

STANFORD UNIVERSITY Research Consent Form

Protocol Director: Victor Carrion, M.D.

IRB Use OnlyApproval Date: June 11, 2019
Expiration Date: June 11, 2020**Protocol Title: Child Characteristics, Neuromarkers, and Intervention Components Impacting Treatment Outcome: A Randomized-Controlled Trial of Cue-Centered Treatment, Trauma-Focused Cognitive-Behavioral Therapy, and Treatment as Usual**

Please check one of the following:

- You are an adult participant in this study.
- You are the parent or guardian granting permission for a child in this study.

Print child's name here:

The following information applies to the adult participant or to the child or ward. If the participant is a child or ward, the use of "you" refers to "your child" or "your ward."

Are you participating in any other research studies? Yes No**INTRODUCTION TO RESEARCH STUDIES**

A research study is designed to answer specific questions, sometimes about a drug's or device's safety and effectiveness. Being in a research study is different from being a patient. When you are a patient, you and your doctor have a great deal of freedom in making decisions about your health care. When you are a research participant, the Protocol Director and the research staff will follow the rules of the research study (protocol) as closely as possible, without compromising your health.

PURPOSE OF RESEARCH

You and your child are invited to participate in a research study of two treatment conditions for children and adolescents who have gone through traumatic experiences and develop symptoms after those experiences. In general terms, this condition is known as Posttraumatic Stress Disorder (PTSD). We hope to learn which treatment is most effective for which youth and to identify which components of treatment are most effective. As a caregiver, we are asking you to be an active participant in the treatment. Your child is being selected as a possible participant in this study because you have responded to a flyer that was either posted or distributed in a public space, through a community organization, youth center or from a physician or clinician..

This research study is looking for 135 children with a traumatic experience in their past and at least one of their caregivers to enter the study. The enrollment will be at Stanford Youth Solutions in Sacramento and at UCSF Child and Adolescent Services in San Francisco and through a Stanford University staff clinician. We expect to enroll 95 research study participants and at least one of their caregivers at our Stanford Youth Solutions site in Sacramento.

Your and your child's participation in this study is entirely voluntary. If your child decides not to participate, you are free to withdraw your consent, including your authorization regarding the use and disclosure of your health information, and to discontinue participation at any time without prejudice to you or effect on your

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child's medical care or ongoing or future treatment. If you decide to withdraw from this study, it is important that you contact both your child's therapist and the study coordinator, Cynthia Marquez Miranda (916-344-0199, extension: 213) so that they can provide appropriate referral services as necessary.

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.

DURATION OF STUDY INVOLVEMENT

This research study is expected to last four years. Your child will actively participate during 3-4 months; in which he/she will take part in a 45-minute psychotherapy session almost each week for 15 therapy sessions. As the child's caregiver, you will be asked to volunteer to participate in approximately 3-15 of those sessions.

PROCEDURES

If you choose to participate, you have the option of Dr. Victor Carrion and his research study staff enrolling you and your child in a treatment trial. Your child will be randomly assigned to one of two treatment conditions: Cue-Centered Treatment or Trauma-Focused Cognitive Behavioral Therapy. Your child's treatment will be provided by a Stanford University therapist and will not include additional services. Your child will begin treatment immediately with weekly 45 minute sessions lasting 15 weeks. The purpose is to evaluate which treatment works best for which children and what components of treatment are most effective in reducing psychological, cognitive, and behavioral symptoms.

As the child's caregiver, you will be asked to volunteer to participate in approximately 3-15 of the 15 sessions, depending on which treatment group the participant is assigned to. The sessions should take approximately 3-4 months to complete (16 weeks; approximately 45 minutes for each session). At the end of treatment your child's therapist will make recommendations regarding whether your child should receive additional services or treatment and then provide you with appropriate referral information. If your child needs to take an unexpected break from treatment due to illness, injury, or other reasons, your child's therapist and the research staff will work with you to determine if and when your child should resume therapy. If your child is not able to continue participating in the study, then your child's therapist and research staff will provide appropriate referrals for care. Each of the potential treatments are described below.

