Automated Harness Tightener for Child Safety Seat

NCT04408417

Informed Consent Form – 04/19/2021

Children's Hospital of Philadelphia

INFORMED CONSENT FORM

Study Title: Automated harness tightener for child safety seat

Version Date: April 19, 2021

Consent Name: AHT Informed Consent

Principal Investigator:	Allison E. Curry, PhD, MPH	Telephone: 267-425-1525
Study Coordinator:	Lauren O'Malley, MPH	Telephone: 267-425-0382

You and your child 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. If you are a parent or legal guardian who is giving permission for a child, please note that the word "you" refers to you as the parent or legal guardian and "your child" refers to your child.

Study Overview

You are being asked to take part in this research study because you have a child between the age of 6 months and 4 years and have recently used a child car seat.

The purpose of this research study is to understand new ways in which to make using a child car seat safer and easier for parents.

If you agree to take part, you and your child will be asked to participate in a one-day study about child safety seats. You will be asked to complete a brief online survey prior to your visit. Then, you will be asked to come to our office for one in-person study visit. During the visit, we will take measurements of your child and ask you to harness your child into two different car seats for a total of four installations. After each installation, we will ask you to answer a short survey. At the end of the visit, we will interview you about your seat preferences.

This is a minimal risk study and there are no known risks or discomforts beyond what you would encounter in day-to-day living. There is the possibility that your child will become uncomfortable while being measured and harnessed/un-harnessed into the car seats four times. If your child becomes too uncomfortable, we do not have to complete all of the procedures. There is also the possibility of a breach of confidentiality. However, the study team takes many precautions to protect the confidentiality of your data.

You will not benefit directly from participating in this study.

If there is anything in this form you do not understand, please ask questions. Please take your time. You do not have to take part in this study if you do not want to. If you take part, you can leave the study at any time.

Participation in this study is voluntary. You are free to withdraw from the study at any time.

If you are interested in learning more about the study, please continue to read below.

How many people will take part?

About 130 parents and 130 children will take part in this study. There is the possibility that 30 additional children will take part in some of the procedures.

What are the study procedures?

If you agree to take part in the study, you will be asked to perform the following procedures:

Online Intake Survey: You will complete a brief online survey prior to your study visit. The survey will ask you questions about yourself such as your age, race, and income, and current car seat use, behaviors, and preferences.

Child Measurements: At the start of the study visit, we will measure your child's weight, height, and height in the car seat.

Car Seat Installations: We will ask you to harness your child into two (2) different car seats, for a total of four (4) installations. The order of the four installations will be randomly assigned (e.g., like the flip of a coin). The car seats will be provided by the research team.

Surveys: After each installation is completed, we will ask you to answer a short survey about your experience with the car seat.

Interview: At the end of the study visit, we will interview you about which car seat you liked best.

You may withdraw from the study at any time.

What will be done with my data during this study?

All of the information collected from you during the study will be stored on a secure server at the Children's Hospital of Philadelphia or in a locked filing cabinet in our center.

What are the risks of this study?

Taking part in a research study involves inconveniences and risks. The main risks of taking part in this study are discussed below.

Risk associated with Installations, Measurements, Questionnaires, and Surveys

There are no physical risks associated with harnessing your child into the different car seats, and no difference in risk based on the harnessing order to which you are randomly assigned. You might experience momentary embarrassment or discomfort from survey questions. You do not have to answer any questions that make you too uncomfortable. Your child might experience discomfort from being measured and/or harnessed/un-harnessed into the car seats. If your child becomes too uncomfortable, we do not have to complete all of the procedures.

For any study involving the collection of data, there is the possibility of breach of confidentiality of data or loss of your privacy. Every precaution will be taken to secure your personal information to ensure your privacy and confidentiality.

Each participant will be assigned a study identification number. This number will be used on any data collection forms instead of your name and other private information.

Are there any benefits to taking part in this study?

There will be no direct benefit to you or your child from taking part 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. 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?

If you decide to participate in this study, you must tell us that you agree. A copy of this form will be given to you to keep as a record.

What are your responsibilities?

Please consider the study time commitments and responsibilities as a research subject when making your decision about participating in this study. The study time commitments and responsibilities include a 20-minute online intake survey and a 90-minute in-person study visit.

In addition, as the product that you evaluated is under development, we ask that you respect the confidentiality of the product technology and do not discuss it with others.

What happens if you decide not to take part in this study?

Participation in this study is voluntary. You and your child do not have to take part in order to receive care at CHOP.

If you and your child 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. Your child's current and future medical care at CHOP will not be affected by your decision.

Can you stop your participation in the study early?

You and your child can stop being in the study at any time. You do not have to give a reason.

What choices do you have other than this study?

The alternative to participating in this study is to not participate.

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

As part of this research, health information about you and your child will be collected. This will include information from the study questionnaires, interviews, and observations. CHOP staff are required to keep your and your child's 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 Health Solutions, 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 signing this document, 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.

Allison E. Curry, PhD MPH
Center for Injury Research and Prevention
Children's Hospital of Philadelphia
2716 South Street, 13th floor
Philadelphia, PA 19146
currya@email.chop.edu

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*?**

Parents 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 also gift your child with a board book to take home.

If you receive payment using a bankcard, the bank will have access to identifiable information. The bank will not have access to any medical information.

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. You may also talk to your own care team if you have questions or concerns.

The Institutional Review Board (IRB) at The Children's Hospital of Philadelphia has reviewed and approved this study. The IRB looks at research studies like these and makes sure research subjects' rights and welfare are protected. If you have questions about your rights or if you have a complaint, you can call the IRB Office at 215-590-2830.

What will be done with my data when this study is over?

We will use and may share data for future research. They may be shared with researchers/institutions outside of CHOP. This could include for profit companies. We will not ask for your consent before using or sharing them. We will remove identifiers from your data, which means that nobody who works with them for future research will know who you are. Therefore, you will not receive any results or financial benefit from future research done on your data.

Optional: Contact in the Future

We may wish to contact you and your child again at a later date to obtain follow-up information or for future research studies. Please indicate whether or not we may contact you in the future if we have additional questions, updates, or research opportunities.

_____ Yes, participant indicates he/she may be contacted at a later time.

_____ No, participant indicates he/she does not wish to be contacted again at a later time.

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

Documentation of Verbal Consent/Parental Permission and HIPAA Authorization for Child's Participation:

_____

Name of Child Subject

The research study and consent form was explained to:

_____ _____

Person Providing Consent | Relation to Child Subject:
☐ Parent ☐ Legal Guardian

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

They confirmed that they were legally authorized to consent to their/their child's participation.

They agreed to let CHOP use and share their/their child's health information.

Person Obtaining Consent	Signature of Person Obtaining Consent
	Date

Documentation of Verbal Consent and HIPAA Authorization for Parent's Participation:

The research study and consent form was explained to:

Name of Parent Subject

The person who provided consent confirmed that all of their questions had been answered and they agreed to their/their child's 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