FOR OFFICE USE ONLY

StudyID: _____ Consenting Date:__/__/____

Staff Review on Scan Day: Date: / /

University of Wisconsin-Madison
Consent/Assent to Participate in Research
and
Authorization to Use Protected Health Information for Research

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Study Title for Participants: RESTORE

Formal Study Title: *Sleep and emotion processing in adolescent post-traumatic stress disorder*

Lead Researcher: *Stephanie Jones, Ph.D. Department of Psychiatry, 6001 Research Park Blvd., Madison WI 53719* (Phone: 608.263.6068)

Institution: *Wisconsin Institute for Sleep and Consciousness*

Key Information

The information in this section is to help you decide whether or not to be a part of this study. You can find more detailed information later on in this form.

Why are researchers doing this study?

Post-Traumatic Stress Disorder (PTSD) in youth is a growing problem with few treatment options. Most of these involve therapy, but therapy does not always work to improve symptoms. There is some reason to think that improving sleep quality, which is often poor in people experiencing PTSD, may help when therapy alone does not. Researchers are doing this study to learn more about how sleep quality affects emotions in youth generally and whether improving sleep quality through the use of the SmartSleep headband device can lead to improvements in mood and decreases in PTSD symptomology.

We are inviting you (the youth participant) to take part in this study because you are between 15-18 years old and either: 1) you are generally healthy with no history of having experienced trauma, 2) you have experienced trauma but do not have a current PTSD diagnosis, or 3) you do meet the criteria for a current PTSD diagnosis. If you agree to participate, we will confirm whether or not you meet the criteria for diagnosis through our own clinical assessment.

We are also inviting your parent or guardian to participate in some parts of the study as well as to provide consent for your participation if you are under 18.

What will I need to do in this study?

For this study, you and your parent will complete the following study visits:

1. Study Visit 1: Consenting and clinical screening visit
2. Study Visit 2: Assessments and optional MRI
3. Overnight Sleep Visit 1
4. One week of at-home sleep recordings
5. One week of at-home sleep recordings
6. Overnight Sleep Visit 2

Specifically, the first visit includes obtaining informed consent followed by a clinical assessment and takes about 2 hours. The second visit takes about 3 hours and will include a surveys, tasks on a tablet and training on how to run the study at home. As described later in this form, you may also be asked to complete an optional MRI scan. You will be sent home with the WatchPAT, a finger cuff that can detect sleep apnea, to wear at-home for one night. Sometime after these visits, you will come in to sleep in the lab with monitoring equipment and perform a computer task before and after sleep. Then, up to four weeks later, you will be asked to wear the SmartSleep headband and heart-rate watch to sleep at home for up to 7 nights, followed by another week of wearing the SmartSleep headband and heart-rate watch for up to 7 nights, totaling up to 14 nights. You will also be asked to respond to a short survey about your emotions four times each day you complete an overnight recording. Up to four weeks later you will come in to sleep in the lab with additional monitoring equipment and perform a computer task before and after sleep one last time. Your parent may accompany you to the in-laboratory sleep visits but is not required. We expect you will be in this study between five and ten weeks.

You can find detailed information about the study procedures in the section called **If I take part in the study, what will I do?**

What are some reasons I might – or might not – want to be in this study?

You may want to be in this study if you are:	**You may NOT want to be in this study if you:**
• You and your parent are both comfortable having researchers ask questions about your experience with trauma and PTSD symptoms • You are able and willing to complete an MRI scan	• You or your parent prefer not to answer questions about your experience with trauma and/or PTSD symptoms • You or your parent do not have time for the in-person visits or you do not wish to sleep overnight in the lab

• You and your parent are willing to commit to the in-person visits, including two overnights for you • You are willing to wear the SmartSleep headband and heart-rate watch while sleeping at home for up to two weeks • You are interested in contributing to scientific knowledge even though you won't benefit directly from the study	• You do not wish to wear the SmartSleep device or heart-rate watch while sleeping at home

Do I have to be in the study?

No, you do not have to be in this study. Taking part in research is voluntary. If you as the youth participant decide not to be in this study, your dissent will be honored. Your choice will not affect your healthcare or any services you receive. There will be no penalty to you. You will not lose medical care or any legal rights. You can ask all the questions you want before you decide.

