TITLE OF THE STUDY: Learning Observation in Kids (LOKI)

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INVITATION
We invite you and your child to take part in a research study about observational learning between a youth and their caregiver and how that process may differ in youth who have and have not been exposed to maltreatment and/or have posttraumatic stress disorder (PTSD). We are also interested in whether we can see these differences in the brain during the learning process. We are inviting you and your child because you may meet the eligibility requirements for one of these groups.

The purpose of this consent and authorization form is to give you and your child the information you need to decide whether to be in the study. It also explains how health information will be used for this study and for other research in the future and requests you and your child’s authorization (permission) to use your health information. Please ask questions about anything in this form that is not clear. If either of you want to talk to your family and friends before making your decision, you can. When we have answered all of your questions, you and your child can decide if you want to be in the study. This process is called “informed consent.”

If you are the parent or legal guardian of a minor who is invited to take part in this study, your child can participate in the study only if you give your permission. We will also ask your child if he/she is willing to take part in the study.

IMPORTANT THINGS TO KNOW ABOUT ANY RESEARCH STUDY
Taking part in research is voluntary. You can choose not to be in this study or to stop at any time. If you decide not to be in this study, 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.
STUDY SUMMARY

What is this study about?
The purpose of this study is to better understand how youth with maltreatment and/or PTSD learn through experience and from their caregivers. We also are interested in whether we can see these differences in the brain during the learning process. Since learning is not an immediate process, we are having participants complete three consecutive days of the learning task. We will be using an MRI to see how the brain changes in youth, and also collecting information about body and physiology changes. Finally, we will also be asking both you and your child questions about your physical and mental health.

How much time will I spend on the study?
There will be five study visits in total, three of which will be completed on consecutive days. All visits should be within a few weeks of each other. Each study visit will take 2-4 hours. Study visits are located either at the Health Emotions Research Institute or the Waisman Center in Madison, Wisconsin. The final set of online surveys that will be completed 6 months later should take approximately 1 hour each.

Could taking part in the study help me?
Being in this study will not help you directly, but your participation in the study may benefit other people in the future by helping us learn more about how the relationship between a child and their caregiver may be affected by traumatic experiences and/or PTSD.

What will happen during the study?
First, you and your child will take part in a structured clinical interview that assesses mental health symptoms and trauma history. You and your child will also complete questionnaires addressing similar topics and general medical history. You and your child will then complete a three-day learning task, during which you may feel a mild electrical stimulation. Your child will complete the task while in the MRI scanner, while you will complete the task on a computer while we measure body reactions. Both you and your child will also provide saliva samples. Your child will also provide hair and urine samples. At the final visit, you both will complete additional computer and cognitive tasks, some of which you will work together on. Approximately 6 months later, we will ask you to complete a number of additional online survey questionnaires.

What are the main risks of taking part in the study?
All procedures have possible risks. The risks of this study are low, and we will watch for any problems during the study procedures so that we can stop if necessary. The consent form explains the possible risks in more detail. For this study, there are some important risks for you to know. First, you may have difficulty discussing health history and mental health symptoms, trauma history, and possible pregnancy. You may be unable or unwilling to handle the stimulation. You may feel discomfort during biological sample collection. There is also a small risk to your confidentiality if someone outside the study team obtained the study data.
What are the main risks of taking part in the study? (contd.)
There are also risks associated with the MRI scanner including:
- The MRI scanner uses a very strong magnet, making it unsafe for people with metal on or in their body to have an MRI scan.
- We do not know if MRI scans are safe during pregnancy, so if you think your child might be pregnant, you should not be in the study.
- Your child might feel anxious in the small space of the MRI scanner. Your child will be able to stop the scan at any time.
- Your child might be uncomfortable lying on their back during the scan.
- The MRI scanner makes loud noises. Your child will wear ear protection.

How is research different from health care?
When you take part in a study, you are helping to answer a research question. Test results will not be used for your health care.

