TITLE OF THE STUDY: Cognitive-Emotional Development in Adolescence (CEDA)

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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. In this consent form, “you” means the child who takes part in the study. “Your caregiver” means you as the parent/guardian. As the parent/guardian, you are also asked to participate in the study. Your involvement is described in this document as well.

PURPOSE OF THIS STUDY AND INVITATION
You and your caregiver are invited to be in a research study that looks at how the brain develops during adolescence and how that process may differ in youth with or without mental illness like depression, anxiety, or PTSD. We are also interested in how development may be impacted by traumatic experience. Participants in this study will be between 10 and 16 years old at the beginning of their participation, and we plan to enroll 140 youth in total, as well as their respective caregivers. Funding for this study is provided by the National Institutes of Health.

IMPORTANT THINGS TO KNOW ABOUT ANY RESEARCH STUDY
Taking part in research is voluntary. You can choose not to be in this study, or 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 the research study is to better understand why some youth develop mood (affective) and/or stress-related disorders (PTSD) after maltreatment. Since youth during adolescence develop so rapidly, we’re having participants repeat study activities every year for two years to see what changes. We will be using an MRI to see how the brain changes, and also collecting biological samples to see how the body changes. We’ll also be asking questions to you (the child), and your parent/caregiver in regards to mental and physical health.

How much time will I spend on the study?
There will be three study visits, all scheduled within a few weeks. These visits are repeated every year for two years, for a total of six study visits. Each study visit will take 3-4 hours. Study visits are located either at the Health Emotions Research Institute, the Waisman Center in Madison, Wisconsin, or virtually.

What will happen during the study?
You and your caregiver will take part in a structured clinical interview assessing mental health symptoms and trauma history. You and your caregiver will also complete questionnaires assessing mental health symptoms and health history. You (the child) will be scanned in an MRI and provide saliva, fecal, hair, and urine. You and your caregiver will also complete some tasks on a computer while we measure your body’s reactions. These study activities are repeated every year for two years.

Could taking part 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 mood disorders and maltreatment affect adolescent development.

What are the main risks of taking part in this 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, the most important risks to know about are: Difficulty discussing health history, trauma history, possible pregnancy, and mental health symptoms. 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.

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 you might be pregnant, you should not be in the study.
- You might feel anxious in the small space of the MRI scanner. You will be able to stop the scan at any time.
- You might be uncomfortable lying on your back during the scan.
- The MRI scanner makes loud noises. You will wear ear protection.

How is research different from healthcare?
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 bravemyouthlab@psychiatry.wisc.edu

Questions about your rights as a research participant?
Have a complaint about the research?
Confidential Research Compliance line at 1-833-652-2506.
MORE INFORMATION ABOUT THIS STUDY

WHAT WILL MY PARTICIPATION INVOLVE?
You and your caregiver will be asked to complete three study visits every year for two years. Each visit will be around 3-4 hours long, and you will complete a total of 6 visits over the course of the study. If you choose to participate, activities that you will complete include the following: answering questions about your mood and health; providing stool, saliva, urine, and hair samples; and undergoing scans of your brain.

VISIT 1: INTERVIEW DAY (3-4 hours)
The focus of this visit is to get a clear picture of your everyday experience. During Visit 1, you and your caregiver will be interviewed individually and in more depth. The questions will ask about various symptoms, past experiences, and thought patterns. We’ll also ask some questions about your medical and trauma history. You and your caregiver 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 caregiver. To assure you can safely be scanned, we may require that your caregiver obtain written permission from doctors for things such as previous surgeries. We would also talk with you and your caregiver 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, you may 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 will be done at the Health-Emotions Research Institute (HERI) brain-imaging lab in the Psychiatry department or at the Brain Imaging Core at the Waisman center, and it will last about 20 minutes. The MRI simulator looks similar to the real scanner but does not use a magnetic field. The purpose of the practice MRI scan is to help you get used to being in a scanner, in preparation for the real MRI. This means that we will not actually be taking pictures of your brain during the fake scan. To get a good scan, it is important that people keep their entire body very still. This can take practice, and when in the MRI simulator, we will make sure to help you get as comfortable as possible, and we will also give you some pointers about how to best keep your head and body still. During both the real MRI and the MRI simulator, you will be lying on your back on a table, and the table will move you backwards into the main circular feature, called the bore. The MRI is a small space that makes loud noises. At the simulation session, we will play a variety of these noises for you, and at the scan itself you will have earplugs to protect your hearing. You will also be taught how to play the games we will ask you to play in the scanner. The games will be shorter, simpler versions of what you will play in the real MRI. The games are about viewing and responding to different pictures. These pictures will be displayed on a screen behind you in the MRI, and you will be looking up at a small mirror that’s attached to the piece that goes around your head, called the coil. The mirror will be tilted toward the screen behind your head. If additional practice is needed, we can schedule the MRI simulator session on a different day before Visit 2.

