INFORMATION COLLECTION REQUEST (ICR):
OMB supporting statement and privacy impact assessment for:
Child Strength Study

A. JUSTIFICATION

A.1 Circumstances Making the Collection of Information Necessary

This is a request to implement a strength data collection study of children ages 3 months through 5 years old. CPSC uses data on human strength and capabilities to develop product safety standards and to inform other CPSC staff activities. Strength capabilities of children are essential information to develop product performance requirements in standards to reduce or eliminate the risk such products might pose to a child (*e.g.*, breaking, collapsing, or liberating a small part). Manufacturers can also use this information when designing products intended for children. In addition, products that are not intended for children, but that can be hazardous to children, can be made safer by adopting performance requirements that consider children's ability to interact with product components.

In the 1970s, CPSC sponsored studies to conduct research on human size and strength, particularly the landmark Snyder et al. (1975 and 1977) studies on child anthropometry and Owings et al. (1975 and 1977) studies on child strength.[1] Although the research results were instrumental in developing product safety standards for many years, the information needs an update, given that these strength studies were conducted more than 40 years ago. CPSC expects the information collection activity to provide information that more accurately reflects the strength capabilities of today's children and provide data that are missing from the currently available literature, including data for younger children and additional strength measures. Accordingly, CPSC seeks to update its data on child strength through a new study.

[1] Owings, C. L., Chaffin, D. B., Snyder, R. G., & Norcutt, R. H. (1975). Strength Characteristics of U.S. Children for Product Safety Design. U.S. Consumer Product Safety Commission, Bethesda, MD.
Owings, C.L., Norcutt, R.H., Snyder, R.G., Golomb, D.H. and Lloyd, K.Y. (1977). Gripping Strength Measurements of Children for Product Safety Design (Contract No. CPSC-C-76-0119).
Snyder, R.G., Spencer, M.L., Owings, C.L., & Schneider, L.W. (1975). The Physical Characteristics of Children as Related to Death and Injury for Consumer Product Design and Use (Report No. UM-HSRI-BI-75-5). Prepared for the U.S. Consumer Product Safety Commission. Ann Arbor, MI: The Highway Safety Research Institute, University of Michigan.
Snyder, R.G., Schneider, L.W., Owings, C.L., Reynolds, H.M., Golomb, D.H., and Schork, M.A. (1977). Anthropometry of Infants, Children, and Youths to Age 18 for Product Safety Design. Final Report UM-HSRI-77-17. University of Michigan Transportation Research Institute, Ann Arbor, MI. Prepared for the U.S. Consumer Product Safety Commission, Washington, D.C. 014926-F.

A.2 Purpose and Use of the Information Collection

CPSC awarded a contract to the University of Michigan to conduct a study to update and expand child strength data with a focus on real-world scenarios. The information collected from this study will provide CPSC with updated child strength measures, including upper and lower extremities and bite strength, with expanded age ranges (strength data for children from 6 months through 5 years of age and bite strength for children from 3 months through 5 years of age). With this information, CPSC staff will be able to offer more accurate and up-to-date data for voluntary and mandatory standard development activities. These data will also help staff to analyze injuries and deaths of children interacting with consumer products and determine whether a product presents a safety hazard. The study seeks to collect strength information from up to 800 children who reside in the United States. The contractor will create a customized tool for data collection and feedback, which will allow the contractor to tailor the interface for each exertion of interest; check values against expected ranges to identify potential errors; and gather and synchronize data from multiple sensors.

A team of researchers at the University of Michigan Transportation Research Institute (UMTRI), which has decades of experience in human measurement, including extensive anthropometry and ergonomics research involving child participants and strength measurement, will lead the study. The research team will obtain an Institutional Review Board (IRB) approval for this project from the University of Michigan Health Sciences and Behavioral Sciences (IRB HSBS, FWA00004969).

A.2.1 Description of study

The research team at UMTRI conducted pilot studies with children and designed fixtures. For the actual study, CPSC staff anticipates that, over the 3-year period of this request, the contractor will collect data from 800 children ranging in age 3 months to 5 years. The study will take up to 2 hours per participant. UMTRI researchers will recruit children via their caregivers through the University of Michigan Engage site, Craigslist, and with flyers placed at UMTRI. (For an example of the flyer and online advertisement text to be used for recruitment, see the document called Flyer and Ad Text.) The participants will be screened via a phone conversation with the caregiver. (For an example of the phone screening conversation, see the document called Telephone Screening Script.) Inclusion criteria will be based on age, lack of current illness or injury; age-appropriate cognitive and motor development, as reported by the caregiver; and the caregiver's ability to understand written and spoken English (children in the older age categories should be able to understand spoken English). UMTRI researchers will assign a subject ID number to each participant. UMTRI researchers will retain the key file linking the subject ID to identifiable information separately from the data and will destroy the key file at the conclusion of the testing. The study will be conducted at UMTRI Laboratories in Ann Arbor, MI. Figure 1 shows the laboratory and a test fixture.

