

Informed Consent for a Research Study

TITLE: Patterns and Consequences of Injuries Occurring in Collisions of Vehicles with Modern Occupant Protection Systems (CIREN)

PROTOCOL NO.: 15-2001
IRB Protocol #20204318
15-2001

SPONSOR: National Highway Traffic Safety Administration (NHTSA)

INVESTIGATOR: Elizabeth Franco, MD
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**STUDY-RELATED
PHONE NUMBER(S):** 703-776-2274

In this consent form, “you” always refers to the subject. If you are a parent or guardian, or legally authorized representative, please remember that “you” refers to the study subject.

Introduction

You may be eligible to take part in a research study because you were injured in a motor vehicle crash. The purpose of this study is to gather information on injuries received by occupants of motor vehicles involved in crashes. It is hoped that we will learn how to reduce the severity of motor vehicle injuries by improved vehicle design once we are able to correlate different types of injuries with identifiable features of the crash, treatment at the scene, and medical care provided following the trauma.

This research consent form gives you important information about the study. It explains why this research study is being done, what is involved in participating in the research study, the possible risk and benefits of participation, choices for participation and your rights as a research participant. Please take your time to review this information carefully. You may also wish to talk to others (for example, your family, friends, or other doctors) about your participation. The decision to participate is yours.

You may leave the study at any time without losing any benefits you would have normally received. If you decide to take part in the study, you will be asked to initial each page and sign and date at the end of this form. We will give you a copy of the form so that you can refer to it while you are involved in this research study. We encourage you to ask questions now and at any time in the future.

The investigator (person in charge of this research study) is Elizabeth Franco, MD.

What is the purpose this study?

The purpose of the research at Inova Fairfax Hospital is to determine how a vehicle and its occupant move during a crash and to determine how different safety features of motor vehicles affect the injuries people receive. The ultimate goal is to improve the design of vehicles and the care of patients involved in motor vehicle crashes in order to improve the prevention, treatment and rehabilitation of motor vehicle crash injuries. It also hopes to reduce the death, disability and human and economic costs of motor vehicle injuries by these improvements.

How long will I be in this study?

If you agree to participate you will be interviewed as outlined below. Your total participation time in the hospital once you have finished reading this form should take no more than 30 minutes. Your telephone interviews will take place at 6 and 12 months after you crash and should take no more than 20 minutes each.

You can refuse to participate or stop participating at any time without penalty or loss of benefits to which you are otherwise entitled. Your decision to participate is completely voluntary. You are not waiving any legal claims or rights because of your participation in this study.

What will happen if I take part in this research study?

The study will consist of a patient interview in the hospital with a series of questions regarding information about the crash, views about your health and activities, your use of alcohol and drugs, general information, and a medical evaluation of injuries as related to the vehicle crash.

The research staff will have access to your medical record to obtain information about your injury. You will also be asked questions and your cooperation in answering questions will be of great help in providing services to families of other trauma patients. The interview should require approximately 20 to 30 minutes of your time. Information on the nature of your injuries will be recorded and photographs of injuries will be taken, if possible. Information on the hospital and professional charges during your hospital stay will also be recorded, as will detailed information about the crash. In addition, we would like to contact you by telephone for follow-up interviews in 6 and 12 months. Again, you will be asked questions 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.

VEHICLE OWNERS

If you are also the vehicle owner we are asking you to authorize an accident reconstruction specialist to inspect your vehicle and take measurements and pictures. This person is an employee of the CIREN research project and is not affiliated with any outside legal or law enforcement agency. The information they will collect is only for use in this research project and will be entered into a confidential database.

In some cases members of the local police department may have already inspected your vehicle. If this is the case, we are asking you, as owner of the vehicle, to also authorize the release of any data obtained by the local law enforcement agency during their routine investigation. If you agree to make this information available to us, this information will be entered into a confidential database.

You will be asked to answer some questions about your vehicle. The questions will ask you if the vehicle has been in a crash before, and if so what alterations have been made to the vehicle. You will also need to provide the researchers with the current location (tow lot site) of the vehicle if you know it.

What risks can I expect from being in the study?

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. There is also a risk of breach of confidentiality; however, the study team will take steps to minimize this risk.

Are there benefits to taking part in this study?

If you agree to take part in this study, there may or may not be direct benefit to you. However, your participation will enable the researchers to get a clearer picture of how motor vehicle injuries occur and how they may be prevented in the future. We hope the information learned from this study will benefit others in the future.

CONFIDENTIALITY

The researchers at Inova Fairfax Hospital 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.

Will my medical information be kept private?

Any information gathered from you will be identified by a random number and will remain as confidential as permitted by law. You will not be identified by name.

Efforts will be made to protect your personal information to the extent allowed by law. Medical records and research material of research study participants are stored and kept according to legal requirements. You will not be identified in any reports or publications resulting from this study. The sponsor of the study, government regulatory authorities, Human Research Protection Program, Institutional Review Board (IRB) may request, inspect and/or copy your research and medical records

for quality assurance and data analysis. Members of the research team will also have access to your research records.

You understand that your patient photographs, X-rays, CT-scans, MRIs, and detailed medical information and/or history (e.g., surgical procedures and medical treatment, pre-existing medical conditions, laboratory results) will be entered into a database that will be accessible to trauma centers that are CIREN participants and their funding private sector partners, NHSTA, and Volpe. Further, you understand that NHSTA may authorize access to this data by others for limited research purposes and that NHTSA will protect all sensitive medical information residing on the CIREN database from public dissemination to the full extent authorized by 5 USC 552.

What are the costs of taking part in this study?

You will not be responsible for any of the costs of the procedures related to the study. You will not be paid for your participation in this study. The results from this study may lead to new commercial products or tests. If this happens you will not receive any compensation.

What other choices do I have if I do not take part in this study?

This is not a treatment study. Your alternative is to not participate. Taking part in this study is voluntary. You may choose not to take part in or leave the study at any time. If you choose to not take part in or to leave the study, your medical care will not be affected and you will not lose any of the benefits you would have received normally.

You will be told about new information that may affect your health, welfare, or participation in this study.

What if I am injured because I took part in this study?

If you believe you have been injured as a direct result of participating in this study, treatment will be provided. You should contact the Principal Investigator, Elizabeth Franco, MD, at 703-776-2274. The charges for any medical treatment you receive will be billed to you or your insurance carrier. You will be responsible for any amount your insurance does not cover.

Inova and the study doctor do not routinely provide funds or free medical treatment for injuries that result from taking part in this study. There are no plans to pay you for lost wages, disability, or discomfort. However, by signing this form you have not given up any of your legal rights.

Who can answer my questions about the study?

Please ask any questions or concerns you have about the study now. Should you have any questions, concerns, or complaints related to the study, any injury, or bad effect, you should immediately contact the Principal Investigator. Should you have any problem or question that may arise in connection with this study or with regard to your rights as a participant in research, you may contact **Dr. Elizabeth Franco** at **(703) 776-2274**.

You should know that Inova Fairfax Hospital, and Dr. Franco as the primary investigator, are being reimbursed by the sponsor to cover the cost to conduct this research study.

This research is being overseen by WCG IRB. An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289 or researchquestions@wcgirb.com if:

- ☐ You have questions, concerns, or complaints that are not being answered by the research team.
- ☐ You are not getting answers from the research team.
- ☐ You cannot reach the research team.
- ☐ You want to talk to someone else about the research.
- ☐ You have questions about your rights as a research subject.

If you would like more information about your rights as a participant in a research study, contact the Human Research Protection Office (HRPO) at (888) 534-6682. The HRPO may contact you by mail or telephone to find out if you were satisfied with your study participation.

Signature Page

- All adult subjects and children unable to consent are required to assent, unless the investigator determines that the capability of the subject is so limited that the subject cannot reasonably be consulted.
- If assent is obtained, have the person obtaining assent document assent on the consent form.

As a member of the research team, I have explained the purpose, the procedures, the benefits and risks that are involved in this research study. Any questions that have been raised have been answered to the individual's satisfaction.

Signature of Person Obtaining Consent* Printed Name Date

You, the undersigned have been informed about this study's purpose, procedures, possible benefits and risks, and you have read this consent and received a copy of this consent. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask other questions at any time. You voluntarily agree to give your consent to participate in this research study.

You are free to withdraw from the study at any time and you do not have to say why you no longer wish to participate. You will notify the Principal Investigator if you are leaving the study because of any side effects you might experience. This withdrawal will not in any way affect your future treatment or medical management. You agree to cooperate with Elizabeth Franco, MD, and the research staff and to inform them immediately if you experience any unexpected or unusual symptoms.

Signature of Subject Date

Printed Name of Subject

Signature of Legally Authorized Representative (When applicable)
or Parent/Legal Guardian Date

Printed Name of Legally Authorized Representative or Parent/Legal Guardian and Relationship to Participant

**The following witness lines may be left blank, unless an impartial witness is required.*

An impartial witness, who is a witness to the informed consent process that is not involved in the conduct of the research, is required when a non-English speaking subject is encountered, an interpreter is used and consent is documented through the use of a short form or when the subject cannot read the consent form.

Signature of Witness

Printed Name of Witness

Date

Documentation of assent if subject is a child or adult who requires consent via legally authorized representative:

☐ I have explained the study to the extent compatible with the subject's capability, and the subject has agreed to be in the study.

OR

☐ The subject is not able to assent because the capability of the subject is so limited that the subject cannot reasonably be consulted.

Signature of person obtaining assent

Date