

Supporting Statement: Part A

OMB# 0920-16CA

May 19, 2016

“Update seat belt fit recommendation for children”

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SUMMARY TABLE

- Goal of the study: This study will inform when children can safely transition from using booster seats to using only seat belts.
- Intended use of the resulting data: The data collected will be used to inform child passenger safety recommendations regarding when children can safely transition from using a booster seat to using only a seat belt. Selected study findings may eventually be published in a peer-reviewed journal.
- Methods to be used to collect data: Study data will be collected during measurement sessions. Prospective participants will answer a series of screening questions. Individuals who meet the screening criteria and are willing to participate will complete an in-person measurement session lasting approximately 2.5 hours.
- The subpopulation to be studied: The study population includes children aged 6-12 years in the greater DC area. Up to 425 children will participate in this study.
- How data will be analyzed: Data will be analyzed using descriptive statistics, mean, standard deviation, and logistic regression.

A. JUSTIFICATION

A.1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) is seeking OMB approval to conduct a new information collection for a study entitled, “Update Seat Belt Fit Recommendation for Children,” over a period of three years.

The scientific basis for the current height recommendation for when children can transition from using a booster seat to just a seat belt is from a 1993 study that is outdated and used poor methodology (Durbin et al., 2011; Reed et al., 2013). The goal of the new collection is to use the latest technology to measure how seat belts fit children in vehicles with and without booster seats, among the largest sample of children to date. Findings from this data collection will inform CDC in how to make recommendations regarding the safe transition from using a booster seat with the seat belt to using only the seat belt among children. This study will also provide information on ways to further reduce motor vehicle-related injuries and deaths among

children. Prospective study participants will be children aged 6-12 years old in the greater D.C. area. Parents of prospective study participants will answer a series of screening questions to determine eligibility. Children who meet the screening criteria and are willing to participate will complete an in-person measurement session lasting approximately 2.5 hours. In-person measurement sessions will collect data on up to 425 children aged 6-12 years. Data will be analyzed using descriptive statistics, mean, standard deviation, and logistic regression. Selected findings will eventually be published in a peer-reviewed journal.

Background

Motor vehicle crashes are a leading cause of death among children in the US (CDC, WISQARS, 2016). Proper restraint use is critical for children in order to prevent injuries and death in a motor vehicle crash. Booster seat use reduces the risk for serious injury by 45% for children aged 4–8 years when compared with seat belt use alone (Arbogast, 2009). For older children and adults, seat belt use reduces the risk for death and serious injury by approximately half (NHTSA, 2013). Based on this evidence, CDC recommends using age- and size-appropriate child restraints (including child safety seats and booster seats) in the back seat until adult seat belts fit properly (i.e. when the lap belt lies across the upper thighs, not the stomach; and the shoulder belt lies across the shoulder and chest, not the neck or face).

For maximum protection, it is especially important for children to not transition to using only a seat belt before they are large enough for the seat belt to properly fit. The current recommendation for when children can safely transition to a seat belt is 57 inches tall. The recommendation of 57 inches was derived from a study of 155 children aged 6 to 12 years who were assessed for seat belt fit in 3 different types of vehicles in 1993 (Klinich, 1994). Because the 1993 study is outdated and used poor methodology, the American Academy of Pediatrics called for height for proper seat belt fit among children to be updated in 2011 (Durbin et al., 2011; Reed et al., 2013). In the event of a crash, properly fitting seat belts distribute the crash forces onto the skeleton/bones (e.g., shoulder and hip bones) instead of the soft tissues (e.g., stomach or neck). However the methodology used by Klinich et al. (1994) was not able to determine belt fit with respect to the child's skeletal landmarks. Also, since 1993, both children and the vehicle fleet have changed. Children are physically different today than they were in 1993 (Xi, 2014; Fryar, 2014). For example, abdominal obesity has increased among children over the past 20 years (Xi, 2014; Fryar, 2014). Additionally, current vehicles are narrower and their seats are more contoured than they were in the early 1990's (Reed, 2011). In order to further reduce motor vehicle-related injuries and deaths among children, the recommendation for proper seat belt fit should be validated using methodology that can quantify belt fit with respect to skeletal landmarks of today's children in the current vehicle fleet.

Authority for CDC's National Center for Injury Prevention and Control to collect this data is granted by Section 301 of the Public Health Service Act (42 U.S.C. 241) (Attachment A). This act gives federal health agencies, such as CDC, broad authority to collect data and do other public health activities, including this type of study.

