Wake Forest School of Medicine

Atrium Health

Department of Biomedical Engineering

INFORMED CONSENT FORM TO PARTICIPATE IN RESEARCH:

Vehicle access and event data recorder authorization for:

Crash Injury Research and Engineering Network (CIREN):

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

R. Shayn Martin, MD, Co-Principal Investigator (Wake Forest)

Joel D. Stitzel, PhD, Co-Principal Investigator (Wake Forest)

Addison K. May, MD, Co-Investigator (Carolinas Medical Center)

INTRODUCTION

CIREN is the Crash Injury Research and Engineering Network center at Wake Forest University School of Medicine, under the policies and regulations of the National Highway Traffic Safety Administration (NHTSA), US Department of Transportation (DOT). Seven CIREN centers across the country form a network of Level One trauma centers to conduct motor vehicle crash investigations in order to conduct research that will improve the prevention, treatment, and rehabilitation of crash injuries, and to reduce the deaths, disabilities, and economic costs of these crashes. The data from the affected motor vehicle crashes and medical records will be collected and stored at NHTSA's secure location. All personally identifiable information will be removed from the data before storage.

WHAT IS INVOLVED IN THE STUDY?

You are being asked to participate in the CIREN research study because your vehicle was involved in a collision. The purpose of the study is to collect information about vehicles and individuals who have been injured in crashes in order to help researchers find ways to improve vehicle safety. The study includes the following procedures to investigate the vehicle:

- Your vehicle will be accessed to measure and photograph evidence and impacts to help investigators determine what happened in the crash.
- The crash investigator might disassemble damaged interior trim, panels, covers, and seats so that damage to concealed structural members, compressed shear capsules, seat-back frames, and seat pans can be photographed and documented.

- Data will be electronically downloaded from the event data recorder (EDR), if the vehicle is so equipped. The EDR is an electronic device located on the vehicle whose purpose is to determine which safety systems should be activated in a crash. The EDR monitors sensors in the vehicle relevant to a crash, such as belt use, travel speed, and brake activation, and then makes decisions as to which safety systems are deployed. This information aids the crash investigator in creating an accurate reconstruction while learning essential information regarding the vehicle's safety performance. Accessing the EDR may require removing small pieces of interior trim from the vehicle, which will be reinstalled by the crash investigator. The EDR device will not be physically removed in most circumstances. On rare occasions, excessive damage to the vehicle's electrical system will require EDR module removal to access the data. In this event, the module will be returned after downloading if requested.

Note: No personal identification information is associated with the EDR data. Any personal identifying information is removed automatically when downloading the data.

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

When you sign this consent and authorization form you authorize or give permission for the use of your vehicle information as described in the consent form. Note: no personal health information is collected during the of vehicle inspection processes described within this document. 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 vehicle information at any time. You do this by sending a written notice to the investigators 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

Addison K. May, MD, Co-Investigator
Atrium Health Carolinas Medical Center
1000 Blythe Blvd.
Charlotte, NC 28203

SIGNATURES

- I agree to take part in this study and authorize the crash investigator to access my vehicle to take measurements and photographs.

- I authorize the CIREN study team to download data from the event data recorder located on my vehicle, and if necessary, to remove and send the recorder to a laboratory to download the data.

- I authorize the study team to temporarily remove and reinstall parts of my vehicle to access the event data recorder and to inspect other structural components of my vehicle.

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.

Vehicle year, make, and model: _____

Vehicle owner name (printed):_____

Vehicle owner signature:_____date_____time_____am pm

Person obtaining consent (printed):_____date_____time_____am pm

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

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Legally authorized representative name (printed) _____

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

Legally authorized representative
Signature_____date_____time_____am pm

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