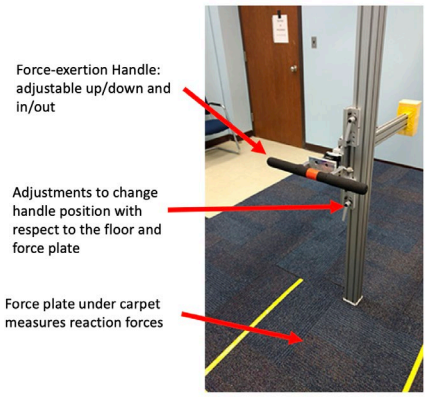

Figure 1. Test fixture for measuring strength for pushing and pulling tasks in the UMTRI Laboratory.

A research assistant will explain and demonstrate the procedures to the caregiver and child. Written consent will be obtained from the caregivers, who will remain with the children at all times. Researchers will obtain verbal assent from the children who are old enough to provide it. (For an example of the written consent form, see the document called Research Study Consent.)

Researchers will obtain several standard anthropometric measurements from each child, including body weight and standing height. Researchers will record the participant's body shape using a whole-body laser scanner (VITUS XXL) and a Microsoft Kinect sensor.

In the laboratory, the children will perform a sequence of tasks to test maximal exertions with their hands and feet, using the test fixture shown in Figure 1. For standing tasks, they will grip a padded handle with one or both hands, as instructed, and push or pull as hard as they can. Each exertion will be targeted for approximately 5 seconds, including the ramp-up and release. Feedback will be provided to the participants via a graphic display that shows their maximum level achieved, so that they can be encouraged to go beyond that level, if possible.

For some trials, the participant will be seated in a specially constructed laboratory chair, which is adjustable, based on the child's size. Seated exertions will include pushes and pulls with the hands, and pushes with one foot and both feet. Conditions will be varied to avoid exertion of one part of the body consecutively. For example, a hand pull might be followed by a hand or foot push.

The research team will use video and images to assess the children's performance, particularly their tactics in achieving the requested exertions. The number of trials to be performed will depend on the capability and attention of the child, but the maximum duration of a child's participation will be 2 hours for a single session. Caregivers and children may be asked to return for a second session to collect additional strength measures. A 5-minute break will be taken at least every 20 minutes to allow the child to relax and play. The caregiver and child can take a break or discontinue participation at any time. The caregiver will receive a payment of $40 to

$50 per session (up to 2 hours of participation) as compensation for their time; the amount is based on the portion of the study that the participant completes.

Please note that examples of all IRB-approved instruments, including flyer and ad text, telephone screening, and written consent, are provided in this collection request. At different points throughout the study, these instruments will be revised when child strength data for children of various age ranges will be collected. All instruments will receive IRB approval before use in the Child Strength Study.

A.2.2 Audiences of data and results

CPSC technical staff will be the primary audience of the data and results. UMTRI researchers will provide de-identified raw strength and position data, along with a report to CPSC staff. The report will include an executive summary, background, methods, description of instrumentation and methodology for each strength measure, including a drawing or picture; description of validation of instrumentation and method; detailed discussion of the methods used to conduct the study, including participant selection and recruitment, demographic characteristics, and relevant anthropometric data, including weight and height; total sample size for each age group and strength measure; results, including summary of data analysis by age group, including sample sizes, 5th, 50th, and 95th percentile values, standard deviation, mean, minimum, and maximum values for males, females, and combined; and data, including both anthropometric and strength measurements.

A.2.3 Methods of dissemination

The Commission will publicly release the contractor's final report, after it has been reviewed and approved by CPSC staff, by disseminating the report on the agency's website, and through staff presentations at meetings and conferences related to the subject matter. The Commission, its staff, agents, and representatives will disseminate the information in accordance with the law and Commission policy to ensure the information is accurate and not misleading.

To encourage dissemination of the findings, the report will be freely accessible on cpsc.gov. The work will be prepared in the course of the author's official contracting duties with CPSC. Thus, Title 17 U.S.C. Section 105 applies, which provides that there can be no copyright in a United States government publication.