A.2. Purpose and Use of Information Collection

The purpose of this information collection effort is inform the seat belt fit recommendation for children. Updating the seat belt fit recommendation for children was identified as a need in 2011 when the American Academy of Pediatrics released their updated child passenger safety recommendations (Durbin et al., 2011). The proposed study will be the largest seat belt fit study among children to date. The proposed study will investigate seat belt fit among children in the current vehicle fleet, year model 2015 and newer sedans, minivans, and SUVs, will be assessed using two kinds of comparisons: 1) a comparison of the fit of the shoulder belt when the child is buckled with the seat belt only, with a high-back booster, and a backless booster seat; and 2) a comparison of the fit of the lap belt when the child is buckled with the seat belt only, with a high-back booster seat, and a backless booster seat. Details of these comparisons are described in greater detail in Section A.16 and Part B of this application.

The current proposed data collection will sample up to 425 children. The children will be recruited to be 1/3 non-Hispanic white, 1/3 non-Hispanic Black, and 1/3 Hispanic and ½ male and ½ female. This is to ensure a large enough sample size in each race/ethnicity to obtain stable standalone estimates for each race/ethnic group. The final sample will include 30 children for ages 6 and 7; and 73 children for ages 8, 9, 10, 11, and 12. The sample allocation is concentrated near the ages 8-12 because these are the ages where children transition to seat belts only (no booster seats) and are more likely to have proper seat belt fit without a booster seat (which is the focus of the study). Additionally, BMI information will be collected in the screener to ensure inclusion of high BMI children (Attachment H). Height and weight percentile thresholds by age and gender have been calculated from 2011-2012 NHANES data (Attachment J). These thresholds will be used as a guide for participant recruitment, to ensure that study participants collectively include both the range and distribution of children's measurements of height, weight, and BMI, as well as observations in the likely vicinity of the criteria for good belt fit (e.g., 4 feet, 9 inches). Height, weight, BMI variability will allow for variability of BMI which has never before been assessed in a comparable study. BMI can affect seat belt fit; therefore, BMI info will be collected to account for this variable/information.

Without this study, decisions for when to transition a child from a booster seat to a seat belt only will be based on an outdated, methodologically unsound recommendation. As previously mentioned, proper restraint use is critical for children in order to prevent a leading cause of death among children, motor vehicle crashes injury.

A.3. Use of Improved Information Technology and Burden Reduction

Much care was put into designing the data collection instruments to collect the minimum amount of information necessary to achieve study goals. Measurements that will be collected include only those that are most important to achieving the study goals.

This study is taking advantage of the latest technology for determining seat belt fit, the FARO arm and H-point machine. FARO arms (FA) allow measurements to be digitized in 3 dimensions at the touch of a button once the point to be measured is located. This tool eliminates the need to

take several measurements using tape measures, rulers, and calipers. Having the ability to take a number of measurements quickly will significantly reduce the burden on participants. In order for the FA to make 3 dimensional measurements, each child measurement needs to have a reference point on the vehicle (2015 or newer sedan, minivan, and SUV), traditionally the vehicle seat's centerline. The H-point machine is used to measure the centerline of the vehicle seat. The machine allows for reference points to be quickly determined and further reduces the length of time needed for participant measurement sessions.

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

CDC contacted leading child passenger safety partners including National Highway Traffic Safety Administration (NHTSA), University of Michigan's Transportation Research Institute (UMTRI), and the Children's Hospital of Philadelphia (CHOP) to identify any duplicative studies. In addition, CDC has communicated with the American Academy of Pediatrics about this study; therefore, experts in the field are aware of this work. Also a literature search was conducted between November 2014 and December 2014 of the PubMed and Scopus databases. These efforts identified 1 study conducted by UMTRI that measured static belt fit in children (Reed, 2008). This study was federally-funded by NHTSA. CDC staff have consulted with both NHTSA staff and UMTRI staff on the current proposed data collection. As a result, this study has been designed to complement the previous study and fill key gaps that were not covered in the previous data collection. The 2008 Reed et al. child belt fit study had two key limitations: 1) belt fit measurements were not taken in vehicles and 2) a small sample size of 44 kids. The previous study utilized a lab mock-up of a 2002 year model seat buck to measure how seat belts fit children with and without booster seats. The study authors noted the principle limitation was using a lab environment and not actual vehicles. Seat belt fit measurements for the current proposed data collection will be obtained while children are seated in actual vehicles (2015 or newer SUV, sedan, and minivan). Also, the previous study's small sample size did not include sufficient minority races or children with high Body Mass Index (BMI).