Detailed Information

The following is more detailed information about this study in addition to the information listed above.

How is research different from health care?

When you take part in a research study, you are helping to answer a research question. Study tests and procedures are not for your health care.

Who can I talk to about this study?

If you have questions, concerns, or complaints, or think that participating in the research has hurt you, talk to the lead researcher, Stephanie Jones. She can be reached by email at sgjones2@wisc.edu, or you can write to her:

Stephanie Jones
Department of Psychiatry
6001 Research Park Blvd.
Madison WI 53719

If you have any questions about your rights as a research participant or have complaints about the research study or study team, call the confidential research compliance line at 1-833-652-2506. Staff will work with you to address concerns about research participation and assist in resolving problems.

If I take part in the study, what will I do?

All study visits will take place at WISPIC, located at 6001 Research Park Boulevard, Madison, WI 53719.

Your first visit will take approximately 2 hours. At this visit, after discussing the study with staff and providing consent to participate, you, the youth participant will be interviewed. The questions will ask about various symptoms, past experiences, and thought patterns. We will also ask some questions about your medical and trauma history. You may choose not to answer any questions that make you uncomfortable. The time it takes to complete the interview and questionnaires will vary depending on your personal history.

When you arrive for the second visit, we will review study procedures. Then you will do some tasks on a tablet that will measure different aspects of intelligence. We will then ask you to privately fill out some surveys. When this is over, study staff will train you both on how to use the SmartSleep and heart-rate devices at home and we will schedule your participation in the at-home portions of the study as well as the two overnight laboratory visits. You will also be sent home with the WatchPAT device, which you will wear on your finger at-home for one night to detect sleep apnea. In total, this visit is expected to last 2-3 hours.

For the next portion of the study, we will ask you to come back to the lab for an overnight sleep visit. Your parent may accompany you to this visit but is not required. You will be asked to arrive about 4 hours before your regular bedtime, and dinner may be provided if you arrive before your dinner time. Upon arrival, if you have PTSD and/or trauma history, you will be asked to complete a few surveys asking about any symptoms you experienced over the course of the week.

Then, we will apply an electrode net to your head to measure brain activity and apply additional sensors to measure physical emotional responses before asking you to do a task on the computer. The task involves viewing pictures of neutral or negative scenes which you will be asked to remember for the following morning. After viewing each picture, you will be asked to rate the intensity of any emotional reaction experienced while viewing the picture. After the task, you will go to sleep while still wearing the electrode net. You may also have other sensors on the body to measure things like eye movements, oxygen level, leg movements. These are standard equipment used in overnight sleep studies. In the morning, we will spend some time reapplying the electrode night in case any sensors became disconnected during the night. Then you will perform the picture viewing task again. Some of the pictures will be repeated from the night before and some will be new. You will be asked whether you believe each picture is old or new in addition to rating your intensity of emotional reaction while viewing it.

Sometime within 4 weeks of the in-lab overnight, you will complete the at-home portion of the study.

The next portion of the study involves you wearing the SmartSleep and heart-rate devices to sleep at home for up to seven nights, two times for a total of up to 14 nights. The sleep headband has sensors in it that measure your brain activity while you are asleep. This headband also includes headphones that can play quiet audio sounds to enhance slow wave sleep. Some of the nights, the device will play the audio tones, but you will not know when that will happen. You will also wear a watch on your wrist to record your heart-rate day and night for a total of 14 days. Each day after wearing the device, you will be asked to download data from the device onto a laptop that we will provide you with. You will also respond to a short survey about your emotions at four different times during the day. We are asking for both your and your parent's cell phone numbers so that we can send reminder text messages when it is time to perform study activities, but you may opt to have reminders sent via email instead. Should any issues arise, technical or other, at any time either of you will be able to contact study personnel. At the end of each at home sleep week, a study team member will call you to ask you some questions about how you've been feeling physically after wearing the SmartSleep device.

Then, you will come back to the lab for the second in-lab overnight visit. It will be similar to the first one, except you will only perform the picture viewing task on one of the overnight visits. Some youth will perform it at their first overnight visit, and others will perform it at their second visit.

