You Are Being Asked to Be in a Research Study

Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study you will be one of 250 people who are being studied, at Emory.

Why is this study being done?

This study is being done to collect data to improve the crash safety of vehicles so that vehicle occupants and others involved in crashes, like bicyclists and pedestrians, are better protected. You are being asked to be in this research study because you have been involved in a motor vehicle crash and have injuries that are of research interest.

Do you have to be in the study?

It is your choice to join this research study. You do not have to be in it. Your choice will not affect your access to medical care for your condition. Before you choose, take time to learn about the study.

What do you have to do if you choose to join this study?

If you qualify and choose to join the study, you will be asked for permission to access your medical records to collect information on your treatment and medical history. You will be asked to provide information on the crash. You will be asked for your permission to access your vehicle, including downloading the on-board event data recorder, if one is present. You will be asked to allow a trained investigator to take photographs of your injuries and a small number of basic measurements of body dimensions. The in-person interview should take no more than one hour. Study staff may need to follow back up with you at a later time to confirm details about your crash and will request permission to contact you.

How is this study going to help you?

If you are in the study, you will be helping the researchers answer the study question. The study is not designed to benefit you directly. This study is designed to learn more about the cause of injuries in motor-vehicle crashes and the treatment of people injured in crashes. The study results may be used to help others in the future.

What are the risks or discomforts you should know about before deciding?

The study will take time. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious. Risks for this study include:

- loss of privacy
- breach of confidentiality
- emotional distress associated with discussing crash events

You can find a full list of expected risks, their frequency and severity in the section titled "What are the possible risks and discomforts?"

Alternatives to Joining This Study
Since this is not a treatment study, the alternative is not to participate.

Costs
There will be no costs to you for participating in this study. You will not be charged for any of the research activities.

There is more information in the "Costs" section further below.

What Should You Do Next?
Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions such as how much time you will have to spend on the study, any words you do not understand and more details about study procedures. Make sure you understand. Take time to think about this and talk about it with your family and friends.

Emory University and Grady Health System
Consent to be a Research Subject / HIPAA Authorization

Title: Crash Investigation Research and Engineering Network (CIREN), Emory/Grady Center

IRB #: STUDY00005031

Principal Investigator: Jonathan Rupp, Ph.D., Emory Department of Emergency Medicine

Sponsor: United States Department of Transportation, National Highway Traffic Safety Administration (NHTSA)

If you are the legal guardian of a child who is being asked to participate, the term "you" refers to the child.

Introduction
You are being asked to be in a medical research study. This form tells you what you need to think about before you choose if you want to join the study. **It is your choice. If you choose to join, you can change your mind later and leave the study.** Your choice will not cause you to lose any medical benefits. If you choose not to join this study, your doctor will still treat you.

Before you decide:
- Read this form or have it read to you
- Listen to the study doctor or study staff explain the study to you
- Ask questions about anything that is not clear

You will get a copy of this form. Take your time to think about joining the study. You may wish to discuss it with family or friends. Do not sign this form if you still have questions or something does not make sense to you. By signing this form, you will not give up any legal rights.

What is the purpose of this study?
The purpose of this study is to collect data that can be used to improve the crash safety of vehicles so that vehicle occupants and others involved in crashes, like bicyclists and pedestrians, are better protected. The data that we collect from you or your child data will be combined with data from other people involved in motor-vehicle crashes and used by researchers and the National Highway Traffic Safety Administration to study injury trends in crashes and to support research and rulemaking efforts to improve vehicle safety. You are being asked to join this study because you have been identified as being involved in a motor vehicle crash either as a case occupant or pedestrian and have injuries that are of research interest.

What will you be asked to do?
You will be asked for permission to access your medical records to collect information on your treatment and medical history. You will be asked to provide information on the crash. You will be asked for your permission to access your vehicle, including downloading the on-board event data recorder, if one is present. You will also be asked for permission for study personnel to contact you after discharge to discuss your crash. Lastly, you will be asked to allow a trained investigator to take photographs of your injuries and make a small number of basic measurements of body dimensions. The in-person interview should take no more than one hour. Study staff may need to follow back up with you at a later time to confirm details about your crash and will request permission to contact you. None of these procedures will be paid for by the study.

Who owns your study data and samples?

If you join this study, you will be donating your study information. You will not be paid if your data is used to make a new product. If you leave the study, the data that was already collected may still be used for this study. After enrollment all study data will be sanitized of any personally identifiable information and uploaded into a national database. Once the data has been entered into the database it cannot be removed.

What are the possible risks and discomforts?

There may be side effects from the study procedures that are not known at this time.
The most common risks and discomforts expected in this study are:

- Emotional distress associated with discussing crash events

The less common risks and discomforts expected in this study are:

- Accidental breach of confidentiality

Will you benefit from the study?

You may not benefit from joining the study. The study results may be used to help others in the future.

Will you be paid for your time and effort?

You will not be compensated for being in this study.

What are your other options?

If you decide not to enter this study, your care will not be affected.

How will your private information be protected?

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Certificate of Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory and Grady Health System will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory and Grady Health System received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory and Grady Health System from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.

Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

Storing and Sharing your Information

We will store all the data that you provide using a code. We need this code so that we can keep track of your data over time. This code will not include information that can identify you (identifiers). Specifically, it will not include your name, initials, date of birth, or medical record number. We will keep a file that links this code to your identifiers in a secure location separate from the data.

We will not allow your name and any other fact that might point to you to appear when we present or publish the results of this study.

Your data may be useful for other research being done by investigators at Emory and Grady Health System or elsewhere. We may share the data, linked by the study code, with other researchers at Emory and Grady Health System, or with researchers at other institutions that maintain at least the same level of data security that we maintain at Emory and Grady Health System. We will not share the link between the study code and your identity.