CDC has also consulted with NHTSA and UMTRI on the data collection methods and data collection instruments so that the current proposed data collection will be able to directly complement previous research. NHTSA is collaborating with CDC on this data collection, and has agreed to lend CDC their H-point machine for use as one of the data collection instruments.

A.5. Impact on Small Businesses or Other Small Entities

All participants will be recruited through advertisements in local papers, web sites (Craigslist), and flyers posted in facilities frequented by drivers with children (local stores that sell various child restraint systems (CRSs); community centers; day care centers; pediatric and/obstetric offices) (Attachment L). In addition, there are an average of 21 car seat check events held in Montgomery County each month, which provide excellent recruiting opportunities for contacting parents and other caregivers who may be interested in allowing their child to participate in the study (Attachment K). The ads will provide a brief description of the study and provide contact information for interested parties..

A.6. Consequences of Collecting the Information Less Frequently

This request is for a one-time study. These data are needed to inform child passenger safety recommendations regarding when children can safely transition from using a booster seat to using only a seat belt. Without this study, seat belt fit recommendations will remain based on an outdated, methodologically unsound study from 1993. As previously mentioned, proper restraint use is critical for children in order to prevent injuries and death in a motor vehicle crash. Without this study, CDC will also be limited in information on ways (such as proper restraint use) to further reduce motor vehicle-related injuries and deaths among children.

There are no legal obstacles to reduce the burden.

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

This request fully complies with the regulation 5 CFR 1320.5.

A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency

A.8.a) Federal Register Notice

A 60-day Federal Register Notice was published in the Federal Register on November 9, 2015 Vol. 80, No. 216, pp. 69223 (Attachment B). CDC received one anonymous non-substantive comment (Attachment C). Follow up information was not provided, so there was no reply from CDC to the non-substantive comment.

A.8.b) Efforts to Consult Outside the Agency

CDC consulted with both NHTSA and UMTRI regarding gaps in previous data collections, the current proposed data collections' study design, collection methods, collection instruments, and data elements to be recorded/measured. Additionally, study protocol including data collection instruments, data dictionary, recruitment plan, and data collection procedures were designed in collaboration with researchers at Westat. Staff from CDC provided oversight and guidance to Westat researchers responsible for the data collection instrument design, data dictionary design, recruitment plan design, and data collection procedures. These staff included:

Name	Title	Affiliation	Phone Number
Matt Reed	Research Professor and Head of the Biosciences Group	UMTRI	734-936-1111
Stephen Ridella	Director, Office of Vehicle Crashworthiness Research	NHTSA	

A.9. Explanation of Any Payment or Gift to Respondents.

Participation in the proposed study will include allowing a researcher to physically locate key skeletal landmarks through “palpating” or pushing to feel specific bones in the child’s body. To measure lap belt fit, the researcher will have to physically palpate around a child’s hip/pelvis area in order to locate the child’s ASIS (anterior-superior iliac spine) which is the junction of the thigh bone and pelvis. Another data collection point that is potentially sensitive for female participants involves the measurement of shoulder belt fit. To measure shoulder belt fit with respect to the child’s clavicle (collarbone), the researcher will have to palpate the child’s shoulders and upper chest in order to locate the child’s clavicle. Our experience with previous studies have shown that research involving physical palpation of sensitive areas of a child’s body makes participant recruitment difficult.

The proposed study also places a travel burden on participants and their parent/guardian. We plan to recruit children from the Washington, D.C. area. Specifically, this study will be conducted in a vehicle research lab in Rockville, Maryland. Therefore, participants and their parent/guardian must travel to the lab in Rockville, MD to complete the approximately 2.5 hour long in-person study session. While the focus of the study is children, some burden is placed on the parent/guardian as the adult will need to work with project staff in order complete the recruitment process, schedule the data collection session, and drive the child to the session. In addition, the researchers will require that the guardian be present for the entire 2.5 hours of data collection in order to ensure that the child is at ease, and that the parent is comfortable with what is being asked of the child as they step through the session. While researchers will make every effort to accommodate the participant’s schedule, data collection sessions will occur Monday-Friday between 9AM-6PM. Therefore, in order to participate, parents/caregivers may need to take time off from work. Also, parents may need to take their child out of prepaid daycare or after school care. To encourage participation and offset lost work time, travel expenses, and acknowledge the sensitive nature of the data collection, each participant will receive a \$50 incentive and a CDC Child Passenger Safety brochure which outlines the current recommendations for proper restraint use among children by age group.