Any of your study visits (including consenting, clinical assessments, and in-laboratory sleep visits) may be audio or video recorded for purposes of training, as well as standardizing and assuring the quality of our research methods. Videos will be coded using your subject ID and stored where only study personnel will have access to these videos. Recordings of clinical assessment visits may be stored indefinitely, while recordings of in-lab sleep visits will be deleted within one month of the study visit. While we code the data using your subject ID, your faces and auditory dialogue will be recorded. This includes any personal information you choose to say while the camera will be recording.

Protected health information (PHI) used in this study
Protected health information, also called PHI, is information about your physical or mental health that includes your name or other information that can identify you, like your date of birth or medical record number. To do this study, we will use the following kinds of PHI:

- Results of tests or procedures done as part of the study (including MRI)
- Things you tell the researchers about your health

What happens if I say yes, but I change my mind later?

You can leave the research at any time. If you choose to leave the study, your choice will not affect your healthcare or any services you receive. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

If you stop being in the research, already collected data may not be removed from the study database. You may be asked whether the investigator can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

Your authorization for researchers to use your protected health information (PHI) does not have an end date. However:

- You can choose to take back your authorization for researchers to use your health information. You can do this at any time before or during your participation in the research.
- If you take back your authorization, information that was already collected may still be used and shared with others, but the researchers will no longer be able to collect NEW information about you.
- If you take back your authorization, you will not be able to take part in the research study.
- To take back your authorization, you will need to tell the researchers by writing to the Lead Researcher, Stephanie Jones, at **6001 Research Park Blvd., Madison WI 53719.**

Will being in this study help me in any way?

Being in this study is unlikely to benefit you directly. The audio tones played by the SmartSleep device might not affect you at all, or they may be disruptive to your sleep. However, your participation in this study may help other people in the future by helping us learn more about the relationship between sleep and emotions in youth.

What are the study risks?

There is a risk that your information could become known to someone not involved in this study. If this happens, it could affect your relationships with family and friends, affect your employment, or make it harder to get insurance or a job.

<u>Psychological Discomfort</u>

Some questions may make you feel uncomfortable. These questions are similar to what would be asked in a clinic. You may choose not to answer such questions. Some

people may also feel uncomfortable answering questions about their thoughts and feelings. This may be especially true for participants when asked about their traumatic experiences. It may be painful or upsetting to recall details of the event.

Possible Pregnancy in Youth

If the research team learns that you could possibly be pregnant, you will not be able to participate in the study at this time. To protect your privacy, we may not tell your parent, but we strongly recommend follow-up care. However, the research team would consider your age, maturity, and cognitive level and would inform your parent if we think they need to know so they can help take care of you. Additionally, if pregnancy was the result of sexual assault, we would be required to notify the appropriate authorities and possibly your mental health clinician, if you listed one.

EEG, SmartSleep, and other recording equipment

You may experience mild discomfort and/or possible skin irritation associated with the placement of recording electrodes, SmartSleep device, or peripheral sensory stimuli. You may also experience sleep disruption during recording and/or stimulation nights.

What happens to the information collected for the research?

We have strict rules to protect your personal information and protected health information (PHI). We will limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information.

However, we cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials and to study sponsors responsible for monitoring this study. This includes University of Wisconsin and its representatives and affiliates, including those responsible for monitoring or ensuring compliance, such as the Human Research Protection Program and the National Institute of Mental Health (our sponsor).

We may also have to tell appropriate authorities, such as child protective services or health care providers, if we learn during the study that you or others are at risk of harm (for example, due to child or elder abuse, or suicidal thoughts).

Authorizing the research team to use your PHI means that we can release it to the people or groups listed in this form for the purposes described in this form. Once your health information is released outside UW-Madison it may not be protected by privacy laws and might be shared with others.

The data collected by the heart-rate watch (movement, heart-rate, and skin conductance) will be stored in the Empatica cloud using a code. The data is downloaded via Bluetooth to Empatica's CareLab app on an iPhone that will be

provided to you by the study team. The data will be uploaded via the provided cell phone, so there is no phone number or IP address associated with you that could link you to this data.

Also, with appropriate confidentiality protections, we might use information that we collect during this study for other research, or share it with other researchers without additional consent from you. However, no video and/or audio recordings will be shared to anyone outside of the study team for any reason nor will the videos be included in any professional presentations or other avenues of data dissemination.

