Department of Transportation Office of the Chief Information Officer

Supporting Statement
Pediatric Shoulder Response in Frontal Loading

INTRODUCTION

This is to request the Office of Management and Budget's (OMB) review and approval of a new National Highway Traffic Safety Administration (NHTSA) information collection request (ICR) titled "Pediatric Shoulder Response in Frontal Loading." This research is primarily observational in nature and voluntary, in which members of the public perform a light push/pull exercise activity (similar to rowing) while their shoulder movements are observed using a motion capture system. The information collection aspect of this research includes signature of the participant's parent/guardian granting consent for participation, the participant's name and birthdate, and anthropometry measurements (height, weight, shoulder breadth, etc.) of the participant. There is no Part B required for this information collection, as this collection is an observational study.

A signature granting consent is required because the study participants will be minors (age 8 – 12). The study details of what their child will be doing and how the observational data is used will be clearly delineated on the consent form per Institutional Review Board (IRB) requirements. The parent/guardian will be on site for the testing and in view of the participant throughout the testing, which is expected to take approximately one hour, including check-in, participant measurements, and motion capture setup tasks. The participant's name must be included on the consent form per IRB. This is the only place their name will be collected. A test ID number will be assigned and used henceforth to document the participant's age (from birthdate), sex, and size (from anthropometry measurements made by researchers). The consent form will be a hard copy, while all other measurements will be entered electronically via computer (associated with a test ID number).

The observational aspect of this research includes a fun, low-intensity activity or game where the participant's shoulder movement is tracked with motion capture software while resisting forces generated by the test apparatus are collected using a data acquisition system. The activity, which resembles a rowing motion, will simulate the shoulder motions experienced in a crash event, but at a much lower intensity. The forces generated with respect to the movements are used to develop a "response target" that serves as design guidance for the relevant crash dummy component.

The age/sex/anthropometry collection will provide contractor/NHTSA researchers with independent variables for the purpose of binning and normalizing the experimental responses to a particular child dummy size. For example, responses from males age 8 – 9 that have a shoulder breadth in a certain range may be compared with responses from males age 10 – 12 having the same shoulder breadth range to determine if there is a statistical difference between those cohorts. If there is no statistical difference between cohorts, then observational data from both

cohorts may be combined to create the response target for the LODC. Work using similar numbers of volunteers is common in this type of research[1, 2]. A very similar study to this proposed study included only seven adult volunteers[3]. The age range in this particular study will be 8-12 years old, and while the data will be explored in many different ways, the goal is to use the mean of the data to help create corridors, as this is the age range used to develop this particular ATD. Additionally, these data are the first data of its kind for the pediatric population, so this sample size will provide an important foundation. If we do not see a lot of variation based on size and age, then we will be confident in our data. If a lot of variation is present in the data, we may need to alter our analysis.

Part A. Justification

Subchapter V of Title 49 of the United States Code (U.S.C.) authorizes the Secretary of Transportation to conduct "motor vehicle safety research, development, and testing programs and activities, including activities related to new and emerging technologies that impact or may impact motor vehicle safety." 49 U.S.C. §30182. Pursuant to Section 1.95 of Title 49 of the Code of Federal Regulations (CFR), the Secretary has delegated this authority to the National Highway Traffic Safety Administration (NHTSA).

1. CIRCUMSTANCES THAT MAKE COLLECTION OF INFORMATION NECESSARY

In the early 2000's, NHTSA evaluated the Hybrid III 10-year-old child dummy. While this dummy was deemed adequate for the evaluation of large child restraints and eventually federalized in 2012, one of the shortcomings NHTSA identified of the child dummy is a shoulder that has very little mobility with no interaction with the ribcage. In 2011, the NHTSA Vehicle Research & Test Center Applied Biomechanics Division initiated a research program to develop a new crash dummy representing a large child with improved biofidelity called the Large Omnidirectional Child (LODC) dummy. NHTSA used pediatric biomechanical information from literature to guide the design of the LODC prototype. However, there was very little biomechanical information on the response of the pediatric shoulder. As the shoulder is a very important structure of the body for managing interaction of the restraint and body in a motor vehicle crash, new biomechanical data is needed to guide the design of the LODC shoulder.

Historically, child dummy component responses have simply been scaled from adult post-mortem surrogate tests. However, there is a large body of research that has demonstrated that children are not simply small adults when it comes to behavior in a high-speed crash scenario. Developmental anatomy must be considered in addition to mass and anthropometry in the creation of design targets for child dummies.

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[1] **Boucher LC**, Bing J, Bolte JH. Biofidelity evaluation of a prototype Hybrid III 6-year-old ATD lower extremity. *Annals of Biomedical Engineering*. 2016; 44(9):2794-2804. DOI: 10.1007/s10439-016-1562-1.

