

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

Study Title for Participants: Brains, Emotion, and Sleep Together (BEST) study

Formal Study Title: Studies of anxiety and sleep in youth

Lead Researcher: Dr. Ned Kalin, (608) 263-6079, 6001 Research Park Blvd,
Madison, WI, 53719

Institution: *University of Wisconsin-Madison*

Key Information

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

Why are researchers doing this study?

The purpose of this research study is to better understand the links between anxiety and sleep disruptions. While many individuals that experience anxiety also have sleep problems, not much is known about how they relate to one another, or to brain activity. In this study we will examine the relation between anxiety, sleep and the brain and body. This may help with the development of better treatments to improve the lives of individuals with anxiety.

We invite you and your child to take part in this research study because your child is a female between ages 8-11 who based on the information provided during study screening is safe for a magnetic resonance imaging (MRI) scan.

What will my child need to do in this study?

The research team will ask you to complete up to 6 study visits, which involve clinical assessments, surveys, MRI brain scans, behavioral tasks, saliva and cheek cell sample collection, and sleep studies both at home and in the laboratory.

We expect that you will be in this research study for about 3 months to complete all 6 visits. We will aim to schedule the visits between 1-3 weeks apart. This timeline may be extended to allow for flexibility in scheduling of study visits.

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

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

You may want your child to be in this study if you and your child are:	You may NOT want your child to be in this study if you and your child:
<ul style="list-style-type: none">• Comfortable having researchers ask questions about your child’s mental health.• Willing to have your child complete an MRI scan.• Willing for your child to collect sleep and mood information for a 2-week period.• Willing to have your child give saliva and cheek cell samples for research tests.• Willing to have your child complete overnight visits in the sleep laboratory with you or another parent/legal guardian in attendance.• Interested in contributing to scientific knowledge even though your child won’t benefit directly from the study.	<ul style="list-style-type: none">• Want to be in a study that might help improve your child’s own health.• Are not comfortable having researchers ask questions about your child’s mental health.• Do not want your child to complete the MRI or sleep study sessions.

Does my child have to be in the study?

No, your child does not have to be in this study. Taking part in research is voluntary. If you and your child decide not to be in this study, your choice will not affect your healthcare or any services you or your child receive. There will be no penalty to you or your child. You and your child will not lose medical care or any legal rights. You and your child 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 child's 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 research team. You can reach principal investigator Dr. Kalin at (608) 263-6079 or study scientist Dr. Williams at (608) 262-2430. General questions about the study can be directed to our laboratory number 608-263-2338.

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 my child take part in the study, what will they do?

Your child may be asked to participate in up to six study sessions, as well as the collection of sleep data at home, which are described below.

Study Visit 1 – Informed Consent and Assent, Clinical Interview, Rating Scales (3-4 hours)

Visit 1 may take place remotely via a video interview, or it may take place in our laboratory space at the HealthEmotions Research Institute (HERI). Video interviews will be conducted using a University-approved system that is secure and protects you and your child's private information. At the beginning of Visit 1 you will meet with members of our study team to review this informed consent document and the procedures involved in the study. There will be time for you and your child to ask any questions you have about the study. If after this discussion you and your child agree to participate in the study, you will sign this form and we will collect and document verbal agreement/assent from your child.

Then you and your child will each be asked to complete a structured interview about your child with trained study team members. The questions involved in this interview relate to your child's mental health, mood and behaviors, and will take about 2 hours. Some of the questions may be embarrassing or make your child uncomfortable. You and/or your child can choose not to answer any questions that make either of you uncomfortable. If Visit 1 is being completed by video interview, a researcher who collaborates with Dr. Kalin from the National Institute of Health may also be a part of the video interview. The purpose of

this researcher joining the video interview is to check that the interview is being administered the same way to all participants.

With your permission, the interview will be audio recorded. The purpose of this audio recording is so that we can check that the interview is being administered correctly and consistently to all participants. Audio recordings of the interviews will be shared with researchers at the National Institute of Health who are collaborating with Dr. Kalin. These recordings will not be used for purposes outside of the study or in any papers or publications. Audio recordings will be destroyed, no later than 1 year from the date they are obtained. All study materials, including audio recordings, will be kept in locked storage, or on secure, University-approved, password-protected electronic systems and servers. Study materials will only be accessible to the research investigators and their staff, and other qualified researchers. Published reports will not identify specific individuals.

