VIRTUAL REALITY BY MOBILE PHONE: IMPROVING CHILD PEDESTRIAN SAFETY

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STATEMENT OF COMPLIANCE

The trial will be conducted in accordance with International Conference on Harmonisation Good Clinical Practice (ICH GCP) and applicable United States (US) Code of Federal Regulations (CFR). The Principal Investigator will assure that no deviation from, or changes to, the protocol will take place without prior documented approval from the Institutional Review Board (IRB), except where necessary to eliminate an immediate hazard(s) to the trial participants. All personnel involved in the conduct of this study have completed Human Subjects Protection and ICH GCP Training.

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the local Institutional Review Board (IRB) for review and approval. Approval of both the protocol and the consent form must be obtained before any participant is enrolled. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. All changes to the consent form will be IRB approved; a determination will be made regarding whether a new consent needs to be obtained from participants who provided consent, using a previously approved consent form.

1 PROTOCOL SUMMARY

1.1 SYNOPSIS

Title:	Virtual Reality by Mobile Phone: Improving Child Pedestrian Safety
Study Background:	Pedestrian injury is a serious public health concern for children in the United States and around the world. We have previously studied virtual reality as a mechanism to train children to be safer pedestrians. Virtual reality offers the opportunity for repeated practice at the complex cognitive-perceptual task of crossing a street, and we have demonstrated that it is effective to help 7- and 8-year-old children learn to cross streets more safely.
Objectives:	This protocol extends previous work in two ways. First, we are unsure how much practice and training children need to achieve adult levels of pedestrian safety. We will offer children in this study up to 25 sessions of practice crossing the street in a virtual world to see when they achieve adult levels of safety. Second, we will evaluate whether training using a virtual reality program delivered to a mobile smartphone platform is as effective as training in a larger semi-immersive virtual pedestrian environment we have used previously.
Study Population:	7 and 8 year old children
Phase:	III
Description of Study Intervention:	Pedestrian safety training in virtual reality

2 INTRODUCTION

2.1 STUDY RATIONALE

Pedestrian injury is a serious public health risk for children in the United States and worldwide. One way to reduce pedestrian injury risk is by training children to cross streets more safely. Previous research indicates virtual reality may be an ethical and safe way to provide such training, and this trial was designed to further evaluate virtual reality as a means to teach children pedestrian street-crossing skills.

2.2 BACKGROUND

We have conducted two clinical trials evaluating whether training in a virtual reality environment helps children learn to cross the street more safely. In the first, 240 children were randomly assigned to one of four conditions. Children trained in the virtual reality environment achieved levels of pedestrian safety that were approximately equivalent to children trained individually at streetside locations. They performed better than children trained using websites and videos, and better than children in a no-contact control group.

In the second trial, we evaluated whether training in a virtual reality environment placed in community settings (schools or YMCAs) was effective. We found children did learn to be safer pedestrians through that training, although they did not achieve levels of safety as much as children in the previous study. One reason for this may be that children in this second trial were exposed to six 15-minute training sessions whereas children in the first trial were exposed to six 30-minute training sessions, or double the amount.

We have conducted previous work demonstrating the Google Cardboard platform delivering virtual reality to children by mobile phone is usable, feasible, and safe. Other laboratories also use virtual reality for evaluation of children's pedestrian, bicycling, and other behaviors.

2.3 RISK/BENEFIT ASSESSMENT

2.3.1 KNOWN POTENTIAL RISKS

Physical risk includes (a) minor risk of motion sickness while engaging in a virtual environment, (b) risk of injury from moving traffic while completing the "shout" and "two-step" assessments at streetside locations off the road but near moving traffic, and (c) slight chance of iatrogenic risks, whereby children or parents take greater risk following participation in training because they think the children are safer.

Psychological risks include (a) embarrassment from being videotaped or engaging in the research protocol, and (b) embarrassment for parents to answer questionnaires that are mildly invasive.

Social risks. We believe there is minimal social risk from participating in this study. The primary risk results from the possibility for a breach of confidentiality. No data we collect will be highly personal, but we will collect information that participants may wish to keep private (such as household income), and the risk of a confidentiality breach is a social risk.

There are no anticipated economic or legal risks.

2.3.2 KNOWN POTENTIAL BENEFITS

It is now known, which is why we are conducting this research, but children may learn to be safer pedestrians through participation in this study.

3 STUDY DESIGN

3.1 OVERALL DESIGN

A non-inferiority randomized controlled trial will be conducted.