The sponsor, monitors, auditors, and the IRB will be granted direct access to your medical records to conduct and oversee the research. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Will information from this study go in my medical record?
None of the information we collect for this study will go in your medical record. The researchers are not required to release health information to you if it is not part of your medical record.

Will I receive the results of research tests?
All of the tests that are part of this study are for research purposes only. Because of this, we will not tell you or your doctors the results of these research tests with the exception of the scenarios outlined below:

Psychological Assessments
The questionnaires and/or diagnostic assessments you will complete in this study may show that you may be in danger of being hurt by someone, are contemplating harming others, or considering self-harm or suicide. If we believe that your responses on the interview questions indicate potential for self-harm or danger to self or others, or if you endorse questions about suicide on the questionnaires, we will contact a member of the study team with clinical expertiseor call 988 to complete a risk assessment process. If we determine that you are at immediate risk, we will call your parent or guardian immediately. We will always call to disclose this information to your parent or guardian, regardless of whether you are under or over the age of 18. If you are in a study visit when we identify this risk and our assessment deems it necessary, we may also facilitate transportation to the Emergency for your safety. We will also provide your parent with resources for follow-up clinical care. Finally, we will let you and your parent

know that you will be suspended from study participation until there is no longer any immediate risk.

If signs of child and/or elder abuse and/or neglect are observed/disclosed during any of the study visits, members of the study team may be required by state law to report this to the appropriate authorities or protective services. This includes responses to questions on any study surveys. If your parent is suspected of mistreating you, another legal guardian would need to be willing to take part in this study in their place. The study team would also need to clarify that any maltreatment has been properly reported.

Can I be removed from the research without my agreement?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include:

- Any indications of abuse or suicidality revealed in study interviews or symptom assessments
- you do not follow the study rules or no longer meet the requirements to be in the study
- the study is stopped by the sponsor or the researchers

What else do I need to know?

What happens if I am injured or get sick because of this study?

If you are injured or get sick because of this study, medical care is available to you through UW Health, your local provider, or emergency services, as it is to all sick or injured people.

- If it is an emergency, call 911 right away or go to the emergency room.
- For non-emergency medical problems, inform the study team and contact your regular health care provider.
- Call the Lead Researcher, Stephanie Jones, at 608-275-1709 to report your sickness or injury.

Here are some things you need to know if you get sick or are injured because of this research:

- If the sickness or injury requires medical care, the costs for the care will be billed to you or your insurance, just like any other medical costs.
- Your health insurance company may or may not pay for this care.
- No other compensation (such as lost wages or damages) is usually available.
- UW-Madison and UW Health do not have a program to pay you if you get sick or are injured because of this study.
- By signing this consent form and taking part in this study, you are not giving up any legal rights you may have. You keep your legal rights to seek payment for care required because of a sickness or injury resulting from this study.

Hair styling and safety
If you agree to take part in this research study, you are agreeing to remove any hair braids, weaves, hair extensions or other types of artificial hair or tight-to-scalp hair style. This is because some of the equipment we use during the in-lab sleep portion of the study must contact your scalp. Additionally, if you are in the MRI group of the study, we are not sure if artificial hair is safe to be in the MRI. For these reasons, you will be asked to make sure these types of hair styles are removed before participation.

Will I receive anything for participating?
If you agree to take part in this research study, you will be paid $150/night spent in the laboratory, up to $35/night of wearing Smartsleep at home and answering surveys ($15/night for wearing the SmartSleep Device, and $5/ daily survey completed), $75 for in-person consent and clinical interview assessment, $75 for the Cognitive Assessment visit, $25 bonus for wearing the WatchPAT, $50/week of wearing the heartrate detecting watch, $100 bonus for completing the study, and a $10 Amazon gift card for completing the web and phone screening for an expected total of $1,175.

If you are asked to remove any type of hair style to participate in the study, we will compensate you at the rate of $150/in-lab sleep night, to have the hair style put back in.

Permission to communicate about the study by email
We are requesting your email address so we can contact you during the study about any scheduling issues that may arise. Email is generally not a secure way to communicate about your health as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. If you need to talk to someone immediately, please contact Stephanie Jones, Lead Researcher, at 608-275-1709. You do not have to provide your email address to participate in this study.

Text Message Communication [PARENT/GUARDIAN]
We are also requesting your cell number so we can text you if we need to communicate any urgent scheduling issues. You do not have to provide your cell number to participate in this study. Please indicate your choice below.

- ○ Yes, you may use text messaging to contact me, the parent/guardian, for this study.
- ○ No, I, the parent/guardian, do not want to be contacted by text message.

Text Message Communication [YOUTH]

We are also requesting your cell number so we can text you if we need to communicate any urgent scheduling issues. You do not have to provide your cell number to participate in this study. Please indicate your choice below.

○ Yes, you may use text messaging to contact me, the youth participant, for this study.

○ No, I, the youth participant, do not want to be contacted by text message.

How many people will be in this study?
We expect about 180 people will be in this study.

Who is funding this study?
This research is being funded by the National Institute of Mental Health.

What will happen to my data after my participation ends?
We will keep your data for an indefinite period of time, meaning we have no plans of ever destroying it. Keeping data or biospecimens for future research is called “banking.” The banked data will be kept in a secure location for use by researchers. The banked data will be labeled with a code number that allows only the members of this research team to identify you.

We will use the data in future research projects about sleep and emotion processing. We may also use them for other types of research. The data may be shared with other researchers at the University of Wisconsin-Madison and outside the University. Outside researchers may be at other universities, private companies, or other kinds of organizations. Banked data will not be shared with your health care providers or used in your treatment outside this study. You can request to have your data removed from the bank by contacting the research team at any time**.**

Certificate of Confidentiality

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. We can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. For example, if there is a court subpoena, we will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency-funded projects 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, or a member of your family, from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then we will not use the Certificate to withhold that information.

Sharing Data with the National Institutes of Health

Data from this study, including hdEEG sleep data, SmartSleep recordings, responses to questionnaires, and basic information about you (e.g., gender, age, diagnosis, etc.), may be submitted to the National Institute of Mental Health Data Archive (NDA) or another NIH-designated data repository. The NDA is a data repository run by the National Institute of Mental Health (NIMH) that allows researchers studying mental illness to collect and share de-identified information with each other. A data repository is a large database where information from many studies is stored and managed. De-identified information means that all personal information about research participants, such as name, address, and phone number, is removed and replaced with a code number. The link to the code would be kept securely at the UW.

During and after the study, the researchers will send the de-identified information about you listed above to the NDA or other data repository. These data repositories will store your information and other researchers nationwide can file an application with the NIMH to obtain access to your de-identified study data for research purposes. Experts at the NIMH who know how to protect health and science information will look at every request carefully to minimize risks to your privacy. With an easier way to share data, researchers hope to learn new and important things about mental illnesses more quickly than before.

You may not benefit directly from allowing your information to be shared with the NDA or other data repository. The information provided to a data repository may help researchers around the world treat future children and adults with mental illnesses so that they have better outcomes. The NIMH will also report to Congress and on its website about the different studies that researchers are conducting using data from these repositories. However, you will not be contacted directly about the data you contributed to a repository.

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

Optional Study Activities

This part of the consent form is about additional research activities that you can choose to take part in. Things to know about these activities:

- They are optional. You can still take part in the main study even if you say "no" to any or all of these activities.
- These activities will not help you or your child directly. We hope the results of these optional activities will increase your participation in future scientific studies, ensure proper training of scientists and study staff, and to help us understand how the caregiver-youth relationship develops over time.
- We will not tell you the results of these optional activities, and we will not put the results in your medical records.
- Taking part in the optional activities will not cost you anything.

Please state your preference by initialing the appropriate line for each of the following research activities.

Interview Summary Report

As part of this study, we can provide a mental health provider with a summary of our findings from the clinical interview and questionnaires that youth participant completes.

Allowing us to release this report to the youth's mental health provider is optional. The report may help the mental health provider plan their treatment, and it is possible that the report will end up in their medical record.

_____ **Yes, please send** the report to the youth's mental health provider (listed below).

_____ **No, please do not** send a report.

Full Name of Clinician: _____

Clinic/City/State: _____

Contact for Future Studies

We would like to use your contact information to reach you for possible future studies, furthering our efforts to better understand sleep, the brain, and experiences that may affect child development. Your contact information will be kept in a secure location. This is completely voluntary and optional and you can choose not be contacted for any follow-up studies.

