****

Please check all that are applicable:

__ I am an adult participant in this study.

Print your name here:

_____

__ I am the parent or guardian granting permission for a child in this study (the use of "you" refers to "your child" or "your ward.")

Print child's name here:

_____

Are you participating in any other research studies? _____ Yes _____No

PURPOSE OF RESEARCH

You are invited to participate in a research study using a wrist-worn electronic device and a mobile-phone based app to improve our understanding of when and why patients with complex regional pain syndrome (CRPS) have pain exacerbations ("flares").

The primary purpose of this study is to identify medical historical, environmental, activity, dietary or physiologic triggers for pain flares. In addition, physiologic patterns of pain flares will be identified.

You will be asked to wear an electronic device on your wrist daily for up to 6 months. This device is able to gather information on your heart rate, breathing, activity and sleep. In addition, you will be asked to download an app on your phone (Medeloop) in which you input pain symptoms during flares, answer questions and perform assigned activities if you choose. Tasks may include taking photographs of your meals, the recording of your voice, which can indicate blood glucose level, or video of your affected limb. These videos may be analyzed but

will be discarded after analysis. You will also be asked to allow us to access your child's electronic medical record (EMR) at the clinic or medical center at which the CRPS is being treated. If you choose not to allow access to the EMR, your child may still participate in the study. At the end of this form you will be asked to indicate your consent or denial of consent for EMR access separately.

Your child was selected as a possible participant in this study because they have CRPS and are between the ages of 10 and 18 years of age.

If you decide to terminate your child's participation in this study, you should notify one of the study investigators, Dr. Elliot Krane at (650) 725-5874, Dr. Andrew Dinh at (650) 497-8977 or Dr. Sara Williams at (650) 736-3656.

This research study is looking for 100 pediatric patients suffering from CRPS. Enrollment will occur only at Stanford University, which expects to enroll all research study participants.

VOLUNTARY PARTICIPATION

Your (child's) participation in this study is entirely voluntary. Your decision not to participate will not have any negative effect on your child or their medical care. You can decide to participate now but withdraw your consent later and stop being in the study without any loss of benefits or medical care to which you are entitled. You should review and participate in the study only after you have reviewed and agree to the Medeloop's terms of use, privacy, etc.

DURATION OF STUDY INVOLVEMENT

This research study is expected to take approximately 1 year. Your child's participation in this study is expected to last approximately 6 months.

PROCEDURES

If you choose to participate, Dr. Elliot Krane and his research study staff will determine eligibility to participate in the research project. If eligible, you will be explained the risks, benefits and procedures of the study.

You will be asked to fill out a questionnaire to assess your child's current age, age at diagnosis of CRPS and current stage of CRPS. You have the right to refuse any individual questions you do not wish to answer. This will take approximately 5 minutes of your time.

You will be given a wrist worn device for your child to wear as much as possible over a 6-month time period. This device will measure physiologic parameters such as heart rate, respiratory rate, activity level, as well as environmental data in your area.

You will also be asked to download the Medeloop app onto a smartphone used by the participant (or parent). Through this app, your child will be able to perform brief tasks such as inputting symptoms during pain flares and taking daily photos of food they eat for nutritional information, each of these steps takes less than 5 minutes and is entirely voluntary.

You will be asked to access your child's electronic medical record at the treating clinic or medical center by using this Medeloop app, and if you agree to this the information in the EMR will be available for analysis by the research team. Examples of the information we would like to access include the child's birth history, medical history including accidents and surgeries, medication history and current medications being taken, and any recent physical examination of the limb with CRPS by your child's doctor(s).

This information, along with the physiologic and environmental data from the wrist worn device, will help the research team to identify triggers for and factors associated with pain flares.

In order to minimize the risk of data leak, the Medeloop platform performs in a privacy-preserving manner to ensure security through the NIST 800-53 "Security and Privacy Controls for Federal Information Systems and Organizations" to provide a standard approach around security controls in order to protect the confidentiality, integrity and availability of participant data within the information system. In addition, the platform adopts NIST 800-171 "Protecting Controlled Unclassified Information in Nonfederal Systems and Organizations" for the handling, backup and transfer of private data. To ensure control of Personally Identifiable Information, Medeloop adopts NIST 800-121 "Guide to Protecting Confidentiality of Personally Identifiable Information" to ensure that identity is properly partitioned from sensitive data.

Research using private information and/or specimens is an important way to try to understand human disease. You are being given this information because the investigators want to save private information and/or specimens for future research.

Identifiers will be removed from identifiable private information and, after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

The results of the study of your data from this project will be used for research purposes only, and you will not be told the results of the tests although findings may be published, in which case you will be informed of the publication.

With this study, we aim to record environmental, dietary and physiologic factors at the time of pain flares. If successful, by the end of the study we should be able to identify factors associated with pain flares, thereby informing CRPS patients and care teams what may trigger flares and potentially when to escalate treatment strategies.

Do you consent to access of your electronic medical record?

____ Yes ____ No

PARTICIPANT RESPONSIBILITIES

As a participant, you and your child's responsibilities include:

- Follow the instructions of the Protocol Director, study investigators, and study staff.
- Follow the instructions for wearing the wrist worn device and using the Medeloop app appropriately.
- Tell the Protocol Director, study investigators, or research study staff about any side effects, doctor visits, or hospitalizations that you may have.

- Tell the Protocol Director, study investigators, or research staff if you believe your child might be pregnant or gotten their partner pregnant.
- Complete your questionnaires as instructed.
- Ask questions as you think of them.
- Tell the Protocol Director, study investigators, or research staff if you change your mind about staying in the study.

WITHDRAWAL FROM STUDY

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

If you decide to withdraw your consent to participate in this study, you should notify one of the study investigators Dr. Elliot Krane at (650) 725-5874 or Dr. Sara Williams at (650) 736-3656.

The Protocol Director, study investigators, or research study staff 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, study investigators, and study staff.
- The Protocol Director, study investigators, or research study staff decides that continuing your participation could be harmful to you.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

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, study investigators, or research study staff if you have any questions. Some reasonably expected discomforts and inconveniences include answering questionnaires, logging pain flares, wearing a wrist worn device for 6 months, and photographing foods eaten. You may experience skin sensitivity at the site of the wrist worn device.

The procedures in this study may involve risks to you, which are currently unforeseeable.

POTENTIAL BENEFITS

We cannot and do not guarantee or promise that you will receive any benefits from this study. If the Study is successful in identifying triggers to pain flares, this information may be of value to you, and this acquisition of important knowledge may benefit future patients with CRPS.

ALTERNATIVES

The procedures in this study are not expected to affect your condition or interfere with your standard treatment. There are no alternative procedures to those in this study that might be advantageous to you. The alternative is not to participate.

PARTICIPANT'S RIGHTS

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction. If you decide not to participate, tell the Protocol Director, study investigators, and research study staff.

You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

ClinicalTrials.gov

This investigation is not considered an applicable clinical trial (ACT) and therefore registration on http://www.clinicaltrials.gov is voluntary as required by U.S. Law. Results reporting is not required.

The study was voluntarily registered, and a description of this clinical trial is available on *http://www.ClinicalTrials.gov (Trial NCT06337526)*. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results, though is not required. You can search this Web site at any time.

CONFIDENTIALITY

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. You and/or your child's identity and/or personal health information will not be disclosed except as authorized by you or as required by law**.** However, there is always some risk that even de-identified information might be re-identified.

Patient information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

The purpose of this research study is to obtain data or information on potential triggers and associated factors with pain flares in CRPS; the results will be provided to the sponsor, the Food and Drug Administration and other federal and regulatory agencies as required.

Authorization To Use Your Health Information For Research Purposes

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?

This research study will investigate factors associated with pain flares in CRPS to improve the treatment as well as characterization of CRPS. As part of your participation in this study, you will be asked to complete a few questionnaires, which include questions regarding your pain, wear a wrist worn device to record your physiological parameters and environmental data, and document food intake with photos. You have the right to refuse any individual question or task you do not wish to answer. If the results of this study are published, it is possible that your responses to the questionnaires or physiologic data would be included. However, none of your personal information will be included and you cannot be identified from the information published.

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, you must write to: Dr. Sara Williams, 321 Middlefield Rd, Ste 225, Menlo Park, CA 94025, 650-736-3656 or contact the protocol director Dr. Elliot Krane at (650) 725-5874.

What Personal Information Will Be Obtained, Used or Disclosed?

Your health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to:

- Name
- Telephone number
- Postal address
- Email address
- Date of birth
- If consent is given, also medical history (including, if available, birth history, history of illnesses, accidents, surgery, medications taken in the past and presently, and observations of the part of your child's body that has CRPS by their doctor(s))

- Answers to the study questionnaire
- Recorded physiologic and environmental data

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. Elliot Krane
- 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
- The Food and Drug Administration
- Medeloop

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 December 31, 2045 or when the research project ends, whichever is earlier.

_____ _____

Signature of Adult Participant Date

_____

Print Name of Adult Participant

_____ _____

Signature of Legally Authorized Representative (LAR) Date

(e.g., parent, guardian or conservator)

_____

Print Name of LAR

_____

LAR's Authority to Act for Participant

(e.g., parent, guardian or conservator)

FINANCIAL CONSIDERATIONS

Payment

There will be no monetary compensation for participation in this study.

Costs

There is no cost to you for participating in this study, other than basic expenses like the personal time it will take to complete the questionnaires.

Sponsor

None.

Consultative or Financial Relationships

Drs. Elliot Krane and Andrew Dinh are paid advisors to, and equity holders in Medeloop, the company owning the Medeloop App.

COMPENSATION for Research-Related Injury

All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director, study investigators, and the research study staff will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. **You will be responsible for any associated co-payments or deductibles as required by your insurance.**

If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. If you are unable to pay for such costs, the Protocol Director, study investigators, and research study staff will assist you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital.

You do not waive any liability rights for personal injury by signing this form.

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 study investigators, Dr. Elliot Krane at (650) 725-5874 or Dr. Sara Williams at (650) 736-3656. You should also contact them at any time if you feel you have been hurt by being a part of this study. You may also contact the protocol director, Dr. Elliot Krane at (650) 725-5874.

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, 1705 El Camino Real, Palo Alto, CA 94306.

Appointment Contact: If you cannot reach the Protocol Director or study investigators, please contact Ryan Ma at ryanma@stanford.edu.

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;
- 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 Adult Participant Date

_____

Print Name of Adult Participant

_____ _____

Signature of Legally Authorized Representative (LAR) Date

(e.g., parent, guardian or conservator)

_____

Print Name of LAR

_____

LAR's Authority to Act for Participant

(e.g., parent, guardian or conservator)

_____ _____

(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 in accordance with 21 CFR 50.55.

_____ _____

Signature of Person Obtaining Consent Date

_____

Print Name of Person Obtaining Consent