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The Ohio State University Parental Permission For Child's Participation in Research

Study Title: Frontal Shoulder Response in Pediatric Volunteers

Principal Investigator: Laura C. Boucher, PhD, ATC

Sponsor: National Highway Traffic Safety Administration

- **This is a parental permission form for research participation.** It contains important information about this study and what to expect if you permit your child to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to permit your child to participate.

- **Your child's participation is voluntary.** You or your child may refuse participation in this study. If your child takes part in the study, you or your child may decide to leave the study at any time. No matter what decision you make, there will be no penalty to your child and neither you nor your child will lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you or your child is a student or employee at Ohio State, your decision will not affect your grades or employment status.

- **Your child may or may not benefit as a result of participating in this study.** Also, as explained below, your child's participation may result in unintended or harmful effects for him or her that may be minor or may be serious depending on the nature of the research.

- **You and your child will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you permit your child to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider permitting your child to participate in this study for the reasons explained below.

1. Why is this study being done?

The purpose of this study is to learn more about how the shoulder moves in kids 8 to 12 years old, to help develop a new crash test dummy (Anthropomorphic Test Devices or ATD). Data collected in this study will help ATD designers ensure that the new design is the proper size and that the shoulder moves in realistic ways.

2. How many people will take part in this study?

There will be approximately 25 children enrolled in this study.

3. What will happen if my child takes part in this study?

If your child takes part in this study, several measurements will be taken with a tape measure. Your child will be asked to wear a tank top or sleeveless shirt, so that bony landmarks around the shoulder can be identified. Measurements will include height, seated height, upper arm length, shoulder width, and other dimensions related to proper seatbelt fit. Next, sensors will be attached to the shoulder over designated landmarks to record the movement of the shoulder girdle. The range of motion of your child's shoulder will be examined during different shoulder movements. For this, your child will be asked to try to move their arm forward, backward, and up over their head, etc. They will then be seated in a custom seat and asked to lean up against a stabilizing chest-plate positioned on the "breast bone" (sternum). They will then be asked to reach their arms forward and place them in a holder. Once securely positioned, they will be asked to relax and allow the arm to be moved forward at various angles to assess how the shoulder girdle moves. This movement will be repeated 2 times in each position. Next, a standard seatbelt (lap and shoulder belt) will be positioned on the child while sitting in the seat, the same as the seatbelt used in the rear seat of a vehicle. Again, the child will be asked to relax and allow their arm to be moved forward at various angles, to assess how the shoulder belt may change this movement. This movement will also be repeated 2 times in each position.

4. How long will my child be in the study?

The session will last approximately 60 minutes. There is no follow-up.

5. Can my child stop being in the study?

Your child may leave the study at any time. If you or your child decides to stop participation in the study, there will be no penalty and neither you nor your child will lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can my child expect from being in the study?

There are no major risks or side effects expected for your child. Your child will be asked to quietly sit on a custom seat while most of the measurements are being taken. Your child will also be asked to move their arms so the shoulder girdle can be assessed. If your child indicates that this is painful or uncomfortable, the trial will be stopped. You (the parent or caregiver) will be present and can also stop the trial at any time.

7. What benefits can my child expect from being in the study?

There are no direct benefits to your child for being in the study. However, your child's participation will provide information that has not been published before, which will contribute to the improvement of a new ATD, which is under development.

8. What other choices does my child have if he/she does not take part in the study?

You or your child may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. What personal information will be collected during the course of the study and how will be it be handled?

As part of the recruitment process we will collect your name as the parent/guardian, phone number, and email address. This information is kept separate from any study related

material, with the Principal Investigator on an Ohio State University Medical Center password protected/encrypted computer. Once scheduling and data collection are completed, documents containing your personal information will be deleted/destroyed.

