CONSENT FORM

A Longitudinal Study Examining Three RDoC Constructs in Adolescents with Non-Suicidal Self-Injury Consent Form (BRIDGES)

NOTICE: You are likely aware of the ongoing COVID-19 (Coronavirus) outbreak and the growing emergency measures that are being put in place to limit the spread of the outbreak, including government and institutional restrictions. These restrictions may affect how the study is conducted during this time. Please be aware of possible changes, which could impact you, directly. These changes can include, for example, use of available technology for remote monitoring/data collection, "virtual" study visits, electronic completion/transmission of study-related questionnaires, and/or any other changes deemed necessary until the pandemic and associated government/institutional restrictions are lifted. Your study doctor/study staff will inform you in a timely manner about any new information and the need to make changes to any part of the study as described in this Informed Consent Form.

You and your child are invited to participate in a research study about brain development in adolescents with and without self-harm behaviors. We ask that you read this form and ask any questions you may have before agreeing to be in the study.

This study is being conducted by Kathryn Cullen, M.D., in the Department of Psychiatry at the University of Minnesota. The study is funded by the National Institute of Mental Health.

Study Purpose

The purpose of the study is to understand the brain abnormalities that underlie self-harm in adolescents. Specifically, we are examining brain systems that support how we respond to threat, how we think about ourselves, and how we control our impulses. We will test whether these systems are related to self-harm behaviors during early adolescence, and we will measure how these systems change over three years during adolescent development.

Study Procedures

If you agree to participate in this study, we will ask you to do the following: (a) you and your child will participate in a clinical assessment which would include an interview, questionnaires and tests of their thinking, (b) your child will have a brain MRI, (c) your child will give a speech and provide saliva samples, and (d) complete some questionnaires online. We will ask you to complete these activities three separate times over the course of three years.

In the first visit, you and your child will be interviewed by experienced, clinically-trained research team members. We will ask questions about your child's health history and clinical symptoms. The research team will then review the information provided to determine if your child qualifies for the study and that it is safe for them to participate. You and your child will be asked to fill out some questionnaires. This session will take about 2 to 4 hours and will be done via Zoom. The interview portion will be kept to three hours maximum. If it is not complete by the end of the 3-hour window, you will be asked to schedule a time to finish up the interview. You will also have the option to continue on with the interview that day. Your child will be compensated for the extra time.

The next study session will involve a procedure called the Trier Social Stress Test (TSST), which will take place via zoom or at the Masonic Institute for the Developing Brain. For this, your child will be asked to prepare a short speech for 5 minutes and deliver that speech for in front of an audience with another task to follow. This activity will be videotaped. After your child has completed the speech task, they will be asked to complete a number of paper and computer tests which will measure things like attention and memory. During one of the computer tasks, we will be using an eye-tracker to monitor your child's gaze. The eye-tracker consists of a long bar that works like a video camera. It sits under the computer monitor and does not require anything to be attached to the participant that may cause discomfort. Your child will be asked to provide five saliva samples throughout the course of this visit so we can measure cortisol, a hormone related to stress. During the COVID-19 pandemic, the speech will be done remotely via Zoom; the salivary collection be completed at home, (the kit will be sent via U.S. mail); the eye-tracking task will not take place; and the computer task will be shifted to the MRI appointment.

We will also ask your child to provide five more saliva samples when they are at home during a normal day, and bring those back with them to their next appointment. We will ask that your child fill out a "daily diary" that accompanies the samples and provides information related to the day. They will be compensated for the home saliva samples as well as completing the diary. If your child does not complete the speech appointment, we may still ask for them to collect home saliva samples as their own choice.

You and your child will be asked to visit the Center for Magnetic Resonance Research (CMRR) for a brain MRI. The MRI scan is noninvasive and the whole visit takes about 2 ½ to 3 ½ hours. Your child will be asked to provide a urine sample and complete a drug test prior to the MRI scan.

If staff suspects metal in your body, you will have the option to undergo a low dose, whole body Computed Tomography (CT) scan prior to the MRI in order to ensure their safety and eligibility. The CT scan will take place at the CMRR at the University of Minnesota.

Before the actual MRI scan, your child may choose to have a session with our "practice scanner", to help get comfortable with the scanner environment, before the real thing. The MRI involves taking pictures of the brain. For the scan, your child will be asked to lie down quietly on a scanner bed. Once your child is inside the scanner, it will start to take pictures. While the scanner is working, your child will hear noises, like knocking or beeping sounds. We will give your child headphones to reduce the noise to a more comfortable level. While your child is in the scanner, they will be doing things like resting, listening to music, and playing games using a button box. The games your child will be playing in the scanner will involve things like matching pictures of faces and deciding whether phrases apply to them or not. After they have completed the scan, we will have your child complete some questionnaires about their experiences in the scanner.

On rare occasions, the MRI data that we collect does not have the high quality that we need for the data analyses. If this were to happen, we would invite your child to return to the CMRR to repeat all

or a portion of the MRI visit. This would be scheduled within a couple of weeks of the first scan. If you and your child agreed to have her repeat the MRI scan, your child would be compensated again.

During the COVID-19 pandemic, the MRI visit will also include the computer tasks and assessment originally scheduled for the second session. Depending on the length of time that has elapsed between the MRI visit and the most recent clinical interview, we may also schedule a short Zoom visit with your child prior to the MRI visit to administer a short assessment.

Finally, we will ask your child to complete some online questionnaires at their own pace. The total time to complete the online assessments is approximately 1 hour and 45 minutes. We will compensate for the time spent completing the online questionnaires upon completion.

You and your child will be asked to come back to repeat these activities (clinical assessment, speech and saliva tasks, MRI, and online questionnaires) one and two years following the completion of the first set of activities.

Data Sharing
The data that you provide is valuable and can be used for other studies of adolescent health problems. As part of this study, we will upload the de-identified data to the National Institute of Mental Health's Research Domain Criteria Database (RDoCdb).

RDoCdb 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 deidentified information about your health and behavior and in some cases, your genetic information, to RDoCdb. Other researchers nationwide can then file an application with the NIMH to obtain access to your deidentified 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 RDoCdb. The information provided to RDoCdb may help researchers around the world treat future children and adults with mental illnesses so that they have better outcomes. NIMH will also report to Congress and on its web site about the different studies that researchers are conducting using RDoCdb data. However, you will not be contacted directly about the data you contributed to RDoCdb.

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

Risks of Study Participation
The study has the following risks.

1. Clinical assessment. Some of the questions that will be asked in the interviews or study questionnaires may make you or your child feel uncomfortable. The study includes questions about mental health, health problems, eating disorders, self-harm, suicidal thoughts and actions, abuse (physical, emotional, sexual, and psychological) and puberty. Neither you nor your child has to answer any question that makes you feel uncomfortable.

2. MRI. MRI machines use a strong magnet and radiofrequency magnetic fields to take images of your body. The scanning process is similar to an x-ray or CT scan, but MRI does not use ionizing radiation (high-energy radiation that can potentially cause damage to DNA) like x-rays or CT scans. The risks associated with MRI scans are:

Projectiles: Objects with magnetic properties can be pulled into the magnet and turn into projectiles. To minimize this risk we ask that subjects remove all metallic items (watches, cell phones, hair pins, etc.) prior to entering the scanner and by controlling access to the scanner.

Claustrophobia: The scanner is a long narrow tube that may cause some people to feel claustrophobic.

Hearing Damage: The noise generated by the operation of the scanner during a study is loud enough to cause hearing damage if you do not wear hearing protection. Hearing protection is required and is provided by the investigator.

Nerve Stimulation: Some people experience localized tingling, twitching, or muscle contractions during MRI scans. This is expected, but we will tell your child that if they become uncomfortable they should notify the investigator.

Disruption of Devices: Some devices can be damaged by magnetic fields and should not be brought into the scanner room. This includes some implanted devices such as pacemakers, cochlear implants, insulin pumps, nerve stimulators, etc. If your child has any implanted device, please notify the investigator.

Heating of Devices: The radiofrequency waves used in MRI can heat conductive materials such as metal implants (screws, plates, rods, wires, artificial joints, etc.), certain tattoo inks, certain clothing fabrics, jewelry, medication patches, wigs, etc. Your child will be asked to remove these items if possible. If they cannot be removed, your child will be asked to provide more information to allow MRI staff to be able to make determination on the safety of proceeding with the scan.

The risks of exposure to high magnetic fields are unknown for fetuses. Therefore, if you have any reason to believe that your child might be pregnant, they should not participate in this part of the study.

Part of the MRI scan is designed to induce different kinds of feelings, both negative and positive, so that we can understand how the brain is functioning during negative and positive feelings. It is possible that your child will become sad or distressed by the negative pictures. We will encourage your child to let us know if they are feeling upset, and we will plan to discontinue the procedure whenever your child wishes to stop.