Whether or not you are willing to have the interview recorded it up to you. The purpose of making these recordings is to ensure the interview is being administered correctly and consistently across all participants. The recording will be stripped of all possible identifying information, and will be destroyed or erased no later than 1 year from the date it is obtained. Please indicate your preference by signing your name in the appropriate space below:

_____ Please do not record me or my child

_____ I give my permission to record the interview

You and your child will also complete some questionnaires about your child on a computer. If Visit 1 is taking place in our lab space, these may be launched for you to complete on a study device. If Visit 1 is taking place by video interview, and you agree that we may contact you by email for study-related matters, we will email you a link for you and our child to complete the questionnaires at home.

The interview and questionnaires will be reviewed by the study team to determine if your child is a good fit for future study visits.

Study Visit 2: Physiology data collection, training for home sleep data collection, and rating scales (2-3 hours)

Visit 2 will take place in our laboratory space at HERI. Your child will complete some activities with study team members in which they are asked to define some words and complete some patterns. Your child may have small sensors attached to their forehead and to their hands to provide measures of muscle and nervous system activity. A slightly salty gel is placed under the sensors to ensure the collection of good quality signals. These sensors typically cause no discomfort. In a small number of participants with sensitive skin, they may cause minor skin irritation (from the salty gel) or reddening when removed. While wearing the sensors child may also be asked to view some images of faces on a computer screen and listen to some sounds over headphones. The sounds

are loud enough to be a bit startling, but not so loud that they are painful. The sounds may be emotional, like a scream noise. Pictures on a computer screen will tell your child when the loud sounds are likely to occur. Your child may also be asked some questions about the images and sounds they see and hear. We may watch your child's face over a video feed to make sure they are looking at the computer screen while the images and sounds are being presented, but we will not make a recording. This activity will take up to 90 minutes.

Between Visit 2 and Visit 3, your child may be asked to collect some sleep, mood, and saliva samples at home. At Visit 2 we will provide you with all the equipment needed for this at-home data collection and train you on how to use it.

You and your child will complete some scales about your child's physical development. We will also ask you and your child to complete several rating scales related to your child's health, mood and behavior. Some of the questions may be embarrassing or make you or your child uncomfortable. You and your child can choose not to answer any questions that make you or your child uncomfortable. These scales may be completed electronically on a laboratory device during the session. If you agree that we may contact you by email for study-related matters, we may email you a link for you and/or your child to complete the questionnaires at home.

Between Study Visits 2 and 3: Two weeks of Home Sleep Data Collection

Between study Visit 2 and Study Visit 3, your child will be asked to wear a device that looks like a headband while sleeping at home, for up to five nights a week for two weeks. The sleep headband has sensors in it that measure and record your child's brain activity while they are asleep. The headband is made of fabric and will fit in a circle around your child's head with the sensors on their forehead (picture to the right). The strap of the headband can be adjusted to fit your child's head snugly. Data from the sleep headband will need to be downloaded to a provided laptop computer each day, as the headband only stores one night of data. We will train you at Visit 2 on how to put on and operate the headband, and how to download the data to the laptop. Should any issues arise, technical or other, at any time you and your child will be able to contact study personnel.



Picture of the sleep headband

On days when the sleep data is being collected, your child will also be asked to report on how they feel throughout the day, before they go to sleep, and when they wake up in the morning. We will provide a study-owned personal electronic device (e.g. phone or tablet) to collect this information, and each of these assessments will take 5-10 minutes. Up to 3 times during the day (morning, afternoon, evening) your child will be asked about their mood, feelings, and worries. When putting on the headband before sleep and upon awakening, your child will be asked about their current mood and feelings. Upon awakening your child will be asked about how they felt the night before when falling asleep, and about their night of sleep. All these data would be collected using a secure,

University-approved electronic system. We will work with you to determine the best times for data collection for your child's schedule.

If any of the equipment is lost or broken you can contact study personnel and we will make arrangements to get you replacement equipment. This equipment can only be used for study-related procedures, no other actions or uses are permitted with the study-owned laptop and electronic device for collecting rating data. The study team and UW-Madison are not responsible for any actions performed on these devices outside of study procedures. All equipment will be returned to the study team at the end of the data collection period.

Your child may also be asked to provide saliva samples up to 3 times throughout the day, at the same time as the mood assessments. This would involve your child drooling into a tube, and then storing the tube in the freezer until Study Visit 3.

