IRB Use Only
Approval Date: July 31, 2016
Expiration Date: December 31, 2016

Protocol Title: Courage to Act with Pain: Teens Identifying Values, Acceptance, and Treatment Effects (CAPTIVATE)

Are you participating in other research studies? Yes:___ No:___

CONSENT FORM

DESCRIPTION: You are invited to participate in a research study of the impact of a pediatric pain support group for teens and their parents on functioning, pain, and quality of life. The Pediatric Pain Management Clinic will provide group therapy to adolescents 12 to 18 years old and their parents/caregivers. The CAPTIVATE program – "Courage to Act with Pain: Teens Identifying Values, Acceptance, and Treatment Effects" – will meet for 8 group sessions over the course of 10 weeks. The 2 additional weeks will be for an individual session & wrap-up meeting. The teen group will focus on 1) developing coping skills to help manage discomfort, and 2) increasing functioning in valued life areas. The parent/caregiver group will include pain-related education and management strategies, skill development (i.e., skills taught to youth will also be shared with parents), and how to support valued functional domains (e.g., academics, friendships, athletics) for your child.

In addition, you and your child will be asked to complete secure online questionnaires before the start of the group. If you did not have a chance to complete them before start of group, you will use a Stanford-encrypted iPad to complete the questionnaires now. The questionnaires focus on demographics, medical history, and functioning (e.g., sleep, school, activity), as well as thoughts, feelings, and behaviors related to the experience of pain for your child and family (e.g., stress, sadness, and other pain concerns); however, at any time, you have the right to refuse to answer particular questions. If you agree to participate in the study after learning more from our research team (e.g., examples of questions, frequency of questionnaires, how the study happens online, how to stop participation if wanted at any time for any reason), you will be asked similar questions via email at the middle and end of the treatment group as well as at three months after you and your child's graduation from CAPTIVATE.

STUDY PURPOSE: Improve emotional, behavioral, and general functioning in youth with discomfort. We also anticipate that the parallel caregiver group will empower parents to feel more comfortable with and confident in their approach to helping their teen with chronic pain. Finally, your participation will help us to determine how helpful pediatric pain group therapy can be – and which elements are most useful – based on 1) information that you will share before, during and after the completion of the treatment and 2) your feedback at the end of the program.

Specifically, the program will involve two treatments that research indicates are helpful for pain management: 1) Cognitive-Behavioral Therapy (CBT) and 2) Acceptance & Commitment Therapy (ACT). We hope that discussions with peers, skills practice, homework assignments, and family sessions will improve outcomes related to emotions (e.g., sadness & anxiety), behavioral control over discomfort (e.g., coping skills), and functioning in activities (e.g., sports, socialization, academics) most important to your child. Ultimately, we believe that your involvement, insight, and feedback will help us to improve what and how we use these treatments in pediatric pain management

RISKS AND BENEFITS:

Risks: Questionnaires and therapy sessions might increase your family's awareness of how pain has affected your lives, but we do not expect discomfort. Group discussions are, by nature, less private than individual therapy. Seeing other teens or parents may also increase awareness of how you manage pain.

Benefits: We cannot and do not guarantee or promise that you will receive any benefits from this study; however, you and/or your child may develop skills to help your family feel more in control of discomfort vs. pain controlling your lives. Your family may experience positive feelings due to: identifying, learning from, and giving support to other families managing chronic pain. Some families may also enjoy research involvement that may help to advance pediatric pain treatments.

TIME INVOLVEMENT:

1. Your family's total time involvement if you agree to participate will be 10 weeks.
2. CAPTIVATE program meetings will occur once per week for 90 minutes over the course of 8 sessions. One individual meeting with your child (50 – 60 min) will occur after 4 group sessions, and one 60-minute graduation/final meeting will occur at the end of the program. The anticipated schedule for the 8 group sessions:

4 – 4:50	Teen Group with Dr. Huestis / Caregiver Group with postdoc
4:50 – 5 p.m.	Break
5 – 5:30 p.m.	Family Discussion

3. You will also be asked to complete questionnaires at three times:
    a. The first set will be completed online and take approximately 30 – 45 minutes for parents, and 20 – 30 minutes for youth.
    b. The second set will consist of short questionnaires (5 – 10 min) completed halfway through the CAPTIVATE 10-week program.
    c. The final set will consist of questionnaires similar to the first set, and take approximately 30 minutes for parents and 20 – 30 minutes for youth.
    d. You have the right to refuse to answer particular questions.
4. You and your child will also be asked to complete abbreviated follow-up questionnaires at 3 months following the completion of the group to assess progress.

