ReSeT (Recovery After Stress Toolkit)
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Cincinnati sIRB site consent form (revised form dated 07/05/2022)

Title of research study: RECOVERY AFTER STRESS TOOLKIT (RESET) STUDY

Site Investigator:
Shari L. Wade, Ph.D.

Contact Info: *513-636-3370 or (513) 620-5922*

Funding: National Institute of Child Health and Human Development (NICHD)

Key Information:

The following is a short summary of this study to help you decide whether to be a participant in it. More detailed information about the study is listed later in this form. This document does not replace the discussion you should have with the research team about this study including having any questions or concerns answered.

If you are 18 years and older: This is a consent form. It explains this research study. If you decide that you want to be in this research study, then you will sign this form to show that you agree to be part of this study. If you sign this form, you will receive a signed copy of it for your records.

Parents/Guardians: You have the option of having your child or teen join this research study. This is a parental permission form. It explains this research study. If you decide that your child can be in this study, you will sign this form to show that you agree. If you sign this form, you will receive a signed copy for your records.

COMBINED Parental Permission/Assent: If you are a parent or legal guardian of a child who may take part in this study, permission from you is required. The assent (agreement) of your child may also be required. When we say "you" in this form, we mean you or your child; "we" means the study doctor and other staff.

Reason for the study:

The main reason for this research study is to learn how an online treatment program compares to care as usual (in other words, not receiving the treatment program) in helping children who have experienced a trauma with their recovery.

We are asking up to 106 children with a history of trauma to be in this research study.

Procedures:

We are asking you to be in this study because your child has experienced a traumatic event. If you are chosen to participate in this study, you will have an equal chance of receiving an online therapy program (the Recovery after Stress Toolkit; ReSeT) or not receiving the program (in other words, the care as usual group). In both groups, your child will be asked to complete one short survey about their emotions each week (less than 5 minutes) for up to 12 weeks. If you are chosen to participate in the ReSeT treatment group, your child will complete 8 online modules to help them manage stress after an injury and participate in 8 virtual videoconference therapy sessions. You and

your child will be asked to complete surveys in 3 months and 6 months from now. We expect that you will be in this research study for up to 6 months.

More detailed information about the study procedures can be found under ***"(Detailed Procedures)"***

Risks to Participate:

There are minimal risks related to being in this study. There is a chance that families may experience discomfort when discussing your child's trauma and medical history. To reduce this possibility, the therapist conducting the sessions is trained and supervised by a licensed psychologist.

There may be other risks that we do not know about yet.

You will be able to reach the study investigator during office hours to report any adverse effects or concerns. In case of an emergency please go to your nearest Emergency Department or call 911.

Benefits to Participate:

We cannot promise any benefits to you or others from your taking part in this research. However, it is possible that your child may experience a reduction of their post-traumatic stress symptoms during their participation in this study.

Other Options:

Participation in research is completely voluntary. Your decision to participate or not to participate will not affect the care you receive. Your alternative to participating in this research study is to not participate.

Cost to Participate:

Neither you nor your insurance company will be charged for your participation in this study.

Payment:

If you agree to take part in this research study, we will pay you up to $200 for your time and effort. In about one month, your family will receive a payment of $50. If your child is in the care as usual group, you will receive the first payment after 4 weeks of short weekly surveys about your child's emotions (less than 5 minutes per week). If your child is in the ReSeT therapy group, you will receive the first payment after 4 ReSeT therapy sessions are completed. Your child will continue completing weekly surveys for up to 3 months. In about 3 months when you and your child will complete the follow-up questionnaires, your family will receive a payment of $75. In about 6 months when you

and your child complete the final follow up surveys, your family will receive a payment of $50. You will receive a bonus $25 if all surveys for the study are completed.

You (your child) will receive payment for this study in the form of a reloadable debit card (Clincard). We will give you (your child) a handout that will explain how to use the card. Because you (your child) are being paid for your participation, Cincinnati Children's is required by the Internal Revenue Service (IRS) to collect and use your (your child's) social security number (SSN) or taxpayer identification number (TIN) to track the amount of money that we pay. You will need to complete a Federal W-9 form for this income tax reporting. This form requires your child's Social Security number. This form will be given to the Cincinnati Children's business office. It will not be kept as part of your child's study chart. If you move, you will need to complete another W-9 with an updated address.