Once scheduled to come in for the study, we also will collect your child's full name and your name as the parent/guardian on this parental consent form. Immediately following consent, a numerical identifier will be assigned to your child. That numerical identifier will be used on all data collection sheets. The only link to the data collection sheet will be this parental permission form. On the data collection sheet, your child's birth month and year will be recorded along with the measurements for the study. We will share with the researchers involved in this project and project sponsor (the National Highway Traffic Safety Administration) only data about your child that is not linked or linkable to your, his or her name or personal information (we call this "de-identified" data). Both Ohio State and the study sponsor, NHTSA, may publicly release the de-identified data in final reports or other publications or media for scientific, educational, research or outreach purposes.

The de-identified data are stored on an Ohio State University Medical Center, password protected/encrypted computer of the Principal Investigator during the study collection process and data analysis process. The de-identified data will be stored on an Ohio State University Medical Center password protected and encrypted database owned and managed by the Injury Biomechanics Research Center (the lab in which the principal investigator belongs) for a minimum of five years following the study closeout data, as required by the Ohio State University Research Data Policy. The study sponsor may also obtain and securely store a copy of the de-identified research data.

We will store the parental permission forms in a separate locked filing cabinet located in a locked office for a minimum of five years following the study closeout data, as required by the Ohio State University Research Data Policy. After that timeframe, the documents will be securely destroyed. The parental permission forms will be the only link to the subject number and are never stored in the same location as a research data.

Before or during data collection, we may ask you for additional permission to allow us to photograph or videotape a short clip of your child. You will need to sign a separate permission form prior to us recording either still or videotaped images of your child. In granting us permission to take these images or video, you also will be giving Ohio State and NHTSA consent to the use of the images in future scientific presentations and publications. In so doing, you also will give the study sponsor, NHTSA, the right to use the images for scientific, educational, research or outreach purposes. However, we will

ensure that your child's face is blurred (also called pixilated) in all such images and that, the images remain de-identified in connection with all uses by Ohio State and NHTSA. All images and/or video associated with this study will be stored in the same secure fashion and in the same location as the data sheets. There will be no link of the data to the image or any identifiable information. Only key study personnel and the study sponsor will have access to these data. Additionally, NHTSA may be required to release data due to a Freedom of Information Act (FOIA) or other Open Government Initiative request. Any data released to satisfy these legal requirements will be de-identified and not contain any links to you or your children.

10. Will my child's study data be kept confidential? If not, with whom will it be shared?

As described above, efforts will be made to keep your child's study-related information confidential.

However, there may be circumstances when this information must be released. For example, personal information regarding your child's participation in this study may be disclosed if required by state law.

Also, your child's records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- As detailed above, the sponsor supporting the study, their agents or study monitors;
- Your insurance company (if charges are billed to insurance).

If this study is related to your child's medical care, your child's study-related information may be placed in their permanent hospital, clinic, or physician's office records. Authorized Ohio State University staff not involved in the study may be aware that your child is participating in a research study and have access to your child's information.

You may also be asked to sign a separate Health Insurance Portability and Accountability Act (HIPAA) research authorization form if the study involves the use of your child's protected health information.

10. What are the costs of taking part in this study?

There are no costs for taking part in this study. If you park in a parking garage, you will be given a parking pass to exit for free.

11. Will I or my child be paid for taking part in this study?

We will provide a $25 gift card in exchange for your participation. By law, payments to subjects are considered taxable income.

12. What happens if my child is injured because he/she took part in this study?

If your child suffers an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if your child should obtain medical treatment at The Ohio State University Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

13. What are my child's rights if he/she takes part in this study?

If you and your child choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights your child may have as a participant in this study.

You and your child will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You or your child may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

14. Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact **Laura Boucher, PhD**: Phone: 614-685-0262 / Email: Laura.Boucher@osumc.edu

For questions about your child's rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

If your child is injured as a result of participating in this study or for questions about a study-related injury, you may contact Laura Boucher, PhD.

Signing the parental permission form

I have read (or someone has read to me) this form and I am aware that I am being asked to provide permission for my child to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to permit my child to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form**.**

Printed name of subject	
Printed name of person authorized to provide permission for subject	**Signature of person authorized to provide permission for subject**
Relationship to the subject	**Date and time** **AM/PM**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	Date and time **AM/PM**

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness**
	AM/PM
	Date and time
Printed name of witness	**Signature of witness**
	AM/PM
	Date and time