THE UNIVERSITY OF ALABAMA AT BIRMINGHAM
DEPARTMENT OF SURGERY

CONSENT TO PARTICIPATE IN A RESEARCH STUDY
Children/Minors Ages 0-18 Years

Title of Research: Crash Injury Research and Engineering Network (CIREN)

IRB Protocol Number: IRB-100606010

Investigator: Shannon Carroll, MD

Sponsor: National Highway Traffic Safety Administration, U.S. Dept. of Transportation

For Children/Minors (persons under 18 years of age) participating in this study, the term *You* addresses both the participant ("you") and the parent or legally authorized representative ("your child").

Purpose of the Research

Motor vehicle crashes kill and injure thousands of people each year. Today's vehicles have better safety features such as airbags, seatbelts, collapsible steering columns and padding which decrease the amount of force you may experience when you are involved in a crash. Most of the improvements in vehicle safety have been the result of tests done by auto manufacturers using crash dummies to simulate human injuries, as well as reports of injuries which occur in actual crashes. However, there is limited information available which links actual human injuries with exact vehicle crash data. We are asking you to participate in this study to provide information about your involvement in a motor vehicle accident, either as a vehicle occupant or a pedestrian.

The purpose of this study is to relate the physical injury experienced by individuals involved in motor vehicle crashes with the physical damage seen in or on the vehicle. The information gained from this study will ultimately help in the design of better and safer vehicles and help further reduce crash-related injuries and fatalities.
University of Alabama at Birmingham Hospital along with Children's of Alabama is one of six centers that are currently involved with this study. UAB Hospital and Children's Hospital will enroll approximately 65 participants per year into this study.

Explanation of Procedures

The study will consist of an interview in the hospital with a series of questions regarding information about the crash, views about your health and activities, general demographic information and a medical evaluation of injuries as related to the vehicle crash. Photographs of your injuries will be taken as is considered appropriate by your physician. All information that you share with us will be kept strictly confidential. The interview should only require about 20-30 minutes of your time. Your answers to the interview questions will be entered into a database in which you will not be identified with your

answer. Your hospital records, copies of the police accident report recorded following your motor vehicle collision, and EMS (Emergency Medical Services) patient care record will be obtained. A crash investigator will view your vehicle and take measurements and digital images of the vehicle damage. The crash investigator will also attempt to download the data from the event data recorder (EDR) that is located in the vehicle as part of the vehicle inspection process. We will obtain multiple measurements of the affected body part(s), when considered appropriate. In addition, we would like to contact you by telephone for follow-up interviews in 6 and 12 months to ask 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. We will conduct the interview with the legal guardian of children less than seven years old.

Benefits

There are no direct benefits to you for participating in the study. However, your cooperation in answering questions will be of great help in hopefully reducing the effects of vehicular trauma in the future.

Risks and Discomforts

There are no known risks for participating in this study. There is the possibility that you may become upset when you talk about the crash and your injuries. Should that occur, a social worker and/or chaplain is available to you free of charge for counseling. Although we maintain strict guidelines to maintain confidentiality, there is always a potential risk for loss of confidentiality.

Alternatives

Your treatment will not be changed in any manner by participation in this study.

Confidentiality

Information obtained about you for this study will be kept confidential to the extent allowed by law. However, research information that identifies you may be shared with people or organizations for quality assurance or data analysis, or with those responsible for ensuring compliance with laws and regulations related to research. They include:

- the UAB Institutional Review Board (IRB). An IRB is a group that reviews the study to protect the rights and welfare of research participants.
- The National Highway Traffic Safety Administration (NHTSA)
- the Food and Drug Administration (FDA)
- the Office for Human Research Protections (OHRP)

The information from the research may be published for scientific purposes; however, your identity will not be given out.

Your consent form will be placed in your medical record at UAB Health System or Children's of Alabama. This may include either a paper medical record or electronic medical record (EMR). An EMR is an electronic version of a paper medical record of your care within this health system. Your EMR may indicate that you are on a clinical trial and provide the name and contact information for the principal investigator.

If you are receiving care or have received care within this health system (outpatient or inpatient) and are participating in a research study, results of research tests or procedures (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing medical record.

If you have never received care within this health system (outpatient or inpatient) and are participating in a research study, a medical record will be created for you to maintain results of research tests or procedures.

Results of research tests or procedures may be placed in your medical record. All information within your medical record can be viewed by individuals authorized to access the record.