During Wave 2 visit 1 will be a combination of remote and self-administered assessments. The youth and caregiver will complete a 30-minute video session where they will complete staff administered REDCap assessments, and an MRI screener. Both caregiver and youth participants will also receive an email with a link to complete online questionnaires through REDCap, and a link will be sent to complete the self-administered K-SADS. This link will be sent to families approximately 1 week before the MRI scan visit (Visit 2). The at-home questionnaires need to be completed within +/- 2 weeks of the MRI scan; if they are not completed within this window, we may ask participant to repeat the questionnaires.
OPTIONAL ADDITIONAL VISIT: (1 hour)
In the event that you are tired or unable to complete the MRI simulator session at the first visit, or you would like more practice in the MRI simulator, you will have the option to schedule an additional practice session before Visit 2. Additionally, if there is a delay with scheduling the scans, and they take place more than four months past the Visit 1 Interview Day, we may ask that you repeat the Interview Day.

WITHIN +/- 2 DAYS OF VISIT 2: FECAL COLLECTION (30 minutes)
Research staff will give you a fecal (stool) collection kit to take home during Wave 1 of your participation. We will also give you a pre-paid shipping label. We ask that you ship the sample on a Monday, Tuesday, or Wednesday, also avoiding holidays. These samples will be analyzed at the Wisconsin Institute of Discovery. You will not repeat the fecal collection at any subsequent waves.

WITHIN +/- 2 WEEKS OF VISIT 2: QUESTIONNAIRES (1.5 hours)
We will also email a link to some questionnaires for you and your caregiver to fill out at home around the time of your second visit. These questionnaires should take about 45 minutes to complete.

VISIT 2: SCAN AND BIOSAMPLES DAY (3.5-4 hours)
At the beginning of Visit 2, you will do another MRI simulator session, review the games one more time, and go over a few reminders to help you stay still in the MRI scanner. Once this is finished, we will offer you a break to use the restroom, and then we will set up for the real MRI scan.

Just like in the MRI simulator, when in the real scanner, you will view a screen by looking up at a small mirror. In the real scanner, there may be a set of cameras that will track your eye movements as you look at each picture. The cameras will not record pictures of your eyes, rather they will record data about the direction your eyes are looking. You will also get earplugs and have padding on the sides of your head to reduce noise levels and help you hold your head as still as possible. We will also place a small sensor over your index finger to record your heart rate and the amount of oxygen in your blood. A respiration belt will be placed around the upper part of your waist to measure your breathing. Small circular sensors placed above your eyebrow will record muscle movement, and they will also be placed on the third and fourth fingers of your left hand to record changes in sweat levels.

Some of the MRI scans take pictures of brain anatomy, while other scans measure brain activity changes that can occur while you are resting or playing simple games. It is possible that the pictures in these games could give you strong feelings and/or make you uncomfortable. If at any point you feel too uncomfortable during the MRI, you will have the option to immediately stop the scan or ask for a break. During the scan, you will also be able to talk to and hear the person running the scanner. In total, you will be in the scanner for about 90-120 minutes, with a break halfway through.

During the MRI scan, some people have said they felt tingling or muscle twitches in different parts of their body. These feelings are not painful and will not cause you any harm. You will be asked not to touch your hands together or cross your legs during the scan, because these can occasionally cause a mild shocking sensation. If this occurs, you should know that it is not harmful.