In addition, there is a risk of unknown effects related to participation in MRI research. Long-term effects of exposure to high magnetic fields are unknown. Most people experience no short-term ill effects from the strong magnetic field, but some people report dizziness, mild nausea, headache, a metallic taste in their mouth, or sensations of flashing lights. These symptoms, if present, subside shortly after leaving the magnet. If any sensations experienced during participation cause discomfort or pain to your child, they should notify the researcher right away and their participation will stop and they will be taken out of the magnetic field.

A thorough pre-scan questionnaire will allow us to minimize the risk of device disruption and heating. Your child will be in constant contact with the investigator and should notify the investigator immediately, via the squeeze ball, if they notice anything unusual, becomes claustrophobic, thinks that their hearing protection is not adequate, or if they experience nerve stimulation that is uncomfortable.

The MRI scanning for this study is for research purposes only and is not intended to provide health care to your child. However, if a member of our research team notices that the MRI results show something unusual, a radiologist trained in reading the pictures will look at them. The MRI results will not contain any personal information except your child's age and pertinent medical history collected as part of the research. There will be no charge to you for having the radiologist look at your child's MRI results. While these results are normally viewed shortly after the scan, results might not be seen before your child completes participation in the study. If the results do show something unusual, any medical follow up cost will be your responsibility and/or the responsibility of your child's health insurance carrier.

3. CT Scan. If staff suspects metal in your body, you may be asked to undergo one low dose CT scan. This procedure involves exposure to ionizing radiation. This radiation exposure is not necessary for your medical care and is for research purposes only. The average amount of radiation that the average person would receive from this procedure is less than 90% of that received from natural sources of radiation by a Minnesota resident in one year (3 mSv). This exposure involves minimal risk and in certain cases (e.g. concern about possible metal in the body) is necessary to obtain the research information desired.

4. Speech Task. The speech task is intended to elicit a mild stress response in your child. Rarely, some participants become very distressed during the task (for example, rarely a participant will cry). If at any point your child becomes too distressed, we will discontinue the procedure. Additionally, if at any point your child would like to discontinue the protocol, they may do so. If your child experiences any adverse effects from the speech task, please contact the study coordinator at (612) 626-8534, or the researchers on the study at (612) 273-9762.

Will I know about any new information about the effects of MRIs on human health?
Notification of Significant New Findings
You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

Benefits of Study Participation
There is no direct benefit to you for participating in this study.

Study Costs/Compensation
Participation in this study will be at no cost to you or your child. Lodging costs may be provided to families who do not live in the area and transportation cost may be provided to participants, please ask the study team for more details. We will reimburse you for parking costs.

Payment will be made using a pre-paid debit card called Greenphire ClinCard. It works like a bank debit card. We will give you a debit card and each time you receive a payment for participation in this study, the money will be added to the card after each completed visit.

You may use this card at any store that accepts MasterCard or you can use a bank machine to remove cash. However, there may be fees drawn against the balance of the card for cash withdrawals (ATM use) and inactivity (no use for 3 months). We will give you the ClinCard Frequently Asked Questions information sheet that answers common questions about the debit card. You will also receive letters with additional information on how you can use this card and who to call if you have any questions. Be sure to read these letters, including the cardholder agreement, for details about fees.

The debit card system is administered by an outside company. The company, Greenphire, will be given your name. They will use this information only as part of the payment system. Your

information will not be used for any other purposes and will not be given or sold to any other company. Greenphire will not receive any information about your health status or the study in which you are participating.

Any demographic information collected and provided to Greenphire is stored in a secure fashion and will be kept confidential, except as required by law.

Payment you receive as compensation for participation in research is considered taxable income. If payment to an individual exceeds $600 in any one calendar year, the University of Minnesota is required to report this information to the Internal Revenue Service (IRS). Research payments to study participants exceeding $600.00 during any calendar year will result in a FORM 1099 (Miscellaneous Income) being issued to you and a copy sent to the IRS.

Participants and their families will receive compensation up to $450 ($150 per year). For each of the three clinical assessments adolescents will receive $40. For each additional hour in the interview, they will receive $20. For each of the three speech task appointments, adolescents will receive $30. For each of the three MRI scans, the adolescents will receive $50. For each of the online assessments, adolescents will receive $20. For each time they complete the home saliva samples and diary, they will receive $10. If your child starts, but does not finish the study, compensation will be pro-rated according to each completed visit.

