Informed Consent for a Research Study

Sponsor:	National Highway Traffic Safety Administration (NHTSA)
Principal Investigator:	Terral Goode, M.D.
Site of Investigation:	Winchester Medical Center 1840 Amherst Street PO Box 3340 Winchester, VA 22061

INTRODUCTION

You may be eligible to take part in a research study. Please take your time to make your decision. Discuss it with your family and friends. It is important that you read and understand several general principles that apply to all who take part in our studies:

(a) Taking part in the study is entirely voluntary;
(b) Personal benefit to you may or may not result from taking part in the study, but knowledge may be gained from your participation that may benefit others;
(c) You may withdraw from the study at any time without any of the benefits you would have received normally being limited or taken away.

The nature of the study, the benefits, risks, discomforts and other information about the study is discussed below. Any new information discovered which might affect participation in the study, will be provided to you. You are urged to ask any questions you have about this study with the staff members who explain it to you. The investigator (person in charge of this research study) is Terral Goode, MD.

BACKGROUND

You are being asked to take part in a research study because you were injured in a motor vehicle crash. The purpose of this study is to gather information on injuries received by occupants of motor vehicles involved in crashes. It is hoped that we will learn how to reduce the severity of motor vehicle injuries by improved vehicle design once we are able to correlate different types of injuries with identifiable features of the crash, treatment at the scene, and medical care provided following the trauma.

PURPOSE

The purpose of the research at Winchester Medical Center is to determine 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.

PROCEDURES

The study will consist of a patient interview in the hospital with a series of questions regarding information about the crash, views about your health and activities, your use of alcohol and drugs, general information, and a medical evaluation of injuries as related to the vehicle crash.

The research staff will have access to your medical record to obtain information about your injury. You will also be asked questions and your cooperation in answering questions will be of great help in providing services to families of other trauma patients. The interview should require approximately 20 to 30 minutes of your time. Information on the nature of your injuries will be recorded and photographs of injuries will be taken, if possible. Information on the hospital and professional charges during your hospital stay will also be recorded, as will detailed information about the crash. In addition, we would like to contact you by telephone for follow-up interviews in 6-12 months. Again, you will be asked questions about your health status, medical follow-up and your recovery process. These telephone interviews will take approximately 15-20 minutes and will be scheduled at your convenience.

VEHICLE OWNERS

If you are also the vehicle owner we are asking you to authorize an accident reconstruction specialist to inspect your vehicle and take measurements and pictures. This person is an employee of the CIREN research project and is <u>not</u> affiliated with any outside legal or law enforcement agency. The information they will collect is only for use in this research project and will be entered into a confidential database.

In some cases members of the local police department may have already inspected your vehicle. If this is the case, we are asking you, as owner of the vehicle, to also authorize the release of any data obtained by the local law enforcement agency during their routine investigation. If you agree to make this information available to us, this information will be entered into a confidential database.

You will be asked to answer some questions about your vehicle. The questions will ask you if the vehicle has been in a crash before, and if so what alterations have been made to the vehicle. You will also need to provide the researchers with the current location (tow lot site) of the vehicle if you know it.

LENGTH OF PARTICIPATION

If you agree to participate you will be interviewed as outlined above. Your total participation time in the hospital once you have finished reading this form should take no more than 30 minutes. Your telephone interviews will take place at 6 and 12 months after you crash and should take no more than 20 minutes each.

You can stop participating at any time without penalty or loss of benefits to you. Your decision to participate is completely voluntary. You are not waiving any legal claims or rights because of your participation in this study.

RISKS

Participation in this study is voluntary and 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.

BENEFITS

If you agree to take part in this study, there may or may not be direct benefit to you. However, your participation will enable the researchers to get a clearer picture of how motor vehicle injuries occur and how they may be prevented in the future. We hope the information learned from this study will benefit others in the future.

CONFIDENTIALITY

The researchers at Winchester Medical Center have obtained a Certificate of Confidentiality from the Department of Health and Human Services and the National Institutes of Health which will help them protect your privacy, unless you consent in writing to the release of research information. However, if the researchers learn that you or someone else is in serious danger of harm (such as in cases of child abuse) they may make disclosures to protect you and/or the other person. The Certificate of Confidentiality does not indicate an endorsement of the CIREN research by the Department of Health and Human Services or the National Institutes of Health.

