Consent, Parental Permission, and Authorization Cover Letter *PECARN (CIRB):* Development and Testing of a Pediatric Cervical Spine Injury Risk Assessment Tool

The purpose of this research study is to try to develop a computerized decision support tool for use by emergency medical service (EMS) providers and emergency physicians who evaluate children after blunt trauma. We are doing this study because this project has the potential to improve the care of injured children.

Project staff members also reviewed your child's medical record to collect information regarding your child's diagnosis and hospital care.

This study pertains to children aged 0 to 17 years who experience blunt trauma and undergo the usual process of ED care. To participate, your child must not have had any x-rays of his/her neck after their injury. If your child meets this criteria, you may be contacted by phone 21 to 28 days after your child's hospital visit for a brief phone follow-up interview about your child's injury. We want to collect data to see if your child developed any neck injury symptoms. Your child will not benefit from this research. This research will not be used to make any decisions about your child's medical care. We have protections in place to protect your child's information so there is minimal risk that your child's information could be seen outside of the research team.

If you have any questions complaints or if you feel you have been harmed by this research please contact **Annie Truelove** the project manager. His/her contact information is listed below.

Address: 700 Children's Drive Columbus, OH, 43205
Email: annie.truelove@nationwidechildrens.org
Phone: (614)355-5791

Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which 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.

The phone interview should take approximately 5 minutes. Participation in this study is voluntary. You can choose not to take part. If you would like to opt out of the phone interview, please contact **Annie Truelove** the project manager at **(614)355-5791** within 3 weeks of your ED visit. You can choose not to finish the phone interview or omit any question you prefer not to answer without penalty or loss of benefits. By responding to the phone interview, you are giving your consent and authorization to participate and allow us to use information, as described below.

AUTHORIZATION FOR USE OF YOUR CHILD'S PROTECTED HEALTH INFORMATION

Agreeing to this document means you allow us, the researchers in this study, and others working with us to use some information about your child's health for this research study.

This is the information we will use and include in our research records:
Demographic and identifying information like date of birth.

- Related medical information regarding your child's diagnosis and hospital care.

How we will protect and share your child's information:

- We will do everything we can to keep your child's information private but we cannot guarantee this. Study information will be kept in a secured manner and electronic records will be password protected. Study information may be stored with other information in your child's medical record. Other doctors, nurses, and third parties (like insurance companies) may be able to see this information as part of the regular treatment, payment, and health care operations of the hospital. We may also need to disclose information if required by law.

- 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 we share your child's identifying information with groups outside of Nationwide Children's Hospital, and the University of Utah Data Coordinating Center, we will not share your child's name or identifying information. We will label your child's information with a code number, so they will not know your child's identity.

- If you do not want us to use information about your child's health, you should not be part of this research. If you choose not to participate, you can still receive health care services at **Nationwide Children's Hospital.**

What if I decide to Not Participate after I agree to the Consent and Authorization Form?
You can tell us anytime that you do not want to be in this study and do not want us to use your child's health information. You can also tell us in writing. If you change your mind, we will not be able to collect new information about your child, and you will be withdrawn from the research study. However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research.

This authorization does not have an expiration date.

You have a right to information used to make decisions about your child's health care. However, your information from this study will not be available during the study; it will be available after the study is finished.

Thank you for your participation in our study.