Participants who do the remote speech visit during the pandemic will be compensated $20. Those complete the MRI visit during the pandemic will be compensated $60 to adjust for the change in allocation of study activities. In the IGT task, the participants are told that they will be able to keep any winnings (anything above the starting amount of $5.00) but that they will not have to pay if they lose money in the game (i.e., if they have less than $5.00 at the end). Any winnings (maximum = $5.00) will be added to the usual compensation for that visit ($60).

Can I be removed from the research?
The person in charge of the research study or the sponsor can remove you/your child from the research study without your approval. Possible reasons for removal include if you/your child experience severe adverse events, active suicidal ideation, or any unanticipated problems where the study doctor feels it would be unsafe for you to continue on the study.

Research Related Injury
In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. The sponsor of the study has some funds available to pay for care for injuries resulting directly from being in this study. If you think that you have suffered a research related injury and that you may be eligible for reimbursement of some medical care costs, let the study physicians know right away.

Confidentiality
The records of this study will be kept private. In any publications or presentations, your child will not be identified by name or other recognizable way on any records, results or publications relating to the study. For quality control purposes, the University of Minnesota Institutional Review Board, CMRR personnel and other regulatory entities may have access to the records upon request. Otherwise, only researchers associated with this study will have access to the records; research records will be kept in a locked file.

Any information obtained in connection with this study that can be identified with your child will remain confidential and will be disclosed only with your permission. However, mental health professionals are mandated reporters, which means that we are obliged to report alleged or probable abuse, as well as known abuse. If there are any concerns about maltreatment, they will be reported in accordance to the law. If you tell us that someone (including yourself) is in danger of serious harm, we may need to obtain outside assistance.

To these extents, confidentiality is not absolute.

Protected Health Information (PHI)
Your PHI created or received for the purposes of this study is protected under the federal regulation known as HIPAA. Refer to the attached HIPAA authorization for details concerning the use of this information.

Certificate of Confidentiality
To help protect your privacy, the National Institutes of Health has granted a Certificate of Confidentiality. The researchers can use this Certificate legally to 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. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.
The Certificate does not prevent a researcher from reporting information learned in research when required by other state or federal laws, such as mandatory reports to local health authorities for abuse or neglect of children/vulnerable adults, or information to the Food and Drug Administration (FDA) when required in an FDA audit. However, the Certificate limits the researcher from disclosing such information in follow up civil, criminal, legislative or administrative legal proceedings if the information was created or compiled for purposes of the research.
You also 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 the researchers will not use the Certificate to withhold that information.

Voluntary Nature of the Study
Participation in this study is voluntary. Your decision whether or not to participate in this study will not affect your current or future relations with the University, University of Minnesota Medical Center, or Fairview. If you decide to participate, you are free to withdraw at any time without affecting those relationships.You may decide not to participate or withdraw without penalty or loss of benefits to which the participant is otherwise entitled.

Will anyone besides the study team be at my consent meeting?
You may be asked by the study team for your permission for an auditor to observe your consent meeting. Observing the consent meeting is one way that the University of Minnesota makes sure that your rights as a research participant are protected. The auditor is there to observe the consent meeting, which will be carried out by the people on the study team. The auditor will not document any personal (e.g. name, date of birth) or confidential information about you. The auditor will not observe your consent meeting without your permission ahead of time.

Contacts and Questions
The researchers conducting this study are Kathryn Cullen, M.D. and Bonnie Klimes-Dougan, Ph.D. You may ask any questions you have now, or if you have questions later, **you are encouraged to** contact them at *612-273-9762.*

This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Will I have a chance to provide feedback after the study is over?
The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.
If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the "Investigator Contact Information" of this form for study team contact information and "Whom do I contact if I have questions, concerns or feedback about my experience?" of this form for HRPP contact information.

Permission for Future Re-Contact
I will allow the members of the study team to contact me in the future to request information about my progress, and possibly to request further participation in an expanded portion of this study. Please select the appropriate choice below:

_____ I do not agree to be re-contacted.

_____ I agree to be re-contacted.

Statement of Consent
I have read the above information. I have asked questions and have received answers. I voluntarily consent to participate in the study.

_____
Subject Name (Print)

_____	_____	_____
Guardian Name (Print)	Guardian Signature	Date
_____	_____	_____
Research Representative (Print)	Research Representative Signature	Date