The Children's Hospital *of* Philadelphia®

Consent Form

Study Title: Sensor Network with Active Instructional Content to Prevent Child Safety Seat Misuse Phase II

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Study Coordinator:	Morgan O'Donald, MPH	Telephone: 267-499-4114

You may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of this research study, and the risks and possible benefits of participating.

In the sections that follow, the word "we" means the principal investigator and other research staff.

Why are you being asked to take part in this study?

You are being asked to take part in this research study because you have used a child car seat within the past five (5) years.

What is the purpose of this research study?

The purpose of this research study is to evaluate a new type of car seat technology aimed at preventing car seat misuse and reducing deaths and injuries in children riding in motor vehicles. This technology includes both a sensor system built into the car seat and a smartphone app that provides relevant messages and instructional materials.

What is involved in the study?

If you agree to take part in this study, you will be asked to complete a brief online survey and participate in a one-time study visit that will take up to two (1.5) hours. After receiving an orientation to the car seat technology, you will be asked to install a car seat and complete a series of car seat misuse scenarios. These scenarios will involve you attempting to both identify and correct a car seat error. There will be up to three (3) scenarios in total, with each scenario taking up to ten (10) minutes. At the end of the study visit, you will have the opportunity to provide feedback on the new technology.

What are the risks and benefits of this study?

This is a minimal risk study and there are no known risks or discomforts beyond what you would encounter in day-to-day living. As with any study involving collection of data, there is also the possibility of a breach of confidentiality. However, every precaution will be taken to secure your personal information to ensure confidentiality.

You will not benefit directly from participating in this study. The study team will not be able to give you personalized feedback about your car seat installation technique because not all members of the study team are certified Child Passenger Safety Technicians. However, at the end of your study visit, you will be provided with information about where to find additional resources about how to correctly use car seats. Additionally, the knowledge gained from this study may help researchers develop better technology to help improve child passenger safety.

Do you need to give your consent in order to participate?

By continuing in this study, you are indicating that you have had your questions answered, and you agree to take part in this research study. If there is anything in this form you do not understand, please ask questions. Please take your time when making your decision.

Participation in this study is voluntary. You do not have to take part in order to receive care at CHOP. If you decide not to take part or if you change your mind later there will be no penalties or loss of any benefits to which you are otherwise entitled. You can stop being in the study at any time.

What about privacy, authorization for use of Personal Health Information (PHI) and confidentiality?

As part of this research, health information about you will be collected. This will include information from the study survey. CHOP staff are required to keep your information private. Information that could identify you will not be shared with anyone - unless you provide your written consent, or it is required or allowed by law. We will do our best to keep your personal information private and confidential. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

The results of this study may be shown at meetings and published in journals to inform other researchers and health professionals. We will keep your identity private in any publication or presentation.

Several people and organizations may review or receive your identifiable information. They will need this information to conduct the research, to assure the quality of the data, or to analyze the data or samples. These groups include:

- Members of the research team and other authorized staff at CHOP, Minnesota HealthSolutions, and Britax Child Safety, Inc. (the car seat creators);
- People from agencies and organizations that perform independent accreditation and/or oversight of research, such as the Department of Health and Human Services and Office for Human Research Protections;
- Groups monitoring the safety of this study;
- The National Institute of Child Health and Human Development who is sponsoring this research;
- Public health authorities that are required by law to receive information for the prevention or control of disease, injury, or disability (e.g., child abuse).

By law, CHOP is required to protect your health information. The research staff will only allow access to your health information to the groups listed above. By consenting to participate in the study, you are authorizing CHOP to use and/or release your health information for this research.

There is no set time for destroying the information that will be collected for this study.

Your permission to use and share the information and data from this study will continue until the research study ends and will not expire. Researchers continue to analyze data for many years and it is not possible to know when they will be completely done.

Certificate of Confidentiality (CoC)

A Certificate of Confidentiality (CoC) issued by the NIH covers this research. A CoC helps protect your identifiable information.

A CoC protects your private information from all legal proceedings. Unless you consent, information from this research study that identifies you will not be shared outside this research.

- No one can be forced to share your identifiable information for a lawsuit.
- Your information can't be used as evidence even if there is a court subpoena.

If you consent, your information could be shared for:

- other scientific research.

The CoC does not prevent some disclosures.

- The researchers can't refuse requests for information from those funding this research. The NIH may need information to assess this project.
- You can still share information about yourself. You can also freely discuss your involvement in this research.

The researchers must disclose things required by law. This includes suspected child abuse and neglect, harm to self or others, or communicable diseases.

Can you change your mind about the use of personal information?

You may change your mind and withdraw your permission to use and disclose your health information at any time. To take back your permission, it is preferred that you inform the investigator in writing.

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In the letter, state that you changed your mind and do not want any more of your health information collected. The personal information that has been collected already will be used if necessary for the research. No new information will be collected. If you withdraw your permission to use your personal health information, you will be withdrawn from the study.

Financial Information

Will there be any costs to you?

There are no costs to you or your insurance for participating. The study sponsors are providing financial support and material for this study and the procedures described above.

***Will you be paid for taking part in this study*?**

Participants will be paid $50 for their time and effort. Compensation will be provided at the study visit in the form of a CHOP-issued participant research card.

We may share your data with third parties (other researchers/institutions or for profit companies). Your data may be used for commercial profit. You will not receive any financial benefit from the use of your data.

Who is funding this research study?

The National Institute of Child Health and Human Development is providing funding for this study.

Please ask Dr. Allison Curry if you have any questions about how this study is funded.

What if you have questions about the study?

If you have questions about this study or how your data are going to be used, contact the principal investigator, Dr. Curry at currya@email.chop.edu or 267-425-1525.

Documentation of Verbal Consent to Take Part in this Research Study and Authorization to Use and Disclose Health Information for the Research

The research study and consent form was explained to:

_____

Name of Subject Providing Consent

The person who provided consent confirmed that all of their questions had been answered and they agreed to their participation in this research study.

They agreed to let CHOP use and share their health information.

_____	_____
Person Obtaining Consent	Signature of Person Obtaining Consent
	_____
	Date