While you are completing the MRI scan, your caregiver will complete the same tasks in a separate room, in addition to an emotional response task, with similar sensors placed above their eyebrow, a respiration band around their waist, stickers on their torso, and stickers on their left hand.
After the MRI scan, we will collect saliva samples by having you spit into a small tube. The spit samples will be processed to allow us to look at your DNA, RNA, and other markers. DNA, or deoxyribonucleic acid, carries the genetic instructions for the cells that make up your body. RNA, or ribonucleic acid, acts as a messenger and carries instructions from DNA to control the transcribing, regulation, and expression of genes. Genes tell your body how to do things like grow your bones, form your spine, and what color your eyes should be. We are collecting genetic information in this study so that we can understand how genes might contribute to symptoms of anxiety, depression, and/or PTSD, as well as how genes relate to differences in brain function and structure.

A couple small samples of hair will also be collected from the back of your head. The hair will be cut as close to the scalp as possible so the missing hair will be hard to notice. We will collect hair about 3mm in width. The hair samples will be used to examine cortisol levels, a chemical your body releases during times of stress. Finally, we will also collect a urine sample to gain information about hormone levels and metabolites in your body.

VISIT 3: GAMES AND QUESTIONNAIRES DAY (3-4 hours)
At this visit, you will complete several tasks on an iPad that look at things like vocabulary, ways of thinking, and emotions. Your caregiver will complete very similar tasks on the iPad. We will also use this visit to finish any other study activities (such as biological samples, questionnaires, etc.) that could not be completed at Visit 1, Visit 2, or at home. Lastly, there will also be a task that you will complete with your caregiver 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.

OPTIONAL REMOTE/MODIFIED VISITS
During Wave 1 of this study, you will have the opportunity to complete the Visit 1 Interview Day remotely. In this scenario, a study 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 similar place in your home with access to internet and a computer or laptop to complete your interviews. This video chat 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 Visit 2 (Scan Day) may be modified or dropped in order to maximize social distancing between you and the research staff members during the MRI scan. Finally, you may also be given the opportunity to complete Visit 3 (Games and Questionnaires Day) remotely. This may mean that you will not complete some of the study activities from this visit that are not able to be completed virtually.

WHAT INFORMATION WILL WE COLLECT?
We will collect the following health information about you and your caregiver:

1. From you:
   - Information about you and your caregiver, such as your names, phone numbers, e-mail addresses, and birth dates.
   - Information about your and your caregiver’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

2. From medical tests or other procedures done for this study:
• Brain images collected from you with the MRI scanner.
• Body responses from you and your caregiver, including muscle tension, perspiration, heart rate, and respiration.
• Biological samples from you, including saliva, stool, urine, and hair.
• Questionnaire and interview information provided by you and your caregiver about your thoughts and experiences.

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 608-263-3610. You do not have to provide your email address to participate in this study.

The Etch-a-Sketch task, which was previously described, requires the use of a video camera. Only study personnel will have access to these video recordings, which will be stored on a secure server. While we store coded data using your subject ID, your faces and dialogue will be in the video recording. This includes any personal information you choose to say while the camera is recording. A written copy (transcript) of the recordings may be used for research purposes.

TO BE COMPLETED AND INITIALED BY THE CAREGIVER PARTICIPANT ONLY (AND YOUTH IF 15+)

To give permission for us to video record you and your caregiver, initial below.

_____ I, the Youth Participant, consent to being video recorded for study purposes.

_____ I, the Caregiver Participant, consent to being video recorded for study purposes.

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.

ARE THERE ANY RISKS?
Some questions may make you or your caregiver feel uncomfortable. These questions are similar to what would be asked in a clinic. You and your caregiver 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.

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

While your data are kept in very secure locations, there is a risk that your information could become known to someone not involved in this study. If this happens, it could result in damage to your reputation, which could also affect your relationships with family and friends, affect your employment, or make it harder to get insurance or a job.

There are also risks of collecting genetic information. For example, personal stigmatization and/or discrimination if you 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.

We might find out during the study if you or your caregiver 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 your caregiver is suspected of mistreating you, 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 responses on the questionnaires or interview questions indicate potential for self-harm, or danger to self or others, or if your child endorses questions about suicide on the questionnaires, your caregiver will be informed and provided with a resources for follow-up clinical care.

**MRI SAFETY**

To determine if you are eligible for our study, you will be asked a series of questions including previous surgeries, whether you 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 you to be in the MRI, these questions will be asked again
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.

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 that problem. Uncertain clinical significance means that the MRI 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. In this study, you will be informed of any findings of clear clinical significance that may be discovered during the imaging procedure, but you will not be informed if there are findings of uncertain clinical significance. In order to assist us in interpreting the results of your MRI, we are also seeking your permission to review your medical records if you are or have been a patient at this hospital. The MRI images and report from this research study will not be placed in your medical record.