Additional Study Information:

The following is more detailed information about this study in addition to the Key Information.

If I have Questions or would like to know about:

Who to talk to…	**You can call …**	**At …**
• Emergencies • General study questions • Research-related injuries • Any research concerns or complaints	**Dr. Shari L. Wade, Ph.D.**	Phone: 513-636-3370
• Emergencies • General study questions • Research-related injuries • Any research concerns or complaints	**Jamie Patronick**	Phone: (513) 620-5922
• Your child's rights as a research participant	**Institutional Review Board** This is a group of scientists and community members who make sure research meets legal and ethical standards.	Phone: (513) 636-8039

Detailed Procedures:

Which treatment option (the ReSeT program or care as usual) you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what treatment you get. You will have an equal chance of being given each treatment.

If you are chosen to be in the no treatment group/care as usual group, your child will complete short weekly surveys about their emotions (less than 5 minutes) for up to 12 weeks. Your child will continue to receive care that is typically offered from the trauma services at the hospital. It is important for us to have this group to understand how children and families are doing after the injury without the ReSeT treatment so that we can test if the treatment works. In 3 months and again in 6 months, you and your child will be asked to complete online surveys that will take you approximately 30-45 minutes.

If you are chosen to participate in the ReSeT treatment group, your child will complete 8 online modules (the Recovering after Stress Toolkit) to help them manage stress after an injury. If your child qualifies and decide you want your child to be in the study, you and your child will be given instructions on how to get online to access the study content. Your child will complete the modules independently and then meet with a therapist via videoconferencing to review the content. You as the parent will meet with the therapist during the first and last videoconference session, and as needed. All sessions with the therapist, either with your child or with you, will last between 30 and 60 minutes. Sessions will be video/audio recorded for the study team to check that the program content is the same for each child and for supervision purposes. The therapist is trained and supervised by a licensed clinical psychologist who specializes in trauma. Recordings will not be used for any other purpose. Sessions will be scheduled at your convenience and can happen weekly or bi-weekly until all sessions are complete (up to 12 weeks).

Your child will view eight sessions that will focus on Coping Cognitive-Behavioral Therapy (Coping CBT) and Trauma Narrative. Coping CBT modules will help develop skills that will help your child cope with stress symptoms such as deep breathing and looking at their thoughts in different ways. Trauma Narrative treatment will help your child retell and reframe the trauma experience. At the end of the program, your child will provide feedback on the content and their experience. You will also be asked to provide feedback on the four parent sessions that focus on how you can support your child, positive parenting strategies, manage your own stress, and help with your child's sleep. Your child will be asked to complete short weekly surveys about their emotions. In 3 months and again in 6 months, you and your child will be asked to complete online surveys that will take you approximately 30-45 minutes.

Change of Mind/Study Withdrawal:

You can leave the research at any time; it will not be held against you.

If you decide to leave the research, contact the investigator so that the investigator can remove you from the study. The data collected up to the point of your withdrawal will be stored in password protected files and all identifying information will be removed.

Privacy:

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete privacy. Organizations that may inspect and copy your information include the Institutional Review Board (This is a group of scientists and community members who make sure research meets legal and ethical standards) and other representatives of this organization. Deidentified data may be analyzed by staff at other study sites.

An identification number will be assigned to each research participant. That identification number will be entered into a computer and stored in a password protected file only accessible to the investigator and the staff at Cincinnati Children's Hospital Medical Center. Information pertaining to you or your child's name, social security number, address, telephone number email address date of birth and contact information for one or more close contacts will also be entered into a computer and placed in password protected file accessible only to the investigator and the employees at Cincinnati Children's Hospital Medical Center. All protected health information entered on computers and through RedCap will be password protected and accessible only to the investigator and team members involved with the research study.

Because this research study involves payment for participation, we are required by Internal Revenue Service (IRS) rules to collect and use your social security number (SSN) or taxpayer identification number (TIN) in order to track the amount of money that we pay you.

