IRB Use Only
Approval Date: 02/28/16
Expiration Date: 02/28/17

Protocol Title: Assessment of Pediatric Pain: Enhancing Understanding of Initial Presentation, Treatment Responsiveness, and Psychosocial Factors in Pediatric Pain Patients

CONSENT FORM

DESCRIPTION: You are invited to participate in a research study to better understand pain conditions and psychosocial outcomes related to your pain. You recently completed secure online questionnaires before your appointment at the Pediatric Pain Clinic at Stanford Children's Health. If you did not have a chance to complete them before your appointment, you will use a Stanford-encrypted iPad to complete the questionnaires now. Your responses help to inform patient care for our pediatric providers. The questionnaires focused on demographics, medical history, and functioning (e.g., sleep, school, activity), as well as thoughts, feelings, and behaviors related to your pain experience (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 three, six, nine, 12, and 24 months after your initial visit to the Pediatric Pain Clinic. If you receive routine outpatient care at the clinic (e.g., pain psychology, acupuncture) you will also be asked to complete abbreviated, clinically oriented surveys no more than every two weeks.

STUDY PURPOSE: With your assistance, the investigators of this project hope to develop a better understanding of medical, behavioral, and psychosocial factors associated with youth with chronic pain. This is a project that may help us to learn more about: 1) coping, functioning, emotions, and levels of discomfort (i.e., pain) at the time you are first evaluated at LPCH/Stanford, and 2) how these areas change over time (e.g., if there is higher functioning, lower pain) in the outpatient clinic, or after receiving care from the intensive rehabilitation treatment program.

RISKS AND BENEFITS: Other than needing time to complete the questionnaires, we do not anticipate any risks in this study. The questionnaires might make you notice the way that pain has affected your life, but we do not expect discomfort. We cannot and do not guarantee or promise that you will receive benefits from this study.

TIME INVOLVEMENT:

Pediatric Pain Management Clinic/Outpatient Clinic (PPMC): if you choose to follow-up the Pediatric Pain Management Clinic after this first visit, and agree to participate in this research, you will each be asked to complete similar questionnaires in three, six, nine, 12, and 24 months. Baseline questionnaires will take approximately 45 minutes online, while subsequent questionnaires at follow-up will approximately 30 minutes to complete online. The abbreviated follow-up surveys if you receive routine outpatient care will take approximately 10 minutes to complete online.

PAYMENTS: There is no monetary reimbursement for participation in this study.

PARTICIPANT'S RIGHTS: If you have read this form and have decided to participate in this project, please understand your participation is voluntary. The alternative is not to participate. If participating, you have the right to withdraw your consent or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. Your individual privacy will be maintained in all published data resulting from the study.

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. Rashmi Bhandari at (650) 724-5333 or Protocol Co-Director, Dr. Samantha Huestis at (650) 736-3482

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 continuing your 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 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.

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

This study is meant to inform and enhance the quality of clinical care for pediatric patients with chronic pain. Collecting information from the first Pain Clinic assessment through follow-up treatments may clarify – through a patient- and family-centered lens – the Clinic's understanding of how physical wellbeing, family functioning, and emotional health relate to pain and other medical domains. Such clarification may then help to improve established interventions for chronic pain.

Do I have to agree to be in this study?

No, you do not have to agree to participate in this study. If you do not wish to participate it is your choice and will not affect the care you receive. Agreeing to the study 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: Samantha Huestis, Ph.D. at shuestis@stanford.edu.

What personal information will be obtained, used or disclosed?

The health information we are looking to use includes protected medical information about you. We will need to know your name, in addition to your: 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 you have received for pain management (medications, physical therapy, psychotherapy, occupational therapy, massage, acupuncture, etc.). We will also collect information on how you are 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.

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-Directors: 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 on February 28, 2030 or whenever the research project ends, whichever is earlier.

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).

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, Samantha Huestis, Ph.D. You may contact her now or later at (650) 736-3482.

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.

Alternate Contact: If you cannot reach the Protocol Director, please contact Protocol Co-Director Rashmi Bhandari, Ph.D. at (650) 724-5333.