CONSENT FORM

DESCRIPTION: You and your child are invited to participate in a research study to better understand pain conditions and psychosocial outcomes related to pediatric pain. You and your child will use a Stanford-encrypted iPad to complete secure online questionnaires. Your responses help to inform patient care for our pediatric providers. 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 anytime, 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 six months, nine months, one year, two year, and three years after your completion of the Pediatric Pain Rehabilitation Program (PReP). A research staff may contact you via phone/email remind you to complete these follow-up questionnaires.

STUDY PURPOSE: With your family's 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 and your child notice the way that pain has affected your lives, but we do not expect discomfort. We cannot and do not guarantee or promise that your child will receive benefits from this study.

WHAT YOU WILL BE DOING:

1. You and your child will answer questions on an iPad or on paper with pencil that will take about 45 minutes on your first day in the program. We will make sure you have time in your schedule to finish the questions. You will answer these questions again when you end the program in several weeks and again in a few months.

2. Your child will be asked to take some pictures with their smartphone or one of our digital cameras to explain how pain has been a problem for them. Your child will be asked to take pictures of things to tell a story about their pain. Your child's pictures should not have anything that could show that it is from them, so no pictures of their face or anyone else's face, no names,

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no addresses, or anything that could link the pictures to your child. We make this request in order to maintain confidentiality and privacy since these pictures may be used for public viewing upon completion of the PReP program at the graduation with your approval.

3. You and your child will also answer questions on an iPad or on paper with pencil that will take about 15 minutes once a week.

TIME INVOLVEMENT:

Pediatric Rehabilitation Pain Program (PReP): if you agree to participate in this research, after your child's graduation from the rehabilitation pain program, you and your child will answer the same questions 6 months, 9 months, 1, 2, and 3 years after completion of the program. The first time you and your child answer the questions it might take about 45 minutes, but the subsequent weekly questions will only take about 15 minutes. Once you and your child finish the program you will both be asked to answer all of the questions again and that might take 30 to 45 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 and to allow your child to participate in this project, please understand you and your child's participation is voluntary. The alternative is not to participate. If participating, you have the right to refuse to answer particular questions and you have the right to withdraw you and your child's consent 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 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. Anya Griffin at (650) 736-3656 or Protocol Co-Director, Dr. Amanda Feinstein at (650) 736-3494

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.

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

Because information about your child's health is personal and private, it generally cannot be used in this research study without your written authorization. The form is intended to inform you about how your child's health information will be used or disclosed in the study. Your child's 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 agreeing to it.

What is the purpose of this research study and how will my child's 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 PReP assessment through follow-up treatments may clarify – through a patient- and family-centered lens – the Clinic's understanding of how physical well being, 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 the study?

No, you do not have to sign to participate in the study. However, the questions that you will answer are still part of your PReP treatment plan and will be used to make sure we know how well the program is helping you. If you choose to not participate in the study that is your choice, but these questions will be necessary to complete as part of your clinical care in PReP. You do not have to agree this authorization form. But if you do not, you will not be able to participate in this research study. Agreeing to this form is not a condition for receiving any medical care outside the study.

If I agree to participate, can I revoke 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 child's 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: Anya Griffin, Ph.D. at anyag@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 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 a photo from your child at the beginning and end of treatment. 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 initial visit and over time.

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: Anya Griffin, Ph.D.
- The Protocol Co-Directors: Amanda Feinstein, 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, Anya Griffin, Ph.D. You may contact her now or later at (650) 736-3656.

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 Amanda Feinstein, Ph.D. at (650) 736-3494.

PHOTO AUTHORIZATION:

You are agreeing to grant Stanford University and the Pediatric Pain Management Clinic use of your child's photo(s), as well as the ability to store and share these photos for educational and clinical purposes.

I understand that if I decide to revoke permission to use my child's photo, I will notify Anya Griffin, PhD, at (650) 736-3656.