UNIVERSITY of MARYLAND BALTIMORE

RESEARCH CONSENT FORM /INFORMATION SHEET

Protocol Title: Core Protocol for Biomechanics Studies

Study No.: HP-40290

Principal Investigator: Margaret Lauerman, MD
R Adams Cowley Shock Trauma Center
National Study Center for Trauma and EMS
University of Maryland, Baltimore
22 South Greene Street
Baltimore, MD 21201
410-328-3587

Sponsor: National Highway Traffic Safety Administration (NHTSA)

This is a research study to determine the types and severity of injuries that may be sustained as the result of a motor vehicle crash. Participation is voluntary and you may ask questions at any time. If you are reading this consent form as a legally authorized representative for someone who is unable to read for themselves, the word "you" in this document will refer to the person you are reading for (family member, etc).

PURPOSE OF STUDY

The purpose of this study is to gather information on injuries received by pedestrian (on foot) or occupants of motor vehicle crashes. Since you were involved in a crash, we would like to include you in this study. A total of 11,500 people at five trauma centers across the country will be included in this study. You will be one of approximately 1,600 people participating at this location. Other trauma centers participating in this project include Fairfax Inova Hospital, University of Alabama Birmingham, Wake Forest University, and Grady Memorial Hospital.

PROCEDURES

You will be one of approximately 1,600 subjects included in the study at the R Adams Cowley Shock Trauma Center at the University of Maryland. If you agree to participate in this study, we will ask you some questions relating to the circumstances surrounding your crash and some additional questions relating to your injuries, your health and activities, your use of alcohol and drugs, and other general information. Your cooperation in answering these questions will be of great help in providing services to families of other trauma patients and will hopefully aid in reducing the effects of vehicular trauma in the future. The interview should only require about 10

to 20 minutes of your time. If your injuries and crash circumstance meet the inclusion criteria we will document the nature and extent of your injuries and photographs of your injuries will be taken, if possible. Information on your hospital, professional and rehabilitation charges will also be recorded, as will detailed information about the crash and vehicle damage. We ask your permission to look at your medical records to get vital signs (pulse, blood pressure, etc), to document your injuries, and to describe any procedures (surgeries, x-rays and CT scans) that were performed as part of your care while at Shock Trauma. If you do not meet the inclusion criteria you will be withdrawn from the study and no further data will be collected. This study is an ongoing effort by the National Highway Traffic Safety Administration.

POTENTIAL RISKS/DISCOMFORTS:

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. This study requires the use of confidential information (name, medical record number) in order to obtain all the data required for analysis. To avoid any breach of confidentiality, this information will only be available to the researchers involved directly with the project and will be maintained in a locked offices and filing cabinets. This is an observational study and, in the event that you may be pregnant, there is no risk to the fetus.

POTENTIAL BENEFITS

You will receive no direct benefit from participation in this study. However, your participation may help the investigators better understand how injuries occur in a motor vehicle crash and will provide information to the National Highway Traffic Safety Administration and to automobile manufacturers that will assist them in developing rules and safety systems that may help prevent serious injuries from occurring. Research findings from this study may be published by NHTSA and in relevant medical journals.

ALTERNATIVES TO PARTICIPATION

This is not a treatment study. Your alternative is to not take part. If you choose not to take part, your healthcare at University of Maryland, Baltimore will not be affected.

COSTS TO PARTICIPANTS

There are no costs to you as a consequence of your participation in this research study.

CONFIDENTIALITY AND ACCESS TO RECORDS

This study involves the collection of confidential information. Information collected will only be available to the researchers involved directly with the project and will be maintained in a locked offices and filing cabinets. Prior to disclosure to any entity outside of the research team at the

University of Maryland, all data is sanitized and any identifying names/numbers are removed from the information collected. The researchers 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. The data from the study may be published. However, you will not be identified by name. People designated from the institutions where the study is being conducted and people from the sponsor will be allowed to inspect sections of your medical and research records related to the study. Everyone using study information will work to keep your personal information confidential. Your personal information will not be given out unless required by law.

RIGHT TO WITHDRAW

Your participation in this study is voluntary. You do not have to take part in this research. You are free to withdraw at any time. Refusal to take part or to stop taking part in the study will involve no penalty or loss of benefits to which you are otherwise entitled. If you decide to stop taking part, if you have questions, concerns, or complaints, or if you need to report a medical injury related to the research, please contact the investigator Margaret Lauerman, MD at 410-328-3587. There are no adverse consequences (physical, social, economic, legal, or psychological) of your decision to withdraw from the research.

UNIVERSITY STATEMENT CONCERNING RESEARCH RISKS

The University is committed to providing participants in its research all rights due them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in the research project. This research has been reviewed and approved by the Institutional Review Board (IRB). Please call the Institutional Review Board (IRB) if you have questions about your rights as a research participant.