Study Visit 3: Physiology data collection, practice MRI scan, and rating scales (2-3 hours)

Visit 3 will take place in our laboratory space at the HealthEmotions Research Institute (HERI). At this visit you will return the equipment and samples collected during the home sleep data collection period. You and your child will also complete some rating scales about your child recent mood and behaviors.

Similar to Visit 2, your child may have small sensors attached to their forehead and to their hands to provide measures of muscle and nervous system activity. While wearing the sensors child may also be asked to view some images of faces on a computer screen and listen to some sounds over headphones. Your child may also be asked some questions about the images and sounds they see and hear. We may watch your child's face over a video feed to make sure they are looking at the computer screen while the images and sounds are being presented, but we will not make a recording. This activity will take up to 90 minutes.

At this visit we will also review the questions on the MRI screening form to confirm your child is still safe for an MRI scan. Your child will then complete a mock/practice MRI machine so they can experience what being in the MRI will be like. The MRI machine is a confined space and generates loud noises. Over the years we have learned that a practice session helps people feel more at ease when inside the scanner. To get a good scan it is important that people keep their heads still. The practice session helps with this. The practice session will be done in the simulator room of the HERI brain-imaging lab and will last about 30 minutes, but may take longer depending on the person. The simulator room looks very much like the actual MR scanning room, except that the MRI machine is not real and there is no magnetic field produced. This means that we will not actually be taking pictures of your child's brain during this part of the visit, but that they will get used to being in the scanner for the real MRI session. Your child will be asked if they are comfortable when in the mock scanner. Your child will also be asked to practice and may be given some pointers about how to best keep their head still in the MRI. Your child will see pictures projected above their head, similar to the real MRI scan. If your child needs more practice with the mock scanner, we may ask you and your child to return for an additional training visit.

Study Visit 4: MRI scan, cheek cell scraping and saliva samples (3 hours)

Visit 4 will take place in our laboratory space at HERI. At this visit we will review the questions on the MRI screening form to confirm your child is still safe for an MRI scan. Then your child will complete another session in the mock/practice MRI scanner before the actual MRI scan. You and your child will also complete some rating scales about your child recent mood and behaviors.

Your child will be brought into the MRI scanning room and will receive earplugs and headphones and/or padding around the head that will block-out some of the sounds from the scanner. A covering will be placed over your child's index finger to record their heart rate and the amount of oxygen in your child's blood. Two small sensors will be taped on the third and fourth fingers of your child's right hand to record changes in sweat level. By using a magnetic field the MRI scanner allows us to construct pictures of the structure of the brain and to understand how it functions. During the scan your child will be able to talk to and hear the person running the scanner. Some of the MRI scans will take detailed pictures of how the brain is built (structural scans) and the connective 'wiring' of the brain. Other scans will be done that will measure the functional activation of the brain while your child is resting or viewing pictures of facial expressions, geometric shapes, or other images that may potentially evoke a pleasant or unpleasant emotional response presented for very short time periods. After your child sees the picture, they might be asked to comment on specific aspects of the content of the pictures or how viewing the pictures makes them feel. The scan session will take about 90 minutes and your child will have the opportunity for a break partway through the scan. While the MRI machine takes pictures of your child's brain it makes loud tapping and pinging noises. Earplugs and headphones and/or padding around the head will be given to your child to help block out these noises. During the MRI scan it is important that your child lie still, and not move. Occasionally, some people have said they felt tingling or muscle twitches in different parts of their body during the scan. These feelings are not painful and will not cause your child any harm. Your child will be asked not to hold their hands together during the MRI scan, because occasionally people who have held their hands together experience a mild shocking sensation. In the unlikely event this occurs you should know that it is not harmful. Throughout the scanning session support will be provided to keep your child from becoming uncomfortable, and they will be able to withdraw from the study at any time. During the scan your child will have a button that they can press to alert the MRI operator that they would like to pause or stop the scan, even in the middle of a scan.

