UNIVERSITY OF MICHIGAN CONSENT TO BE PART OF A RESEARCH STUDY

Paperwork Reduction Act Statement

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2127-XXXX. The information collected in this study will be used to create a database of vehicle occupant body size, shape, and posture. The data will be used to improve vehicle safety. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Information Collection Clearance Officer, National Highway Traffic Safety Administration, 1200 New Jersey Ave, S.E., Room W45-205, Washington, DC, 20590.

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Vehicle Occupant Anthropometry, Posture, and Motion

Principal Investigator: Matthew P. Reed, PhD, University of Michigan Transportation Research Institute (UMTRI)

Study Sponsor: National Highway Traffic Safety Administration

You are invited to take part in a research study. This form contains information that will help you decide whether to join the study. Taking part in this research project is voluntary. You do not have to participate, and you can stop at any time. Please take time to read this entire form and ask questions before deciding whether to take part in this research project.

1.1 Key Information

- The purpose of this study is to gather data on how drivers and passengers sit and move in passenger cars and light trucks.
- If you choose to participate, we will measure your body size and shape. You will be asked to sit in a variety of simulated vehicle environments while we measure your posture.
- Risks or discomforts from this research include becoming uncomfortable from holding a posture for up to a minute, skin irritation from marking paint, slip and fall in the laboratory, and breach of confidentiality.
- There are no direct benefits to you of your participation.

2. PURPOSE OF THIS STUDY

The purpose of this research study is to gather data on how drivers and passengers sit and move in passenger cars and light trucks. These data will be used to improve vehicle designs and in particular to improve systems that protect people in crashes. The data may be used to improve the human surrogates used to assess vehicle safety, such as crash test dummies.

3. WHO CAN PARTICIPATE IN THE STUDY

3.1 Who can take part in this study?

The study is open to adults 18 years of age and older. The other requirements are:

- Able to read and speak English
- Able to drive for two hours continuously
- Hold a current, unrestricted U.S. driver's license
- Have been licensed to drive for at least one year
- Drives a car daily for an average of at least 15 minutes
- Comfortable driving on the highway and local roads

You are not eligible if you have:

- Musculoskeletal ailments impeding your ability to walk or sit comfortably
- Musculoskeletal deformities such as scoliosis or amputations

3.2 How many people are expected to take part in this study?

Up to 300 people.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen in this study?

If you agree to participate, we will measure your body dimensions and record your body weight and your body composition. We will ask you to change into tight-fitting clothing provided by the investigators. This laboratory clothing is necessary for us to measure your body shape accurately. We will use water-soluble face paint to put dots on your body at several locations. We will use camera-based systems to record the three-dimensional shape of your whole body, including your head and face. We will also use manual instruments, like tape measures, to record your body dimensions. You will need to hold still in specified postures for up to 15 seconds during these measurements. We will measure your grip strength using a force-measurement gage.

During most of the study, you will sit in a mockup of a vehicle interior and assume either a driver or passenger posture. We will record your body posture using a

camera-based system and using a mechanical coordinate measurement device. The investigator will touch parts of your body to locate body landmarks, such as the top of your sternum, and touch the measurement device to these locations to record their position. Some landmarks needed to measure safety belt fit are in your pelvic region at the front of the hip bones. You will need to hold still for about a minute for each of these measurements. You will be asked to get in and out of the mockup multiple times as the investigators change the seats and other test conditions. We will take photographs of you to document your posture in each condition.

4.2 How much of my time will be needed to take part in this study?

The data collection session will require approximately two hours.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

The risks of participation include:

- discomfort and fatigue due to getting in and out of the mockup and sitting still,
- skin discomfort due to the body paint used to identify skin landmarks, and
- the risk of tripping and falling when moving about the laboratory.

The investigators will mitigate these risks by giving you rest time between conditions and allowing you to discontinue participation at any time. Skin irritation will be minimized by using water-soluble body paint that can be easily removed. The investigators have also placed handrails and other safety systems throughout the laboratory to minimize the chance of slipping or tripping.

You also are at risk of a breach of confidentiality. The researchers will try to minimize these risks by:

- Labeling your data with a code rather than your personal information, such as your name, and
- Maintaining information security through password-protected servers accessible only to the study team.

See below for more information on how the study team will protect your confidentiality and privacy.

5.2 How could I benefit if I take part in this study? How could others benefit?

You will not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study through improvements in the design of vehicles and safety devices used to test vehicles.