_____ **Yes,** the research team **may** contact me for possible future studies.

_____ **No, I do not want** the research team to contact me for any future studies.

MRI Scan

Up to a third of participants in this study will be chosen to participate in an MRI scan if it is safe for them to do so, and if they agree to participate in the scan. If chosen, there is some additional information to know:

At the clinical interview visit, if participating in the MRI, study staff will go through the MRI screening form with both of you. To assure you can be safely scanned, we may require that you obtain written permission from doctors for things such as previous surgeries. We would also talk with you about what types of clothing are best for you to wear for the MRI, as well as what *not* to wear, such as jewelry, make-up, and certain brands of clothing.

After your interview and MRI screening, you will do a practice MRI scan in a simulator to get a feel for what it will be like inside the real MRI. The MRI simulator looks similar to the real scanner but does not use a magnetic field. The purpose of the practice MRI scan is to help you get comfortable being in a scanner, in preparation for the real MRI. This means that we will not actually be taking pictures of your brain during the fake scan. To get a good scan, it is important that you keep your entire body very still. This can take practice, and when in the MRI simulator, we will make sure to help you get as comfortable as possible, then give you some pointers about how to best keep your head and body still. During both the real MRI and MRI simulator, you will be lying on your back on a table, and the table will move you backwards into the main circular feature, called the bore. The MRI is a small space that makes loud noises. At the simulation session, we will play a variety of these noises, and at the scan itself, you will have earplugs to protect your hearing. In total, the MRI simulator session should last no more than 20 minutes. At the end of this visit, we will schedule a time for the real MRI visit if we have not already done so.

If additional practice is needed, we can. Schedule another MRI simulator session on a different day before the first scan and/or finish incomplete study procedures. All additional study visits to finish study activities will be compensated at $50/visit. If a study visit needs to be fully re-done (e.g., a clinical assessment visit occurred more than 6 weeks before the next visit is completed), you will be compensated at the rate of the visit.

The MRI scan will occur during the second visit to the lab. On this day, you will come to the lab, confirm that nothing has changed on the MRI safety form, and will go into the real MRI scanner. Some of the MRI scans will take pictures of brain anatomy, while other scans measure brain activity changes that can occur while you are resting. We will ask you to try not to fall asleep during the scan. If at any point you feel too uncomfortable during the MRI, you will have the option to immediately stop the scan or ask for a break. During the scan, you will also be able to talk to and hear the person running the scanner. Additionally, a study team member will be available to you at any time before, during, and after the scan. In total, the scan should last no more than 30

minutes. During this visit, your parent has no tasks to complete. They may wait in one of the waiting rooms, or may leave.

Additional Risks with MRI:

MRI Safety

To determine if you are eligible for our study, we will ask a series of questions about you, including previous surgeries, whether you have implanted devices of any time, the possibility of pregnancy, etc. Some people cannot or should not participate in MRI studies. This includes people with metallic implants, such as prostheses or aneurysm clips, or people with electronic implants like heart pumps or pacemakers. The magnetic field of the MRI machine can cause some metal implants to move or break down. Also, people who are pregnant are excluded from participating in MRI scans in studies, as risks to the fetus are unknown. To make sure it is safe for you to be in the MRI, these questions will be asked again before the real MRI scan.

Some people report anxiety or claustrophobia (fear of small spaces) in the MRI scanner since your upper body and head must be fully inside the scanner bore. As mentioned above, the scanner produces a variety of sounds that can get very loud, which could also be anxiety provoking. MRI scans include acquisition software that is not FDA approved. The manufacturer of this software has provided assurance that this software does not pose any significant risk. In addition, the MRI scanner has built-in checks to make sure that the software does not exceed any guidelines set by the FDA. During the MRI scan, some people have said they felt tingling or muscle twitches in different parts of their body. These feelings are not painful and will not cause any harm. The youth participant will be asked not to touch their hands together or cross their legs during the scan, because these can occasionally cause a mild shocking sensation. If this occurs, you should both know that it is not harmful.

If you complete the MRI scan, you will receive an additional $75.

