Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

TITLE OF RESEARCH: Examine the Feasibility and Acceptability of Project Support

Concise Summary

You and your child are being asked to volunteer for a research study. Research studies are voluntary and only include people who choose to take part. The purpose of this research study is to examine the feasibility and acceptability of delivering a brief parenting program called Project Support to families on the waitlist for trauma services.

It involves participating in up to 4 counseling sessions designed to help parents communicate with their children. It also involves participating in 2 assessment sessions, where both you and your child would be asked to fill out questionnaires. In total there would be up to 6 sessions over the course of two months. Each counseling session would last about an hour. The questionnaire assessment sessions would last about 30 minutes. All visits would take place remotely, using telehealth.

Participation in this study may improve the parent-child relationship and your confidence in your parenting abilities, but that cannot be guaranteed. Risks of this study include the risk of loss of privacy when engaging in the counseling sessions using telehealth and some of the questions the researchers ask may be upsetting, or you or your child may feel uncomfortable answering them. If you or your child do not wish to answer a question, you can skip it and go to the next question. Neither you nor your child must participate in this study, your family will continue to be on the waitlist for trauma services.

If you are interested in learning more about this study, please continue reading below.

A. PURPOSE OF THE RESEARCH

Please read this consent form carefully and take your time making your decision. As study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand.

You and your child are being asked to participate in this study because your child is on the waitlist to receive trauma-focused mental health services. This research study will evaluate whether it is feasible and acceptable to deliver a brief parenting program, Project Support, via telehealth to families waiting for trauma services. This is an investigational treatment and Project Support is not currently used as standard of care. The investigator in charge of this study at MUSC is Dr. Caitlin Rancher. A grant from the National Institutes of Health (NIH) will sponsor this study. Portions of Dr. Rancher's and

her research team's salaries will be paid by this grant. The study is being done at one site. Approximately 30 child and caregiver pairs will take part in this study.

B. PROCEDURES

If you agree to be in this study, the following will happen:

1. You and your child will complete a baseline questionnaire assessment on demographic characteristics, parenting behaviors, and mental health symptoms. You will be asked to answer questions such as: "How often do you have pleasant conversations with your child?" "How often do you feel the only way to get your child to do what you want is to yell?" and "How often does your child seem to feel sad, unhappy?"
2. You (the caregiver) will then receive the Project Support intervention. This involves up to four counseling sessions designed to teach parents how to listen to and comfort their child. You will receive one-on-one instruction and feedback on the use of the skills in role-plays with a treatment provider using real-time videoconferencing. In the role-plays, the provider will first demonstrate how to use the skill in a brief example of typical situations in which the skill could be used. In these examples you (the caregiver) will take on the role of your child and the provider will take on the role of the caregiver. Subsequently you and the provider switch roles so that you have an opportunity to practice the skill. Project Support counseling sessions will be recorded in order to make sure the intervention is being delivered as it was designed.
3. Approximately 4-6 weeks after the baseline questionnaire assessment, you and your child will complete a post-test questionnaire assessment. This will include the same questions on parenting behaviors and mental health symptoms as well as some new questions on service satisfaction and acceptability of the Project Support intervention. You will be asked to answer questions such as: "Did the services help you communicate with your child?" and "How would you change the program?"

C. RISKS AND DISCOMFORTS

There is a risk of loss of confidentiality of you and your child's information that is used in this study. For example, it is possible that other people could overhear your sessions with a treatment provider. However, such risks are minimized by procedures such as rescheduling the appointment to a more convenient time and taking steps to insure privacy (e.g., private location, use of headphones).

Participant data will only be identified with a study ID. The codes that link the name of the participant and the study ID will be kept confidential in a separate location from study data by the Principal Investigator in a secured file.

There is a risk of emotional distress. Some of the questions the researchers ask you or your child may be upsetting, or you or your child may feel uncomfortable answering them. If you or your child do not wish to answer a question, you and your child can skip it and go to the next question.

D. MEDICAL RECORDS and/or CERTIFICATE OF CONFIDENTIALITY

Information about you and your child's study participation will not be in your medical record. This means that neither you nor your child's research participation nor any of your research results will be included in any MUSC medical record.

E. BENEFITS

The potential benefit to you is that the treatment you receive may improve the parent-child relationship and your confidence in your parenting abilities, although this cannot be guaranteed.

F. COSTS

This study takes place completely remotely and you and your child will be required to use your own device (e.g., cell phone, computer, tablet) to participate. This may incur additional costs for Wi-Fi or cellular data usage and your normal usage rates will apply. There will be no cost to you or your child to receive the counseling sessions.

G. PAYMENT TO PARTICIPANTS

In return for your time and effort, you will be paid a $20 gift card for completing the baseline questionnaire assessment and a $40 gift card if you complete the post-test questionnaire assessment. You will be sent an electronic link to the gift card by email. You will not receive payment for participating in the counseling sessions.

Payments that you receive from MUSC for participating in a research study are considered taxable income per IRS regulations. Payment types may include, but are not limited to: checks, cash, gift certificates/cards, personal property, and other items of value. If the total amount of payment you receive from MUSC reaches or exceeds $600.00 in a calendar year, you will be issued a Form 1099.

H. ALTERNATIVES

In addition to remaining on the waitlist for standard treatment you do always have the option to contact the clinic to request an update on your status on the waitlist or contact emergency services such as 911, NAMI Information Helpline 1-800-950-6264 (10am-6pm EST), or the Crisis Text Line | Text HOME to 741741 (24/7) if you are in need of immediate mental health care. At this time there is not alternative standard treatment provided by the clinic for families on the waitlist.

I. DATA SHARING

Information about you and your child (including your identifiable private information and/or any identifiable biospecimens) may have all of your identifiers removed and used for future research studies or distributed to other researchers for future research without additional informed consent from you or your legally authorized representative.

J. DISCLOSURE OF RESULTS

No individual research results will be shared with subjects.

K. AUTHORIZATION TO USE AND DISCLOSE (RELEASE) MEDICAL INFORMATION

As part of this research study, your study doctor and his/her research team will keep records of your participation in this study.

The health information MUSC may use or disclose (release) for this research study includes information in your medical record, results of physical exams, medical history, lab tests or certain health information indicating or relating to your condition.

Your study doctor and his/her research team will use and disclose (release) your health information to conduct this study. The health information listed above may be used by and/or disclosed (released) to the following, as applicable:

- The sponsor of the study including its agents such as data repositories or contract research organizations monitoring the study;
- Other institutions and investigators participating in the study;
- Data Safety Monitoring Boards;
- Accrediting agencies;
- Clinical staff not involved in the study whom may become involved if it is relevant;
- Parents of minor children if less than 16 years old. Parents of children 16 years old or older require authorization from the child; or
- Health insurer or payer in order to secure payment for covered treatment;

- Federal and state agencies and MUSC committees having authority over the study such as:

    - The Institutional Review Board (IRB) overseeing this study; Committees with quality improvement responsibilities; Office of Human Research Protections; Food and Drug Administration; National Institutes of Health or Other governmental offices, such as a public health agency or as required by law.

Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them. You do not have to sign this consent form. If you choose not to sign, it will not affect your treatment, payment or enrollment in any health plan or affect your eligibility for benefits. However, you will not be allowed to be a participant in this research study.

You will be given a copy of this consent form. Your authorization will expire at the conclusion of this study or, if you are participating in a study designed for the development of a drug or device, your authorization will remain in effect until the drug or device is approved by the FDA or until the company's application to study the drug/device is withdrawn. You have the right to withdraw your agreement at any time. You can do this by giving written notice to your study doctor. If you withdraw your agreement, you will not be allowed to continue participation in this research study. However, the information that has already been collected will still be used and released as described above. You have the right to review your health information that is created during your participation in this study. After the study is completed, you may request this information.

Your health information will be used or disclosed when required by law. Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability and for conducting public health surveillance, investigations or interventions. No publication or public presentation about the research study will reveal your identity without another signed authorization from you.

If you have questions or concerns about this Authorization or your privacy rights, please contact MUSC's Privacy Officer at (843) 792-8740.

L. CLINICAL TRIALS.GOV

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The investigators associated with this study, the sponsor, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

In the event that your child is injured as a result of participation in this study, you should immediately take your child to the emergency room of the Medical University Hospital, or in case of an emergency go to the nearest hospital, and tell the physician on call that your child is in a research study. They will call your child's study doctor who will make arrangements for your child's treatment. If the study sponsor does not pay for your child's treatment, the Medical University Hospital and the physicians who render treatment to your child will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to your child.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my child's participation in this study or study related injury, I may contact **Dr. Caitlin Rancher at 843-608-0491.** I may contact the Medical University of SC Patient and Family Care Liaison (843) 792-5555 concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input about my child's rights as a research subject in this study, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148. This includes any questions about my rights as a research subject in this study.

I agree to participate in this study. I have been given a copy of this form for my own records.

If you wish to participate, you should sign below.

_____ _____
Signature of Person Obtaining Consent Date *Printed Name of Minor Participant

_____
Signature of Adult Participant Date

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*For child participants: "My participation has been explained to me, and all of my questions have been answered. I am willing to participate."

Signature: _____