By signing this consent form you are giving permission for representatives of the (Cincinnati Children's Hospital Medical Center, the Investigator and Cincinnati Children's Hospital Medical Center employees involved with this research study including the Institutional Review Board and the Office for Research Compliance, as well as study staff at Cincinnati Children's Hospital Medical Center, to inspect sections of your medical and research records related to this study.

The information from this research study may be published; however, your child will not be identified in such publication. The publication will not contain information about your child that would enable someone to determine his or her identity as a research participant without your authorization.

Please note that if any study staff person suspects child abuse or neglect they are mandated to report the suspected abuse or neglect to local law enforcement or children's services agency. Likewise, if any study staff person believes any member of your family is an imminent and serious danger to themselves or others, that staff person is obligated to report this concern to local law enforcement.

AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION FOR RESEARCH

To be in this research study you must also give your permission (or authorization) to use and disclose (or share) your child's "protected health information" (called PHI for short).

What protected health information will be used and shared during this study?

CCHMC will need to use and share your child's PHI as part of this study. This PHI will come from:

- Your child's CCHMC medical records
- Your child's research records

The types of information that will be used and shared from these records include:

- Laboratory test results, diagnosis, and medications
- Reports and notes from clinical and research observations
- Study measure results or reports
- Imaging (like CT scans, MRI scans, x-rays, etc.) studies and reports
- If applicable, information concerning HIV testing or the treatment of AIDS or AIDS-related conditions, drug or alcohol abuse, drug-related conditions, alcoholism, and/or psychiatric/psychological conditions (but not psychotherapy notes).

Who will share, receive and/or use your child's protected health information in this study?

- Staff at all the research study sites (including CCHMC, Nationwide Children's Hospital, the University of Utah, and the University of Houston)
- Personnel who provide services related to your child's injury and/or as part of this study
- Other individuals and organizations that need to use your child's PHI in connection with the research, including people at the sponsor and organizations that the sponsor may use to oversee or conduct the study.
- The members of the CCHMC Institutional Review Board and staff of the Office of Research Compliance and Regulatory Affairs.

How will you know that your child's PHI is not misused?

People that receive your child's PHI as part of the research are generally limited in how they can use your child's PHI. In addition, most people who receive your child's PHI are also required by federal privacy laws to protect your child's PHI. However, some people that may receive your child's PHI may not be required to protect it and may share the information with others without your permission, if permitted by the laws that apply to them.

Can you change your mind?

You may choose to withdraw your permission at any time. A withdrawal of your permission to use and share your child's PHI would also include a withdrawal from participation in the research study. If you wish to withdraw your permission to use and share your child's PHI you need to notify the study doctor, listed on the first page of this document, in writing. Your request will be effective immediately and no new PHI about your child will be used or shared. The only exceptions are (1) any use or sharing of PHI that has already occurred or was in process prior to you withdrawing your permission and (2) any use or sharing that is needed to maintain the integrity of the research.

Will this permission expire?

Your permission will expire at the end of the study. If the study involves the creation or maintenance of a research database repository, this authorization will not expire.

Will your child's other medical care be impacted?

By signing this document you agree for child to participate in this research study and give permission to CCHMC to use and share your child's PHI for the purpose of this research study. If you refuse to sign this document your child will not be able to participate in the study. However, your child's rights concerning treatment <u>not</u> related to this study, payment for services, enrollment in a health plan or eligibility of benefits will not be affected.

SIGNATURES

The research team has discussed this study with you and answered all of your questions. Like any research, the researchers cannot predict exactly what will happen. Once you have had enough time to consider whether you/your child should participate in this research, you will document your permission by signature below.

You will receive a copy of this signed document for your records.

_____
Printed Name of Research Participant

_____ _____
Signature of Research Participant Indicating Consent or Assent Date

_____ _____
Signature of Parent or Legally Authorized Representative* Date

_____
* If signed by a legally authorized representative, a description of such representative's authority must be provided

_____ _____
Signature of Individual Obtaining Consent Date