UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

(Consent Form: Aim 1 – Qualitative Interviews / Usability Testing**)**

Study Title:
Usability Testing of Virtual Reality for Opioid-Sparing Pain Management Among Diverse Patients

This study is about gathering user feedback on virtual reality for pain management. The study we are conducting is on behalf of the U.S. Food and Drug Administration. The study researchers, Courtney Lyles, PhD and Urmimala Sarkar, MD, MPH, and their team from the UCSF Department of Medicine at Zuckerberg San Francisco General Hospital and Trauma Center (ZSFG), will explain this study to you.

Research studies include only people who choose to take part. Please take your time to make your decision about participating, and discuss your decision with your family or friends if you wish. If you have any questions, you may ask the researchers.

You are being asked to take part in this study because we are looking for the opinions of people who experience pain about approaches to managing their pain.

Why is this study being done?

The purpose of this study is to understand and address ways technology could be used by all patients with pain.

How many people will take part in this study?

We will interview about 20 patients and 20 health care workers.

What will happen if I take part in this research study?

Study activities will take place here in a private office at ZSFG. During the interview, the researcher will ask you some demographic questions and questions about your experience with technology. Then, the same member will ask you about your experiences with and perceptions of pain management approaches, including virtual reality. Then, the researcher will invite you to try the virtual reality headset and ask you what you think about it.

The researcher will make an audio recording of your conversation. After the interview, someone will type into a computer a transcription of the audio from the tape and will remove any mention of names or personal health information. The recording will then be destroyed at the end of the study. Only members of the research team will have access to this information.

How long will I be in the study?

The interview will take approximately 60 minutes.

Can I stop being in the study?

Yes. You can decide to stop at any time. Just tell the study researcher right away if you wish to stop being in the study.

Also, the study researcher may stop you from taking part in this study at any time if he or she believes it is in your best interest.

What side effects or risks can I expect from being in the study?

You will be recorded during the interview, during which you may discuss personal information and opinions that you may not want linked to your identity. There is the potential loss of confidentiality of private information. However, we will take steps to maintain your privacy, including storing your information securely, removing your identity from transcripts from the interviews, and destroying recordings when the study is completed. Your name and information will be kept secure to the extent provided by law.

The interviews will focus on your opinions about pain management and technology, including asking you about your experiences. Therefore, your personal opinions about your care could be discussed. However, you do not need to provide any information that makes you feel uncomfortable, and you can choose to not answer any questions at any time.

There are risks to trying the virtual reality headset. They include acute virtual reality discomfort (e.g. headache, vertigo, nausea, eye strain). The virtual reality headset may pose risks to people with seizure disorders. We ask that if you have any of these conditions you decline to participate. There are no expected long-term risks from participating in this study. Even if you don't have any of these conditions, you do not have to try on the headset if you do not want to. If you try on the headset and wish to stop, you may stop at any time.

Are there benefits to taking part in the study?

You may not benefit from taking part in this study. You may learn new information about pain management and technology. In addition, the information that you provide will help researchers and device developers improve pain management approaches with technology.

What other choices do I have if I do not take part in this study?

You are free to choose not to participate in the study. If you decide not to participate in this study, there will be no penalty to you. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

Will information about me be kept private?

We will do our best to make sure that the personal information gathered for this study is

kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

The University of California and Food and Drug Administration may look at and/or copy your research records for research, quality assurance, and data analysis.

What are the costs of taking part in this study?

You will not be charged for any of the study treatments or procedures.

Will I be paid for taking part in this study?

In return for your time, effort and travel expenses, you will receive $25 in cash as a token of appreciation for taking part in this study at the end of the interview.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you in any way. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

Who can answer my questions about the study?

You can talk to the researchers about any questions, concerns, or complaints you have about this study. Contact Dr. Urmimala Sarkar at 628-206-4273.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the UCSF Institutional Review Board at 415-476-1814.

CONSENT

You have been given a copy of this consent form to keep.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to be in this study, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

Date	Participant's Signature for Consent

Date	Person Obtaining Consent