Questions about the study?
Contact the research team:
The BRAVE Research Center: 608-265-3610 braveyouthlab@psychiatry.wisc.edu

Questions about your rights as a research participant?
Contact University of Wisconsin Hospital and Clinics Patient Relations Representatives at 608-263-8009
MORE INFORMATION ABOUT THIS STUDY

Why are researchers doing this study?

The purpose of this research study is to understand more about how youth learn from watching their caregiver and how that process may be different in youth that have been exposed to traumatic experiences or have posttraumatic stress disorder (PTSD). We are also interested in whether we can see these differences in the brain during the learning process. We are doing this research because we want to learn more about how youth learn about safety from their parents, and if the learning process is affected by things like trauma or PTDS. We hope that any differences we find will help us improve the ability to diagnose these youth in the future and create better treatment options.

This study is being done at the University of Wisconsin-Madison (UW-Madison). A total of about 120 youth between the ages of 10-14 and their caregivers will participate in this study. Funding for this study is provided by National Institutes of Health (NIH).

What will happen in this study?

Overview

If you decide to participate in this research study, the researchers will ask you and your child to participate in five study visits over the course of 1-2 months that will take place either at the Health-Emotions Research Institute (HERI) or at the Waisman Center in Madison, Wisconsin. You may also have the option to complete some study visits remotely via video chat. Visits may range from 2-4 hours in length. There will also be two sets of surveys for you and your child to complete at home, one set within two weeks before or after the scan days and one set approximately 6 months after the final study visit. If you choose to participate, study activities will include the following: both you and your child answering questions about your thoughts, feelings, and behaviors in-person and online; your child completing a task that involves mild electrical stimulation while undergoing a brain scan; having your child watch you complete portions of the same task in a separate room; you and your child providing saliva samples; your child providing urine and hair samples; working with your child on a behavioral task; and both you and your child undergoing cognitive assessments. You and your child may skip any question during the online or in-person questionnaires that you do not wish to answer.

Study Day 1: Interview Day (3-4 hours)

The focus of this visit is to get a clear picture of you and your child’s everyday experience. During Visit 1, you and your child will be interviewed individually. The questions will ask about various symptoms, past experiences, and thought patterns. We will also ask some questions about you and your child’s medical and trauma history. You and your child 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. Next, we will go through the MRI Screening Form with both you and your child. To assure your child can safely be scanned, we may require that you obtain written permission from doctors for things such as previous surgeries. We would also talk with you and your child about what types of clothing are best to wear for the MRI, as well as what not to wear, such as jewelry, make-up, and certain brands of clothing.
After your interviews and MRI screening, your child 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 them get comfortable being in a scanner, in preparation for the real MRI. This means that we will not actually be taking pictures of their brain during the fake scan. To get a good scan, it is important that people keep their entire body very still. This can take practice, and when in the MRI simulator, we will make sure to help them get as comfortable as possible, then give them some pointers about how to best keep their head and body still. During both the real MRI and the MRI simulator, your child will be lying on their back on a table, and the table will move them 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, your child will have earplugs to protect their hearing. In total, the MRI simulator session should last no more than 20 minutes. If additional practice is needed, we can schedule another MRI simulator session on a different day before the first scan.

Finally, we will ask you to schedule the three scan days. If there is a delay with scheduling the scans, and they take place more than four months past the Interview Day, we may ask that you repeat the Interview Day.

The week before your scans, you can expect an email with a link to the online surveys. Both you and your child would need to complete the surveys within 2 weeks of the scan. The surveys will ask you both about your thoughts, behaviors, feelings, and things you have experienced in your life, so there is no right answer to any of the questions. These surveys should take each of you around 1 hour to complete.

**Study Day 2-4: Scan Days**

For all three scan days, you will arrive at the scanning facility and check-in with a study team member, who will briefly confirm MRI eligibility. Your child will also complete an MRI simulator session on the first scan day, but the simulator sessions on Scan Days 2 and 3 are optional. Once finished, your child will be set up for the real MRI scan while you will be set up for the computer tasks in a separate room.