As part of the Program for the International Assessment of Adult Competencies (PIAAC) (OMB Number: 1850-0870. Expiration date 02/28/2015) sponsored by the Organization for Economic Co-operation and Development (OECD), Westat was required by the OMB to complete a field test respondent incentive experiment to examine the effect of increasing respondent incentives from \$35 to \$50. The rational for the higher incentive was due to time burden (2 hour study), and inflation.

Table 01 shows several studies (similar in design, duration, etc. that involved children) where equivalent incentives were used.

Table 01.

Study Name	Age Group	Duration	Incentive Amount
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Rural Education Collaboration (Grant funded and did not require OMB approval)	5-8 years	45 minutes	\$35
The Bayley Child Development (OMB Number: 0925-0661)	Infants	45 minutes	\$25 + infant gift
Early Childhood Longitudinal Study	8-10 years	60 minutes	\$25
Early Childhood Longitudinal Study-Kindergarten Class of 1998 (ECLS-K) (OMB Number:1850-0750)	School Age	60 minutes	\$25
National Assessment of Educational Progress (NAEP) (OMB Number:1850-0790)	4 th graders	60 minutes	\$50

A.10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The CDC Office of the Chief Information Officer has determined that the Privacy Act does apply. The applicable System of Records Notice (SORN) is 09-20-0160 “Records of Subjects in Health Promotion and Education Studies” published in the Federal Register on November 24, 1986, Vol. 51, No. 226, page 42484-42485. The Privacy Impact Assessment (PIA) is attached (Attachment F).

All procedures have been developed, in accordance with Federal, State, and local guidelines, to ensure that the rights and privacy of children and their parent/guardians are protected. All respondents will be informed that the information they provide will be treated in a secure manner and will be used only for the purpose of this research, unless otherwise compelled by law. Copies of assent and consent forms provided in writing to children and their parent/guardians are provided in (Attachment E1 and E2). Trained researchers will assure children and their parent/guardians that names (or other identifiable information including telephone numbers, etc.) will not be associated with measurements taken and that information obtained from all of the measurements will be combined into a summary report (so that details of individual measurements cannot be linked to a specific participant). To ensure privacy, personal identifiable information (PII) will only be collected during the screener and maintained in the password-protected recruitment database on the Contractor's secure network server. During the recruitment process, we will use a tracking database to store prospective participant contact information, generate personalized mailing labels (or email addresses), and personalized participant

instruction letters (or emails) (Attachment M). For those individuals who have access to email, all documentation will be provided via email. However, it is assumed that some participants may not have access to email, which will require the use of the US postal service to provide the participant instructions, directions (Attachment N). A participant ID will be assigned to each subject. After the screener, only the ID and other (non-PII) categorical variables necessary for analysis will be available outside the screener database. Within 3 months of the end of the study period, Westat will destroy the link between the ID code and the participant's personal identifiable information. No PII (names, addresses, or telephone numbers) will be in the database delivered to CDC.

Seat belt fit measurement data that was recorded with a camera will be immediately transferred to a secure password protected server at the end of the measurement session. Only the recruiting and senior project manager staff will have access to study data and study applications and/or be able to conduct screener interviews. The screener information will be kept separate from the seat belt fit and anthropometric measurement database since the screener contains personal identifiable information (e.g., names, phone numbers, and address) that is unnecessary for the data entry in the seat belt fit and anthropometric measurement database. The screener information will be stored only on a DFS server on Westat's network which has been configured to comply with the Federal Information Security Management Act (FISMA) of 2002. Non-PII categorical elements (gender, grade, birthdate, reported height & weight, etc.) will be extracted from the screener information for use in the seat belt fit and anthropometric measurement database.

