the storage, use, and sharing of the samples and health information for other research.

Do you agree to let us store and use your samples and health information for other research related to **PTSD and sleep disturbances?**

☐ YES ☐ NO Initial _____

Will you get the results of this research study?

You should not expect to get information about the results of the research study or the results of your individual participation in the research study. We will study images and information from many people. It could take many years before anyone knows whether the results have any meaning. There is a small chance that we could find out something from the study that might be important to your health. If this happens, we may contact you to find out if you would like to

learn more. However, even if we find something important to your health, we cannot guarantee that you will be contacted.

What are the risks and possible discomforts from being in this research study?

Risks of Answering Interview Questions and Study Questionnaires

There are some sensitive questions posed in the assessment interview and questionnaires that may cause discomfort for some subjects. You may skip any items that you do not wish to answer.

Risks of home sleep recording

On rare occasions electrodes can cause minor scalp irritation. Removing some of the sleep electrodes attached with tape may pull slightly on your skin and feel like a band-aid being removed. All of the materials used to attach electrodes come off readily in the shower.
Home sleep recording can sometimes prevent you from sleeping as deeply as usual. If you feel you have had insufficient sleep or feel sleepy as a result of home sleep recording, you should avoid driving or operating other potentially dangerous equipment until you have had another night's sleep.

Risks of Near Infrared Spectroscopy (NIRS)

Non-invasive NIN has been in use for over 30 years and no harmful side effects have been reported. However, it is possible that effects not yet reported may occur. The light used to make the measurements has very low power, below the American National Standards Institute limit for long-term exposure to infrared light. The amount of light used to monitor your brain will be less than the amount of light the brain would receive during an outdoor walk on a sunny day. Although the NIRS devices do not require eye protection even with inadvertent eye exposure, you should never look in the sources of light on the probe, and should keep your eyes closed during NIRS probe attachment.

NIRS monitoring requires placing a probe against the skin on the scalp. This is done by fastening the sensors to a pad or cap, placing it over the head, and holding it in place with a strap. Your hair may need to be parted in the location of the probe to provide better contact with your skin. The procedure does not cause pain. On rare occasions, the skin beneath the probe can become irritated.

Skin electrodes may generate mild skin irritation. You will be asked if you have any known allergies to adhesive electrodes, and we will also use hypo-allergenic electrodes to minimize the risk of skin irritation.

Fatigue and/or boredom while participating in the NIN tasks could occur during this portion of the study. You will have rest periods to try to reduce both.

Risks of the fMRI Procedures

Risk of MRI Scans MRIs use powerful magnets to make images. There are no known radiation risks associated with MRI. However, persons with metal implants, such as surgical clips, or pacemakers should not have an MRI. All credit cards and other items with magnetic strips should also be kept out of the MRI room. People who feel uncomfortable in confined spaces (claustrophobia) may feel uncomfortable in the narrow tube. The MRI makes loud banging noises as it takes images. Earplugs can be used to reduce the noises. The MRI can be stopped at any time at your request. If you are or suspect you are pregnant, you should not participate in this study. The MRI has the potential, during normal routine use, to cause localized warming of your skin and the underlying tissues. You should immediately inform us if you experience discomfort due to warming and the procedure will be stopped.

Some people experience dizziness or rarely nausea when going into an MRI scanner and these sensations may be more common in scans with higher magnetic fields. In most cases, these symptoms only last a short time. However, some people may experience them throughout the scan and/or continue to experience them for a short period of time after; generally, less than half an hour. No case of permanent problems is known.

The MRI being done for this study is designed to position the NIRS sensors, not to examine your brain medically. This MRI is not a substitute for one a doctor would order. It may not show problems that would be picked up by a medical MRI. However, if we believe that there is something unusual in your MRI, we will ask a doctor trained to read MRIs to look at your MRI. If the specialist thinks that there may be something unusual in your MRI, we will contact you and refer you to another doctor for follow-up. If you have a primary care doctor, we can also contact your doctor (with your permission) and help get the right care for you. The results of your research MRI will not routinely become part of your hospital record. If we think there might be a problem, but do not actually find one, you might be worried unnecessarily.

Risk of script-driven imagery sessions

You may experience emotional distress as you recall memories of your traumatic event life experiences or your nightmares that are related to these experiences. Based on our past experience, we expect such distress to be short-lived. You can stop the sessions any time you wish and then either continue or not continue them depending on how you are feeling. If you experience any distress, you may speak with the Principal Investigator or with one of the study's psychologists who will be available throughout your script-driven imagery sessions.

What are the possible benefits from being in this research study?

You will not benefit directly from taking part in this research study. What we learn by doing this study may help us improve a treatment for PTSD called Prolonged Exposure Therapy.

What other treatments or procedures are available for your condition?