The research described in this consent form has been classified as minimal risk by the IRB of the University of Maryland, Baltimore (UMB). The IRB is a group of scientists, physicians, experts, and other persons. The IRB's membership includes persons who are not affiliated with UMB and persons who do not conduct research projects. The IRB's decision that the research is minimal risk does not mean that the research is risk-free. You are assuming risks of injury as a result of research participation, as discussed in the consent form.

If you are harmed as a result of the negligence of a researcher, you can make a claim for compensation. If you have questions, concerns, complaints, or believe you have been harmed through participation in this research study as a result of researcher negligence, you can contact members of the IRB or the staff of the Human Research Protections Office (HRPO) to ask questions, discuss problems or concerns, obtain

information, or offer input about your rights as a research participant. The contact information for the IRB and the HRPO is:

University of Maryland Baltimore
Human Research Protections Office
620 W. Lexington Street, Second Floor
Baltimore, MD 21201
410-706-5037

Health Insurance Portability and Accountability Act (HIPAA)
AUTHORIZATION TO OBTAIN, USE AND DISCLOSE
PROTECTED HEALTH INFORMATION FOR RESEARCH

Name of Study Volunteer: _____

Date of Birth: _____ **Medical Record Number**: _____

NAME OF THIS RESEARCH STUDY: *Patterns and Consequences of Injuries Occurring in Collisions of Vehicles with Modern Occupant Restraint Systems*

UMB IRB APPROVAL NUMBER: *40290*

RESEARCHER'S NAME: *DR. MARGARET LAUERMAN*

RESEARCHER'S CONTACT INFORMATION:

National Study Center for Trauma and EMS
University of Maryland School of Medicine (UMSOM)
110 South Paca Street – 4th Floor
410-328-5085

This research study will use health information that identifies you/your child. If you/your child agree to participate, this researcher will use just the health information listed below.

THE SPECIFIC HEALTH INFORMATION TO BE USED OR SHARED:

- *Health-related information you/your child have been asked to provide for the study during interviews and questionnaires.*
- *Information collected from you/your child's medical records from the University of Maryland Medical Center (UMMC) relating to eligibility for the study and participation in the study including: doctors' notes or summaries, treatments, laboratory results, reports of x-rays and other diagnostic tests.*
- *Health information about you/your child obtained from your clinical care providers.*
- *Information related to the damage sustained by your vehicle in the crash.*

Federal laws require this researcher to protect the privacy of this health information. He/she will share it only with the people and groups described here.

PEOPLE AND ORGANIZATIONS WHO WILL USE OR SHARE THIS INFORMATION:

- UMMC Medical Records staff

- Dr. Lauerman and her research team.
- The National Highway Traffic Safety Administration (NHTSA)
- Investigators conducting similar research at the following institutions: Inova Fairfax Hospital and the University of Virginia, Wake Forest University and Medical Center, Emory University and Grady Memorial Hospital, Medical College of Wisconsin, and the University of Alabama Birmingham.
- Prior to disclosure to any entity outside of the research team at the University of Maryland, all data is sanitized and any identifying names/numbers are removed from the information collected. A Federal Certificate of Confidentiality has been obtained to protect the privacy of research subjects from the involuntary release of their identities to any persons not connected with this research.

THIS AUTHORIZATION WILL NOT EXPIRE. BUT YOU CAN REVOKE IT AT ANY TIME.

To revoke this Authorization, send a letter to this researcher stating your decision. He/she will stop collecting health information about you/your child. This researcher might not allow you/your child to continue in this study. He/she can use or share health information already gathered. The data will be destroyed at the time indicated below:

- There is no scheduled date at which this information will be destroyed or no longer used. This is because information that is collected for research purposes may be analyzed for many more years and it's not possible to determine when analysis will be complete.

ADDITIONAL INFORMATION:

- You can refuse to be in this study. If you refuse, you cannot participate in this study. This will not affect the care you/your child receive at:
    - University Physicians, Inc. (UPI)
    - University of Maryland Medical System (UMMS)

  It will not cause any loss of benefits to which you/your child are otherwise entitled.
- Sometimes, government agencies such as the Food and Drug Administration or the Department of Social Services request copies of health information. The law may require this researcher, the UMSOM, UPI, or UMMS to give it to them.
- This researcher will take reasonable steps to protect your/your child's health information. However, federal protection laws may not apply to people or groups outside the UMSOM, UMB, UPI or UMMS.
- Except for certain special cases, you/your child have the right to a copy of your/your child's health information created during this research study. You may have to wait until the study ends. Ask this research how to get a copy of this information from him/her.