Trauma-Focused Cognitive-Behavioral Therapy: This is an evidence-based, short-term treatment that involves both individual child sessions as well as joint parent-child sessions. The specific components of treatment include: 1) psychoeducation about the impact of trauma and common trauma reactions, 2) parenting skills to optimize your child's emotional and behavioral adjustment, 3) coping and relaxation strategies individualized to the child and parent, 4) helping your child identify and cope with a range of emotions, 5) cognitive processing to help the child modify unhelpful or inaccurate thoughts about the trauma, 6) trauma narration in which the child describes his/her traumatic experiences, 7) exposure to traumatic reminders to help your child overcome avoidance of situations that may be reminding him/her of the trauma, 8) parent-child sessions to facilitate

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communication between the caregiver and child about the traumatic experiences, and 9) enhancing future safety and consolidation of skills learned.

Cue-Centered Treatment: This is an evidence-based, short term-treatment that involves both individual child sessions as well as joint parent-child sessions. It is a multi-modal approach combining elements from cognitive, behavioral, psychodynamic, expressive, and family therapies. There are several unique components to Cue-Centered Treatment that distinguish it from Trauma-Focused Cognitive-Behavioral Therapy. First, the treatment supplements the trauma narrative with use of a lifeline to examine both circumscribed traumatic events as well as other daily of life stressors. Additionally, Cue-Centered Treatment has several sessions focusing on teaching youth and their caregivers about the conditioning process that occurs through repeated exposure to trauma. Furthermore, the treatment is more insight oriented compared to traditional cognitive behavioral therapy to help the child link trauma history, emotions and cognitions while placing current behaviors in an empathic context. Finally, in addition to using emotional, cognitive, and behavioral approaches to develop new responses, the treatment also includes a physiological approach.

We will ask you and your child to complete assessments at four time points (prior to treatment, during treatment, post treatment and at 3 month follow-up). These assessments include questionnaires and interviews about mood, thoughts and behavior. You may choose not to answer any questions you do not wish to answer in any of the assessments. It is possible that, based on information gained from this study, the investigators may have serious concerns (relating to matters such as severe depression, physical abuse, etc.) about you or your child's health and/or safety; in such a case, the investigators may contact you and provide a referral for additional care.

In addition to the assessments, your child will have the option to participate in neuroimaging. The purpose is to examine whether imaging findings are predictors of better treatment outcome. We are using functional Near Infrared Spectroscopy (fNIRS) to examine the effects of trauma on the developing brain. A typical session lasts about 90 minutes, and includes a series of self and parent report questionnaires followed by a 30 minute NIRS scan. fNIRS is a non-invasive, neuroimaging technique. Children wear a cap with light emitting and receiving probes while completing a series of tasks on a computer. The cap may cause slight discomfort for some children. If your child becomes upset by the cap they may discontinue participation at any time. Given that these assessments can take up to two hours to complete, you and your child may become tired, bored, or uncomfortable. Every effort will be made to help reduce discomfort for you and your child including offering breaks and spacing out the initial assessment over two separate time points.

AUDIO RECORDING

All treatment sessions with your child will be audio recorded by his/her therapist to assess treatment fidelity. These recordings will be identified only by subject number, will be kept in a locked file cabinet, and in a locked

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office. Only research staff on this project will have access to this data. The recordings will be destroyed after completion of the study.

I give consent for my child to be audiotaped during this study: Yes No

I give consent for my child's audiotapes to be used in scientific meetings: Yes No

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the Protocol Director and study staff.
- Keep your study appointments (therapy and assessment sessions). If it is necessary to miss an appointment, please contact the Protocol Director or research study staff to reschedule as soon as you know you will miss the appointment.
- Tell the Protocol Director or research study staff about adverse events that occur during the 3-4 months of therapy.
- Complete your questionnaires as instructed.
- Tell the Protocol Director or research staff if you change your mind about staying in the study.

While participating in this study, you should not take part in any other treatment interventions without approval from all of the investigators.

WITHDRAWAL FROM STUDY

If you and your child agree to participate and then later change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect you and your child's ability to receive medical care and you will not lose any benefits to which you would otherwise be entitled.

If you and your child decide not to participate, you are free to withdraw your consent, including your authorization regarding the use and disclosure of your child's health information, and to discontinue participation at any time without prejudice to you or your child, and will have no effect on your current or future medical care. If you decide to withdraw from this study, it is important that you contact both your child's therapist and the study coordinator, Cynthia Marquez Miranda (916-344-0199, extension: 213), so that we can note your reason for withdrawing and provide appropriate referral services if necessary.

The Protocol Director may also withdraw you from the study without your consent for one or more of the following reasons:

- The Protocol Director decides that continuing your participation could be harmful to you or your child
- Failure to follow the instructions of the Protocol Director and study staff.

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- Your child needs treatment not allowed in the study.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

If you have any questions, feel free to contact our study coordinator, Cynthia Marquez Miranda at 916-344-0199, extension: 213.

POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES

There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. You should talk with the Protocol Director if you have any questions.

Risks/Discomfort: For some children, talking about scary or traumatic experiences can cause them to feel uncomfortable, stressed or upset. Although this is a common reaction, it can be overwhelming for some people. In the event that you or your child become overwhelmed or distressed, trained mental health staff will be readily available to help. Our Stanford University therapist will be readily available to assist during all therapy and assessment sessions. You will also be able to contact the therapist outside of sessions should you or your child experience any negative reactions outside of therapy such as at home or at school. In case of an emergency, please call 911.

We will keep your child's study data as confidential as possible, with the exception of certain information that we must report for legal or ethical reasons, such as suspected child abuse or neglect (e.g. physical or sexual abuse), suspected elder abuse or neglect, or intent to harm yourself or others. In the event that you or your child tell the research staff that you are thinking about killing yourself or answer yes to a question about having thoughts about suicide, the research staff will ask you more questions about the thoughts. Depending on how intense you or your child's thoughts are or how much you or your child feel like hurting yourself, the research staff may provide you or your child with referrals for treatment, work with you or your child to contact your personal physician, trusted family member, or therapist to discuss you or your child's thoughts of harming yourself; or work with you or your child on a plan that may include getting you or your child to a hospital for safety.

Subject information may be provided to Federal and regulatory agencies as required. If information is revealed about child abuse or neglect, elder abuse or neglect, or potentially dangerous future behavior to others or yourself, the law requires that this information be reported to the proper authorities.

POTENTIAL BENEFITS

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This study may or may not directly benefit your child above and beyond the typical benefits provided by treatment. This study will, however, help researchers understand which therapies work best for different types of children. Results will be used to help provide more effective care for future children seeking treatment.

WE CANNOT AND DO NOT GUARANTEE OR PROMISE THAT YOU WILL RECEIVE ANY BENEFITS FROM THIS STUDY.

ALTERNATIVES

Alternatives to participating in this study include other community based mental health care services available to you. At the end of treatment, your child's therapist may recommend additional therapy or medication assessment for your child. Whenever these recommendations are given, the risks and benefits of the specified recommendations will be presented. This study does not require that you follow any of the recommendations given.

PARTICIPANT'S RIGHTS

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction. If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time.

If during the course of the study assessments or treatment your child reports additional symptoms in need of immediate attention, you and your child may withdraw participation to treat those additional concerns. Examples may include drug and alcohol dependence, self-harm, serious aggression, or other severe emotional or behavioral symptoms.

CONFIDENTIALITY

All records will be confidential. Confidentiality will be assured by assigning all materials for each participant with a computer-generated code. Although confidentiality cannot be guaranteed, it will be protected. Information about the code will be kept in a secure location and access limited to research study personnel. All records will be in the locked offices of the Protocol Director and accessed only by the study's staff.

Your identity will be kept as confidential as possible as required by law. Except as required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier.

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. However, your identity will not be disclosed.