[2] **Boucher LC**, Chaudhari AMW, Kang, YS, Bolte IV JH. Range of Motion and Stiffness of the Pediatric Ankle and Implications for Current ATDs. *International Research Council on the Biomechanics of Injury Conference*, Gothenburg, Sweden. 2013;IRC13-28: 195-207.

[3] **Tornvall FV**, Holmqvist K, Martinsson J, Davidsson J. (2005). Comparison of shoulder girdle range-of-motion and stiffness between volunteers, Hybrid III, and THOR Alpha in static frontal impact loading. International Journal of Crashworthiness, 10:2, 151-160. DOI: 10.11533/ijcr.2005.0334.

Because testing of pediatric post-mortem surrogates raises ethical concerns, researchers are compelled to find creative ways to gather biomechanical information from living children. The historical approach for obtaining body region response information is to design a fun, low-intensity activity or game where the participant movement is captured in some manner while resisting forces are collected. The forces generated with respect to the movements are used to develop a "response target" that serves as design guidance for the relevant crash dummy component.

2. HOW, BY WHOM, AND FOR WHAT PURPOSE THE INFORMATION IS TO BE USED

There is an information collection aspect and observational aspect to this study, which will be conducted by The Ohio State University under a contract with NHTSA.

The information collection aspect of this research includes a participant's parent/guardian filling out a form with the participant's name, the participant's birthdate and sex, and anthropometry measurements (height, weight, shoulder breadth, etc.) of the participant, and consent from the parent/guardian.

A signature granting consent is required because the study participants will be minors (age 8 – 12). The study details of what their child will be doing and how the observational data is used will be clearly delineated on the consent form per Institutional Review Board (IRB) requirements. The parent/guardian will be on site for the testing and in view of the participant throughout the testing, which is expected to take approximately one hour, including check-in, participant measurements, and motion capture setup tasks. The participant's name must be included on the consent form per IRB. This is the only place their name will be collected. A test ID number will be assigned and used henceforth to document the participant's age (from birthdate), sex, and size (from anthropometry measurements made by researchers). The consent form will be a hard copy, while all other measurements will be entered electronically via computer (associated with a test ID number).

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3. EXTENT OF AUTOMATED INFORMATION COLLECTION

Information collection from the test participant will be conducted manually. In the observational experiments, a data acquisition system and motion capture software will be used to record shoulder motions and associated test apparatus forces.

4. EFFORTS TO IDENTIFY DUPLICATION

The information collected during participant recruitment is specific to the particular individuals that will participate in the experiment. Therefore, similar information collected from other individuals is not relevant or applicable. The agency is also not aware of any other sources of this information.

NHTSA is not aware of any studies where pediatric shoulder frontal, belt-restrained responses have been collected dynamically in a controlled experiment simulating shoulder movements typical of motor vehicle occupants.

5. EFFORTS TO MINIMIZE THE BURDEN ON SMALL BUSINESSES

This collection of information involves individuals only and will not affect small businesses or other small entities.

6. IMPACT OF LESS FREQUENT COLLECTION OF INFORMATION

This information collection has only one instance.

If the information is not collected, NHTSA will not be able to conduct the study because the agency would be unable to schedule participants for the study. Further, without collecting candidate information, NHTSA would be unable to confirm that participants meet the prerequisite age/size requirements for the observational data.

If the observational data is not collected, NHTSA will be unable to confirm that the LODC shoulder possesses the appropriate shoulder response to mimic a child occupant in the evaluation of a restraint system in a motor vehicle. Once the observational data is processed, the LODC dummy will be coupled to the same test apparatus and the same force applied by the participants will be applied to the LODC through the apparatus. Then, for a given applied force, the shoulder motion of the LODC will be compared to that of the participants. This comparison will guide whether the LODC shoulder should be stiffened, softened, or remain the same as it is currently.

7. SPECIAL CIRCUMSTANCES

No special circumstances require the collection to be conducted in a manner inconsistent with the guidelines in 5 CFR 1320.6.

8. COMPLIANCE WITH 5 CFR 1320.8

NHTSA published a notice in the Federal Register with a 60-day public comment period to announce this proposed information collection on September 12, 2018.

NHTSA published a notice in the Federal Register with a 30-day public comment period that announced this information would be sent to OMB for approval on May 3, 2019.