A.3 Use of Information Technology

Detailed child measurements, of the type to be taken in the Child Strength Study, must be taken in a laboratory setting. UMTRI researchers will utilize information technology to manage data that is reported electronically, including but not limited to online screening and consent, where applicable and if paper or in-person collection is not appropriate. Data collected electronically

will be protected according to UMTRI procedures and all data provided to CPSC will be deidentified. (Section A.10 provides additional detail on confidentiality assurances provided to respondents.)

A.4 Efforts to Identify Duplication and Use of Similar Information

The intent of this data collection is to obtain information that is not readily available elsewhere. The last time CPSC collected this type of data was more than 40 years ago. Other, more recent studies collected data from a very small number of children, typically fewer than 20 per age group.

A.5 Impact on Small Businesses or Other Small Entities

The information will not be collected from small businesses or other small entities.

A.6 Consequences to federal program or policy activities if collection is not conducted or is conducted less frequently

If this collection is not conducted, CPSC staff will have to use outdated strength data for children, and the voluntary and mandatory standards will not benefit from updated data that more accurately reflect the strength capabilities of today's children. Staff will also continue to lack child strength data for measures that are relevant to children's interactions with products, including bite strength data and strength data for younger children. This could hinder the analysis of a product involved in a death or injury to a child, resulting in preventing or delaying CPSC from taking action to remove a dangerous product from the public.

A.7 Special Circumstances Relating to the Guidelines of 5 CFR §1320.5

There are no special circumstances. This information collection is consistent with the guidelines prescribed in 5 CFR §1320.5.

A.8 Consultation and Public Comments

Part A. Public Notice

A 60-Day Federal Register Notice (FRN) for the collection published on August 31, 2020. The 60-Day FRN citation is 85 FR 53800.

CPSC received four comments in response to the August 31, 2020 notice. All four commenters supported the information collection; however, two of the commenters also suggested specific or additional measures to collect or analyze as part of the study.

One commenter recommended collecting metrics on children's hand grip strength, push strength, pull strength, push-up head strength, and seated leg press strength. CPSC already plans to collect information about children's hand grip strength, push strength, pull strength, and seated leg press strength, as part of this study. Although CPSC does not plan to collect information about children's push up head strength, the commenter suggested this measure for purposes of evaluating entrapment hazards, and CPSC already plans to collect children's head entrapment measures as part of the study.

The same commenter also recommended directly correlating data with the age of the child tested, to provide more detailed information to identify safe product designs. CPSC plans to group data into 3-month, 6-month, and 1-year age ranges, with smaller groupings for younger ages. Each age group will include approximately 50 participants. This approach will provide more age-specific information than previous studies, which grouped children into 3-year age ranges. CPSC could provide results for specific ages, however, this information would have limited use, because each specific age likely will have a small number of participants.

Another commenter recommended collecting a wide range of information on static anthropometry, functional anthropometry, physical abilities, and psychological abilities. The static anthropometry measures (*e.g.*, weight, head breadth) that the commenter requested would not require any modifications to the study. Rather, they would involve additional analysis of information that will already be collected as part of the body scan data in the study. CPSC agrees that this information may be useful and plans to request this additional data analysis as part of the final study report.

In contrast, the functional anthropometry measures (*e.g.*, overhead reach to grip) that the commenter requested would require modifying the study to collect additional measures. Based on study design and participant fatigue, child participants can only be in the laboratory for 2 hours. The data collection that is already part of the study will take 2 hours; additional measures would exceed the 2-hour allotted time. If CPSC determines, upon review of the final study report, that more information is necessary, and that additional measures need to be evaluated, staff will consider collecting supplemental information at that time.

CPSC already plans to collect most of the physical abilities measures (*e.g.*, pushing forward, pinch force) that the commenter recommended. CPSC is not collecting the psychological abilities measures (*e.g.*, reaction time to visual stimuli) that the commenter requested because those measures are not within the scope of this study. The focus of this study is on children's anthropometrics and strength.

This commenter also recommended compiling data for children from various countries, so that a comprehensive data set is available for companies that distribute products globally. CPSC cannot collect data from participants in other countries or compel other countries to collect child strength data. However, the data CPSC collects as part of this study will be publicly available, so

interested parties may combine it with information from other countries to create a comprehensive data set.

Part B. Consultation

CPSC has consulted with UMTRI. Specifically, UMTRI has helped inform CPSC's decisions regarding the availability of the requested information, data collection techniques, and the clarity of information and instructions provided to participants.

CPSC has also received input from organizations and institutions regarding the design and need for this study. Agency staff communicated with stakeholders, including research organizations, universities, test laboratories, safety consultants, advocates, trade associations, and manufacturers, who all recognized and supported the effort to expand and update child strength data. Stakeholders rely on relevant child strength data to improve consumer product safety, by developing requirements and test methods to reduce the risk of injury to children from consumer products.