We may also collect cheek cells from your child by using a small brush to gently scrape the inside of the cheek. Some of the test we will perform on your child's cheek cell samples will be genetic testing, which is done on your DNA. DNA, or deoxyribonucleic acid, carries the genetic instructions for the cells that make up your body. Genes tell your body how to do things like form your spine, or what color your eyes should be. We may also do whole genome testing for this study. Your "genome" is the complete DNA instruction book. "Whole genome testing" means making a list of the entire order, or sequence, of the DNA in your genome. Your child's sample will be used to understand how genes may contribute to the symptoms of anxiety, sleep, and brain function. These samples will be stored for use in current and future research to examine the role genetic

variations may play in the development of anxiety symptoms and differences in sleep. We will also collect up to 2 saliva samples from your child throughout the MRI session to measure levels of cortisol, a hormone related to stress, as well as to measure hormones related to sexual development. The tests on saliva and cheek cell samples are being done only for research purposes, and will not be useful for your child's health care. They will not be released to you or placed in your child's medical record.

Study Visit 5 and Study Visit 6: Laboratory Sleep Nights (11-14 hours each)

Study Visit 5 and Study Visit 6 will take place in our laboratory at Wisconsin Sleep. The procedures will be the same, and the visits will be scheduled 1-3 weeks apart. You and your child will come to the sleep lab about 2 hours before your child's typical bedtime. We will measure your child's brain activity throughout the study visit using electroencephalography (EEG), which involves your child wearing a head-net covered with electrodes for this entire visit, including during sleep. After your child's head is measured and the proper sized cap is put on, each electrode will be filled with a gel to ensure the collection of good quality signals. These sensors typically cause no discomfort. In a small number of participants with sensitive skin, they may cause minor skin irritation (from the gel) or reddening when removed. In addition to the head-net, we will place a few patches around your child's eyes, on their chin, and behind their ears. We will also place sensors on their finger and under their nose, along with belts around their waist and chest. This allows us to monitor your child's physiological activity while they are sleeping to determine whether they have any sleep disorders, such as obstructive sleep apnea or snoring. You and your child will also complete some rating scales about your child recent mood and behaviors. Upon awakening we will do some additional, short (4min) waking recordings with the EEG net on. While sleeping, your child will be monitored by a research staff member and audio and video will be recorded. Each visit, including sleep time, might last between 11- 14 hours, depending on how long your child sleeps the following morning. You, or another parent or guardian must stay with your child for the whole night of sleep, either in the same room or in an adjoining room if preferred. We have spare beds in each of the bedrooms for this purpose.

The overnight sleep studies will be recorded using audio and video recording equipment. These are all stored on a secure server and will be destroyed after the study has been scored and reviewed by a sleep physician. These recordings will not be used for purposes outside of the study or in any papers or publications. If you do not consent to audio or video recordings being taken during the overnight sleep studies, you will not be able to take part in this research study. Please indicate that you consent to audio and video recordings being taken during the overnight sleep study if you choose to participate in this study:

_____ Yes I consent to audio and video recordings being taken during the overnight sleep study visits

We may also ask your child to complete daily ratings of mood, feelings, worries, and sleep for 3 days prior to each laboratory sleep session, as your child did during the home sleep

data collection. We will provide your child with a study-owned personal electronic device (e.g. phone or tablet) for this data collection.

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
- Things you tell the researchers about your health

What happens if my child says yes, but they change their mind later?

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

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

If your child withdraws from the study, data that has been collected from them up to that point will be stored and use for analysis. Your child can choose to withdraw from one study visit and still participate in other study visits.

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, Dr. Ned Kalin, at 6001 Research Park Blvd, Madison, WI, 53719.

Will being in this study help me/my child in any way?

Being in this study will not help you directly. Your participation in the study may benefit other people in the future by helping us learn more about the relation between anxiety, sleep and the brain.

What are the study risks?

The main risk of taking part in this study is that your child's study information could become known to someone who is not involved in performing or monitoring this study. A breach of confidentiality could result in damage to your child or your child's reputation, or legal implications, but the chances that this will happen are very small. All study data will be stored in locked cabinets in our laboratory space, or on secure servers or University-approved databases. Only members of our study team will have access to your data. Data collected from your child will be labeled with a code, and personal information will be stored in a separate secure location that only our study team will have access to. One exception is that if you agree to provide us with an email address for use in the study, this email will be linked with your child's study data in a secure, password-protected database that will allow us to send you links to complete study questionnaires at home.

It is possible that some questions posed to participants may make you or your child uncomfortable. You and your child can choose not to answer any questions that you don't want to answer. The diagnostic interview (K-SADS) and some of the questionnaires ask about the child's history of abuse and risk of abuse, potentially putting others besides the subject at risk from a breach of confidentiality or mandatory reporting requirements. If information that suggests child abuse or neglect is reported during the K-SADS interview or on questionnaires, or is observed during a study visit, members of the study team may be required by state law to report this to the appropriate authorities. This may include reporting to the local law enforcement or protective service agencies, resulting in legal or social risks to you or other members of your household. Your and/or your child's confidentiality cannot be guaranteed in cases of child abuse.

