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Approval Date: November 15, 2017
Expiration Date: August 31, 2018

CONSENT FORM

FOR QUESTIONS ABOUT THE STUDY, CONTACT: 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

DESCRIPTION: You are invited to participate in a research study to better understand pain conditions and psychosocial outcomes related to pediatric pain. You will use a Stanford-encrypted iPad to complete secure online questionnaires. 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 months and one, two, three year after your initial visit to the Pediatric Pain Clinic.

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 Rehabilitation Pain Program (PReP): if you agree to participate in this research, after your graduation from the rehabilitation pain program, you will answer the same questions 3, 6, 9 months and 1, 2, 3 year after completion of the program. The first time you answer the questions it might take about 45 minutes, but the subsequent weekly questions will only take about 15 minutes. Once you finish the program you will be asked to answer all of the questions again and that might take 30 to 45 minutes to complete online.

WHAT YOU WILL BE DOING:

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1. You 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. You will be asked to take some pictures with your smartphone or one of our digital cameras to explain how pain has been a problem for you. You will be asked to take pictures of things to tell a story about your pain. Your pictures should not have anything that could show that it is from you, so no pictures of you face or anyone else's face, no names, no addresses, or anything that could link the pictures to you. 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 will also answer questions on an iPad or on paper with pencil that will take about 15 minutes once a week.

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 refuse to answer particular questions and 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.

WITHDRAWAL FROM STUDY:
The Protocol Director may also withdraw you 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 your health is personal and private, it generally cannot be used in this research study without your written authorization. This 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?

This study is meant to inform and enhance the quality of clinical care for the pediatric and adult population over 18 year old 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 sign this authorization form?

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

If I sign 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 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 321 Middlefield Rd., Suite 225, Menlo Park, CA, 94025. She may also be reached via email 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. 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 be collecting a photo at the beginning and end of your treatment. 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: 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.

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

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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.

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:

_____
Participant's Email Address

_____ _____
Phone #1 Phone #2

_____ _____ _____
Street Address City State & Zip

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Print Name of Person Obtaining Consent

PHOTO AUTHORIZATION:

You are agreeing to grant Stanford University and the Pediatric Pain Management Clinic use of your 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 photo, I will notify Anya Griffin, PhD, at (650) 736-3656.

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant