

## ASSENT FORM TO BE IN A RESEARCH STUDY

Child ages 7-14

Participant's Name \_\_\_\_\_ Medical Record # \_\_\_\_\_

### Why would we like to speak with you?

We want to talk with you about being a part of something called a research study. A research study is when doctors collect information to learn more about a disease. Doctors who do research are also called researchers.

If you have any questions during our talk about this study, you can ask them. Don't worry about waiting until the person talking stops speaking to you. You can stop them at any time and ask your question.

Doctors at the University of Virginia are doing this research study to learn more about children who are in motor vehicle collisions. After we tell you about this research study, we will ask you if you'd like to be in this research study or not. If you decide to be in this research study, you will be asked to sign this paper and you can take a copy of it home with you.

It's okay to say 'NO' if you don't want to be in the study. It is also okay to be in the study now and leave it at any time. You should speak with your parent/guardian about your decision.

This research study is not about getting treatment. You will have treatment for your injuries, whether or not you agree to be part of this research study.

The doctor in charge of this study is **Dr. Thomas Hartka**.

This study will take place here at the UVA Hospital and will last for **one visit, up to one-hour total**.

### Why are we doing this research study?

We will be getting information from lots of boys and girls like you. In this research study, there will be up to 125 children or adults who have been injured in a car crash and qualify for this study at UVA.


You will not have to come back for any return visits.

### What will happen to you if you are in the research study?

*If you agree to be in the research study, this is what you will be asked to do:*

1. *Answer questions about what you were wearing and where you were sitting during the car crash*
2. *Take pictures, if you are comfortable, of your injuries.*
3. *Allow the researchers to follow your care on the computer to see how you are doing.*

### What things may bother or hurt you about being in this study?

	IRB-HSR Approval Date: 27Nov2017
	IRB-HSR Expiration Date: 26Nov2018

Sometimes things happen to people in research studies that may hurt them or make them feel bad. These are called risks. You may not want to answer certain questions or take pictures, and you can refuse any part of this study.

**Will this study help me?**

People also may have good things happen to them because they are in research studies. These are called benefits. There aren't any direct benefits to you for being in this study, but we hope the information learned from this study will benefit all of us in the future by helping to design and build safer vehicles.

**Will you be paid for being in this study?**

You will not receive payment for being in this research study.

**Do you have to be in this research study?**

No. No one will be upset with you if you don't want to be in this research study. If you don't want to be in this research study, just tell us. If you want to be in the research study, tell us that. And, remember, you can say yes now, and change your mind later. It's up to you.

Please talk this over with your parents before you decide whether or not to be in the research study. Your parents have said that it is okay with them if you want to be in the research study. Even though your parents have said it is okay with them, you can still say 'No'.

**What if you have questions?**

You may ask questions at any time. You can ask now or later. You may talk to the doctor or someone else. Your parents/guardians have the information on who you or they may call after you go home.

**What about your privacy?**

The doctor will talk about you and the research study with your parent/guardian, but will not talk about it with anyone else except the people working here. If the doctor needs to talk to anyone else about you he/she will ask you and your parent/guardian if it is OK.

**Saying Yes or No to being in this research study**

You can say yes or no. If you say yes, remember:

1. You can stop being in the study any time you want to
2. You can call the doctor any time you have any questions
3. Besides your parents/guardian, your information will only be shared with the doctor and nurses in this study

If you sign this paper, it means that you have read this and you have talked with someone about it. It also means you have had all your questions for today answered and you want to be in the research study. If you don't want to be in the study, don't sign this paper.

Please ask as many questions as you need to make sure you understand the study before you sign this form. Being in the study is up to you, and no one will be upset if you don't sign this paper or if you change your mind later.

**Consent from the parent/guardian MUST be obtained on the main consent form before approaching the child for their assent.**

Parent(s)/Guardian has signed Main informed consent \_\_\_ Yes \_\_\_ No

Name of Person Obtaining Consent of the Parent(s)/Legal Guardian \_\_\_\_\_

Signature of Person Obtaining Consent of the Parent(s)/Legal Guardian \_\_\_\_\_

**Assent from Child (7-14 years of age)**

\_\_\_\_\_  
CHILD  
(SIGNATURE)

\_\_\_\_\_  
CHILD  
(PRINT NAME)

\_\_\_\_\_  
DATE

**Person Obtaining Assent of the Child (7-14 years of age)**

By signing below you confirm that the study has been explained to the child (less than 18 years of age), all questions have been answered and the child has voluntarily agreed to participate.

\_\_\_\_\_  
PERSON OBTAINING ASSENT OF  
THE CHILD  
(SIGNATURE)

\_\_\_\_\_  
PERSON OBTAINING ASSENT  
OF THE CHILD  
(PRINT NAME)

\_\_\_\_\_  
DATE

**Signature from Impartial Witness**

If this assent form is read to the minor subject because the minor subject is blind or illiterate, an impartial witness not affiliated with the research or study doctor must be present for the consenting process and sign the following statement. The minor subject may place an X on the Assent from Child Signature line above.

I agree the information in this informed consent form was presented orally in my presence to the minor subject who has had the opportunity to ask any questions he/she had about the study. I also agree that the minor subject freely gave their assent to participate in this trial.

\_\_\_\_\_  
IMPARTIAL WITNESS  
(SIGNATURE)

\_\_\_\_\_  
IMPARTIAL WITNESS  
(PRINT)

\_\_\_\_\_  
DATE

