UNIVERSITY of MARYLAND
THE FOUNDING CAMPUS

RESEARCH CONSENT FORM AND HIPAA AUTHORIZATION

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 involving a pedestrian. 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 consent for themselves, the word "you" in this document will refer to the person for whom you are consenting (family member, etc).

CONCISE SUMMARY:
The purpose of this study is to gather information on injuries received by pedestrians involved in motor vehicle crashes. A pedestrian is defined as any person who is on a trafficway or on a sidewalk or path contiguous with a trafficway, or on private property when the crash took place.

You are being asked to be in this research study because you were involved in a crash as a pedestrian.

Taking part in this study is voluntary. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your benefits to which you are otherwise entitled. Leaving the study will not affect your medical care. Please read the information below, and ask questions about anything you do not understand, before deciding whether to take part in the study.

Dr. Lauerman and her associates will conduct this study at the following location(s): University of Maryland Baltimore, Shock Trauma Center, University of Maryland Medical System.

If you are interested in learning more about this study, please continue to read below.

PURPOSE OF STUDY
The purpose of this study is to gather information on injuries received by pedestrians involved in motor vehicle crashes. A pedestrian is defined as any person who is on a trafficway or on a sidewalk or path contiguous with a trafficway, or on private property when the crash took place. Since you were involved in a crash as a pedestrian, we would like to ask you to join this study. A total of, 11,500people at five trauma centers across the country will be asked to participate in this study as either a pedestrian or a vehicle occupant. You will be one of approximately 1,600 people to be asked to participate 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 1,600subjects asked to participate 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 20 to 30 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.

WHAT ARE MY RESPONSIBILITIES IF I TAKE PART IN THIS RESEARCH?

If you take part in this research, you will be responsible to complete all study activities

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.

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 your consent 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.

CAN I BE REMOVED FROM THE RESEARCH?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include failure to follow instructions of the research staff, or the person in charge decides that the research study is no longer in your best interest. The sponsor can also end the research study early. The study doctor will tell you about this and you will have the chance to ask questions if this were to happen.

COSTS TO PARTICIPANTS

There will be no fee to enroll in the study. However, you or your insurance will be billed for costs of medical care that you would have needed or received if you were not in the study.

PAYMENT TO PARTICIPANTS

You will not be paid for taking part in this study.

STUDY-RELATED INJURY

If you have an injury, promptly seek medical care from any healthcare provider. <u>If you have an emergency, call 911 or go to the nearest emergency room</u>. You should tell the healthcare provider that you have participated in a research study.

If you believe the injury is related to the study, notify the study doctor. UMB, if requested, will assist you to get medical care or referrals.

UMB and/or its affiliated healthcare facilities or healthcare providers will not provide any financial compensation or reimbursement to you for the cost of medical care or other expenses arising from an injury.

In such cases, you or your insurance may be billed for the costs of medical care.

UNIVERSITY STATEMENT

The University of Maryland, Baltimore (UMB) is committed to providing participants in its research studies all rights due to them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in this study. This study has been reviewed and approved by an Institutional Review Board (IRB). The IRB is a group of scientists, physicians,

experts, and community representatives. The IRB's membership includes persons who are not affiliated with UMB and persons who do not conduct research studies.

If you have questions, concerns, complaints, or believe you have been harmed through participation in this study as a result of researcher negligence, you can contact members of the IRB or 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
Institutional Review Board
Human Research Protections Office
620 W. Lexington Street, Second Floor
Baltimore, MD 21201
410-706-5037

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

If you agree to participate in this study, please sign your name below.

_____
Participant's Signature

_____
Participant's Name

_____
Date & Time

_____
Legally Authorized Representative Signature (when applicable)

_____
Legally Authorized Representative Name (when applicable)

_____
Relationship to Participant

_____
Date & Time

_____
Signature of Investigator or Designee obtaining Consent

_____
Name of Investigator or Designee obtaining consent

_____
Date & Time

UNIVERSITY of MARYLAND BALTIMORE

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

Name of Study Participant:_____

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

NAME OF THIS RESEARCH STUDY: **Core Protocol for Biomechanics Studies**

UMB IRB APPROVAL NUMBER: **HP-00040290**

RESEARCHER'S NAME: **MARGARET LAUERMAN, MD**

Researcher's Contact Information:
R Adams Cowley Shock Trauma Center
National Study Center for Trauma and EMS
University of Maryland, Baltimore
22 South GreeneStreet
Baltimore, MD 21201
410-328-3587

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

THE SPECIFIC HEALTH INFORMATION TO BE USED OR SHARED:

- Your medical records relating to eligibility for the study and participation in the study including: doctors' and nurses' notes or summaries, records of medications and other treatments.
- Results of physical exams, lab tests, x-ray exams, and other diagnostic and treatment procedures received during normal standard of care.
- Health information about you obtained from your clinical care providers.
- *Billing and payment information and the medical information required for justification.*

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

PEOPLE AND ORGANIZATIONS WHO WILL USE OR SHARE THIS INFORMATION:

- Dr. *Margaret Lauerman* and her research team.

- The sponsor of the study, or its agents, such as data repositories or contract research organizations
- Organization that will coordinate health care billing or compliance such as offices within UMSOM; the University of Maryland, Baltimore (UMB); University of Maryland Faculty Physicians, Inc. (FPI) and the faculty practices of the UMB; University of Maryland Medical System (UMMS)
- *Your health insurer to pay for covered treatments*

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. She will stop collecting health information about you/your loved one. This researcher might not allow you/your loved one to continue in this study. She can use or share health information already gathered.

ADDITIONAL INFORMATION:

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

  It will not cause any loss of benefits to which you/your loved one 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, FPI, UMMS to give it to them.
- This researcher will take reasonable steps to protect your/your loved one's health information. However, federal protection laws may not apply to people or groups outside the UMSOM, UMB, FPI, UMMS.
- Except for certain special cases, you/your loved one have the right to a copy of your/your loved one'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 her.

My signature indicates that I authorize the use and sharing of my/my loved one's protected health information for the purposes described above. I also permit my doctors and other health care providers to share my/my loved one's protected health information with this researcher for the purposes described above.

Signature: _____Date: _____

Name (printed) _____

Privacy Questions? Call the UMSOM Privacy Official (410-706-0337) with questions about your/your loved one's rights and protections under privacy rules.

Other Questions? Call the researcher named on this form with any other questions.