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CONSENT TO ACT AS A SUBJECT IN A RESEARCH STUDY

TITLE: Safety of Wheelchair-Seated Drivers and Passengers in Private Vehicles

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National Institute on Disability and Rehabilitation Research, Department of Education

Why is this study being done?
The objective of this research task is to determine and quantify the issues and problems related to providing effective occupant protection for drivers and passengers in private vans who are seated in their wheelchair. In particular, we want to document the current situation of seatbelt fit and usage, and clarify the factors that prevent the use of properly positioned lap and shoulder belts on wheelchair-seated drivers. We also want to study the use of wheelchair securement systems and vehicle operating controls and their safety during transportation.

Who is being asked to take part in this study?
We are seeking input from 15 adult individuals who sit in their wheelchairs when riding as a passenger or driver in a personally licensed vehicle.

What are the procedures of this study?
A questionnaire has been developed to determine your personal opinions regarding your experience of traveling in your vehicle while seated in your wheelchair. The questionnaire is designed to determine your thoughts about wheelchair securement and using occupant restraints, as well as other vehicle safety and usability issues. You will be asked to rate your opinion with regard to safety, usability, and independence when traveling in your vehicle.

A set of measurements has also been developed to quantify the physical relationships between you, your wheelchair, the vehicle restraint systems, and the vehicle interior. A list of items to be measured include dimensions such as the side-view lap-belt angle, belt-to-body contact distances, front- and side view shoulder-belt angles, locations of the lap belt relative to the tops of the thighs, location of the shoulder belt relative to the side of the neck and lateral aspect of the shoulder, etc. In addition, distances between you and important vehicle interior components, such as the center of the steering wheel, hand controls, the B-pillar, and the windshield header will be measured and recorded.

You will be observed while you enter and exit your vehicle and wheelchair station and, if not automatic, have your wheelchair secured and released and belt restraints positioned and removed. Digital video and photo will be recorded to accurately study your position inside your vehicle. With you in position with belt restraints in place, measurements and digital photographs will be taken to document the physical relationship between you, your wheelchair, and the lap and shoulder belts and vehicle setup. We will end the study with an interview asking general questions and requesting personal opinions on safety systems within your vehicle.
The total study should take about 2 hours for which you will be reimbursed.

What are the possible risks and discomforts of this study?
The physical risks are the same as those that you encounter each time you enter and exit your vehicle. These include the risk of physical discomfort when entering or exiting your

vehicle and reaching for belts or other systems in your vehicle. To reduce this risk, researchers will be at hand during the study to assist you if you are unable to complete tasks (securing your wheelchair, buckling your seat belt) independently.

An additional risk is the possibility of a breach of confidentiality, but we will do everything possible to protect your privacy. We will use video recordings only for checking our measurement and observational procedures and they will not be used in any of our publications or presentations. We will de-identify all further data, files and photo's which will be solely used for research purposes and in publications and presentation materials. We will ask you to sign the photo release portion of this consent form, which will allows us to use photos of you in your wheelchair and vehicle for use in research publications and presentations.

Will I benefit from taking part in this study?
You will not receive any direct benefits from participating in the study. However, you may learn more about your vehicle's safety systems and about wheelchair transportation safety as a result of completing our questionnaire and you will receive information about wheelchair transportation safety.

Are there any costs to me or my insurance carrier if I participate in this study?
The only costs associated with the study are those involved in driving your vehicle to the test site. Besides these cost, there are no costs to you for participating in this study.

How much will I be paid if I complete this study?
You will receive a check for $30 upon completion of this study. You will also be reimbursed for your vehicle's mileage expenses up to $5 per vehicle. If you decide to discontinue study participation, you will receive an appropriate amount based on your extent of participation.

