Wake Forest School of Medicine

Department of Biomedical Engineering

INFORMED CONSENT FORM TO PARTICIPATE IN RESEARCH:

Crash Injury Research and Engineering Network (CIREN):

A Study to Correlate Crash Data by Matching Human Injuries with Vehicular Damage

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Joel D. Stitzel, PhD, Co-Principal Investigator

INTRODUCTION

You, or your minor child (if applicable; less than 18 years of age), are invited to participate in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You, or your minor child (if applicable), may or may not receive any benefit from being part of the study. You, or your minor child (if applicable), are being asked to take part in this study because you were involved in a motor vehicle crash as either a vehicle occupant or as a pedestrian. Your participation is voluntary. Please take your time to make your decision, and ask your study doctor or the study staff to explain any words or information that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING PERFORMED?

Motor vehicle crashes kill and injure thousands of people each year. Today's vehicles have better safety features such as air bags, seatbelts, collapsible steering columns, and crash avoidance systems, 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. This study will provide that information.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Approximately 900 individuals will take part in this study at the Wake Forest University Health Science's CIREN Center. The study is funded annually by the National Highway Traffic Safety Administration (NHTSA) for an average of 40 participants per year.

WHAT IS INVOLVED IN THE STUDY?

Our study will not perform experimental procedures or medical interventions on you, or your minor child (if applicable), or your vehicle (if applicable) – we only collect information. You will receive standard medical care for your injuries. This research study will match actual injuries with vehicle crash data after all data are available. Information about you or your minor child (if applicable), your injuries, and the crash will be obtained from you and from your medical records. This information includes your prehospital record from the ambulance or helicopter, police reports about your crash, and pictures of you that show only your injuries, but do not identify you. Digital photographs are routinely taken of trauma patient injuries to use for clinical purposes, just as x-rays and other scanning procedures, for diagnostics, treatment evaluation, to facilitate patient care at morning rounds, and for quality assurance reviews. Photographs will also be taken of your vehicle (if applicable) and the crash site. All photographs will be de-identified so that your identity, your vehicle, and the crash location will not be revealed.

- I hereby authorize the CIREN study team to use these injury photographs and to store these de-identified photographs in a computer database.

The research team may take some measurements such as the length of your leg and the distance from your knee to your foot, in order to determine your general position relative to the vehicle and the distance you were from any intruding parts. You may be asked some general questions regarding what you might recall about the crash sequence, such as your position during the crash, weather conditions, restraint status, and vehicle information.
The vehicle crash data will be obtained by a certified crash investigator who will record measurements and take pictures of the vehicle and the place where your crash occurred. Data from an Event Data Recorder (EDR) may be downloaded and used in the study, if the vehicle is so equipped. The EDR is an electronic device located on the vehicle that records last second information from the vehicle immediately before the crash occurred, such as speed, brake position, air bag deployment, seat belt usage, and other information. Your personal identification information will not be associated with the EDR data.

- I give consent for the Crash Investigator, licensed by the National Highway Traffic Safety Administration (NHTSA), or the CIREN research staff to obtain copies of any and all written reports related to this collision from the State Police, State Highway Patrol, Sheriff's Department, County Police, Municipal Police or any other governmental entity or contract agency working for the governmental entity of the location of the crash which is responsible for completing a report of this collision, whether it be computer-generated or written in hard copy.

HOW LONG WILL I BE IN THE STUDY?

You, or your minor child (if applicable), will be involved in the study for the amount of time it takes to obtain all of the necessary information, which is typically collected during an interview lasting less than an hour.

WHAT ARE THE RISKS OF THE STUDY?

Being in this study involves some minor risk to you, or your minor child (if applicable). Potential risks or discomforts associated with this study include the possibility that you may become upset when you talk about the crash and your injuries. A social worker will be available during the time you are in the hospital. There also may be other side effects that we cannot predict. The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests. You should discuss the risk of being in this study with the study staff.

Taking part in this research study may involve providing information that you consider confidential or private. Procedures are in place to keep your information safe, including de-identifying research records, keeping research records secure, and allowing only authorized CIREN research staff to have access to research records.

Reproductive risks: None - all women are eligible to participate in this study.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

You, or your minor child (if applicable), are not expected to receive any direct benefit from taking part in this research 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 your de-identified information about your injuries and crash, can use this data to make safety changes to automobiles in the future, thereby saving lives and preventing injuries.

