

**Assent (Permission) to Take Part in a Human Research Study
For Child Participants**

TITLE: Patterns and Consequences of Injuries Occurring in Collisions of Vehicles with Modern Occupant Protection Systems (CIREN)

PROTOCOL NO.: 15-2001
IRB Protocol #20204318
15-2001

**STUDY-RELATED
PHONE NUMBER(S):** 703-776-2274

READ THE FOLLOWING CAREFULLY

We want to tell you about a research study we are doing and ask if you want to be part of it. People do research to try to find answers to questions. If you do not understand something, just ask us. We want you to ask questions now and anytime you think of them.

We are working to find out more about injuries received by occupants of motor vehicle crashes and how we can reduce the severity of injuries by improving vehicle design and the care of patients.

You are being asked to be in this study because you were involved in a motor vehicle crash and sustained injuries as a result of the crash. About five children per year will be in the study.

Both you and your parent(s) must agree to you being in this study. You do not have to be in this study if you do not want to, even if your parent(s) said “yes”.

If you decide to be in this study, this is what will happen:

- You will be interviewed in the hospital with a series of questions regarding information about the crash, general health information, and a medical evaluation of injuries as related to the crash.
- The research staff will have access to your medical record to obtain information about your injuries. Photographs of your injuries will be taken, if possible.

There is a little chance that this study will benefit you directly but your participation will enable researchers to find out things that will help other children someday and make cars safer for you in the future.

There is a minimal chance that you could have problems that make you feel bad because of this study.

It is important that you let the study doctors and your parents know if there is a problem right away.

The study is private. The study doctors will not be sharing what they learn about you with your parents (or guardian). The doctors working on the study and the part of the government that makes the rules about research will need to see what is learned, but they are not allowed to tell anyone about you.

You do not have to be in this study if you do not want to. It is up to you. If you say okay now, but you want to stop later, that is okay too. No one will be mad at you if you say no or change your mind. You can stop any time you want. All you have to do is tell the study doctor.

Agreement to Participate

I have read this form or someone has read it to me. I can always ask the study doctor or their assistant a question about the study if I do not understand something. I will be given a copy of this form.

Please check one box:

- ☐ **YES**, I want to be in this research study and I know that I can change my mind later.
- ☐ **NO**, I do not want to be in this study.

Signature of Child

Date

Printed Name of Child

The following should be completed by the study member conducting the assent process if the child agrees to be in the study. Check all that apply.

- ☐ The child is capable of reading and understanding the assent form and has signed above as documentation of assent to take part in this study.
- ☐ The child is not capable of reading the assent form, but the information was verbally explained to him/her. The child signed above as documentation of assent to take part in this study.
- ☐ The child had ample opportunity to have his or her questions answered.

Signature of Person Obtaining Assent

Date

Printed Name of Person Obtaining Assent

The following witness lines may be left blank, unless an impartial witness is required.

An impartial witness, **who is a witness to the informed consent process that is not involved in the conduct of the research**, is required when a non-English speaking subject is encountered, an interpreter is used and consent is documented through the use of a short form or when the subject cannot read the consent form.

Signature of Witness

Date

Printed Name of Witness