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

This study involves a series of two MRI scans, one year apart. Each MRI you have will be reviewed by a physician who normally reads such images (such as a neuroradiologist). We would inform you of findings of clear clinical significance that we discover from any of the two scans.

You may also choose to have your physician informed of any findings of clear clinical significance that we report to you by checking the box below. Please note, however, that if you choose to have your physician informed of findings of clear 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.

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

If you DO wish us to report any findings to your physician, provide your primary physician’s information.

**Name of Physician to Contact**

Full Name of Primary Physician: ______________________________________

City or Clinic: __________________________________________________

**ARE THERE ANY BENEFITS?**

If you are being treated for mental illness, being in the study may help to clarify your diagnosis. We may also be able to direct you to appropriate resources. There will be no other direct benefit to you. Individuals participating who do not have a mental illness are not expected to benefit directly. There is a potential benefit to society of better understanding the effects of affective disorders, traumatic stress, and PTSD during adolescence. This could someday lead to better detection and treatment.

Researchers may develop products from the samples and information you provide for this study. Some of these products may have commercial value. If the research team or others use your samples or information to develop products of commercial value, you will not receive any profits from products created.

**WILL I BE PAID FOR PARTICIPATION?**

You will get up to $640 for participating in the study. You will have already received a $10 gift card for completing the web screening. You will get $290 if you complete all 3 visits in a year (Visit 1: $75, Visit 2: $165, and Visit 3: $50). After completing Year 2 of the study, you will receive a $50 bonus for repeating all 3 visits. If you are asked to complete an additional session (such as additional MRI simulation practice session, described above) you would be compensated $25. If participants are asked to repeat a full visit, they will be compensated at the rate of that visit.

**WHAT IF I AM INJURED AS PART OF THIS STUDY?**

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

- If it is an emergency, call 911 right away or go to the emergency room.
- For non-emergency medical problems, 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 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 MY DATA BE USED, CONFIDENTIALITY PROTECTED, & WHO WILL USE MY HEALTH INFORMATION?
We have strict rules to protect your personal information and protected health information (PHI). We will limit who has access to your health information, 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 and/or government officials responsible for monitoring study procedures and/or data (e.g., monitors, auditors, Institutional Review Boards). This can include accessing medical records so that regulatory authorities can verify study protocol and data. These groups will maintain your confidentiality. By signing this consent form, you are authorizing this access to your records.

Others at UW-Madison and UW Health who may need to use your health information during the course of this research can include:

• Researchers in the University of Wisconsin Department of Psychiatry
• UW-Madison regulatory and research oversight boards and offices
• Accounting and billing personnel at the UW-Madison, University of Wisconsin Medical Foundation, and University of Wisconsin Hospital and Clinics
• Research support services staff at the UW-Madison and its affiliates

Others outside of UW-Madison and UW Health who may need to receive your health information in the course of this research:

• Equipment manufacturers, such as General Electric Healthcare, which makes the MRI machines
• Research oversight agencies, such as the Food and Drug Administration
• National Institute of Mental Health Data Archive (NDA) (described in more detail below)
• Data sharing institutions for pooling de-identified data

People outside of UW-Madison and its affiliates who receive your health information may not be covered by privacy laws and may be able to share your health information with others without your permission. Usually when we share information from research studies with others outside the UW-Madison and UW Health, it is not shared in a way that can identify an individual.

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.

**NIMH DATA SHARING**

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). 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. With an easier way to share, researchers hope to learn new and important things about mental illnesses more quickly than before.

During and after the study, the researchers will send de-identified information about your health and behavior and in some cases, your genetic information, to the NDA. Other researchers nationwide can then 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.

You may not benefit directly from allowing your information to be shared with the NDA. The information provided to the NDA 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 NDA data. However, you will not be contacted directly about the data you contributed to the NDA.

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

**GENETIC DATA SHARING**

At some point in the future, we may be required to share genetic data with federal repositories. Because this research receives funding from the National Institutes of Health (NIH), we will submit your genomic information to a public repository approved by the NIH. The NIH is a national research agency and is part of the federal government. The NIH and other central repositories have developed special data banks that include results of genetic studies, especially when the research looks at all, or large sections of, an individual’s genetic code. This is often called whole-genome sequencing. Genomic information relates to the structure and function of all of the genetic material in the body. These banks will store your genetic information and will share them with qualified and approved researchers for future analyses. The data that we share with federal repositories will be coded in
such a way that you would not be able to be identified. We will not share your name, birth date, or any other
information that could directly identify you. The link to the code will be kept securely at the UW. 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.
The genetic data could be used to study a wide variety of diseases.

What will happen to my data and biospecimens after my participation ends?
We will keep your data and 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.

As part of this study, we will collect video recordings during the Etch-a-Sketch task, and we may also collect
video recordings during study visits if you choose to opt in below. The Etch-a-Sketch video recording is being
collected for data analysis purposes, and the study visit video recordings would be collected for training and
standardization purposes. A written copy of the recordings may also be made for use in the research.

Recordings will be kept indefinitely (banked), meaning we have no plan to destroy the recordings. The
recordings may be used in the future for future research, as well as training and educational purposes. When
the recordings are used in the future, we will edit them whenever possible so that you cannot be directly
identified in the recordings.

HOW LONG WILL MY PERMISSION TO USE MY HEALTH INFORMATION LAST?
By signing this form, you are giving permission for your health information to be used for this study and shared
with the individuals, companies, or institutions described in this form. Unless you withdraw your permission in writing to stop the use of your health information, there is no end date for its use for this research study. You may withdraw your permission at any time by writing to the person whose name is listed here:

Dr. Ryan Herringa, MD, PhD
Department of Psychiatry
University of Wisconsin
6001 Research Park Blvd
Madison, WI 53719

From the moment you withdraw your permission, no new health information will be collected. Any health information that was shared before you withdrew your permission will continue to be used. If you withdraw your permission, you can no longer actively take part in this research study. If you provide permission below, we would retain your contact information so we may contact you for future research opportunities.

WHAT IF I HAVE QUESTIONS?
The experimenter at your session will answer any questions you may have about the study. In addition, you may call the study team at 608-263-3610 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 Confidential Research Compliance line at 1-833-652-2506. The Patient Relations Representatives work with research subjects to address concerns about research participation and assist in resolving problems.

IF I START THE STUDY, CAN I CHANGE MY MIND?
Your participation is completely voluntary; you may stop participating at any time during the study. Stopping the study will not affect present or future medical care at this institution in any way. Furthermore, participation in the research study or refusal to do so will not affect a caregiver participant’s employment or status as a student (e.g., grades or class standing) at the university.
OPTIONAL STUDY ACTIVITIES

TO BE COMPLETED AND INITIALED BY THE CAREGIVER PARTICIPANT ONLY

This part of the consent form is about additional related activities that you can choose to take part in. These activities are optional. You can still take part in the main study even if you say “no” to any or all of these. These activities will not help you directly. We will not tell you the results of these optional components, and we will not put any of these study results in your medical records. Taking part in the optional activities will not cost you anything.

CONTACT FOR FUTURE STUDIES
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 biology 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. Please state your preference by initialing the appropriate line:

Caregiver Initials:

_____ Yes, the research team may keep my contact information for possible future studies conducted in the BRAVE Research Center.

_____ 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.

Study Visit Video Recording
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. Please state your preference by initialing the appropriate line below.

Caregiver Initials:

_____ Yes, the research team may video record all or part of select study visits.

_____ No, I do not want the research team to video record all or part of select study visits.

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 you complete. Allowing us to release this report to your mental health provider is optional. The report may help your mental health provider plan your treatment, and it is possible that the report will end up in your medical record. Please initial below whether you would like us to give the report to your mental health provider.

Caregiver Initials:

_____ Yes, please send the report to my mental health provider (listed below).

_____ No, please do not send a report.

Full Name of Clinician: ______________________________________________

Clinic/City/State: __________________________________________________

TO BE COMPLETED AND INITIALED BY THE CAREGIVER PARTICIPANT ONLY
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

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

Printed Name of Parent/Guardian or Youth Participant Age 18+

Signature of Parent/Guardian or Youth Participant Age 18+ Date

Printed Name of Subject (age 15 – 17)

Signature of Subject (age 15 – 17) Date

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

For administrative use on day of MRI scan:

Reviewed by: Date: Scan sequence:  A  B

IRB Approval Date: 4/21/2022
University of Wisconsin – Madison