We may also place data in public databases accessible to researchers who agree to maintain data confidentiality, if we remove the study code and make sure the data are anonymized to a level that we believe that it is highly unlikely that anyone could identify you. Despite these measures, we cannot guarantee anonymity of your personal data.

Returning Results to Participants/Incidental Findings

The study team includes a certified radiologist who works for Emory University and Grady Memorial Hospital. As part of the research process, they will be reviewing the radiological images you had taken while admitted as a patient. If they find any incidental findings that may be critical to your health, it will be reported and a staff member from Grady Memorial Hospital will reach out to you about follow up.

Medical Record

If you have been an Emory and Grady Health System patient before, then you already have an Emory and Grady Health System medical record. If you have never been an Emory and Grady Health System patient, you do not have one. An Emory and Grady Health System medical record will be made for you if an Emory Atlanta and Grady Health System provider or facility gives you any services or procedures for this study.

Emory and Grady Health System may create study information about you that can help with your care. For example, the results of study tests or procedures. These study results will be put in your Emory and Grady Health System medical record. Anyone who has access to your medical records will be able to have access to all the study information placed there. The confidentiality of the study information in your medical record will be protected by laws like the HIPAA privacy rule. State and federal laws may not protect the research information from disclosure.

Tests and procedures done at non-Emory and Grady Health System places may not become part of your Emory and Grady Health System medical record. Also, if you decide to be in this study, it is up to you to let your other health providers know.

In Case of Injury

If you believe you have become ill or injured from this research, you should contact Dr. David Wright at telephone number 404-778-1709. You should also let any health care provider who treats you know that you are in a research study.

If you get ill or injured from being in the study, Emory and Grady Health System will help you to get medical treatment. Neither Emory and Grady Health System nor the sponsor have set aside money to pay for this medical treatment. Your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurance does not pay, then you will have to pay these costs.

For Emory and Grady Health System, the only exception is if it is proven that your injury or illness is directly caused by the negligence of an Emory and Grady Health System employee. "Negligence" is the failure to follow a standard duty of care. You do not give up any legal rights you may have by being in this study, including any right to bring a claim for negligence.

Costs

There will be no costs to you for participating in this study. You will not be charged for any of the research activities.

Withdrawal from the Study

You have the right to leave a study at any time without penalty.

The researchers also have the right to take you out of the study without your consent for any reason. They may do this if they believe it is in your best interest or if you do not agree to changes that may be made in the study.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for the study.

PHI that Will be Used/Disclosed:

The PHI that we will use or share for the main research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.
- Information about your vehicle, including VIN
- Your driver's license number
- Photographs of your external injuries
- A copy of your consent form

Purposes for Which Your PHI Will be Used/Disclosed:

We will use and share your PHI for the conduct and oversight of the research study and for future studies that are covered by this consent and authorization. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional

Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information. A copy of your consent form may also be disclosed as part of the process for obtaining access to your vehicle.

Use and Disclosure of Your Information That is Required by Law:
We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests or orders that require us to disclose your PHI. These include subpoenas or court orders.

Authorization to Use PHI is Required to Participate:
By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form to authorize the use and disclosure of your PHI. If you do not sign this form, then you may not participate in the research study.

People Who will Use/Disclose Your PHI:
The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study
- Emory and Grady Health System may use and disclose your PHI to run normal business operations.
- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- The National Highway Traffic Safety Administration is the Sponsor of the study. The Sponsor may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- The research team and the Sponsor may use and disclose your PHI, including disclosure to insurance carriers to obtain access to your vehicle.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory and Grady Health System offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Grady Research Oversight Committee, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Government agencies that regulate the research including: Office for Human Research Protections; The National Highway Traffic Safety Administration
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your PHI may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

Expiration of Your Authorization
Your PHI will be used until this research study ends.

Revoking Your Authorization

If you sign this form, at any time later you may revoke (take back) your permission to use your information using a form letter that will be provided to you as part of the consent process. If you want to do this, you must contact the study team at:

Emory/Grady CIREN Study Team
Department of Emergency Medicine
49 Jesse Hill JR DR SE
Atlanta, GA 30303

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data is correct. If you revoke your authorization you will not be able to stay in the study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them. The Sponsor, and people and companies working with the Sponsor on this study are not covered by the Privacy Rules. They will only use and disclose your information as described in this Consent and Authorization.

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information

If you have questions about the study procedures, appointments, research-related injuries or bad reactions, or other questions or concerns about the research or your part in it, contact Dr. Jonathan Rupp at 404-251-8851

This study has been reviewed by an ethics committee to ensure the protection of research participants. If you have questions about your **rights as a research participant**, or if you have **complaints** about the research or an issue you would rather discuss with someone outside the research team, contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu.

To tell the IRB about your experience as a research participant, fill out the Research Participant Survey at https://tinyurl.com/ycewgkke.

If you are a patient receiving care from the Grady Health System and have a question about your rights, you may contact the Office of Research Administration at research@gmh.edu.

Consent and Authorization

TO BE FILLED OUT BY SUBJECT ONLY

Print your name, **sign**, and **date** below if you choose to be in this research study. You will not give up any of your legal rights by signing this form. We will give you a copy of the signed form to keep.

_____

Name of Subject

_____ _____

Signature of Subject (18 or older and able to consent) **Date** **Time**

_____ _____

Signature of Legally Authorized Representative **Date** **Time**

_____

Authority of Legally Authorized Representative or Relationship to Subject

TO BE FILLED OUT BY STUDY TEAM ONLY

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Name of Person Conducting Informed Consent Discussion

_____ _____

Signature of Person Conducting Informed Consent Discussion **Date** **Time**