**Official Title:** Pain Rehabilitation Virtual Reality (PRVR): Innovations to Enhance Mobility in the Presence of Pain

**NCT #:** NCT04636177

**Document date:** 04/23/2024

Informed Consent Form

| **Key Information for You to Consider** |
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| • **Voluntary Consent**. You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate or discontinue participation.<br>• **Purpose**. The purpose is to determine the acceptability, feasibility, and utility of VR.<br>• **Duration.** Your participation in this study will span approximately 5 months in total, with 8 weeks of active participation and a survey-only follow up 3 months later.<br>• **Procedures and Activities.** If you agree to participate in this study, you will use Virtual Reality at home and potentially in PT, complete surveys and attend your physical therapy treatment sessions. Participants' use of VR will be up to the discretion of the clinicians.<br>• **Risks.** The study may present a small amount of risk to you, but we do not believe participation to be harmful or dangerous to you and your pain. There is some risk of emotional discomfort when responding to questionnaire items, as answering questions about psychological or behavioral problems can sometimes make people uncomfortable. However, we hope to minimize any emotional discomfort with the assurance that you are free to skip any question that makes you uncomfortable. Additionally, potential risks for using VR include eye strain, dizziness, lightheadedness, anxiety/stress, nausea, feeling disoriented, seizure.<br>• **Benefits**. We cannot and do not guarantee any direct benefits as a result of participating in this study. You may feel positively about contributing to research that may help future people, as the study will contribute to our understanding of the use of virtual reality in physical rehabilitation and potentially expand treatment options for people in the future. You will be compensated as a thank you for your time.<br>• **Alternatives.** Participation is voluntary and the only alternative is to not participate. |

## FOR QUESTIONS ABOUT THE STUDY, CONTACT:

Dr. Laura Simons
1070 Arastradero Rd,
Palo Alto, CA 94304
(650)-736-0838

## DESCRIPTION:

### Why is this research being conducted? What is its purpose?

You are invited to participate in research using Virtual Reality during Pediatric Pain Rehabilitation. If available and recommended by your clinician, you may use Virtual Reality during physical therapy sessions whether you participate in this study or not. In some cases, devices will be given only for research by the research team and will be stored at the research lab at 1070 Arastradero. The primary goal of this study is to determine the acceptability, feasibility, and utility of VR. We hope that VR can assist in enhancing function and pain management while reducing fear of pain with mobility. Based on our preliminary work and nearly a decade of international research, we anticipate that this novel approach will create a unique opportunity for children with chronic pain or physical rehabilitation needs to benefit from VR interventions.

### Who is conducting this research study, and where is it being conducted?

This research is being conducted through a collaboration between Dr. Laura Simons, PhD at the

Biobehavioral Pediatric Pain Lab, Dr. Courtney Hess, PhD providing clinician at the outpatient, PReP and DRP Program at the Pediatric Pain Management Clinic, and Amy Weisman, PT, DPT, Board-Certified Clinical Specialist in Pediatric Physical Therapy at Stanford's Dept of Rehabilitation Services and private outpatient physical therapy practice locations. This study will be conducted at the Pediatric Pain Management Clinic (PPMC) at Stanford Children's Health.

**How are individuals selected for this study? How many will participate?**
Participants will be referred by their clinician at their physical therapy site and if interested will be put in contact with Dr. Simons, her co-investigators, or trained members of the research team.

We are asking you to participate because you are between the ages of 10-17. In addition, you:

- Have a diagnosis of chronic pain and/or need for physical rehabilitation;
- Experience difficulties in daily functioning as a result of your pain

We plan on enrolling approximately 35 participants in this research study.

## PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the Protocol Director and study staff
- Complete your questionnaires as instructed.
- Ask questions as you think of them.
- Tell the Protocol Director or research staff if you change your mind about staying in the study.

- **VR Headset:** All participants will be loaned a Oculus Quest 2 VR headset and all necessary equipment for the duration of research data collection. The Oculus Quest 3 VR device is not FDA approved for the use in this study. Participant families will be required to return all equipment either in person at their next scheduled appointment, or via pre-paid shipping materials provided by the research team.

  The exact number of sessions will be defined by the research team on a case-by-case basis. VR sessions may occur at home. During the VR module, children are exposed to a virtual reality environment for the purpose of multidisciplinary pain management. The module is displayed through a Oculus Quest 2 VR helmet, which allows participants to be visually immersed in the virtual environment. This experience is similar to wearing 3D glasses at a movie theater, which allows a person to see a scenario depicted in depth.

  *Please note that PR-VR may be video and audio recorded for quality assurance or recruitment purposes. The recording devices will be stored securely in a locked cabinet and the video and audio files will be stored on an encrypted and password

protected computer in the lab to protect your privacy. These videos may be used in the future for training purposes, or to show future participants what the VR experience is like. Therefore, they may be shown to families or individuals beyond the span of this research study. If you do not wish to be videotaped, you have the option to indicate so below.

I give consent for my child to be videotaped during this study.

Please Initial: Yes_____ No_____

Future Use of Private Information

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

Identifiers might 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.

- **Optional:** You have the option to partake in the following research activities
  - **Diary Surveys:** Answering questions in the diary will take approximately 3 minutes to complete. You will be given the option to answer the diaries weekly, daily, and/or when you have PT sessions during study treatment and for one week at 3-month follow-up if you choose. If you choose to complete the diaries daily (and complete 86% of them, you will be compensated a $20 bonus as a thank you for your time if you choose to answer these surveys.

☐ I consent to the diary surveys (Optional)

x_____ Initials

  - **Brief Informational Interview:** This exploratory study seeks to gather reports from participants after undergoing virtual reality exposure, paying particular attention to the language individuals use to describe their experience. Thus, the study procedure may

include an informal and semi-structured interview, that will take place in the clinic after VR exposure. Participants and their parents may be asked to reflect on their condition, and on their experience with VR.

☐ I consent to participate in the brief informational interview (Optional)

x_____ Initials

- **Actigraph Watch:** You can wear a small, electronic study device on your wrist that tracks your activity level and sleep. If you choose to participate in this activity, you will be asked to wear this from the start of the study until your last study treatment session and responsible for returning this electronic study device at the end of your study treatment period.

☐ I consent to wearing the actigraph watch (Optional)

x_____ Initials

☐ I consent to being contacted for possible future follow-up or studies (Optional)

x_____ Initials

☐ I am participating in other research studies (Check if true)

x_____ Initials

**RISKS AND BENEFITS:**

What are the risks of this research study? What could go wrong?

The study may present a small amount of risk to you, but we do not believe participation to be harmful or dangerous to you and your pain. To ensure that is it in your best interest to participate in PRVR and that you are able, you are required to receive medical and psychological clearance from your evaluating pain physician and psychologist beforehand. The Oculus Quest 3 VR device is not FDA approved for the use in this study. You may opt out of any activity that you are not ready to do and may stop VR exposure at any time. We will provide a virtual hands-on safety and training session for both the participant and one parent who will supervise at all times. It is the responsibility of the participant and parent to ensure safe usage of the equipment when using VR at home. VR risks include eye strain, dizziness, lightheadedness, anxiety/stress, nausea, feeling disoriented, and seizures.

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 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 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.

There is some risk of emotional discomfort while reflecting on the VR module during the informal interview, as answering questions about psychological or behavioral problems can sometimes make people uncomfortable. However, we hope to minimize any emotional discomfort with the assurance that you are free to not answer any question that makes you uncomfortable. Remember that all information will be kept confidential. Additionally, Dr. Simons (PI) will be available by voicemail (650) 736-0838 for consultation.

Virtual Reality Equipment Safety: Dr. Maria Menendez from the Stanford Chariot Program will serve as a technical advisor on the safe use of all virtual reality equipment. Dr. Menendez is skilled at both using the VR technology and working alongside different providers with patients. Dr. Menendez will train all research team members on proper set-up, usage, and cleaning of the equipment, and will be available to troubleshoot issues related to VR software or hardware.

What are the benefits of this research study?
We cannot and do not guarantee any direct benefits as a result of participating in the PR-VR program. You may feel positively about contributing to research that may help future patients, as the study will contribute to our understanding of pediatric pain treatment and rehabilitation. The study's results will also provide important information about the feasibility of virtual reality treatments in children and adolescents with pain and expand treatment options for children struggling with pain.

Are there costs associated with this research study?
There is no cost to you for participating in the PRVR program.

Will my employment or medical care be affected by this study?
Your decision whether or not to participate in this study will not affect your employment or medical care.

If I do not want to take part in this research?

Your participation in this study is voluntary. You may withdraw at any time. Your decision not to participate or withdraw will not affect the care you receive from this institution.

Why would I be taken off the study early?
If you fail to follow the study requirements, the Principal Investigator may take you off the study early. The PI also may take you off the study early if she feels it in your best interest to be taken off this study.

**TIME INVOLVEMENT:** Your participation in this study will span approximately 5 months in total, with 8 weeks of active participation and a survey only follow up 3 months later.