The respondent's name, home address, email address, and phone number will be collected and only used to schedule measurement sessions as needed. All data collection and data management staff will be well trained in maintaining information security at all stages of the data collection and data management process. Protocols for data collection will ensure that names, phone number, home addresses, Email and all other PII is kept secure during all stages of data collection. Recruitment lists and survey data will be kept in locked, secure facilities by the contractor. PII will only be collected and maintained in the password-protected screener database on the Contractor's secure network server. A unique participant ID will be assigned to each subject. After the screener, only the unique ID and other (non-PII) categorical variables necessary for analysis will be available outside the screener database.

Respondents will be informed that their participation in any or all parts of the study is voluntary. The assent and consent forms (Attachment E1 and E2) must be signed by each participant and their parent/guardian, respectively. These documents will inform the respondents that their participation in the research study is completely voluntary. Any participant (child or adult guardian) may agree or refuse to participate. If a participant initially agrees to participate, they are informed that they can elect to stop at any time during the study. Both the child participant and their parent/guardian will be informed that responses will only be shared in aggregate.

The results of the study will be used to develop a Final Report that is internal to CDC. Additionally, findings from this study will be disseminated through the publication of manuscripts in peer-reviewed journals. Finally, study findings may also be disseminated through oral or poster presentations. All data will be de-identified prior to analysis and the findings will

be reported in aggregate. No published oral or written reports or presentations of the research will identify any participants.

An android-based tablet will be used to capture FA data as it is being digitized to further reduce the length of time needed with each participant. The tablet will house an Access database with each of the data elements. The tablets will be continuously connected to the FA in order to have digitized data sent directly into the tablet and database. The tablet(s) will be protected with full-disk encryption and credential access for authorized users of the machines. The tablets will remain physically locked in a secure location when not being used for data collection. Upon completion of a data collection session, all data will be transferred to secure network storage for further processing, archiving, and analysis. Within the Contractor's Distributed File System (DFS) network server environment, only authorized and credentialed users will be allowed to work with the collected data for project-approved purposes.

In summary, this study will use FARO Arms (FA), an H-point machine, Android-based Tablets, and digital video cameras to reduce the burden on study participants during the seat belt fit and anthropometric data collection process.

Several cameras with removable media will be used to capture video of the participants as they experience each seating, vehicle, booster, and belt condition. This will likely employ 3-6 cameras positioned to capture details of seat belt fit. After sessions are recorded, media will be moved to a secure network. Video will only be used by authorized individuals. Like the tablets, these cameras are stored securely when not in use.

During the recruitment and screening process, a database will track which participants have been scheduled for and completed the in-person interview/measurement sessions. After completion of the measurement session, the recruitment database will be updated so that no further contact with the participant occurs. The system will reduce participant burden by ensuring that participants are not contacted more than needed. Additionally, screening potential participants for eligibility prior to scheduling the measurements sessions avoids having ineligible participants complete measuring sessions.

A.11. Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB Approval

The CDC National Center for Injury Prevention and Control's human subjects coordinator has determined that CDC will not be engaged in this human subjects research, therefore approval by the CDC IRB is not required (Attachment G). A copy of the contractor's IRB approval notice is included as Attachment D.

Sensitive Questions

The data collection does not contain any sensitive questions.

A.12. Estimates of Annualized Burden Hours and Costs

A.12.a) Burden

Table 2 details the annualized number of respondents, the average response burden per interview, and the total response burden for the screener and measurement session.

Estimates of burden for the screener are based on simulated runs with staff answering each questionnaire. We anticipate that the screener will take approximately 10 minutes to complete. Estimates of burden for the measurement sessions are based on measurement times for the 2008 Reed et al. static belt fit study. We anticipate that each measurement session will take approximately 2.5 hours. Based on past experience, we expect 2000 children will undergo the screener. We expect up to 425 children to ultimately complete the measurement session over the entire 3 year study period. All participants will be recruited through advertisements. The ads will provide a brief description of the study and provide contact information for interested parties. When parents or guardians of potential participants call in response to the advertisements or flyers, they will be given a brief screening that collects information on the child’s age, sex, race/ethnicity, height, and weight (Attachment H).

