Consent to Participate in a Research Study

Title of Study: Expressive Painimation

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Source of Support: Clinical and Translational Science Institute (CTSI)

We are seeking to develop and test an electronic pain assessment tool that engages patients, improves communication of symptoms with providers, and leads to increased satisfaction with care. We are asking approximately 200 adult patients to participate in this study.

If you agree to participate, we will show you a computer tablet and ask you questions. We will show you animations on the tablet that you can use to describe the intensity of your pain. The animations can be increased or decreased in speed, color saturation, focus and size. While this solution is designed to improve communication between patients and their clinicians through the use of a pain assessment tool, it also provides data on pain symptoms that will help clinicians diagnose and treat patients. The information from the questionnaire will be scanned into your medical record. This research lasts for one visit.

This is a very low risk study, but you should be aware of risks. The risks for this study include the potential for breach of confidentiality and the possibility that you may be uncomfortable answering questions about your pain. You may stop participating at any time.

To protect your privacy, Dr. Jonassaint and members of his research team will know your identity, but they will keep your identity confidential. Your responses and study data will be labeled with a code number, and will not be recorded with identifiers (such as your name). Databases linking your identifying information and code numbers will be password-protected and kept in a separate location. If we share your information with other interested researchers, your identity will not be known to those individuals.

Your identity will not be revealed in any description or publications of this research. Although we will do everything in our power to protect your privacy and the confidentiality of your records, we cannot guarantee the privacy of your research records. Authorized representatives from the University of Pittsburgh Research Conduct and Compliance Office may review your identifiable data for the purpose of monitoring the conduct of this study. In rare cases, your identifiable records may be released in response to an order by a court of law. If we learn that you or someone you know is in danger of harm, we may need to inform the appropriate agencies.

You will not benefit from being in this study. We hope to learn more about how to develop this pain tool.

Your participation in this research study is completely voluntary. If you do not agree to participate in this research study, your decision will have no effect on your current or future relationship with the University of Pittsburgh or UPMC.

If you decide you no longer want to participate after you have provided informed consent, you should contact Dr. Jonassaint. If you decide to withdraw from this study, your data generated as part of this research study will be used as described, and it may be difficult or impossible to destroy data once any data analysis has been started. Questions about your rights as a research participant can be answered by the Human Subject Protection Advocate at the University of Pittsburgh IRB Office at 1-866-212-2668.

Voluntary Consent

I have read the above information and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by a qualified individual or the investigator listed on the first page of this consent document. I understand that I may always request that my questions, concerns, or complaints be addressed by a listed investigator.

I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations in the event that the research team is unavailable.

I am age 18 or older.
I have read and understood the information above.
I want to participate in this research and continue with the survey.