Voluntary Participation and Withdrawal
Your participation in this study is your choice. There will be no penalty if you decide not to be in the study. If you decide not to be in the study, you will not lose any benefits you are otherwise owed. You are free to withdraw from this research study at any time. Your choice to leave the study will not affect your relationship with this institution.

Costs of Participation
There will be no cost to you for participating in this study. You will not incur any extra costs for anything specifically related for this study. The costs of your standard medical care will be billed to you or your insurance company in the usual manner.

Payment for Participation in Research
There will be no compensation paid directly to you for participating in this study.

Significant New Findings
You will be told by your doctor or his staff if new information becomes available that might affect your choice to stay in the study.

Questions
If you have any questions, concerns, or complaints about the research, please contact Dr. Shannon Carroll. She will be glad to answer any of your questions. Dr. Carroll's phone number is 205-975-5427. Dr. Carroll may also be reached after hours by paging her at 205-934-3411.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday.

Legal Rights
You are not waiving any of your legal rights by signing this consent form.

Signatures

You are making a decision whether or not to have your child participate in this study. Your signature indicates that you have read (or been read) the information provided above and decided to allow your child to participate.

Signature of Participant 14 Years of Age and Older	Date
Signature of Parent or Guardian	Date
Signature of Investigator or Person Obtaining Consent	Date

Waiver of Assent

The assent of _____ (name of child/minor) was waived because of:

Age _____ Maturity _____ Psychological state of the child _____

Decisionally Impaired due to injuries _____

University of Alabama at Birmingham
AUTHORIZATION FOR USE/DISCLOSURE OF PROTECTED HEALTH INFORMATION (PHI) FOR RESEARCH

Participant Name: _____
Research Protocol: Crash Injury Research: Patterns and Consequences of Injuries Occurring in Motor Vehicle Collisions

UAB IRB Protocol Number: IRB-100606010
Principal Investigator: Shannon Carroll, MD
Sponsor: National Highway Traffic Safety Administration, U.S. Dept. of Transportation

What is the purpose of this form? You are being asked to sign this form so that UAB may use and release your protected health information for research. Participation in research is voluntary. If you choose to participate in the research, you must sign this form so that your protected health information may be used for the research.

Why do the researchers want my protected health information? The researchers want to use your protected health information as part of the research protocol listed above and as described to you in the informed consent.

What protected health information do the researchers want to use? All medical information, including but not limited to information and/or records of any diagnosis or treatment of disease or condition, which may include sexually transmitted diseases (e.g., HIV, etc.) or communicable diseases, drug/alcohol dependency, etc.; all personal identifiers, including but not limited to your name, social security number, medical record number, date of birth, dates of service, etc.; any past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of whatever kind, including but not limited to drug/alcohol treatment, psychiatric/psychological treatment; financial/billing information, including but not limited to copies of your medical bills, and any other information related to or collected for use in the research protocol, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes.

Who will disclose, use and/or receive my protected health information? All Individuals/entities listed in the informed consent documents, including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at UAB or elsewhere); other operating units of UAB, HSF, UAB Highlands, Children's of Alabama, Eye Foundation Hospital, and the Jefferson County Department of Health, as necessary for their operations; the IRB and its staff; the sponsor of the research and its employees and agents, including any CRO; and any outside regulatory agencies, such as the Food and Drug Administration, providing oversight or performing other legal and/or regulatory functions for which access to participant information is required.

How will my protected health information be protected once it is given to others? Your protected health information that is given to the study sponsor will remain private to the extent possible, even though the study sponsor is not required to follow the federal privacy laws. However, once your information is given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected.

How long will this Authorization last? Your authorization for the uses and disclosures described in this Authorization does not have an expiration date.

Can I cancel this Authorization? You may cancel this Authorization at any time by notifying the Principal Investigator, in writing, referencing the research protocol and IRB Protocol Number. If you cancel this Authorization, the study doctor and staff will not use any new health information for research. However, researchers may continue to use the protected health information that was provided before you cancelled your authorization.

Can I see my protected health information? You have a right to request to see your protected health information. However, to ensure the scientific integrity of the research, you will not be able to review the research information until after the research protocol has been completed.

Signature of participant: _____ Date: _____
or participant's legally authorized representative: _____ Date: _____
Printed Name of participant's representative: _____
Relationship to the participant: _____