

**Supporting Statement: Part B**

**OMB# 0920-XXXX**

May 19, 2016

**“Update seat belt fit recommendation for children”**

Point of Contact:

Bethany West, MPH

Contact Information:

Centers for Disease Control and Prevention  
National Center for Injury Prevention and Control  
Division of Unintentional Injury Prevention

4770 Buford Highway NE MS F-62

Atlanta, GA 30341-3717

Phone: 770-488-0602

Fax: 770-488-1317

Email: [bwest2@cdc.gov](mailto:bwest2@cdc.gov)

## CONTENTS

<u>Section</u>	<u>Page</u>
<b>B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS</b>	
B.1. Respondent Universe and Sampling Methods .....	3
B.2. Procedures for the Collection of Information .....	4
B.3. Methods to Maximize Response Rates and Deal with Nonresponse ...	5
B.4. Tests of Procedures or Methods to be Undertaken.....	6
B.5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data.....	6
REFERENCES.....	7

### **Attachments**

- H Screener Script Guide
- I Seat Belt Fit Measurements

## **B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS**

### **B.1. Respondent Universe and Sampling Methods**

The purpose of the proposed study is to inform the updating of the child passenger safety recommendation on when children can safely transition from using a booster seat with a seat belt to using only a seat belt. The target population will be children aged 6-12 located in the greater Washington D.C. area, which presents a diverse population with respect to race/ethnicity and Body Mass Index (BMI). The existing booster seat to seat belt recommendations are based on a very narrow and old study (1993) conducted in a single school. While still operating under the constraint of being limited to a single geographic setting, the proposed study nonetheless seeks to achieve much broader population representation. Although potential geographic bias cannot be ruled out, there is no reason a priori to expect such bias, and it is anticipated that the proposed setting will result in representative and highly informative data. The goal is to generalize to the entire U.S., based on observations made in the DC area, and controlling for the demographic variables (gender, age, height, weight, BMI, race/ethnicity) that are likely to be the significant predictors across the U.S. of good belt fit. Results from this proposed study will be used to inform when children can safely transition from using booster seats to using only seat belts.

Based on previous research experience, we expect that screening approximately 2000 parents of potentially eligible children aged 6-12 will yield up to 425 children who meet the study criteria and agree to participate in the study over the entire 3 year study.

A convenience sample size of up to 425 children will be recruited. 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.

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 (ren) to participate in the study. The ads will provide a brief description of the study and provide contact information for interested parties (Attachment K). 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.

The following criteria will be used for eligibility screening:

- Child is between ages 6-12 years
- Child's gender
- Child's race/ethnicity
- Child's weight and height
- Parent and child's willingness to participate in the 2.5 hour data collection session.

Participants will be selected from a pool of individuals meeting the screening criteria and agreeing to participate in the study.

## **B.2. Procedures for the Collection of Information**

Data collection for this study will be conducted in two phases:

*Screening Phase:* The first phase of data collection will identify individuals who meet the study eligibility criteria and are willing to participate. Inclusion criteria include child's age, gender, race/ethnicity, weight, height, and willingness to participate in a 2.5 hour data collection. Other child restraint use recommendations (such as when to transition from a rear- to forward-facing child safety seat (CSS)) are based on the child's age in concert with the CSS's height and weight limits. Therefore, the child's age, height, and weight are key variables for study inclusion. Additionally, other child characteristics such as gender and race/ethnicity should be considered for application to future national studies. Trained telephone interviewers will query individuals who responded to the recruitment flyers/ads (Attachment K and L) about their eligibility and potential willingness to participate in the study. The screening guide includes questions pertaining to respondent age, height, weight, gender, race/ethnicity, etc. Individuals meeting each of the eligibility criteria will be invited to participate in the study and their response to the invitation will be recorded in a tracking log/database. During the recruitment phase,

interviewers will use the screener script (Attachment H) to determine participant eligibility for study participation.

All participants will be recruited in the greater Washington, DC, area. Participants will be recruited through advertisements in local papers, web sites (Craigslist), and flyers posted in facilities frequented by drivers with children (local toy stores as well as other large box stores; community centers; day care centers; pediatric and/obstetric offices). Additionally, recruitment will occur through monthly car-seat check events (about 21 events occur each month) held in Montgomery County, Maryland. Two kinds of data will be collected: 1) Screener data (Attachment H) and 2) Seat belt fit and anthropometric measurement data (Attachment I).

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).