Any information gathered from you will be identified by a random number and will remain as confidential as permitted by law. You will not be identified by name.

Efforts will be made to protect your personal information to the extent allowed by law. Medical records and research material of research study participants are stored and kept according to legal requirements. You will not be identified in any reports or publications resulting from this study. The sponsor of the study, Human Research Protection Program, Institutional Review Board (IRB) may request, inspect and/or copy your research and medical records for quality assurance and data analysis. Members of the research team will also have access to your research records.

You understand that your patient photographs, X-rays, CT-scans, MRIs, and detailed medical information and/or history (e.g., surgical procedures and medical treatment, pre-existing medical conditions, laboratory results) will be entered into a database that will be accessible to trauma centers that are CIREN participants and their funding private sector partners, NHSTA, and Volpe. Further, you understand that NHSTA may authorize access to this data by others for limited research purposes and that NHSTA will protect all sensitive medical information residing on the CIREN database from public dissemination to the full extent authorized by 5 USC 552.

COST

You will not be paid for your participation in this study. You will not be responsible for any of the costs of the procedures related to the study.

VOLUNTARY PARTICIPATION

Taking part in this study is voluntary. You may choose not to take part in or leave the study at any time. If you choose to not take part in or to leave the study, your medical care will not be affected and you will not lose any of the benefits you would have received normally.

You will be told about new information that may affect your health, welfare, or participation in this study.

INJURY

There is no anticipated injury involved from participating in this study. In the event that you believe participation in this research study has let to harm, contact **Dr. Terral Goode**, principal investigator at **(540) 536-2434** and he will review the matter with you.

You should understand that neither Winchester Medical Center, the investigators, nor the Federal Government, have any programs to provide compensation for persons participating in research projects who may experience injury. However, necessary facilities, emergency treatment and professional services will be available to you. You should not expect anyone to pay you for pain, worry, lost income, or non-medical occur from taking part in this research study. No funds have been set aside, by Winchester Medical Center to repay you in case of injury.

You do not waive any of your legal rights by signing this form.

QUESTIONS

Please ask any questions or concerns you have about the study now. Should you have any questions or concerns related to the study, any injury, or bad effect, you should immediately contact the Principal Investigator. Should you have any problem or question that may arise in connection with this study, or with regard to your rights as a participant in research, you may contact **Dr. Terral Goode** at **(540) 536-2434**.

You should know that Winchester Medical Center, and Dr. Goode as the primary investigator, are being reimbursed by the sponsor to cover the cost to conduct this research study.

If you would like more information about your rights as a participant in a research study, contact the Winchester Medical Center Human Research Protection Program at:

(540) 536-8978
Human Research Protection Program
Winchester Medical Center
1840 Amherst Street
PO Box 3340
Winchester, Virginia 22601

The IRB may contact you by mail or telephone to find out if you were satisfied with your study participation.

Title: Patterns and Consequences of Injuries
Occurring in Collisions of Vehicles with Modern
Occupant Protection Systems
Principal Investigator: Terral Goode, MD

SIGNATURE PAGE

As a member of the research team, I have explained the purpose, the procedures, the benefits and risks that are involved in this research study. Any questions that have been raised have been answered to the individual's satisfaction.

_____ _____ _____ Signature of
Person Obtaining Consent/Witness Printed Name Date

You, the undersigned have been informed about this study's purpose, procedures, possible benefits and risks, and you have read this consent and received a copy of this consent. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask other questions at any time. You voluntarily agree to give your consent to participate in this research study.

You are free to withdraw from the study at any time and you do not have to say why you no longer wish to participate. You will notify the Principal Investigator if you are leaving the study because of any side effects you might experience. This withdrawal will not in any way affect your future treatment or medical management. You agree to cooperate with Terral Goode, MD, and the research staff and to inform them immediately if you experience any unexpected or unusual symptoms.

_____ _____
Signature of Subject Date

_____ Printed
Name of Subject

_____ _____
Signature of Legally Authorized Representative (When applicable) Date

_____
Printed Name of Legally Authorized Representatives and Relationship to Participant

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If the person conducting the informed consent discussion has signed above as witness, the following witness lines may be left blank, unless an impartial witness is required.

_____ _____ _____

Signature of Witness	Printed Name of Witness	Date