Some individuals may experience mild discomfort in response to viewing some of the emotion-related pictures during the study. However, most individuals report that these feelings dissipate quickly. The sensors placed on your child's forehead, head, and hands typically cause no discomfort. However, in a small number of participants with sensitive skin, they may cause minor skin irritation (from the salty gel) or reddening when removed. Your child may feel uncomfortable when listening to the emotional sounds over headphones. The presentation of these sounds is brief (2 seconds or less) to minimize this risk. If children do not want to complete this, or any, part of the study, they can stop the study session at anytime with no penalty.

Your child might be uncomfortable sleeping with the headband on, although this is unlikely. If your child finds the device uncomfortable, your child may stop at any time during the study.

Some individuals should not be in MRI studies. These include persons with metallic implants, such as prostheses (e.g. fake arm or body part) or aneurysm clips, or persons with electronic implants, such as cardiac pacemakers. For the initial screening to get into the study you were asked about whether your child has any of these implants or devices. To confirm that it is safe for your child to be in the MRI, the same questions will be asked at prior to the practice scan, and again prior to the real MRI scan. The magnetic field generated by the MR machine can cause these types of things to move or become displaced or cause malfunctioning of these devices. Above and beyond the risk associated with metallic implants or devices, we know of no other significant risks associated with the scanning procedure. Some of the MRI data will be acquired using investigational software in addition to the standard MRI technology. The investigational software enable newly developed features that are not yet FDA approved for clinical use. Although not approved by the FDA, the system is being operated under the FDA safety specifications. Some subjects report some anxiety or claustrophobia (i.e. fear of confined places) in the MRI scanner since the head must be placed fully inside the scanner tube and because of the noise produced by the scanner. The MRI scanner produces tapping sounds during operation that can reach uncomfortable levels. To minimize discomfort subjects are given disposable earplugs to wear during the scan. In addition, some people may get tired and/or bored during the study. Some people have also reported tingling or tapping sensations, or muscle twitching in different parts of their body during the imaging procedure, though these sensations are not dangerous. Occasionally, people who hold their hands together during the study have reported a feeling of a mild electrical shock in their hands and arms. While this is also not hazardous, subjects are instructed not to hold their hands together during scanning. On rare occasions, individuals with sensitive skin or skin allergies may experience a slight irritation at the sites where sensors are attached to collect physiological measures.

People that are pregnant should not be in MRI studies as risks to the fetus remain unknown. Your child should not be or become pregnant while in this research study. For the initial screening to get into the study you were asked if there is any chance your child may be pregnant. Children who have started their period at the time of the MRI scan visit will need to take a pregnancy test before the MRI scan. This test will involve urinating into a cup, and this urine will be tested by a member of the study team. If the pregnancy test is positive, the child will be excluded from the study, and both the child and their parents will be informed about their pregnancy status by a child psychologist or psychiatrist.

Your child might be frightened or uncomfortable sleeping in the lab environment. We will minimize the risk by giving your child as much time as possible to answer questions and to become acclimated to the lab environment before the sleep visit. You, the parent, will also be required to stay in the sleep laboratory during your child's overnight visit. Your child may also find sleeping with the head-net uncomfortable. We will provide opportunities for your child to try on the head-net and they will wear it prior to sleep. They can ask us to remove the head-net at any time. Your child may also be sleepy after their sleep study visit. To minimize this risk, we will allow them to sleep as late as they would like. We will also schedule these visits so they do not interfere with school.

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. The study is protected by a Certificate of Confidentiality from the National Institute of Health. This means that even if the police or courts ask to look at the data we have collected, we will not share any information that would identify you as a participant in the study.

However, we cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials 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, or the National Institute of Health, since the National Institute of Health supports this study. In the event that you or your child report an injury associated with the study, the University, the equipment manufacturer, and the FDA have the right to review your medical records, but must do so in strict confidentiality.

There is a possibility that responses given during the interview and questionnaire portions of the study will reveal information that requires mandatory reporting. We may have to tell appropriate authorities, such as child protective services or health care providers, if we learn during the study that your child or others are at risk of harm (for example, due to child or elder abuse, or suicidal thoughts).

