Consent Cover Letter for User-centered Design Activities

***PECARN (CIRB):* Development and Testing of a Pediatric Cervical Spine Injury Risk Assessment Tool**

The purpose of this research study is to inform the design of an implementation ready Pediatric Cervical Spine Injury (CSI) Risk Assessment Tool. We will engage clinical end-users in three activities: (1) Applied Cognitive Task Analysis (ACTA) aimed to capture subject workflow and knowledge. The ACTA will include audio-recorded interviews that follow an open-ended question interview guide to obtain information from clinicians that are representative of trauma systems across the U.S.; (2) Iterative design where clinical end-users assess the tool design utilizing mock-ups and formative user testing; and (3) Summative testing where clinical end-users participate in detailed simulation scenario-based usability testing.

The foreseeable risks for this study are minimal. There may be some inconvenience regarding the time you devote to participating in the interview. While the precautions detailed below will be taken to keep the study information confidential, there is always a minor risk that confidentiality may be breached. Interview and survey questions will not be personal in nature and you will be free to not answer any questions or not participate in a discussion if you so desire.

There will be no direct benefits to you for participating in this study. However, the information gained from the study may allow us to inform the design of an implementation ready Pediatric CSI Risk Assessment Tool which will make it easier for you and other physicians to safely limit unnecessary spinal precautions and radiographic testing for millions of children while helping identify those children who are truly at risk for CSI.

We will do everything we can to keep your information private but we cannot guarantee this. Study information will be kept in a secured manner and electronic records will be password protected. Each participant will be assigned a study identification number. This number will be used on study materials and in the study database instead of names and other private information. We may need to disclose information if required by law.

The audio-recordings will be deleted from the recording device immediately after they are saved to computer. Only the primary investigator and key study personnel will have access to these audio files. The tapes will be reviewed and relevant information transcribed into text, omitting names and identifying information to assure confidentiality. These audio recordings will not be used or presented publicly in any way. Computer files will be stored on a password protected computer system in a secure location. The list linking the participants' names to study identification numbers will be removed from the computer system after the study has closed. A de-identified dataset and back-up copies will remain on an encrypted remote back-up system.

Additionally, in order to conduct this study and make sure it is conducted as described in this form, the research records may be used and reviewed by others who are working with us on this research:

- Members of the research team and;
- The University of Utah Institutional Review Board (IRB), who reviews research involving people to make sure the study protects your rights;
- The study sponsor: Eunice Kennedy Shriver National Institute of Child Health and Human Development
- A research coordinating office: University of Utah Data Coordinating Center and Nationwide Children's Hospital as the lead coordinating site

If you have questions, complaints or concerns about this study, please contact Dr. Julie Leonard at Nationwide Children's Hospital in Columbus, Ohio; phone: (614) 355-5860.

Institutional Review Board: Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant or if you have questions or concerns that you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.

Research Participant Advocate: You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at **participant.advocate@hsc.utah.edu**.

It is up to you to decide whether or not to take part in this study. If you decide to take part you are still free to withdraw at any time and without giving a reason. Refusal to participate or the decision to withdraw from this study will involve no penalty or loss of benefits to which you are otherwise entitled.

By contributing to the interviews and completing the surveys, you are giving your consent to participate.

Thank you for your participation in our study.