The set up will be the same on each of the three scan days. Your child will also get earplugs and have padding on the sides of their head to reduce noise levels and help them hold their head as still as possible. We will also place a small sensor over their index finger to record their heart rate and the amount of oxygen in their blood. A respiration belt will be placed around the upper part of your child’s waist to measure their breathing. Small circular sensors placed above their eyebrow will record muscle movement. Small sensors will also be placed on the third and fourth fingers of their left hand to record changes in sweat levels. Finally, we will place the stimulation stickers on your child’s fingers. On the first scan day, you will be able to choose the intensity of the electrical stimulation that they will feel. The stimulation is a buzzing or tingling sensation, and is meant to be annoying but not painful. When choosing the intensity, we will start so low that they won’t even feel it, and slowly increase it until they reach their preferred intensity level. We will use the same chosen intensity on all three scan days.
Some of the MRI scans on each day take pictures of brain anatomy, while other scans measure brain activity changes that can occur while your child is resting or completing one of the tasks, which we will explain in more detail below. If at any point your child feels too uncomfortable during the MRI, they will have the option to immediately stop the scan or ask for a break. During the scan, they will also be able to talk to and hear the person running the scanner. Additionally, a study team member will be available to them at any time before, during, and after the scan. In total, your child will be in the scanner for approximately 45 minutes on Scan Days 1 and 2. Scan Day 3 will include an additional picture of your brain anatomy and will therefore last approximately 90 minutes, with a break in the middle after the learning task is complete. If you would like, we can print out a picture of your child’s brain to give them after one of the MRI scans.

During the MRI scans, 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. Your child 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 and your child should know that it is not harmful.

On each of the three scan days, while your child is completing the MRI scan, you will complete the same tasks in a separate room. You will also have similar sensors placed above your eyebrow, a respiration band around your waist, stickers on your torso, stickers on your left hand, and the stimulation stickers on your right hand. You will choose the stimulation intensity in a similar way as your child did.

It is very important that you do not discuss what you see or do during these study visits with your child until after all three scanning days are complete. This will help prevent you and your child from influencing each other’s responses.

Learning Task
Both of you will complete the learning task. This learning task consists of five to six different phases, but you will only need to complete one or two on each day, over the course of three days. During all phases, you will view neutral pictures on the screen. There is no action for you to do while the task is playing; you will simply watch the images. You may or may not feel a stimulation in each of the phases. On the second day, you will be video recorded during one of the phases, and your child will then watch you do the task during one of their phases. In the video, your child will be able to see your facial and body reactions, as well as the images that you are seeing. At the end of each day, a study team member will ask each of you some questions about how you felt during the task.

Biological Sample Collection
After one of your scans, we will collect a couple of saliva samples from you and your child by having you both spit into small plastic tubes. We do this because we will be able to look at your genes. Genes tell you how to do things like grow your bones, form your spines, or what color your eyes will be. Genes are like a recipe, which is made up of a bunch of letters strung together. We want to look at both the letters that make up your genes, called DNA (deoxyribonucleic acid), and the molecules that will carry out the recipe, called RNA (ribonucleic acid). We want to look at all of this information so that we can understand how genes might contribute to what happens to your child’s body if they have had
a traumatic experience or PTSD, how genes relate to differences in brain function and structure, and what role they play in the learning process between you and your child.

**Study Day 5: Games and Questionnaires Day**

During your final visit, your child will be set up in one of our lab testing spaces to play a series of different tasks while we collect sweat levels, respiration, heart rate, and muscle activity data. These tasks will focus on identifying emotional expressions and will last approximately 20 minutes. After completing these tasks, we will take off all of the stickers and electrodes. We will not measure any of the body responses in any of the concluding tasks, detailed below.

You and your child will separately complete several tasks on an iPad that look at things like vocabulary, ways of thinking, and emotions. The final game will be a cooperative game between you and your child using an Etch-a-Sketch. With your permission, this activity will be video recorded so that we can look at your process for completing this task at a later time, without disrupting you as you work. We may also use this visit to finish any other study activities (such as biological samples, questionnaires, etc.) that could not be completed at Visit 1, your scan visits, or at home.