A.9 Explanation of any Payment or Gift

The contractor will provide $40 to $50 for up to 2 hours of participation. Parents volunteer their children for participation in the study for several reasons, including the benefit of learning more about their child's strength, a belief that contributing to research may benefit others, and affinity or trust in the research being performed by the University of Michigan or CPSC. The compensation provided to participants is an important monetary representation that their time spent participating in the study is valued. Not providing an incentive could jeopardize voluntary participation in the study and weaken our ability to conduct convenience sampling. The amount of compensation provided is reviewed and approved by the University of Michigan IRB, and is based on rates for similar research conducted at the university.

A.10 Assurance of Confidentiality Provided to Respondents

Participation in the study is voluntary, and respondents will be informed of this before the screening, and at the beginning of the study. Participants will be informed of the measures taken to protect their confidentiality in the introductory language read to sampled persons. Information collected from respondents will be kept confidential and only used for research purposes.

UMTRI researchers will assign participants a Random ID number not linked to any personal identifying information. They will take photos and video of the participants in some conditions to document their exertion postures. UMTRI researchers will de-identify the photos and video by blurring or obscuring the faces. UMTRI researchers will share the data with CPSC, only in the form of de-identified information. The data will be retained indefinitely at UMTRI in de-

identified form, to document the performance of the test procedures (*e.g.*, the repeatability of certain exertions).

A.11 Justification for Sensitive Questions

Questions asked in the study typically are not considered sensitive in nature.

A.12 *Estimate of Hour Burden to Respondents*

Below is a discussion of the burden hours to eventually reach 800 children for the lab study. We anticipate the response rates shown below, based on previous studies.

Instrument	Hours per respondent	Total number of participants	Response rate	Number of respondents	Total hours
Invitation					
Invitation for study	0.05	4167	30%	1250	63
Screener					
Invitation for study	0.15	1250	80%	1000	150
Study					
In-lab study	2	1000	80%	800	1600
Total				3050	1813

Total Burden Hours: 1813 hours

The total number of respondents is based on an initial study with 50 participants for each strength measure for the following age categories:

- 3–5 months (bite strength only)
- 6–8 months
- 9–11 months
- 12–17 months
- 18–23 months
- 24–29 months
- 30–35 months
- 36–47 months
- 48–59 months
- 60–71 months

Researchers plan follow-on studies with up to 300 additional participants to collect data for more strength measures and product-specific interactions.

A.13 Estimate of Total Annual Cost Burden to Respondents

There are no costs to respondents and no respondent recordkeeping requirements associated with the study. There are no operating, maintenance, or capital costs associated with the collection.

A.14 Estimate of Annualized Costs to the Federal Government

The contract to design and conduct the child strength study was issued to the University of Michigan under contract number 61320618D0004 for $1,134,502. Salary and benefits costs for government personnel assigned to this study are estimated at $234,048, based on 12 staff months in 2020, at an average level of GS-13 step 5 ($116,353/.676) and a 67.6 percent ratio of wages and salary to total compensation from Table 1 of the September 2017 Employer Costs for Employee Compensation, published by the Bureau of Labor Statistics. Therefore, the estimated cost to the government is $1,134,502, plus $172,120 in government labor costs, for a total of $1,304,858.

A.15 Program Changes or Adjustments

This is not applicable. This is a new request for information collection.

A.16 Publication Plan

The contractor will develop a technical report that will present a description of study design, research methods, summary of results, findings and conclusions.

The Commission will release the final technical report by disseminating the report on the agency's website and through presentations at meetings and conferences related to the subject matter. The procedures to disseminate the information by the Commission, its staff, agents, and representatives will be in accordance with the law and Commission policy to ensure the information is accurate and not misleading. The agency will disseminate the findings when appropriate, strictly following the agency's "Guidelines for Ensuring the Quality of Information Disseminated to the Public."

To encourage dissemination of the findings, the report will be freely accessible on cpsc.gov. The work will be prepared in the course of the author's official contracting duties with CPSC. Thus, Title 17 U.S.C. Section 105 applies, which provides that there can be no copyright in a United States government publication.

A.17 Rationale for Not Displaying the Expiration Date for OMB Approval

No such exception is sought. The OMB data collection number and expiration date will be displayed on the initial screener and informed consent forms to be used as a reference, if needed.

A.18 Exception to the Certification Statement

No such exception is sought. These activities comply with the requirements in *5 CFR § 1320.9*.