Table 2. Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Response Burden (hours)	Total Burden Hours
Parent/guardian of children aged 6-12 years	Screener Script Guide – Attachment H	667	1	10/60	111
Child participants aged 6-12 years	Seat Belt Fit Measurements – Attachment I	142	1	2.5	355
Total					466

The sample size of up to 425 children will be divided by age as follows: 30 children for ages 6 and 7; and 73 children for ages 8, 9, 10, 11, and 12. Within each single year of age, the number of children will be selected evenly by gender (half male, half female), and will be evenly allocated across three race/ethnicity categories (Hispanic, non-Hispanic Black, non-Hispanic White). Height and weight percentile thresholds by age and gender have been calculated from 2011-2012 NHANES data (Attachment J). These thresholds will be used as a guide for participant recruitment, to ensure that study participants collectively represent both the range and distribution of children’s measurements of height, weight, and BMI, as well as observations in the likely vicinity of the criteria for good belt fit (e.g., 4 feet, 9 inches).

A.12.b) Costs

The hourly wage used to calculate the Respondent Costs in Table 3 is \$7.25. The average hourly wage was obtained from the 2015 U.S. Bureau of Labor Statistics which is the minimum wage under the Fair Labor Standards Act (FLSA). Total Respondent Cost for this 3 year study is \$10,139.13.

Table 3. Estimated Annualized Burden Costs

Type of Respondents	Form Name	Hourly Wage Cost	Respondent Cost
Parent/guardian of children aged 6-12 years	Screener Script Guide – Attachment H	\$7.25	\$805.96
Child participants aged 6-12 years	Seat Belt Fit Measurements – Attachment I	\$7.25	\$2,573.75
Total			\$3,379.71

A.13. Estimates of Other Total Annual Cost Burden to Respondents or Record keepers.

Respondents will incur no capital or maintenance costs.

A.14. Annualized Cost to the Government.

The total cost of this 3 year study to the Federal government is \$554,537, which includes \$523,337 in contract costs to Westat and \$31,200 in other costs to the Federal government. The other Federal costs include salary related to the involvement of two federal employees who will each devote 5% FTE to the project. The resulting annualized cost to the government is \$184,846 per year.

Table 4. Estimated Annualized Cost to the Government

Item	Annualized Cost
Contractor	\$174,446
Two technical Monitors @ 5% time	\$10,400
Total	\$184,846

Fixed price contract number 200-2014-F-60745.

A.15. Explanation for Program Changes or Adjustments

This is a new data collection effort.

A.16. Plans for Tabulation and Publication and Project Time Schedule.

Data analysis will include assessing which child attributes (height, weight, age) contribute to proper belt fit in the current vehicle fleet. Specific aims include examining differences in lap and shoulder belt fit across the three seating conditions: 1) seat belt only, 2) seat belt / high-back booster seat, and 3) seat belt / backless booster seat by child characteristics such as height, weight, age, gender, race/ethnicity, BMI, and combinations thereof. In addition, the analysis will explore differences in lap and shoulder belt fit across the three seating conditions by vehicle attributes (seat cushion length and lap and shoulder belt anchorage locations). The vehicle attributes were recorded in a separate data collection and did not require OMB review.

The study plan should include a schedule (list), to be prepared in advance, to ensure proper randomization of vehicle and seating condition order within each sex-by-age (and possibly race/ethnicity) group.

Findings from this study will be summarized in an internal final report. The results of our study also will be used to develop peer-reviewed journal articles (e.g., publications in journals such as: *Pediatrics*, *Traffic Injury Prevention*, *Accident Analysis and Prevention*, and/or *Prevention Science*), conference presentations, research briefs, and Web-based papers for dissemination to researchers, practitioners, policy makers, and the general public. These web-based papers and results of this proposed collection will be included on CDC’s child passenger safety webpage and potentially highlighted on other CDC webpages.

The time schedule for the project activities is summarized in Table 5. Within the first 3 months after receiving OMB approval, we will select the study sample. Data collection will be completed within approximately 7 months of receiving OMB approval. An analytic dataset and codebook will be developed after data collection is complete. Data analysis and report writing will be conducted within 16 months after receiving OMB approval.

Table 5. Time Schedule

Activity	Time schedule (months after OMB clearance)
• Recruitment of study participants	Months 1-12
• Execute Data Collection	Months 3-18
• Data cleaning and analysis	Months 4-24
• Evaluate/interpret findings	Months 18-26
• Write Final Report	Months 26-30
• Manuscript writing and submitting reports for publication	Months 30-36
• Obtain de-identified data set from Contractor	Month 36

A.17. Reason(s) Display of OMB Expiration Date is Inappropriate

Display of OMB expiration date is appropriate for this study.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exemptions to the certification.

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