**Follow-Up Surveys**

Approximately 6 months after the MRI scans, you will receive an email with a link to a final set of online surveys for both you and your child. These surveys will be very similar to those you have already completed and will ask about current thoughts, feelings, behaviors, and experiences.

**Optional Remote/Modified Study Visits**

You may have the opportunity to complete the Study Day 1 remotely. In this scenario, a study team member would walk you and your child through the consent and assent forms via video chat and you would sign an online version of these forms. You and your child would then separately complete the clinical interview with a study member over video chat. The study team member will be in a quiet, private space with a secure computer for the interviews. We would also request that you and your child have a quiet, private place in your home with access to internet and a computer or laptop to complete your interviews. These video chats will be completed using a secure video conferencing software. It will not be recorded or stored in any way, and you will be provided with detailed instructions prior to your visit. If your child has not previously completed a research MRI scan, we will ask that you schedule an in-person visit for your child to be able to do the practice MRI scan in a simulator to get a feel for what it will be like inside the real MRI. If your child has had previous research scans and does not feel the need or wish to attend an in-person practice MRI scan, we may be able to simply talk about the MRI experience during the remote visit and forego an in-person practice.

Some aspects of Study Days 2-4 may be modified or dropped in order to maximize social distancing between you and the research staff members during the MRI scans. Finally, you may also be given the opportunity to complete Study Day 5 (Games and Questionnaires Day) remotely. This may mean that you will not complete the study activities from this visit that are not able to be completed virtually.

The remote visits described here are completely optional, meaning that you may choose to complete these visits in-person if you choose.
Sharing Data Across Studies
If you participate in other studies in Dr. Herringa’s lab, we may be able to share data across studies to decrease burden. Sharing data may mean not having to complete certain tasks at study visits if they have already been completed in the course of another study within a specified timeframe. These data may include information from your web screen, phone screen, clinical interviews, questionnaires, MRI scans, physiological data, and/or behavioral data. If you are interested, a study team member can explain all the options and details of completing more than one study in the Herringa lab.

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 collect and use the following kinds of PHI from both you and your child:

- From You:
  - Information about you and your child, such as your names, phone numbers, e-mail addresses, and birth dates.
  - Information about your and your child’s health, such as pregnancy status and medication use.
  - MRI safety information, such as presence of implanted medical devices (e.g., pacemaker).
  - A video recording of you and your caregiver completing the Etch-a-Sketch task
- From medical tests or other procedures done for this study:
  - Brain images collected from your child with the MRI scanner.
  - Body responses from you and your child, including muscle tension, perspiration, heart rate, and respiration.
  - Saliva samples from you and your child, as well as other biological samples such as urine and hair from your child.
  - Questionnaire and interview information provided by you and your child about your thoughts and experiences.
  - Results of tests or procedures done as part of the study.
  - Things you tell the researchers about your health.

We are requesting your email address so we can schedule appointments, send reminders, or answer any general questions you may have. 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 the study team at 608-265-3610. You do not have to provide your email address to participate in this study.

How long will I be in this study?
Your participation will include up to five study visits. You will be part of the study for approximately 4-6 weeks, as scheduling for each of the visits allows.

**How is being in this study different from my regular health care?**

If you take part in this study, the main difference between you and your child’s regular care and the study is that we do not provide any treatment intervention or follow-up care. This study is observational in nature. This study is not part of your health care.

**Do I have to be in the study? What if I say “yes” now and change my mind later?**

No, you and your child do not have to be in this study. Taking part in research is voluntary. This means that you decide if you want to be in the study. If you decide now to take part, you can choose to leave the study at any time. If you decide to be in the study, the researchers will tell you about new information or changes in the study that may affect your willingness to continue in the study.

If you decide not to take part in the study, or if you choose to leave the study, your choice will not affect any treatment relationship you have with healthcare providers at UW-Madison, UW Health or any affiliated organizations, or any services you receive from them. 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.

Your authorization allows researchers to use your protected health information (PHI) indefinitely. However:

- You can choose to take back your authorization for researchers to use your health information 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 continue 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, Ryan Herringa, MD, PhD, at (608) 263-6068.

**Will being in this study help me in any way?**

Being in this study will not help you or your child directly. Your participation in the study may benefit other people in the future by helping us learn more about youth exposed to interpersonal violence with and without PTSD, and how these experiences may be related to the relationship between the youth and their caregiver. Increasing our knowledge of the biology of pediatric PTSD and its relationship to the process of learning from family members is expected to eventually lead to better detection and treatment of these conditions in youth, experiences that are debilitating for both the child and the family. This study is not a substitute for your regular medical care. You should continue to see your regular medical providers.
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.

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 have the option of being informed of any findings of clear clinical significance that may be discovered during your child’s 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 child’s 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 your child is having symptoms that may require clinical imaging, you should contact their primary care physician.

The first MRI your child has will be reviewed by a physician who normally reads such images (such as a neuroradiologist), but each MRI after that will not necessarily be reviewed by such physician. As a result, we may only inform you of findings of clear clinical significance that we discover from the first MRI.

You may also choose to have your child’s 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__________________________________________________

Psychological Assessments

The questionnaires and/or diagnostic assessments you will complete in this study may show that you or your child may be in danger of being hurt by someone, are contemplating harming others, or considering self-harm or suicide. 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 you are suspected of mistreating your child, another legal guardian would need to be willing to take part in this study in your place. The study team would also need to clarify that any maltreatment has been properly reported. If we believe that your child’s responses on the interview questions indicate potential for self-harm or danger to self or others, or if your child endorses questions about suicide on the questionnaires, you will be informed and provided with resources for follow-up clinical care.

What are the risks?

There is a risk that you or your child’s 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.

**Psychological Discomfort**

Some questions may make you or your child feel uncomfortable. These questions are similar to what would be asked in a clinic. You and your child 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 for Female Participants
If the research team learns that your child could possibly be pregnant, you will not be able to participate in the study at this time. To protect your child’s privacy, we may not tell you, but we strongly recommend follow-up care. However, the research team would consider your child’s age, maturity, and cognitive levels and would inform you if we think you need to know so you can help take care of your child. Additionally, if pregnancy was the result of sexual assault, we would be required to notify the appropriate authorities and possibly the clinician listed as well.

Genomic Testing
There are also risks of collecting genetic information. For example, personal stigmatization and/or discrimination if you or your child were found to carry a gene related to a particular medical condition. This can result in the potential loss of or difficulty in obtaining employment or insurance, either because of what the test results show with respect to the genetics of the tested individual or the genetics of an identified group with which the individual is associated because of a medical condition, ethnicity or social standing. However, the results of any genetic data processing performed in this study will not be released to you, so the risk of these events is very low.

Additionally, the Genetic Information Nondiscrimination Act of 2008 is a Federal law that is supposed to prevent health insurance companies and employers from discriminating against people based on genetic information. There are some limits to this law:

- It does not apply to businesses that employ fewer than 15 people. So, if you work somewhere with fewer than 15 employees, your employer could fire you or make other decisions about employment using genetic information.
- Regardless of where you work, it does not apply to life insurance, disability insurance, or long-term care insurance.
- This means that if you had an abnormal genetic test result, and that result became known, then you could be denied or pay higher rates for life insurance, disability insurance, or long-term care insurance.

MRI Safety
To determine if you are eligible for our study, we will ask you a series of questions about your child, including previous surgeries, whether they have implanted devices of any type, 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 MRI machine can cause some metal implants to move or break down. Also, people who are pregnant are excluded from participating in MRI studies, as risks to the fetus are unknown. To make sure it is safe for your child 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.