*In-person measurement phase:* Individuals who enroll in this study will complete the in-person measurement session at a later time—which will be scheduled by the telephone interviewer. Each session will begin with the researcher providing a brief introduction to the study and pointing out/explaining the purpose of the video cameras, after which each parent will be required to sign a consent form (Attachment E1) and the child participant to complete an assent form (Attachment E2). Westat will provide each participant with a standard uniform to wear while the measurements are made. The researcher will record each of the measurements contained in the data dictionary (Attachment I).

A measurement seat and the area around it will be used to gather basic participant anthropometrics, including sitting and standing height, weight, age, and body mass index (BMI). To measure sitting height, a measurement chair will be placed against a calibrated wall. This chair will be a specially modified version of a pneumatic office chair. The chair's seat pan will be replaced with a flat, level, uncompressible surface with a similarly designed sliding backrest mounted vertically, near the back edge of the typical buttock position. Children will be asked to sit upright with the back of their knees resting against the front edge of the seating surface with their feet extending straight to the floor and with their heels resting flat on the floor. The seat height will be adjusted to accommodate this position, and the backrest will be moved forward until it rests against the buttocks and shoulders of the child. After locking in these positions for seat height and depth, seated stature and seated shoulder height will be measured. Other key measures (e.g., buttock-popliteal length (BPL), etc.) will be captured as the child sits in this position. All measurements will be captured in a database with the child's unique ID, age,

gender, race/ethnicity, standing height, weight, and BMI (without any personally-identifiable information [PII]).

Next, the child will visit each of three vehicle (year model 2015 or newer sedan, minivan, and SUV) stations. Each child will experience two booster seats (1 high-back booster seat and 1 no-back booster seat) mounted in rear outboard seating position as well as the bare vehicle seat condition. In each of these stations the child will be buckled using the vehicle seat belt. This is equal to 9 in-vehicle measurement scenarios per child. See Table 1 for a breakdown of the measurement locations.

**Table 1: Child Measurement Locations**

	Vehicle 1: Sedan			Vehicle 2: SUV			Vehicle 3: Minivan		
Outboard Seating Position	Vehicle Seat	No-back Booster	High-back Booster	Vehicle Seat	No-back Booster	High-back Booster	Vehicle Seat	No-back Booster	High-back Booster

In each case, children will be instructed to climb into the booster or vehicle seating position and the researcher will read a brief script on how to buckle the seat belt. The script will instruct the child on how to properly route and buckle the seatbelt. The direction for the no-back booster driver side outboard passenger seating position will be:

- On your left side the belt goes under the armrest
- On your right side the lap and shoulder be goes under the armrest.
- Place the lapbelt across your thighs
- Pull up on the shoulder to tighten

The direction for the High-Back booster driver side outboard passenger seating position will be:

- On your left side the belt goes under the armrest
- On your right side the lap and shoulder be goes under the armrest.
- Make sure the shoulder belt goes through this guide (the shoulder belt will be routed through the guide already)
- Place the lap belt across your thighs
- Pull up on the shoulder to tighten

The direction for the vehicle seat belt only driver side outboard passenger seating position will be:

- Place the lap belt across your thighs
- Pull up on the shoulder to tighten

A researcher will be on hand to help them buckle the belt, if necessary, but will request that the participants tighten the lap and shoulder belt without assistance whenever possible. If the child does not route the seat belt in the booster seat properly, the researcher will adjust the seat belt so that it is properly routed prior to making the measurements. Belt routings and measurements will be made for each seating type (vehicle seat only, high back booster, and no back booster) in the outboard seating position. Using a FaroArm to record 3D coordinates and the variables outlined in the seat belt fit measurements data dictionary as a guide (Attachment I), measurements of shoulder and lap belt positions will be captured. A FaroArm is a portable coordinate measurement machine that allows researchers to perform 3-D dimensional analysis. Additional measures that contribute to the seat belt fit will also be recorded for comparison. These 3D coordinates, or in some cases center of gravity approximations, will be saved directly into a database set up to capture each measure. Additionally, a Child Passenger Safety (CPS) technician will assess goodness of belt fit for each child/seat belt configuration using the 8 CPS tech questions in the seat belt fit measurements data dictionary as a guide (Attachment I).

The in-vehicle measurement process will be video recorded and then used to assess or confirm measurements and fit parameters post hoc. While measures will be captured during each session, the video will provide a consistent record for verifying measurements and observations throughout the session. One researcher, a trained Child Passenger Safety (CPS) Technician, will be responsible for managing the child's progression through each condition and recording key measures.