A number of different treatment options are available for treating PTSD and include several types of talk therapy (psychotherapy) and medications. We can assist you in locating clinicians and mental health facilities in your area that provide these forms of treatment.

On the first night of home sleep recording, we will screen for sleep disorders such as sleep apnea. This is not the equivalent of a clinical sleep evaluation which usually requires a sleep laboratory. However, if we believe we detect a sleep disorder, we will contact you and refer you to a sleep specialist for follow-up. If you have a primary care doctor, we can also contact your doctor (with your permission) and help get the right care for you.

Can you still get medical care within Partners if you don't take part in this research study, or if you stop taking part?

Yes. Your decision won't change the medical care you get within Partners now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should you do if you want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will you be paid to take part in this research study?

You will paid up to a maximum of $475 for fully completing the study. We will provide free parking at MGH-East in Charlestown. And, if you take public transportation, we will provide a taxi voucher or reimburse your ride-hailing cost on the nights that you have the polysomnography electrodes attached. If you complete only part of the study, we will compensate you as follows.

$30 for an initial visit to read and sign the consent form and provide a urine sample
$70 for completing clinical interviews
$150 for completing Phase 1 of the study (14 days of audio-recording of experienced nightmares, nightmare and sleep diaries, actigraphy, 2 to 4 ambulatory PSG nights, as well as online questionnaires using the MGH fully secure REDCap system.
$125 for completing the 2 script-driven imagery procedures and positioning of fNIRS optodes
$100 bonus for completing entire protocol

There are several reasons that we may decide to discontinue your participation in this study after you sign this form. However, you will be compensated for the activities you have completed based upon the schedule above. You will be discontinued in the study if 1) you do not meet study criteria at the clinical interviews, 2) you produce a positive urine toxicology screen for drugs of abuse, 3) if you produce a positive pregnancy test before your structural MRI, 4) if we detect a sleep disorder on your diagnostic polysomnography night, or 5) if you do not record nightmares.

What will you have to pay for if you take part in this research study?

Study funds will pay for the study visits and all the tests and procedures that will be done only for the research.

We may bill your health insurer for, among other things, routine items and services you would have received even if you did not take part in the research. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care. If you have any questions about costs to you that may result from taking part in the

research, please speak with the study doctors and study staff. If necessary, we will arrange for you to speak with someone in Patient Financial Services about these costs.

What happens if you are injured as a result of taking part in this research 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. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

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 beginning of this consent form.

If you take part in this research study, how will we protect your privacy?

Federal law requires Partners to protect the privacy of health information and related information that identifies you. We refer to this information as "identifiable information."

In this study, we may collect identifiable information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable information and why:

- Partners researchers and staff involved in this study
- The sponsor(s) of the study, and people or groups it hires to help perform this research or to audit the research
- Other researchers and medical centers that are part of this study
- The Partners ethics board or an ethics board outside Partners that oversees the research

- A group that oversees the data (study information) and safety of this study
- Non-research staff within Partners who need identifiable information to do their jobs, such as for treatment, payment (billing), or hospital operations (such as assessing the quality of care or research)
- People or groups that we hire to do certain work for us, such as data storage companies, accreditors, insurers, and lawyers
- Federal agencies (such as the U.S. Department of Health and Human Services (DHHS) and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections), state agencies, and foreign government bodies that oversee, evaluate, and audit research, which may include inspection of your records
- Public health and safety authorities, if we learn information that could mean harm to you or others (such as to make required reports about communicable diseases or about child or elder abuse)
- Other researchers within or outside Partners, for use in other research as allowed by law.

Certificate of Confidentiality

A federal Certificate of Confidentiality (Certificate) has been issued for this research to add special protection for information and specimens that may identify you. With a Certificate, unless you give permission (such as in this form) and except as described above, the researchers are not allowed to share your identifiable information or identifiable specimens, including for a court order or subpoena.

Certain information from the research will be put into your medical record and will not be covered by the Certificate. This includes records of medical tests or procedures done at the hospitals and clinics, and information that treating health care providers may need to care for you. Please ask your study doctor if you have any questions about what information will be included in your medical record. Other researchers receiving your identifiable information or specimens are expected to comply with the privacy protections of the Certificate. The Certificate does not stop you from voluntarily releasing information about yourself or your participation in this study.

Even with these measures to protect your privacy, once your identifiable information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain completely private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your identifiable information. Your permission to use and share your identifiable information does not expire.

The results of this research may be published in a medical book or journal, or used to teach others. However, your name or other identifiable information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your identifiable information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your identifiable information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others, and such information may continue to be used for certain purposes, such as to comply with the law or maintain the reliability of the study.

You have the right to see and get a copy of your identifiable information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my identifiable information to be used and shared as described above.

Subject	Date	Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

Study Doctor or Person Obtaining Consent	Date	Time (optional)

Consent Form Version Date: 10/30/2020