_____ **Yes, my child may participate** in the MRI portion of this study.

_____ **No,** my child **may not** participate in the MRI portion of this study.

_____ **N/A,** my child is **not** being asked to complete the MRI portion of this study.

If you, the youth participant is age 18 at the time of scan:

____ **Yes, I do want** to complete the MRI portion of this study.
____ **No,** I do **not want** to complete the MRI portion of this study.
_____ **N/A,** I am **not** being asked to complete the MRI portion of this study.

Possible Discovery of Findings Related to Medical Imaging

Whenever an MRI of the brain is done, there is the chance of finding something unexpected. Unexpected findings can have clear clinical significance, or uncertain clinical significance. Clear clinical significance means that the MRI shows a problem that may be treatable, and we generally know what the risks are of not treating the problem. Uncertain clinical significance means that the imaging shows something unusual in the brain, but we do not know if it might affect your health, and treatment may not be appropriate or possible. On this study, you will be informed of any findings of clear clinical significance that may be discovered during the imaging procedure, but you will not be informed if there are findings of uncertain clinical significance. The MRI and report from this research study will not be placed in your medical record.

There may be benefits to learning such results (such as early detection and treatment of a medical condition), but there are risks as well (such as problems with getting insurance or a job, or feeling worried about a finding for which no treatment is required or appropriate). The MRI we are using in this research study is not the same quality as a MRI that you may have as part of your health care. If you believe the youth participant is having symptoms that may require clinical imaging, you should contact their primary care physician.

You may also choose to have your physician informed of any findings of clear clinical significance that we report to you by checking the box below. Please note, however, that if you choose to have their physician informed of findings of clinical significance, that report will likely be placed in your medical record.

Please indicate your preference by checking the appropriate box:

____ Yes, please inform my doctor of findings of clinical significance

OR

____ No, please do not inform my doctor of findings of clinical significance

If you do wish us to report any findings to your child's physician, you must provide us with the name and location of their primary physician.

Name of Physician to Contact

Name of primary physician_____

City or clinic_____

For administrative use on day of scan:

Date:___/___/___

If you, the youth participant, are age 18 at the time of scan:

____ Yes, you may disclose any clinically significant findings to my parent/guardian

OR

____ No, please do not inform my parent/guardian of findings of clinical significance

Possible Discovery of Findings Related to Sleep Apnea Assessment
It is possible that when wearing the sleep apnea assessment device at home, that qualified sleep team personnel will determine that you have sleep apnea. If you have a positive diagnosis of sleep apnea, you have the option for your physician to be informed by checking the box below. The report from this research study will not be placed in your medical record by the study team. Please note, however, that if you choose to have your physician informed of this finding, a report will likely be placed in your medical record.

There may be benefits to learning such results (such as early detection and treatment of a medical condition), but there are risks as well (such as problems with getting insurance or a job, or feeling worried about a finding for which no treatment is required or appropriate).

Please indicate your preference by checking the appropriate box:

____ Yes, please inform my doctor of findings of sleep apnea

OR

____ No, please do not inform my doctor of findings of sleep apnea

If you do wish us to report this finding to your child's physician, you must provide us with the name and location of their primary physician.

Name of Physician to Contact

Name of primary physician_____

City or clinic_____

If you, the youth participant, are age 18 at the time of scan:

____ Yes, you may disclose any sleep apnea findings to my parent/guardian

OR

____ No, please do not inform my parent/guardian of findings of sleep apnea

Agreement to participate in the research study

You do not have to sign this form. If you refuse to sign, however, you cannot take part in this research study. If you sign the line below, it means that:

- You have read this consent and authorization form.
- You have had a chance to ask questions about the research study, and the researchers have answered your questions.
- You want to be in this study.
- You give authorization for your protected health information to be used and shared as described in this form.

Youth Consent for Participation of Self (Ages 18+)

_____
Printed Name of Youth Participant

_____
Signature of Youth Participant

_____
Date

Parent/Guardian Consent for Participation of a Minor (Ages 15-17)

_____
Printed Name of Parent/Guardian

_____ _____
Signature of Parent/Guardian Date

Youth Assent for Participation of Self (Ages 15-17)

_____
Printed Name of Youth Participant

_____ _____
Signature of Youth Participant Date

_____ _____
Signature of Person Obtaining Parent/Guardian Consent and Youth Assent Date