Simulation Tolerability
This study involves the use of mild stimulation on your fingers. While the calibration and intensity chosen by you and your child is intended to be physically and psychologically irritating but not painful, you may find you are unable to tolerate the feeling. A study team member will be available at all times before, during, and after the task in order to assist you if an issue arises and you may choose to stop the study at any time.

Will being in the study cost me anything?

There will be no cost to you for any of the study activities or procedures. You may need to pay for basic expenses such as childcare or transportation to our facility. We will offer a taxi service to and from study visits, if needed.

Will I be paid or receive anything for being in this study?

We will pay you $10 for the web screen you have already completed, $75 for Visit 1, $50 for Visit 2, $50 for Visit 3, $100 for Visit 4, and $50 for Visit 5. Payment will be provided at the end of each visit. Finally, you will receive $25 to complete the follow-up surveys six months later. If you complete all the study visits, you will receive $360 for being in this study. If needed, subjects may be invited for additional visits to complete MRI simulation sessions and/or finish incomplete study procedures. Subjects will be compensated $25 per additional session. Additional visits are expected to last no longer than approximately an hour and a half. If participants are asked to repeat a full visit, they will be compensated at the rate of that visit.

If you choose to leave or we take you off the study for any reason, you will only receive the payment for completed visits. If you choose to withdraw from the study at any time during a visit, you will receive payment for that entire visit.

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

If you or your child is injured or gets 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, contact your regular health care provider.
- Call the Lead Researcher, Ryan Herringa, MD, PhD, at (608) 263-6068 to report your sickness or injury.
Here are some things you need to know if you or your child get sick and/or injured because of this research:

- If the sickness and/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.

How will researchers keep my research information confidential?

We have strict rules to protect your personal information and protected health information (PHI). We will limit who has access to your name, address, phone number, and other information that can identify you. We will also store this information securely. We may publish and present what we learn from this study, but none of this information will identify you directly without your permission.

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. 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 below 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 institutional permissions and confidentiality protections, we might use information and biospecimens that we collect during this study for other research or share with other researchers without additional consent or authorization from you or your legally authorized representative.

Who at UW-Madison can use my information?

- Members of the research team
- Offices and committees responsible for the oversight of research
- Personnel who administer the MRI scan in the Lane Neuroimaging Center
- Accounting and billing personnel, or do other tasks related to this study

Who outside the UW-Madison may receive my information?

- U.S. Office for Human Research Protections
- National Institutes of Health
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.

National Institutes of Health Data Archiving

Data from this study, including MRI scan images, biological specimen data, responses to questionnaires, and basic information about you and your caregiver (e.g., gender, age, 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 de-identified information about your health, and behavior, and genomic information, to the NDA or other data repository. Genomic information relates to the structure and function of all of the genetic material in the body. 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.

Even so, there is a possibility that when your genomic information is combined with other information available to researchers, either now or in the future, they may be able to identify a group you belong to (like an ethnic group or a disease population) or, less likely, you personally. NIH prohibits people
from trying to identify individuals whose genomic information is in an NIH-designated repository. We do not think that there will be further risks to your privacy and confidentiality by sharing your genetic information with these banks. However, we cannot predict how genetic information will be used in the future.

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 http://data-archive.nimh.gov.

What will happen to my data after my participation ends?

We will keep all of your data, including recruitment information, study activity data, and biological samples for an indefinite period of time, meaning we have no plans of ever destroying your data and biospecimens. Keeping data or samples for future research is called “banking.” The banked data and biospecimens will be kept in a secure location for use by researchers.

This is what will happen with your banked data and biospecimens:
- We will use the data and biospecimens in future research projects research on mental health. We may also use them for other types of research.
- The data and biospecimens may be shared with other researchers at University of Wisconsin-Madison and outside the University. Outside researchers may be at other universities, private companies, or other kinds of organizations.
- The banked data and biospecimens will be labeled with a code instead of your name.
- When we give your data and biospecimens to other investigators for research projects, they will not be able to use the code to figure out which data and biospecimens are yours.
- The research team will maintain a link between your data and biospecimens and your identifiable information kept by the study team.
- You can request to have your data and biospecimens removed from the bank by contacting the research team at any time.