The results from this study may be included in presentations to other researchers; however, you or your child will not be identified in any publication or talk that results from this research. All data we obtain from you and your child will be kept confidential; physical data files will be stored in secure locked storage in our laboratory areas and electronic data will be stored on University-approved electronic databases and computer servers that are password protected. Only experimenters and their staff and qualified researchers will have access to your child's health information, name, address, phone number, and other information that can identify them. We will also store this information securely.

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 or UW Health it may not be protected by privacy laws and might be shared with others.

Also, with appropriate confidentiality protections, we might use information and biospecimens that we collect during this study for other research, or share it with other researchers without additional consent from you.

We will share information and data from biological samples collected for this study with researchers or organizations outside UW-Madison, including the National Institute of Health, which is the funder of this research. Saliva samples will be stored and analyzed in our laboratory. The cheek cell samples may be shared with other laboratories or researchers for the purposes of analysis. These other laboratories or researchers may be

at University of Wisconsin-Madison and outside the University. Outside researchers may be at other universities, private companies, or other kinds of organizations. Your child's name and contact information would not be shared with the samples.

As described above for study Visit 1, if you consent to the clinical interview being recorded, this recording may be shared with Dr. Daniel Pine at the National Institute of Health who is collaborating with Dr. Kalin. The purpose of this sharing is to check that the interview is being administered correctly and consistently to all participants. Shared interviews will only be labeled with your child's unique study number and will be destroyed after review.

Sharing of Deidentified Data: the National Institute of Mental Health Data Archive (NDA) and other databases

This research study is funded by the NIH. To allow the scientific community to utilize the data that we collect to the fullest extent possible, once this study and our analyses are complete, we have agreed to share data collected during the course of this study, including brain imaging data, sleep EEG data, clinical information from interviews and questionnaires, and information derived from saliva and cheek cell swabs for DNA analysis. Prior to sharing, all personal information about your child (such as name, address, birthdate and phone number) would be removed and replaced with a code number. Interview recordings would not be broadly shared. While there is no direct benefit to you or your child from this data sharing, there are potentially great benefits to the general public through a deeper understanding of the biological basis of anxiety and sleep disruptions. Specifically, studies of the biological variations associated with anxiety are most informative when the study population is large, because a larger sample size increases the chances that the findings are not due to chance, and increase the likelihood that findings will generalize to the greatest number of individuals.

Therefore, data from this study will be submitted to the National Institute of Mental Health Data Archive (NDA) at the National Institutes of Health. NDA is a large database where deidentified study data from many NIH studies are stored and managed. Sharing your deidentified study data helps researchers learn new and important things about brain science more quickly than before.

Deidentified study data means that all personal information about your child (such as name, address, birthdate and phone number) is removed and replaced with a code number. The study researchers will have to collect your child's personal information from you in order to make that code number. The code number cannot be used to identify your child. The study researchers will never send your child's personal information to NDA.

It is possible that your child will participate in more than one study that sends data to NDA. NDA can connect your child's data from different studies by matching the code number on your child's deidentified data from each study. This data matching helps researchers who use NDA data to count your child only one time. It also helps researchers who use

NDA to better understand your child's health and behavior without knowing who you are.

During and after the study, the study researchers will send deidentified study data about your child's health and behavior to the NDA. Other researchers across the world can then request your child's deidentified study data for different research projects. Every researcher (and the institution to which they belong) who requests your deidentified study data must promise to keep your data safe and promise not to try to learn your identity. Experts at the National Institute of Health who know how to keep your child's data safe will review each request carefully to reduce risks to your child's privacy. Sharing your child's study data does have some risks, although these risks are rare. Your child's study data could be accidentally shared with an unauthorized person who may attempt to learn your child's identity. The study researchers will make every attempt to protect your child's identity.

You and your child may not benefit directly from allowing your child's study data to be shared with NDA. The study data provided to NDA may help researchers around the world learn more about brain science and how to help others who have problems with brain science. NIMH will also report to Congress and on its website about the different studies using NDA data. You will not be contacted directly about the study data your child contributed to NDA.