4 STUDY POPULATION

4.1 INCLUSION CRITERIA

- Child age 7 or 8 years

4.2 EXCLUSION CRITERIA

- Inability of child or parent to communicate in English
- Previous participation of a sibling in the study
- Physical or mental disability that prohibits child from valid participation in the study

5 STUDY INTERVENTION

5.1 STUDY INTERVENTION(S) ADMINISTRATION

5.1.1 STUDY INTERVENTION DESCRIPTION

Virtual Reality Platforms

Two virtual reality (VR) platforms will be used, the "kiosk" VR in a laboratory setting and the smartphone-based VR delivered via smartphone. In the kiosk system, children stand on a plywood curb and step down onto a pressure plate to trigger the system for crossing. The system runs on a single Windows 7 PC with an Intel Core i5-3330 3.0GHz Quad-Core desktop processor and GeForce GT 640 video card. The virtual environment is displayed on 3 vertically mounted Samsung MD55C 55" Direct-lit LED displays and is moved vertically on the displays to match the participant's eye-level. In the smartphone system, children use a standard Android mobile smartphone inserted into a durable View-Master® VR viewer. The street-crossing simulator software on both systems are built on top of the Unity game engine with identical virtual environments, game play logic and data collection.

In both VR platforms, prior to children entering the VR, the researcher enters a walking speed (based either on the child's previously-measured walking speed in a separate location or age-based averages), gender, and skin tone (to select sex- and race-matched avatar). Children view a bi-directional roadway modeled after an actual street environment near a local school. Traffic density, traffic speed, and vehicle types are adjusted to researcher preferences and child skill level. Ambient and Doppler-accurate traffic noise are delivered. Over a dozen types of vehicles (including cars, SUVs, pick-ups, and also ambulances, school buses, etc.) appear in random order at researcher-determined frequencies. When children deem it safe, they step off the simulated curb to trigger a pressure plate (semi-immersion) or push a button (smartphone). In the kiosk VR, the virtual world view then changes from first to third-person, permitting children to view themselves crossing. This switch from first to third person happens seamlessly and most users do not even notice the switch when asked about it later. In the smartphone VR, the virtual world remains at first-person view, as the viewpoint follows the avatar across the street.

Following the avatar's crossing, the child is informed about the safety of crossing.

Training Protocol

Children will complete up to 25 training sessions. Training sessions will be scheduled about twice a week and will be identical in both groups except for the VR platform used. Children will engage in the VR for 3 sets of 15 crossings, or 45 crossings at each training session (expected duration ~30 minutes). The first two sets of crossings will be tailored to children's ability level, with traffic density set just beyond the level they previously succeeded crossing at. The third set of crossings will be standardized for all visits, at 30 MPH and 10 vehicles/minute/lane. Along with serving as a training trial, this third set will typically be a little easier for children, providing positive feedback and motivation for training. It also will offer a standardized assessment of ability.

All children will complete six visits to the laboratory for training. Following the sixth and all subsequent visits, we will monitor each child's number of unsafe crossings in the final standardized assessment. When children complete two consecutive visits at a level equal to or safer than the average adult performance, they will be considered "competent" pedestrians functioning like an adult and training will be discontinued. Adult performance will be defined based on previous research with >300 adults.

5.2 MEASURES TO MINIMIZE BIAS: RANDOMIZATION

Random assignment to the condition in which the child received training will be conducted using simple randomization by asking children to draw a slip of paper from a large envelope at the end of baseline data collection.

6 STUDY INTERVENTION DISCONTINUATION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL

6.1 DISCONTINUATION OF STUDY INTERVENTION

Training will be discontinued after 25 sessions if children have not yet reached adult competency at that point. Training will be discontinued also if there is any sign of adverse or iatrogenic effect.

6.2 PARTICIPANT DISCONTINUATION/WITHDRAWAL FROM THE STUDY

Participants are free to withdraw from participation in the study at any time upon request. An investigator may discontinue or withdraw a participant from the study for the following reasons:

- Non-compliance to study protocol
- If any clinical adverse event (AE), laboratory abnormality, or other medical condition or situation occurs such that continued participation in the study would not be in the best interest of the participant

6.3 LOST TO FOLLOW-UP

A participant will be considered lost to follow-up if they fail to attend multiple scheduled visits and/or are unable to be contacted by the study site staff.

7 STUDY ASSESSMENTS AND PROCEDURES

7.1 STUDY ASSESSMENTS

In all pedestrian simulations (both virtual and streetside), several measures will be collected. Unsafe crossings will be the primary outcome, defined as the sum of "hits" with simulated vehicles, plus "close call" instances when the child was within one second of being hit by an oncoming vehicle. We also will assess several secondary measures, including start delay (temporal lapse between a safe gap between vehicles emerging and children entering that gap to cross the street), time to contact (shortest distance between children and an oncoming virtual vehicle), attention to traffic (looks left and right divided by wait time), missed opportunities (rejected gaps $\geq$ 1.5 times participant's crossing time), wait time (average time waiting to cross, divided by cars that pass while waiting), and gap size (temporal gap crossed within).