PAYMENTS: There is no monetary reimbursement for participation in this study, but families will be billed for outpatient treatment as they are for all mental health services in the Pain Clinic.

PARTICIPANT'S RIGHTS: Please understand you and your child's participation is voluntary. The alternative is not to participate. Other alternatives include seeking individual treatment with a current psychologist at the Pain Clinic and/or from an outside mental health provider. You may also find that there is another group offered that fits your interests more at this time. If participating, you have the right to withdraw your consent and your child's assent or discontinue participation at any time without penalty or loss of benefits to which you or your child is otherwise entitled. You and your child's individual privacies will be maintained in all published data resulting from the study.

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CONTACT INFORMATION FOR QUESTIONS: If you have any questions, concerns or complaints about this research, its procedures, risks and benefits, contact the Protocol Director, Dr. Samantha Huestis at (650) 736-3482 or Protocol Co-Director Rashmi Bhandari, PhD at (650) 724-5333.

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

- Failure to follow the instructions of the Protocol Director and study staff.
- The Protocol Director decides that continued participation could be harmful.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

AUTHORIZATION TO USE YOUR HEALTH INFORMATION FOR RESEARCH PURPOSES (HIPAA):

Because information about you and your 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 health information will be used or disclosed in the study. Your 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 health information be utilized in the study?

First, this study is meant to inform families about various skills and methods of coping in order to live full, healthy lives despite discomfort. Second, this study may inform and enhance the quality of clinical psychotherapy treatments for pediatric patients with chronic pain and their families. Collecting questionnaire information at the beginning, middle and end of group therapy will help inform clinicians about work with youth with chronic discomfort regarding *how* and *what* is most helpful about a group treatment that involves youth, caregiver, and family discussions.

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. 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 revocation, 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 revoke your authorization for the research use or disclosure of your health information in this study, please write to: Rashmi Bhandari, Ph.D., and Samantha Huestis, Ph.D. at 321 Middlefield Road, Suite 225, Menlo Park, CA 94025.

What personal information will be obtained, used or disclosed?
The health information we are looking to use includes protected medical information about you and your child. We will need to know you and your child's names, in addition to his or her: medical record number, birth date, pain diagnosis and date this was diagnosed. We will also need to obtain and use your phone number(s), mailing address, email address(es), and the number and type of interventions your child has received for pain management (medications, physical therapy, psychotherapy, occupational therapy, massage, acupuncture, etc.). We will also collect information on how your child is doing over time. Information collected will include how youth are feeling and coping (pain level, stress, behaviors), and how they are functioning in school, at home, with physical activity, and with friends. Similarly, we will also be asking the youth's parent to provide responses regarding observations of their child's emotions, behaviors, and functioning at the beginning and end of group treatment.

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: Samantha Huestis, Ph.D.
- The Protocol Co-Director: Rashmi Bhandari, Ph.D.
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff

Who may receive or use the information?
The parties listed in the preceding paragraph may disclose your 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

Your information may be re-disclosed by the recipients described above, if they 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 end when the research project ends.

Will access to my medical record be limited during the study?
To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health information if it was used to make a medical or billing decision about you (i.e., if included in your official record).

_____ _____
Signature of Legally Authorized Representative Date

_____
Description of Representative's Authority to Act for Subject

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, contact the Protocol Director, Samantha Huestis, Ph.D. at (650) 736-3482 or Protocol Co-Director Rashmi Bhandari, Ph.D. at (650) 724-5333. You may contact them now or later.

Injury Notification: If you feel you have been hurt by being a part of this study, please contact the Protocol Director or Co-Director immediately to discuss next steps.

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 (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

Our team may need to connect with your family in the future to share updates about your involvement in this project. Please provide the contact information you are comfortable with:

_____ _____

Parent Email Address _____ Youth Email Address _____

Phone #1 _____ Phone #2 _____

Street Address _____ City _____ State & Zip _____

You may also choose to share your experiences about the group at its end via audio- or video-recording.

I give consent to be audio/video-recorded at the end of this study.
Please initial: ____ Yes ____ No

_____
Printed Name of **Youth** Participant

_____ _____
Signature of **Parent**, Guardian or Conservator Date

_____
Authority to act for participant

Research involving children: Obtain both parents' permission whenever possible (e.g., both parents bring child to appointment; one parent takes the consent form home for further consideration).

_____ _____
Signature of Other **Parent** Date

_____
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).

_____ _____
Signature of Person Obtaining Consent Date