You may decide now or later that you do not want your child's study data to be added to NDA. Your child can still participate in this research study even if you decide that you do not want your child's data to be added to NDA. If you know now that you do not want your child's data in NDA, please indicate this by checking "No" below. If you decide any time after today that you do not want your child's data to be added to NDA, call or email the study staff who conducted this study, and they will tell NDA to stop sharing your child's study data. Once your child's data is part of NDA, the study researchers cannot take back the study data that was shared before they were notified that you changed your mind. If you would like more information about NDA, it is available on-line at <http://nda.nih.gov>.

Deidentified data may also be shared via websites hosted by the UW-Madison or other public repositories of similar data (e.g. brain imaging data).

You have the right to refuse this sharing of deidentified data. Please indicate your preference by signing your name in the appropriate space below:

_____ Yes, I confirm that my child's deidentified data can be shared in electronic databases

_____ No, I would not like my child's deidentified data to be shared in electronic databases

Will information from this study go in my child’s medical record?

EEG data from the first night of laboratory sleep data will be reviewed by a board-certified Sleep Medicine Specialist. If there are any findings of clinical significance you will be informed, and will have the option of adding this information to your child’s medical record. No other 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?

When MRI scans and EEG data collection are done for research, there is a chance of finding something unexpected. Such findings can potentially be serious, but this is rare; most often they have little or no medical importance. The images obtained during your child’s MRI scan will be reviewed by a radiologist (a physician trained in the interpretation of medical images) to screen for abnormalities. The first night of laboratory sleep data will be reviewed by a board-certified Sleep Medicine Specialist. In this study, you will be informed of any findings of known clinical significance from the MRI and sleep EEG that may be discovered during review by the radiologist and/or sleep medicine specialist. If there are any significant EEG findings you will have to option of having the information added to your child’s medical record.

For MRI studies, occasionally the significance of a finding cannot reliably be determined from the images obtained. Knowing about unsuspected abnormalities on your child’s images may be of some benefit to you, particularly if they are medically important. On the other hand, if the significance of a finding is low or uncertain, there may be little benefit in knowing about it and there may be some risks; for example, it could affect insurability or employability, or just make you worried.

Whether or not you want to be informed of findings of unknown or potential medical significance is up to you. Please indicate your preference by signing your name in the appropriate space below:

- _____ Please inform me
- _____ Please inform me and my child’s doctor
- _____ Please DO NOT inform me and my child’s doctor

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, prior to their scan.

Name of primary physician _____

City or clinic _____

Health Care Provider _____

If you and your child volunteer for this research study, the MRI scans that we will perform are NOT necessarily equivalent to the scans used to diagnose medical problems. Many potentially serious problems may be undetectable on these scans. A negative MRI should not be used to avoid a visit to your child's primary physician. Should your child be having physical symptoms that you are concerned about, they should see their primary physician, who will determine the studies required to arrive at a diagnosis.

You will also be informed of any behavioral or psychiatric findings that are determined by a trained clinician study team member to be of significant concern related to safety, for example thoughts about hurting oneself or others. No other information collected during the study, including the clinical interview and questionnaires, will be shared with anyone outside the research team. Information will not be shared with you, your child, other family members, or any care providers.

Can my child be removed from the research without my/their 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:

- your child's health changes and the study is no longer in their best interest
- your child does not follow the study rules or no longer meets the requirements to be in the study
- the study is stopped by the sponsor or researchers

What else do I need to know?

Will my child receive anything for participating?

If you and your child agree to take part in this research study, we will pay your child for their time and effort as follows:

- Visit's 1, 2, and 3 - \$50 each
- Home Sleep Data Collection - \$25/day for each day complete + a \$50 bonus for completing at least 8 of 10 possible days
- Visit 4 - \$100
- Visits 5 and 6 - \$100 each night, plus \$25 for the 3 days of data collection before each night of laboratory sleep.

Total possible compensation for completing all study visits is \$800. If we have problems with our equipment, or the information we collect during the study session is not very good, you and your child may be given the option to do the study visit over at the same compensation rate detailed above. If we would like your child to come in for an additional practice scanner session before the MRI visit and you agree to, compensation will be \$25.

Payment will be made in the form of a check written to the parent or legal guardian that signs this consent form. For any study sessions conducted remotely, compensation will be sent via mail. Your child will receive payments for any study visits they attempt or complete.