Who will pay if I am injured as a result of taking part in this study?
University of Pittsburgh researchers and their associates who provide services at University of Pittsburgh Medical Center (UPMC) recognize the importance of your voluntary participation in their research studies. These individuals and their staffs will make reasonable efforts to minimize, control, and treat any injuries that may arise as a result of this research. If you believe that you are injured as a result of the research procedures being performed, please contact immediately the Principal Investigator listed on the first page of this form.

Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. It is possible that UPMC may bill your insurance provider for the costs of this emergency treatment, but none of these costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care unless otherwise specifically stated below. There is no plan

for monetary compensation. You do not, however, waive any legal rights by signing this form.

Will anyone know that I am taking part in this study?
We will not report results with personal identifiers (e.g. video recordings) to anyone who is not directly involved in this study. However, de-identified data (masked photos, survey results, measurements etc.) will be shared among researchers and others interested in the study results. Additionally, these de-identified results may be published and presented.

No names will be recorded on any response sheets; only study ID numbers will be used. This same code will be used for storing data on computer; this information will generally consist of numbers with little or no meaning to the casual observer. With your permission, portions of the study may be recorded on video or photo to ensure that our staff is recording information accurately. These videotapes will be safeguarded just like other research data to protect your privacy. At the end of this study, any records or videotapes that personally identify you will remain stored in locked files and will be kept for a minimum of five years per University of Pittsburgh policy. Since this project is being done in collaboration with the University of Michigan Transportation Research Institute, only de-identified data will be shared with the researchers at UMTRI. This means that videotape data will remain at the University of Pittsburgh and will not be shared with the UMTRI.

In unusual cases, your research records may be released in response to an order from a court of law. It is also possible that authorized representatives from the University of Pittsburgh Research Conduct and Compliance Office, the University of Pittsburgh IRB, may review your data for the purpose of monitoring the conduct of this study. Also, if the investigators learn that you or someone with whom you are involved is in serious danger of potential harm, they will need to inform the appropriate agencies, as required by Pennsylvania law.

For how long will the investigators be permitted to use and disclose identifiable information related to my participation in this research study?
The investigators may continue to use and disclose, for the purposes described above, identifiable information related to your participation in this research study indefinitely.

Is my participation in this study voluntary?
Yes! Your participation in this study is completely voluntary. You may refuse to take part in it, or you may stop participating at any time, even after signing this consent form. Your decision will not affect your relationship with the University of Pittsburgh, nor will you lose any benefits that you might be eligible for because of your decision.

May I withdraw, at a future date, my consent to participate in this study?
You have the right, at any time, to withdraw from this study. You need only provide to the Principal Investigator a written and dated notice of that decision. Withdrawal from the

study will not affect your current or future relationship with any University of Pittsburgh affiliated organization. Please note, however, that any identifiable information obtained from you prior to your withdrawal from this study will continue to be used by the investigators, as described above.

How can I get more information about this study?
If you have any further questions about this research study, you may contact the investigators listed at the beginning of this consent form. If you have any questions about your rights as a research subject, please contact the Human Subjects Protection Advocate at the University of Pittsburgh IRB Office (1-866-212-2668).

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PARTICIPANT'S CERTIFICATION:

- I have read the consent form for this study and any questions I had, including explanation of all terminology, have been answered to my satisfaction.
- I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that those questions will be answered by the researchers listed on the first page of this form.
- I understand that it is important that I not withhold any information regarding my past history.
- I understand that my participation in this study is voluntary and that I am free to refuse to participate or to withdraw my consent and discontinue my participation in this study at any time without affecting my future care at this institution.
- I agree to participate in this study and will receive a copy of this document.

_____	_____	_____
Participant's Printed Name	Participant's Signature	Date

CERTIFICATION OF INFORMED CONSENT:

I certify that I have explained the nature and purpose of this research study to the above-named individual, and I have discussed the potential benefits and possible risks of study participation. Any questions the individual has about this study have been answered, and we will always be available to address future questions as they arise.

_____ _____

Signature of Person Obtaining Consent | Role in Research Study

_____ | _____

Printed Name of Person Obtaining Consent | Date