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Subject information may be provided to Federal and regulatory agencies as required. The Food and Drug Administration, for example may inspect research records and learn subjects' identity if this study falls within its jurisdiction. It is possible that, based on information gained from this study, the investigators may be required to report information (e.g., information relating to suicide, physical or sexual abuse, or other abuse or neglect) to the appropriate authorities.

The responses to questions concerning illegal drug use could be self-incriminating and harmful to you if they became known outside the study. As explained above, we do not intend to disclose this information.

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Authorization to Use Your Health Information for Research Purposes

Because information about your child's health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your child's health information will be used or disclosed in the study. This information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my child's health information be utilized in the study?

The purpose of this research study is to learn more about posttraumatic stress disorder treatment for children who have developed symptoms after going through traumatic experiences. We hope to learn what specific components of psychotherapy treatment of children and their caregivers are most effective. Information learned from this study will be used to further develop the treatment manual. We will also publish the results in scientific journals and hold community workshops to teach school counselors how to effectively treat children who have gone through traumatic experiences.

Do I have to sign this authorization form?

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study, including receiving any research-related treatment. Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any withdrawal, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to withdraw your authorization for participation in this study, please contact the study coordinator, *Cynthia Marquez Miranda* at 916-344-0199, extension: 213. If you no longer want the information collected as part of this study included for research use, you must write to:

Dr. Victor Carrion 401 Quarry Road Stanford, CA 94305.

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What Personal Information Will Be Used or Disclosed?

Your child's health information related to this study may be used or disclosed in connection with this research study, including, but not limited to, data about your child's mood, behavior, academic and social functioning, and your own experiences parenting the child.

Who May Use or Disclose the Information?

The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director Dr. Victor Carrion
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- The Research Study Staff

Who May Receive or Use the Information?

The parties listed in the preceding paragraph may disclose your child's health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- Child Protective Services
- UCSF Child and Adolescent Services (CAS)

Your child's information may be re-disclosed if the recipients described above are not required by law to protect the privacy of the information.

When will my authorization expire?

Your authorization for the use and/or disclosure of your health information will expire 12/31/2050.

Will access to my child's medical record be limited during the study?

We will not be requesting or obtaining your child's medical records from past providers as part of this study. To maintain the integrity of this research study, you may not have access to any overall results from this study until it is completed. Any information obtained during the study that would be important for your child's care will be disclosed to you and your child immediately.

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Signature of Participant

Date

Print Name of Participant

Date

Signature of Legally Authorized Representative

Date

Print name of Legally Authorized Representative

Description of Representative's Authority to Act for Subject

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You will receive a \$25 gift card for completion of all assessments and neuroimaging at each time point (total of \$100 for entire study). Payments may only be made to U.S. citizens, legal resident aliens, and those that have a work eligible visa

Costs

There is no cost to you for participating in this study.

Sponsor

The Lucile Packard Children's Hospital, Stanford University School of Medicine, and American Academy of Child & Adolescent Psychiatry are providing financial support and/or material for this study.

CONTACT INFORMATION

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Dr. Victor Carrion at (650) 498-5164. You should also contact him at any time if you feel you have been hurt by being a part of this study.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650)-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 3000 El Camino Real, Five Palo Alto Square, 4th Floor, Palo Alto, CA 94306.

Appointment Contact: If you need to change your appointment, please contact the research coordinator, Cynthia Marquez Miranda at 916-344-0199, extension: 213.

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;

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- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form; and
- be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

May we contact you about future studies that may be of interest to you? Yes No**Signing your name means you agree to be in this study and that you will receive a copy of this signed and dated consent form.**

Signature of Participant

Date

Print Name of Participant

Date

Signature of LAR (Parent, Guardian or Conservator)

Date

Print name if LAR

Authority to act for participant

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(If available) Signature of Other Parent or Guardian

Date

Print name of Other Parent or Guardian

Authority to act for participant

The IRB determined that the permission of one parent is sufficient for research to be conducted under 45 CFR 46.404, in accordance with 45 CFR 46.408(b).

Person Obtaining Consent

Signature of Person Obtaining Consent

Date

Print name of Person Obtaining Consent