WHAT OTHER CHOICES ARE THERE?

You, or your minor child (if applicable), do not have to participate in this study to receive medical treatment. This is not a treatment study. Your alternative is to not participate in this study.

WHAT ABOUT THE USE, DISCLOSURE AND CONFIDENTIALITY OF HEALTH INFORMATION?

By taking part in this research study, your personal health information, or of your minor child (if applicable), as well as information that directly identifies you or your minor child, may be used and disclosed. Information that identifies you includes, but is not

limited to: your name, address, telephone number, and date of birth. Your personal health information includes all information about you that is collected or created during the study for research purposes. It also includes your personal health information that is related to this study and that is maintained in your medical records at this institution and at other places such as other hospitals and clinics where you may have received medical care. Examples of your personal health information include your health history, your family health history, how you respond to study activities or procedures, laboratory and other test results, medical images, and information from study visits, phone calls, surveys, and physical examinations.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being performed correctly, and to provide required reports.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and Wake Forest Baptist Medical Center; representatives from government agencies such as the Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS), and the National Highway Traffic Safety Administration.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. However, all data that are collected about your case and involvement in this study will be de-identified before it is sent outside Wake Forest Baptist Medical Center to the national database. Information stored in the national database will not contain data that could be used to identify you, therefore the potential for re-disclosure of personal information is non-existent. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study.

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. The Certificate of Confidentiality will not be used to prevent disclosure to local

authorities of child abuse and neglect, or harm to self or others. 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.

When you sign this consent and authorization form you authorize or give permission for the use of your health information as described in the consent form. This authorization is valid for six years or five years after the completion of the study, whichever is longer.
You can revoke or take away your authorization to use and disclose your health information at any time. You do this by sending a written notice to the investigator in charge of the study at the following address:

R. Shayn Martin, MD, Co-Principal Investigator
Joel D. Stitzel, PhD, Co-Principal Investigator
Wake Forest University Health Sciences
Medical Center Blvd. Winston-Salem, NC 27157

If you withdraw your authorization you will not be able to be in this study. If you withdraw your authorization, no new health information that identifies you will be gathered after that date. Your health information that has already been gathered may still be used and disclosed to others. This would be performed if it were necessary for the research to be reliable. You will not have access to your health information that is included in the research study records until the end of the study.

WHAT ARE THE COSTS?

There are no costs to you for taking part in this study. All the study costs related directly to the study will be paid by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

WILL YOU BE PAID FOR PARTICIPATING?

No, you will not receive money for being in this study.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by the National Highway Traffic Safety Administration (NHTSA), a Federal agency under the Department of Transportation (DOT). The sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. The investigators also have the right to stop your participation in the study at any time. This could be because new information could indicate you do not meet study inclusion criteria. You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

WHO DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, Dr. Joel Stitzel at 336-716-5597.

The Institutional Review Board (IRB) is a group of people who review and approve the research plan to protect your rights. If you have a question about your rights as a research participant, you should contact the Chair of the IRB at (336) 716-4542.

You will be given a signed copy of this consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (printed) _____

Subject Signature_____date_____time_____am pm

Person Obtaining Consent (printed)_____date_____time_____am pm

Person Obtaining Consent:_____ date:_____ time:_____ am pm

WFU School of Medicine
Institutional Review Board
IRB Number:BG05-483
Meeting Date Approved 7/11/2023
Version Valid Until: 7/10/2024

Legally authorized representative name (printed) _____

Relationship to research subject _____

The above named legally authorized representative has legal authority to act for the research subject based upon (specify health care power of attorney, spouse, parent, etc.):

_____

Legally authorized representative

Signature_____date_____time_____am pm

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Minor Child Subject Name (printed): _____

Minor Child Parent Name (printed): _____

I agree to allow my minor child to take part in this study. I authorize the use and disclosure of his/her health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about my minor child being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Parent Signature_____date_____time_____am pm

Person Obtaining Consent (printed)_____date_____time_____am pm

Person Obtaining Consent:_____ date:_____ time:_____ am pm

WFU School of Medicine
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Legally authorized representative name (printed) _____

Relationship to minor child research subject: _____

The above named legally authorized representative has legal authority to act for the research subject based upon (specify health care power of attorney, spouse, parent, etc.):

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Signature_____date_____time_____am
pm