## Study Protocol and Statistical Analysis Plan

Title: Improving Child Restraint Installation

NCT Number: NCT03508843

Document Date: August 23, 2019

## **Study Protocol**

All study procedures were conducted at Safe Kids Coalition community car seat check events at public locations such as health clinics, shopping centers, and local parks. Following consent processes, participants completed an electronic baseline questionnaire on a study tablet addressing participant and family demographics and perceptions of CRS use. While participants completed the questionnaire, an onsite CPST inspected the CRS and rated the accuracy of seat selection, installation, and child positioning, as detailed below. Participants were not informed about the results of the initial inspection until after the study was complete. If more than one CRS was present in the vehicle, a "target" CRS for the research was randomly chosen and standard in-person CPST consultations were provided for the remaining CRS following completion of the study. When child passengers were present, height and weight measurements were taken onsite; otherwise caregivers estimated their child's measurements.

After baseline measures were complete, participants installed Help Lightning, a commercially available IVP app, on their smartphones using WiFi provided by the study. Participants received instruction from onsite study personnel on how to connect to an off-site CPST via the app to initiate the remote consultation. The remote CPST placed participants in "Receive Help" mode and themselves in "Give Help" mode, which allowed the remote CPST to draw on the live video image and superimpose their hands on the image to signal and indicate relevant features of the CRS and vehicle while the participant observed the merged image. Participants and remote CPST could also communicate verbally throughout the consultation.

No technical concerns about the app's functioning were expressed by participants or remote CPST, but weak internet connections in some rural areas led to occasional dropped calls. On the rare occasions when contact was disconnected, the remote CPST immediately recontacted the participant and resumed instruction. The remote CPST instructed all caregivers on how to inspect their CRS selection and installation and provided corrective feedback when necessary. In most cases, this involved removing the CRS from the vehicle entirely and reinstalling it. New CRS were available onsite for an income-adjusted fee (\$0-\$25) if errors in seat selection were identified that required a new CRS to correct. When the child passenger was present, the remote CPST also instructed the caregiver on how to inspect their positioning of the child in the CRS.

Following the remote consultation, the onsite CPST again inspected the CRS using an objective rating scale while participants completed a post-intervention questionnaire assessing their perceptions of the remote consultation and CRS installation process. Prior to departure, all CRS in the vehicle (including those not randomly selected as the "target" for research purposes if multiple CRS were present) were re-inspected for safety. If needed, participants were assisted with re-installation by the onsite CPST. Participants were offered \$40 cash payment to reimburse them for their time. All onsite and remote CPST held active CPST certification from Safe Kids.

## **Coding Accuracy of CRS Use**

Onsite CPST used a structured coding sheet to rate the accuracy of caregiver's seat selection, installation, and child positioning before and after remote CPST consultation. Baseline installation was only coded when the CRS arrived secured to the vehicle (versus in the original packaging or loose in the vehicle). Child positioning was only coded at baseline and post-intervention when the child passenger for the target CRS was present.

The initial development of the coding sheet is detailed elsewhere (Schwebel, Tillman et al., 2017). Items include criteria from the Safe Kids Worldwide Child Passenger Safety Checklist

and other best practice guidelines. Minor revisions to the previously published coding sheet (Schwebel, Tillman et al., 2017) were made iteratively through input from multiple expert researchers in child safety and injury prevention, including four certified CPST. Coding criteria for four child restraint types and installations were developed, representing rear- and forward-facing CRS and installation with lower anchors or seat belts. Seat selection was evaluated with six items and child positioning was evaluated with five items for all CRS. Installation was evaluated with 15-19 items, depending on the CRS type and installation method. All coding items are presented in Table 1. When items were not relevant to a particular CRS or vehicle, they were omitted.

## **Data Analysis**

Data analyses were conducted separately for CRS selection, installation, and child positioning. Each analysis included only those participants with both baseline and post-intervention data for that analysis. Participants were classified as making no errors or making one or more errors within each category. McNemar's tests were used to evaluate significant changes in the proportion of participants with no errors from baseline to post-intervention. Descriptive statistics were used to specify participant characteristics and the errors in CRS use made by participants at baseline and post-intervention.