This is what will NOT happen with your banked data and biospecimens:
- Banked data and biospecimens will not be shared with your healthcare providers or used in your treatment outside this study.

Will information from this study go in my medical record?

IRB Approval Date: 11/17/2020
University of Wisconsin – Madison
A medical record may be created for you if you do not already have one. None of the information we collect for this study will go in your medical record.

**What if I have questions?**

Study team members are the primary point of contact if you have questions during a study visit. In addition, please contact the study team at 608-265-3610 or email braveyouthlab@psychiatry.wisc.edu with any questions or comments you may have about the study. If you have any questions about your rights as a research subject or have complaints about the research study or study team, contact UW Health Patient Relations at 608-263-8009. The Patient Relations Representatives work with research subjects to address concerns about research participation and assist in resolving problems.
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.

<table>
<thead>
<tr>
<th><strong>Contact for Future Studies</strong></th>
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<tbody>
<tr>
<td>We would like to keep your contact information so that we can reach you for possible future studies, furthering our efforts to better understand how parent-child relationships and experience affect child development. Your contact information will be kept in a secure location. This is completely voluntary and optional. You can choose to have the study team destroy your contact information after this study is completed, and you will not be contacted for any follow-up studies.</td>
</tr>
<tr>
<td>_____ Yes, the research team may keep my contact information for possible future studies conducted in the BRAVE Research Center.</td>
</tr>
<tr>
<td>_____ No, I do not want the research team to keep my contact information after this study is completed, and I do not want to be part of any future studies conducted in the BRAVE Research Center.</td>
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<table>
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<tr>
<th><strong>Study Visit Video Recording</strong></th>
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<tr>
<td>We would like to video record all or part of select study visits for purposes of training, as well as standardizing and assuring the quality of our research methods. See information above about how all video recordings taken during the study are banked for future use.</td>
</tr>
<tr>
<td>_____ Yes, the research team may video record all or part of select study visits.</td>
</tr>
<tr>
<td>_____ No, I do not want the research team to video record all or part of select study visits.</td>
</tr>
</tbody>
</table>
Etch-a-Sketch Task

The Etch-a-Sketch task, which was previously described, requires the use of a video camera. Only study personnel will have access to these videos, which will need to be coded and stored for data analysis. 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. The videos will be stored in a secure place, and will normally be destroyed one year after the study is completed. Please indicate your preference for being included on this task by initialing one of the lines below.

Caregiver

_____ Yes. I, the Caregiver Participant, would like to participate in this task and agree to be recorded for study purposes

_____ No. I, the Caregiver Participant, do not want to be included in this task, and I will not be recorded for this task

Youth

_____ Yes. I, the Youth Participant, would like to participate in this task and agree to be recorded for study purposes

_____ No. I, the Youth Participant, do not want to be included in this task, and I will not be recorded for this task

Interview Summary Report

As part of this study, we can provide your mental health provider with a summary of our findings from the clinical interview and questionnaires that your child completes. Allowing us to release this report to your child’s mental health provider is optional. The report may help your 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 my child’s mental health provider (listed below).

_____ No, please do not send a report.

Full Name of Clinician: ______________________________________________

Clinic/City/State: __________________________________________________
AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY
AND
PERMISSION TO USE AND/OR DISCLOSE MY HEALTH INFORMATION

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 your child’s participation, and the researchers have answered your questions.
- You and your child agree to participate in this study.
- You give authorization for your protected health information to be used and shared as described in this form.

You will receive a signed and dated copy of this form for your records.

Parent/Guardian Consent for the Participation of a Minor

____________________________________
Printed Name of Parent/Guardian

____________________________________
Signature of Parent/Guardian Date

Parent/Guardian Consent for the Participation of Self

____________________________________
Printed Name of Parent/Guardian

____________________________________
Signature of Parent/Guardian Date

____________________________________
Signature of Person Obtaining Parental/Guardian Permission and Authorization and Child Assent Date