Consent of an Adult to Be in a Research Study

In this form "you" means a person 18 years of age or older who is being asked to volunteer to participate in this study.

Parents' or Guardians' Permission for Your Child to Be in a Research Study

Agreement of a Child to Be in a Research Study (child ages 15-17)

In this form "you" means the child in the study *and* the parent or guardian.

- ✓ If you are the parent or guardian, you are being asked to give permission for your child to be in this study.
- ✓ If you are the child, you are being asked if you agree to be in this study.

In this form "we" means the researchers and staff involved in running this study at the University of Virginia.
In this form "you" means the person (your child) who is being asked to be in this study. As the parent or guardian, you are being asked to give permission for your child to be in this study.

Participant's Name _____

Principal Investigator:	Thomas Hartka 1335 Lee Street, MSB 2nd Fl 2266 Charlottesville, VA 22905
Sponsor:	National Highway Traffic Safety Administration (NHTSA)

What is the purpose of this form?

This form will provide you with information about this research study. You do not have to be in the study if you do not want to. You should have all your questions answered before you agree to be in this study.

Please read this form carefully. If you want to be in the study, you will need to sign this form. You will be given a signed copy of this form.

Who is funding this study?

This study is being funded by National Highway Traffic Safety Administration (NHTSA). UVA will have a subcontract with INOVA Health System to complete this study.

Why is this research being done?

The purpose of this study is to learn more about how a vehicle and its occupant move during a crash and to determine how different safety features of motor vehicles affect the injuries people receive. The ultimate goal is to improve the design of vehicles and the care of patients involved in motor vehicle crashes in order to improve the prevention, treatment and rehabilitation of motor vehicle crash injuries. It also hopes to reduce the death, disability and human and economic costs of motor vehicle injuries by these improvements.

You are being asked to be in this study because you were injured in a motor vehicle collision

Up to 25 people per year will be in this study at UVA for a total of 125 people. There is no limit to who can be enrolled in this study at all places.

This study supports an in-depth public information database on crash injuries. The database provides information about vehicles and injuries in way that does not reveal the identities of vehicle owners of the persons injured in the crash. **http://www.nhtsa.gov/CIREN**

What will happen if you are in the study?

If you agree to participate and sign this consent form, the study team will review information about your vehicle and about your injuries to confirm that you should be included. If you are also the owner of the vehicle in the collision, you may be asked to sign a separate consent form to include your vehicle in the study.

Once confirmed, a 15-20 minute interview will be conducted regarding:

- Demographics
- Information about the crash
- Use of alcohol and drugs
- General information
- Medical evaluation of injuries as related to the vehicle crash.

Information on the nature of your injuries will be recorded and photographs of injuries will be taken, if possible. Photos that show your face or any identifying features (i.e. tattoos, notable birthmarks, etc.) and if your face has injuries that must be documented, your eyes or tattoos, etc. will be blocked out prior to sending the photos out of UVA. The study team will also access your medical record to get information about your injuries, as well as information on the hospital and professional charges during your hospital stay. Any additional information surrounding the collision or vehicle, including reports from Emergency Medical Services or police reports, may be collected to

help researchers with your case. No research information collected will be released to any other services.

Could you be helped by being in this study?

You will not benefit from being in this study. We hope the information learned from this study will benefit all of us in the future by helping to design and build safer vehicles. The Federal Government, through access to the database containing de-identified information about your injuries and your crash, may use this data to make safety changes to automobiles in the future, thereby saving lives and preventing injuries.

What are the risks of being in this study?

Participation in this study does not involve any change in your medical care. The interview contains questions about alcohol and drug use. You may refuse to answer any question that makes you uncomfortable.

Your data will be sent to INOVA Health System and entered into a database controlled by the National Highway and Traffic Safety Administration called CISSWeb. This database has multiple levels of access to the case data to keep your information as secure as possible. While this is a highly controlled database, there is always a risk that some of your data could be accessed by non-study personnel. The study team does everything in their power to keep your data secure at both UVA and in the NHTSA database.

Risks of photography:

Photographs of your injuries may be included in this study. Protection of personal privacy is of utmost concern to the CIREN study. Personal, location, and visual identifiers will be masked. Photographs which include a face without masking are not allowed in the CIREN database.

Photographs will not be included in the public database.

What are your other choices if you do not join this study?

You do not have to be in this study to be treated for your condition. You can get all usual treatment for your trauma even if you choose not to be in this study.

If you are an employee of UVa your job will not be affected if you decide not to participate in this study. If you are a student at UVa, your grades will not be affected if you decide not to participate in this study.

Will you be paid for being in this study?

You will not get any money for being in this study.

Will being in this study cost you any money?

All of the procedures in this study will be provided at no cost to you or your health insurance. Costs of your regular medical care, copayments and deductibles which are not related to this study will be the responsibility of you and your insurance company.

What if you are hurt in this study?

If you are hurt as a result of being in this study, there are no plans to pay you for medical expenses, lost wages, disability, or discomfort. The charges for any medical treatment you receive will be billed to your insurance. You will be responsible for any amount your insurance does not cover. You do not give up any legal rights, such as seeking compensation for injury, by signing this form.

What happens if you leave the study early?

You can change your mind about being in the study any time. You can agree to be in the study now and change your mind later. If you decide to stop, please tell us right away. You do not have to be in this study to get services you can normally get at the University of Virginia.

Even if you do not change your mind, the study leader or the sponsor of this study can take you out of the study. Some of the reasons for doing so may include

a) Your injuries do not qualify for inclusion
b) The vehicle you were in during the collision does not qualify or is unable to be inspected
c) A key component in the collision is unable to be assessed

If you decide to stop being in the study, we will ask you to notify Dr. Hartka or the study team at the address listed on page 1.

How will your personal information be shared?

The UVa researchers are asking for your permission to gather, use and share information about you for this database. If you decide not to give your permission, you cannot be in this study, but you can continue to receive regular medical care at UVA.

If you sign this form, we may collect any or all of the following information about you:

- Personal information such as name, address and date of birth
- Your health information, including a review of your medical records and test results from before, during and after the study from any of your doctors or health care providers.
- Information regarding the collision including police reports, insurance documents, and any photos taken by EMS.

Who will see your private information?

- The researchers to make sure they can conduct the study the right way, observe the effects of the study and understand its results
- People or groups that oversee the study to make sure it is done correctly

- The sponsor(s) of this study, and the people or groups it hires to help perform or review this research
- People who evaluate study results, which can include sponsors and other companies that make the drug or device being studied, researchers at other sites conducting the same study, and government agencies that provide oversight such as the Food and Drug Administration (FDA) if the study is regulated by the FDA.
- If you tell us that someone is hurting you, or that you might hurt yourself or someone else, the law may require us to let people in authority know so they can protect you and others.

Some of the people outside of UVa who will see your information may not have to follow the same privacy laws that we follow. They may release your information to others, and it may no longer be protected by those laws.

The information collected from you might be published in a medical journal. This would be done in a way that protects your privacy. No one will be able to find out from the article that you were in the study.

What if you sign the form but then decide you don't want your private information shared?

You can change your mind at any time. Your permission does not end unless you cancel it. To cancel it, please send a letter to the researchers listed on this form. Then you will no longer be in the study. The researchers will still use information about you that was collected before you ended your participation.

Certificate of Confidentiality

We have asked the federal government to issue a Certificate of Confidentiality to help protect the privacy of your study records. If we receive a subpoena or court order demanding information from the study records that would identify you, we will use the Certificate to resist the demand. However, UVa will not use it in the following cases.

- You have agreed in writing to allow UVa to share the information with your employer, your insurance company for billing purposes, or someone else
- Reports to authorities where there is a danger that you may harm yourself or others, or if there is evidence of probable child or elder abuse or neglect.

In addition, the Certificate does not prevent government authorities who oversee research from reviewing this study. This Certificate does not mean that the government either approves or disapproves of this study. It just helps protect your privacy.

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator:
Thomas Hartka
Emergency Medicine, School of Medicine
PO BOX 800699
Charlottesville, Virginia 22908
Telephone: 434-243-2681
e-mail: trh6u@virginia.edu

What if you have a concern about this study?

You may also report a concern about this study or ask questions about your rights as a research subject by contacting the Institutional Review Board listed below.