Once the measurements have been completed for a given vehicle seating position, the researcher will complete a visual assessment of fit to capture such factors as lap belt position/snugness, shoulder belt position/snugness, slouch, leg angle/bend, and sitting height relative to the shoulder belt mount, belt paths, and the seat back. The CPS Technician will also perform the "5-step" test, a recognized method for evaluating seat belt fit. The test is intended to answer the following questions:

1. Does the child sit all the way back on the vehicle seat?
2. Are knees bent comfortably at the edge of the vehicle seat?
3. Does seatbelt cross the shoulder properly? (it should be centered over the collar bone)
4. Is the lap portion of the seatbelt low – touching the thighs?
5. Can the child stay seated this way for the entire ride, every ride (awake and asleep)?

Each session will last up to 150 minutes.

### **B.3. Methods to Maximize Response Rates and Deal with Nonresponse**

This is a convenience sample of volunteers for a study to measure children in vehicle seats and booster seats to characterize the critical aspects of the boosters, rear vehicle seats, seat belt systems, and child size that contribute to proper seat belt fit. The Contractor's normal pattern of ensuring adequate attendance includes telephone recruiting/screening, and for each participant who agrees to participate, mailing out a confirmation letter within 48 hours of the initial call (via email or through the US postal system). The confirmation letter includes an agenda, schedule, and location of the data collection session. It will also include directions to the site, and a contact telephone number in case of cancellation or questions. The Contractor will also make reminder calls within 24 hours of the scheduled session to boost response. Each age group will be actively recruited until that group has been filled and their data collection is complete.

The following procedures will be used to maximize cooperation and response:

- Researchers will attempt to contact participants at varying times.
- Focused training will be provided to researchers on the issues surrounding decisions to participate and the purposes of the data collection effort. We will thoroughly address issues pertaining to data security.
- The interviewers will attempt to address any respondent concerns.
- Each respondent will receive \$50 after completion of the in-person measurement session.

### **B.4. Tests of Procedures or Methods to be Undertaken**

The screening guide and seat belt fit measurements data dictionary are included as Attachments H and I. Multiple phases of survey design, review, and revision were conducted to finalize these instruments. The specific items included on the screening survey (attachment H) are based on our need for information about respondents' eligibility for study participation. The measurements included in the data dictionary are based on our need for information about key attributes of good belt fit. CDC staff have consulted with both NHTSA staff and University of Michigan Transportation Research Institute (UMTRI) staff on the proposed data collection effort. As a result, this study has been designed to complement current knowledge of proper belt fit among children and fill key gaps. In addition, as part of the study design, the Contractor will refine the study procedures by pilot testing the protocol and instructions with 9



participants. All data collection instruments have been designed as brief as possible to guarantee the highest possible response.

Data analysis for this study will involve: 1) mean and standard deviations for lap and shoulder belt fit scores across the three seating conditions by child characteristics, for each vehicle type; and 2) logistic regression to model the relationship between child characteristics and correct/incorrect fit (1/0 outcome) for each of the three seating conditions, for each vehicle type. The basic model form is:

$$\log\left(\frac{p_i}{1-p_i}\right) = \beta_0 + \beta_1 x_{i1} + \beta_2 x_{i2} + \dots + \beta_p x_{ip},$$

Where  $p_i$  denotes the probability of correct fit and  $x_{i1}, \dots, x_{ip}$  are different attribute measurements for participant  $i$ . For each vehicle type, the three fit outcomes can be modeled simultaneously (using multivariate logistic regression) to accommodate the possibility that outcomes are correlated within individuals after accounting for the measured child attributes (i.e., correlated residuals). The fitted equation can be used to identify the best seating condition (i.e., the highest probability of correct fit) for varying combinations of child attributes.

### **B.5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data**

CDC collaborated with the Contractor to design the study protocol and data collection instruments. All instruments and procedures have been reviewed extensively by CDC. Doreen De Leonardis, PhD, MA (301-315-5963), Richard Huey (301-315-5961), and Amy Benedick (240-314-5816) designed the protocol, data collection instrument, and analysis plan. James Green, MA, designed the sampling plan, conducted the power analyses, and provided consultation on the analytic plan. The Contractor will be responsible for conducting the data collection and analysis.

Erin Sauber-Schatz, PhD, MPH (770-488-0566) and Bethany West, MPH (770-488-0602), National Center for Injury Prevention and Control (NCIPC), Division of Unintentional Injury Prevention, CDC are the technical contacts for this project, responsible for providing scientific guidance to the Westat team. Dr. Sauber-Schatz and Ms. West will approve and receive all contract deliverables.