Your information and samples (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

Permission to communicate about the study by email

We are requesting your email address so we can have an alternative method of contact for you if we are having difficulty connecting by phone, to send date and time options for possible study visits, to send reminders for scheduled study visits, and to send links for study-related questionnaires. Your email will also be stored with your child's study data in a secure, University-approved, password protected electronic database, which will allow us to send you links to complete questionnaires at home as well as reminders about study matters if you would like reminders. 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 Dr. Lisa Williams, Co-Investigator and Study Scientist at (608) 262-2430. You do not have to provide your email address to participate in this study. Please indicate whether or not we may use email to contact you for study related purposes by signing in the appropriate space below:

_____ Yes, you may use email to contact me for this study in the manner described above

_____ No, I do not want to be contacted by email for this study

How many people will be in this study?

We expect about 275 people will be in this research study.

Who is funding this study?

This research is being funded by the National Institute of Mental Health.

What will happen to my child's data and biospecimens after their participation ends?

We will keep your biospecimens for an indefinite period of time, meaning we have no plans of ever destroying them. Keeping biospecimens for future research is called "banking." The banked biospecimens will be kept in a secure location for use by researchers. The banked biospecimens will be labeled with a code number that allows only the members of this research team to identify you.

We will use the biospecimens in future research projects about anxiety, sleep, and development. We may also use them for other types of research. The main risk of having samples banked is that your child's information could become known to someone outside of the study team, which may make you uncomfortable. The biospecimens 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 biospecimens will not be shared with your health care providers or used in your treatment outside this study. You can request to have your biospecimens removed from the bank by contacting Dr. Williams at (608) 262-2430. Once this study has ended, all information that may be used to link you to the samples will be destroyed. At that point it will not be possible for you to withdraw your samples.

Information about genetic research

This research study involves genetic testing. The Genetic Information Nondiscrimination Act (GINA) prohibits health insurance companies or health plan administrators from requesting or requiring genetic information of your child or your child's family members, or using such information for decisions regarding your child's eligibility for insurance or your premiums. However, this law does not provide the same protection for disability, life insurance, or long-term care insurance. GINA also prohibits most employers (with 15 employees or more) from using genetic information when making decisions on your employment, including decisions related to hiring, firing, promotion, pay, and job assignments.

Because genomic information can be useful for many different kinds of research, organizations like the National Institutes of Health have created large databases that collect genomic information from research studies. We may share genomic data from this study in a federal database or in other public scientific resources to make the information broadly available for health-related research. We cannot predict how genomic information will be used in the future. Because it can be used for many kinds of research, your genomic information may be used for research that you disagree with or would not choose to be involved in. Your child's individual genomic data and health information may be put in a controlled-access database. This means that only researchers who apply for and get permission to use the information for a specific research project will be able to access the information. Your child's genomic data and health information will not be labeled with your child's name or other information that could be used to identify them. Researchers approved to access information in the database will agree not to attempt to identify your child.

Future contact about other research opportunities

Would you be interested to be contacted about future research opportunities your child may qualify for? Agreeing to be contacted about future opportunities does not obligate you or your child to participate, is completely voluntary, and does not affect your child's participation in the current study or any health care services you may receive. By selecting "Yes" below, you give permission for information about you and your child (name, contact

information, child's age and sex, study eligibility information provided during phone screening, diagnostic information from clinical interview from Session 1) to be stored in a recruitment database for future study opportunities. This database will only be access by members of our study team, and similar to other data collected during the study, will be stored on password-protected computers on our secure computer network. All possible measures to ensure the security of this information will be taken; however there is a small risk of loss of confidentiality.

Please indicate your preference by signing your name in the appropriate space below:

_____ Yes I would like to be contacted about future research opportunities
_____ No I would NOT like to be contacted about future research opportunities

If you selected Yes, please indicated if you prefer to be contacted by email or phone:

By Phone – include preferred number: _____
By Email – include preferred email address: _____

Agreement to participate in the research study

You are making a decision whether or not to have your child participate in this study. You do not have to sign this form. If you refuse to sign, however, your child cannot take part in this research study. If you sign the line below, it means that you have:

- read this consent and authorization form describing the research study procedures, risks and benefits
- had a chance to ask questions about the research study and your child's participation, and received answers to your questions
- decided to allow your child to participate in this study
- given authorization for the person's protected health information to be used and shared as described in this form

Printed name of child

Signature of parent or individual legally authorized to consent to the child's general medical care

Date

Printed name of parent or individual legally authorized to consent to the child's general medical care

- Parent
- Individual legally authorized to consent to the child's general medical care (See note below)

Assent Obtained

Signature of person obtaining consent and assent

Date

Printed name of person obtaining consent