9. PAYMENT OR GIFTS TO RESPONDENTS

After informed consent is obtained, participants will be given a $25 gift card. They will have to sign a "Human Subject Payment Receipt" as required by the IRB. This document is stored with the consent form and indicates that the subject did receive the card. Additionally, on this form will be the card number identifier and so that cards given out can be tracked. Compensation has been determined based on the time burden and precedent of other similar studies done by the contractor[1, 2]. Additionally, other more recent studies by this same contractor with similar research tasks with a pediatric sample are under publication review and in preparation.

10. ASSURANCES OF CONFIDENTIALITY

The informed consent form will explain that NHTSA nor the contractor will not release any information regarding their names. The participant name will only be listed on this consent form. In order to maintain privacy, test participants will be assigned a subject number which will be used instead of their name to identify all data collected.

11. JUSTIFICATION FOR COLLECTION OF SENSITIVE INFORMATION

This research will not include any questions of a sensitive or private nature.

12. ESTIMATES OF BURDEN HOURS FOR INFORMATION REQUESTED

Time burden on confirmed test participants, as well as costs associated with those test participants, are summarized below. The contractor places a solicitation on their university list server for faculty/staff. The solicitation includes a summary of the study and contact information for the primary investigator. Faculty/staff can either choose to respond if they have children that meet the selection criteria for the study or pass the solicitation on to family/friends. Once a respondent is enrolled in the study, the primary investigator coordinates with the respondent on test date/time. The total amount of time associated with both (a) prospective enrollees reviewing the solicitation and (b) correspondence between enrolled respondent and contractor is typically 10 minutes or less. This "pre-test review, enrollment, & correspondence" is included in the table below. We do not expect there to be instances where a respondent goes through the review process before selection and is not chosen for the study. Therefore, no additional costs are included for non-selected respondents here. Historically, the only reason a potential respondent would go through any portion of the review process (after meeting eligibility criteria) and not continue through to the data collection would be due to scheduling incompatibilities. The contractor does not turn away potential participants during the recruitment process until the sample size reaches capacity. In those cases, the contractor simply tells the respondent they are

no longer recruiting subjects and thank them for their interest. Also, once capacity is reached, the solicitation is removed from the contractor's website.

Task	N	Time Per Participant (Hours)	Total Time (Hours)	Cost	Total Cost
Pre-test review, enrollment, and correspondence	24	0.167	4	$25	$100
Explanation of study & signature of informed consent form	24	0.167	4	$25	$100
Anthropometry measurement	24	0.167	4	$25	$100
Test setup	24	0.167	4	$25	$100
Observational experiment	24	0.167	4	$25	$100
Test teardown & confirmation of data collection	24	0.167	4	$25	$100
OVERALL TOTAL:		1.000	24	$25	$600

13. ESTIMATES OF TOTAL ANNUAL COSTS TO RESPONDENTS

There are no additional costs to respondents or record keepers.

14. ESTIMATE OF COST TO THE FEDERAL GOVERNMENT

The total costs incurred by the Federal Government relating to technical support of the conduct of this research are summarized below.

Task	Labor Equivalent	Time (Hours)	Cost (Per Hour)	Total Cost
Study Design	GS-14	600	$57.28	$34,368.00
PRA Clearance Process	GS-14	200	$57.28	$11,456.00
Test Equipment	N/A	N/A	N/A	$5,000.00
Test Preparation	GS-13	400	$48.47	$19,388.00
Recruitment	GS-12	200	$40.76	$8,152.00
Testing & Data Collection	GS-13	480	$48.47	$23,265.60
Data Analysis	GS-13	320	$48.47	$15,510.40
Report Preparation	GS-14	320	$57.28	$18,329.60
TOTAL:				$135,469.60

15. EXPLANATION OF PROGRAM CHANGES OR ADJUSTMENTS

There is a program change because of this new data collection whereby an additional 24 burden hours will be added to NHTSA's overall burden total.

16. PUBLICATION OF RESULTS OF DATA COLLECTION

NHTSA will not publish any personal information. NHTSA may publish the age and gender results from this data collection in aggregate as part of a research report and future Federal Register published documents. Results will be used to compare protocol refinement options and secondary task effects on dependent metrics only.

The duration of this entire study is expected to be two years. The first year (October 1, 2018 – September 30, 2019) will consist of study design, PRA clearance, identification/purchase of test equipment, test preparation, and trial testing with crash dummies. The second year (October 1, 2019 – September 30, 2020) will consist of recruitment, testing & data collection, data analysis, and report preparation. The testing & data collection is expected to occur between October 1, 2019 and March 1, 2020.

17. APPROVAL FOR NOT DISPLAYING THE EXPIRATION DATE OF OMB APPROVAL

NHTSA is not seeking such approval.

18. EXCEPTIONS TO THE CERTIFICATION STATEMENT

No exceptions to the certification are required for this research plan.