**PAYMENTS/REIMBURSEMENTS:** You could be compensated for up to $80:

- **$10 at the start of treatment** for completion of baseline surveys
- **Available $20 bonus** if you choose to answer the daily surveys
- **$20 at the end of treatment** for completion of discharge surveys
- **$30 at 3-month follow up** for completion of 3-month follow up surveys

After you complete each task as noted above, you will be sent the gift card. If you have any questions regarding your compensation for participation, please contact the study staff.

**FUNDING:** This study is funded by the National Institute for Arthritis and Musculoskeletal and Skin Diseases (NIAMS) awarded to Dr. Laura Simons.

**PARTICIPANT'S RIGHTS:**
If you have read this form and decide to participate in this project, please understand your participation is voluntary 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. The results of this research study may be presented at scientific or professional meetings or published in scientific journals. However, your identity will not be disclosed.

You have the right to refuse to answer any questions ask during the study.

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.

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.

**CONFIDENTIALITY**

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your 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.

**CERTIFICATE OF CONFIDENTIALITY**

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institute for Arthritis and Musculoskeletal and Skin Diseases (NIAMS) which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child abuse and neglect, or harm to self or others.
The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document such as including research data in the medical record.

# 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 and date 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 and dating it.

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

The primary goal of this study is to understand changes in physical function and pain-related fear following pain rehabilitation with virtual reality versus standard pain rehabilitation. Your health information will contribute to our understanding of these chronic pain-related behaviors and may help future pain clinic patients.

## Do I have to sign and date this authorization form?

You do not have to sign and date this authorization form. But if you do not, you will not be able to participate in this research study, including receiving any research-related study treatment. Signing and dating the form is not a condition for receiving any medical care outside the study.

## If I sign and date, 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 (for example, 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 the Investigator at the address on the first page of this form.

## 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 your name, zip code, birth date, telephone number, electronic mail address, pain-related medical history, co-morbid psychological diagnoses, audio and video recordings, and medical record number.

Information specific to your physical therapy study treatment will be shared with the Research Team. Information to be shared will include:

- Schedule of appointments and attendance of appointments

## 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 Investigator, Dr. Laura Simons.
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary,
- Research Team at Stanford University involved in this study.

## 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.
- Medical Team at Stanford University directly involved in your care related to the research or arises from it.
- People at Stanford University who oversee, advise, and evaluate research and care. This includes the ethics board and quality improvement program.
- People from agencies and organizations that provide accreditation and oversight of research including Navitas Clinical Research (NCR) for NIAMS.
- People that oversee the study information such as data safety monitoring boards, clinical research organizations, data coordinating centers, and others.
- Sponsors or others who fund the research, including the government or private sponsors such as National Institute of Health, National Institute of Arthritis and Musculoskeletal and Skin Diseases.

- Federal and state agencies that oversee or review research information, such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and public health and safety authorities.
- People or groups that are hired to provide services related to this research or research at Stanford University, including services providers, such as laboratories, and others.

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, 2050 or when the research study 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 (for example, if included in your official medical record).

_____ _____
Signature of Parent/Legal Guardian Date

_____
Print Name of Parent/Legal Guardian

## WITHDRAWAL FROM STUDY

There may be circumstances under which your participation may be terminated by the Investigator.

- **You are not able to attend the study visits required by the study.**
- **You no longer meet the eligibility criteria.**
- **If the Investigator feels it is in your best interest to be taken out of this study.**
- Failure to follow the instructions of the Protocol Director and study staff.
- The Protocol Director decides that continuing your participation could be harmful to you.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

## WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the Investigator at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

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/Alternate Contact**: If you need to change your appointment or you cannot reach the Protocol Director, please contact our research coordinators at (650) 665-3253.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

**Appointment/Alternate Contact**: If you need to change your appointment or you cannot reach the Investigator, please contact our study staff at phone number listed on the first page of this document.

**STUDY PARTICIPANTS' 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 study;
- Be given an explanation of the procedures to be followed in the study, 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 participant reasonably to be expected, if applicable;
- Be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the participant, their relative risks and benefits;
- Be informed of the avenues of medical treatment, if any available to the participant after the study if complications should arise;
- Be given an opportunity to ask questions concerning the study or the procedures involved;
- Be instructed that consent to participate in the study may be withdrawn at any time and the participant 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 study without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the participant's decision.

The extra copy of this signed and dated consent form is for you to keep.

The IRB determined that the permission of one parent is sufficient in accordance with 21 CFR 50.55(3)(e).

_____ _____
Signature of Parent/Legal Guardian Date

_____
Print Name of Parent/Legal Guardian

_____ _____
(If available) Signature of Other Parent/Legal Guardian Date

_____
Print Name of Other Parent/Legal Guardian

_____ _____
Signature of Person Obtaining Consent Date

_____
Print Name of Person Obtaining Consent