6. ENDING THE STUDY

6.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. If you discontinue participation, we will keep and use any data that we have gathered up to that time.

6.2 Could the researchers take me out of the study even if I want to continue to participate?

Yes. There are some reasons why the researchers may need to end your participation in the study. Some examples are:

- You do not follow instructions from the researchers, or
- Problems with the measurement equipment.

7. FINANCIAL INFORMATION

7.1 Will I be paid or given anything for taking part in this study?

You will be paid \$80 in cash for your participation. If you withdraw from the study, you will still receive the same payment.

Because the total compensation for this study is less than \$400, we will not record your Social Security number. If you receive more than \$400 in payments from the University of Michigan in a calendar year, your Social Security number will be recorded, and payment information will be sent to the Internal Revenue Service (IRS) for tax reporting purposes and an extra tax form (Form 1099) will be sent to your home. If you are a University of Michigan employee, your research payments are tracked separately and are not included as part of your payroll.

7.2 Will I need to pay anything to be part of the study?

No, but you will be responsible for transportation to and from the laboratory building.

8. PROTECTING AND SHARING RESEARCH RECORDS

8.1 How will the researchers protect my information?

The data gathered in this experiment is confidential. Your name will appear only on this consent form. Your data will be identified only by a code number that is not linked to your identity in any way. We will blur or obscure your face in any photos or other images that are displayed publicly, for example in research publications.

Your identifying information, such as your name, contact information, photographs and videos of your face, or the surface scan of your head and face, will not be made available to the study sponsor or anyone other than the study team.

8.2 Who will have access to my research records?

There are reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- University, government officials, study sponsors or funders, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Federal or State law may require the study team to give information to government agencies, for example in response to a subpoena.

8.3 What will happen to the information collected in this study?

We will keep the information we collect about you indefinitely. We will not keep your name or other information that can identify you directly, except that we will retain photographs, 3D scans, and videos in which your face is visible. Identifiable information about you, including photographs, 3D scans and videos, will not be distributed or made available outside of the study team.

8.4 Will my information be used for future research or shared with others?

Your information may be used for future research or other applications, including commercial applications. The privacy of the data will be maintained through physical and electronic security systems. The data will be used in scientific publications, presentations, and other applications only in coded form not identifying you.

If we share your information outside of the study team, it will be deidentified, which means that it will not contain your name or other information that can directly identify you. In particularly, we will not share photographs, videos, or three-dimensional data in which you could be identified. If we share photographs or videos that include your face, we will blur your face so that you cannot be recognized. Future research or other applications using your data may be similar to this study or completely different. We will not ask for your additional informed consent for these applications.

The de-identified results of this research, including the information we collect from you, will be submitted to the sponsor, the National Highway Traffic Safety Administration, who may make the data available to the public through an online repository or other means. The research information submitted to the sponsor and made available publicly will not include any information that can be used to identify you, such as photos, videos, or 3D scans that show your face.

9. CONTACT INFORMATION

Who can I contact about this study?

Please contact the researchers listed below to:

Obtain more information about the study

- Ask a question about the study procedures
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Matthew P. Reed, PhD

Email: mreed@umich.edu Phone: 734-936-1111

Study Coordinator: Sheila Ebert Email: ebertshe@umich.edu

Phone: 734-615-5897

If you have questions about your rights as a research participant, or wish to obtain information, ask questions or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

University of Michigan

Health Sciences and Behavioral Sciences Institutional Review Board (IRB-HSBS)

2800 Plymouth Road Building 520, Room 2144 Ann Arbor, MI 48109-2800

Telephone: 734-936-0933 or toll free (866) 936-0933 Fax: 734-936-1852

E-mail: <u>irbhsbs@umich.edu</u>

You can also contact the University of Michigan Compliance Hotline at 1-866-990-0111

11. YOUR CONSENT

Consent to Participate in the Research Study

By signing this document, you are agreeing to be in this study and the storage and use of the collected data. Make sure you understand what the study is about before you sign. We will give you a copy of this document for your records and we will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

I understand what the study is about and my questions so far have been answered. I agree to take part in this study.
Print Legal Name:
Signature:
Date of Signature (mm/dd/yy):
Permission to Contact
I am interested in being contacted if I am determined to be eligible to participate in additional data collection for this study or for new studies.
Signature: