

UNIVERSITY OF MICHIGAN CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Child Strength Measurement

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

Co-Investigator: Monica L.H. Jones, PhD, University of Michigan Transportation Research Institute

Co-Investigator: Prachi Shah, MD, Michigan Medicine

Co-Investigator: Darya Dabiri, DMD, MS, Michigan Medicines

Study Sponsor: U.S. Consumer Product Safety Commission.

Your child is invited to take part in a research study. This form contains information that will help you decide whether your child will join the study. Taking part in this research project is voluntary. Your child does not have to participate, and your child 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.

2. PURPOSE OF THIS STUDY

The purpose of this study is to develop methods to gather data on children's strength and climbing behavior. These data will be used to develop safety standards for furniture and products used by children.

3. WHO CAN PARTICIPATE IN THE STUDY

3.1 Who can take part in this study?

Boys and girls ages 18 to 71 months can participate. The children must have normal physical and cognitive development and be able to follow instructions from the investigators.

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

Up to 500 children will participate in this part of the study.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to my child in this study?

The study will take place entirely in laboratories at the University of Michigan Transportation Research Institute. If you agree that your child may participate, we will measure your child's body dimensions and record his or her weight. We will record your child's body shape using a whole-body surface measurement system. This system uses a red laser light similar to the light used in a supermarket checkout scanner.

We will ask your child to push or pull on a handle placed at various heights above the ground. The handle is attached to an instrument that measures the force your child is exerting. Because we are interested in the maximum force that your child can exert, we will ask you to help us encourage your child to push or pull as hard as he/she can. Some measurements will be conducted with your child seated in a chair. In these trials, he or she may be asked to push using their feet. We also may ask your child to squeeze a handle to measure grip force.

We will interview you and your child about your child's climbing behavior and force exertions on and around furniture. We are interested in climbing behavior related to furniture tip-over. We will ask your child to climb onto a low bar while pulling on a handle, as if climbing on playground equipment. We will ask him/her to lean back and pull as hard as he/she can. We may ask your child to climb into or out of a bin that simulates a dresser drawer.

We will record three-dimensional video of your child as he or she is participating in the study. We need the video to understand how your child performs the tasks. Video recording is required to participate in the study.

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

Your child's total participation time will be up to two hours. The investigator will provide breaks every 20 minutes, and you or your child can take a break at any time. The investigator may also stop the data collection early. Reasons that the investigator may stop the data collection early include lack of cooperation from your child, evidence of fatigue or difficulty in following instructions, or because the investigators have gathered sufficient data from your child to meet the needs of the study.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will my child face by taking part in the study? What will the researchers do to protect him/her against these risks?

Your child might become tired or sore as a result of the forceful exertions. Muscle soreness may not be apparent immediately but may be noticeable 24 to 48 hours after participation. The researchers will try to minimize these risks by limiting the number of instances of any single exertion to no more than five, taking breaks between exertions, and varying the body region involved.

Your child could slip or fall while climbing on the apparatus. We have addressed this risk by keeping the bars low to the ground and by padding the apparatus and the floor.

We will also take photographs and video of your child, which poses a risk to your child's confidentiality. The researchers will address the risk to confidentiality by de-identifying any images or videos shared outside of the project team by blurring your child's face and any other identifying features.

See Section 8 of this document 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. This study will result in the development of new methods for measuring child strength. Using these methods, a subsequent study will gather new data that will result in safer products for children.

6. ENDING THE STUDY

6.1 If my child or I wants 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. You will not lose any benefits to which you may otherwise be entitled. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 "Contact Information". If you choose to tell the researchers why you are leaving the study, your reasons may be kept as part of the study record.

6.2 Could the researchers take my child out of the study even if he or she wants to continue to participate?

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

- Your child does not follow instructions from the researchers.
- The equipment does not work as intended.
- Sufficient data has been collected from your child.

7. FINANCIAL INFORMATION

7.1 Will I be paid or given anything for my child taking part in this study? You will receive \$40 for your child's participation in the study. You may discontinue your child's involvement at any time without any change in payment.

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

To be part of the study, you will need to pay for your costs of travel to the laboratory.

8. PROTECTING AND SHARING RESEARCH RECORDS

8.1 How will the researchers protect my child's information?

The researchers will protect your child's information in several ways. Your child's data will be identified by a code number rather than by name. The key linking the code to your and your child's identity will be destroyed at the conclusion of the study. Images of your child will be de-identified by blurring your child's face. Any video of your child shown outside of the research team will be de-identified by blurring your child's face.

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.

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

We will keep the information we collect from your child during the research, including photos and videos, for purposes of developing strength measurement procedures and for documenting the performance of those procedures. Your child's name and other information that can directly identify him or her will be stored securely and separately from the research information we collected from you. Photos that are stored for future use will be de-identified as described above. Video data will be de-identified only if shown outside the study team. The document linking the data identification number with information identifying your child will be destroyed when data collection is complete.

The results of this study will be shared with the sponsor, but those presentations will not include any information that would allow you or your child to be identified.

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

We may use or share your research information for future research studies. If we share your information with other researchers it will be deidentified, which means that it will not contain your name or other information that can directly identify you. This research may be similar to this study or completely different. We will not ask for your additional informed consent for these studies.

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
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- 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 M. 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 1169 Ann Arbor, MI 48109-2800
 Telephone: 734-936-0933 or toll free (866) 936-0933 Fax: 734-936-1852
 E-mail: irbhsbs@umich.edu

11. YOUR CONSENT

Parent or Legally Authorized Representative Permission

By signing this document, you are agreeing to your child's participation in this study. Make sure you understand what the study is about before you sign. I/We will give you a copy of this document for your records. I/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 for my child to take part in this study.

Printed Child Subject's Name

Printed Parent/Legally Authorized Representative Name and Relationship to Subject
Relationship to subject: Parent Spouse Child Sibling Legal guardian Other

Signature

Date

Documentation of Oral Assent from Child

Investigator Signature

Date