University of Virginia Institutional Review Board for Health Sciences Research
PO Box 800483
Charlottesville, Virginia 22908
Telephone: 434-924-9634

When you call or write about a concern, please give as much information as you can. Include the name of the study leader, the IRB-HSR Number (at the top of this form), and details about the problem. This will help officials look into your concern. When reporting a concern, you do not have to give your name.

Signatures

What does your signature mean?

Before you sign this form, please ask questions about any part of this study that is not clear to you. Your signature below means that you have received this information and all your questions have been answered. If you sign the form it means that you agree to join the study. You will receive a copy of this signed document.

Consent From Adult

_____	_____	_____
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

To be completed by participant if 18 years of age or older.

Person Obtaining Consent

By signing below you confirm that you have fully explained this study to the potential subject, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

PERSON OBTAINING CONSENT (SIGNATURE)	PERSON OBTAINING CONSENT (PRINT)	DATE

Assent from Child (age 15-17)
Consent from the parent/guardian MUST be obtained before approaching the child for their assent.

PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

Person Obtaining Assent of the Child (less than 18 years of age)
Consent from the parent/guardian MUST be obtained before approaching the child for their assent.

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 (SIGNATURE)	PERSON OBTAINING ASSENT (PRINT)	DATE

Parental/ Guardian Permission
By signing below you confirm you have the legal authority to sign for this child.

PARENT/GUARDIAN (SIGNATURE)	PARENT/GUARDIAN (PRINT NAME)	DATE

Person Obtaining Parental/Guardian Permission
By signing below you confirm that you have fully explained this study to the parent/guardian, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

PERSON OBTAINING PARENTAL/ GUARDIAN PERMISSION (SIGNATURE)	PERSON OBTAINING PARENTAL/GUARDIAN PERMISSION (PRINT NAME)	DATE

Surrogate Consent

In the event the adult participant is unable to give informed consent for participation in this study:

_____/_____ _____

PERSON GIVING CONSENT FOR PARTICIPANT (Signature/ Printed) DATE

RELATIONSHIP TO PARTICIPANT: _____

Person Obtaining Consent of the Surrogate

By signing below you confirm that you have fully explained this study to the potential subject's surrogate, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

_____	_____	_____
PERSON OBTAINING CONSENT (SIGNATURE)	PERSON OBTAINING CONSENT (PRINT)	DATE

Person Obtaining Assent of the Adult Subject

The subject is unable to give assent due to the following reason:

_____

OR

By signing below you confirm that the study has been explained to the adult subject, all questions have been answered and the adult subject has not demonstrated resistance or dissent by word or gesture to enroll in the study. You also confirm that if the subject demonstrates resistance or dissent at any point in the study that they will not be subjected to any additional study interventions.

_____	_____	_____
PERSON OBTAINING ASSENT (SIGNATURE)	PERSON OBTAINING ASSENT (PRINT)	DATE

Consent of the Participant to Continue to Be in the Study

Your legal representative gave his/her permission for you to be in this research study. This is because you were not able to make your own decision due to your illness. Your condition is now better. You are being asked to decide whether to continue to be in this study. The decision is up to you. Before you sign this form, please ask questions about any part of this study that is not clear to you. When you sign below, you are saying you understand the information we gave you about the study and in this form.

If you sign this form it means that you agree to continue being in the study.

PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

Person Obtaining Consent of the Subject

By signing below you confirm that you have fully explained this study to the subject, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

PERSON OBTAINING CONSENT (SIGNATURE)	PERSON OBTAINING CONSENT (PRINT)	DATE

Signature from Impartial Witness

If this consent form is read to the subject because the 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 subject may place an X on the Participant Signature line above.

I agree the information in this informed consent form was presented orally in my presence to the **identified individual(s)** who has had the opportunity to ask any questions he/she had about the study. I also agree that the **identified individual(s)** freely gave their informed consent to participate in this trial.

Please indicate with check box the identified individual(s):

- ☐ Subject
- ☐ Parent(s)/Guardian of the subject
- ☐ Subject's surrogate

IMPARTIAL WITNESS (SIGNATURE)	IMPARTIAL WITNESS (PRINT)	DATE