We will collect other measures as potential covariates. Parents will report basic demographic data (e.g., child gender, race/ethnicity, birthdate; family SES), child temperament, and children's pedestrian behavior and habits. Children will complete a screener of verbal intelligence.

7.2 ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

7.2.1 DEFINITION OF ADVERSE EVENTS (AE)

Adverse event means any untoward medical occurrence associated with the use of an intervention in humans, whether or not considered intervention-related (21 CFR 312.32 (a)).

7.2.2 DEFINITION OF SERIOUS ADVERSE EVENTS (SAE)

An adverse event (AE) is considered "serious" if, in the view of either the investigator or sponsor, it results in any of the following outcomes:

- Death
- A life-threatening adverse event (of note, the term "life-threatening" refers to an event in which the participant was at risk of death at the time of the event, rather than to an event which hypothetically might have caused death if it were more severe)
- inpatient hospitalization or prolongation of existing hospitalization

- a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
- or a congenital anomaly/birth defect.

Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the participant and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.

7.2.3 CLASSIFICATION OF AN ADVERSE EVENT

7.2.3.1 SEVERITY OF EVENT

For adverse events (AEs), the following guidelines will be used to describe severity:

- **Mild** – Events require minimal or no treatment and do not interfere with the participant's daily activities.
- **Moderate** – Events result in a low level of inconvenience or concern with the therapeutic measures. Moderate events may cause some interference with functioning.
- **Severe** – Events interrupt a participant's usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually potentially life-threatening or incapacitating. Of note, the term "severe" does not necessarily equate to "serious."

7.2.3.2 RELATIONSHIP TO STUDY INTERVENTION

All adverse events (AEs) must have their relationship to study intervention assessed by the researchers who examine and evaluate the participant based on temporal relationship and his/her clinical judgment. The degree of certainty about causality will be graded using the categories below. In a clinical trial, the study product must always be suspect.

- **Related** – The AE is known to occur with the study intervention, there is a reasonable possibility that the study intervention caused the AE, or there is a temporal relationship between the study intervention and event. Reasonable possibility means that there is evidence to suggest a causal relationship between the study intervention and the AE.
- **Not Related** – There is not a reasonable possibility that the administration of the study intervention caused the event, there is no temporal relationship between the study intervention and event onset, or an alternate etiology has been established.

7.2.3.3 EXPECTEDNESS

The Principal Investigator will be responsible for determining whether an adverse event (AE) is expected or unexpected. An AE will be considered unexpected if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the study intervention.

7.2.4 TIME PERIOD AND FREQUENCY FOR EVENT ASSESSMENT AND FOLLOW-UP

The occurrence of an adverse event (AE) or serious adverse event (SAE) may come to the attention of study personnel during study visits and interviews of a study participant presenting for medical care, or upon review by a study monitor.

All AEs including local and systemic reactions not meeting the criteria for SAEs will be captured on the appropriate case report form (CRF). Information to be collected includes event description, time of onset, clinician's assessment of severity, relationship to study product (assessed only by those with the training and authority to make a diagnosis), and time of resolution/stabilization of the event. All AEs occurring while on study will be documented appropriately regardless of relationship. All AEs will be followed to adequate resolution.

7.2.5 ADVERSE AND SERIOUS ADVERSE EVENT REPORTING

All serious adverse events will be reported to the IRB according to regulatory requirements. The Principal Investigator will report to the sponsor any serious adverse event in a timely manner. All serious adverse events (SAEs) will be followed until satisfactory resolution.

7.3 UNANTICIPATED PROBLEMS

7.3.1 DEFINITION OF UNANTICIPATED PROBLEMS (UP)

The Office for Human Research Protections (OHRP) considers unanticipated problems involving risks to participants or others to include, in general, any incident, experience, or outcome that meets **all** of the following criteria:

- Unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the Institutional Review Board (IRB)-approved research protocol and informed consent document; and (b) the characteristics of the participant population being studied;
- Related or possibly related to participation in the research ("possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

7.3.2 UNANTICIPATED PROBLEM REPORTING

The investigator will report unanticipated problems (UPs) to the reviewing Institutional Review Board (IRB). The UP report will include the following information:

- Protocol identifying information: protocol title and number, PI's name, and the IRB project number;
- A detailed description of the event, incident, experience, or outcome;
- An explanation of the basis for determining that the event, incident, experience, or outcome represents an UP;
- A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the UP.

To satisfy the requirement for prompt reporting, UPs will be reported using the following timeline:

- UPs that are serious adverse events (SAEs) will be reported to the IRB within 10 working days of the investigator becoming aware of the event.
- Any other UP will be reported to the IRB within 10 working days of the investigator becoming aware of the problem.

8 STATISTICAL CONSIDERATIONS

8.1 STATISTICAL HYPOTHESES

- Primary Endpoint(s):

Unsafe crossings and start delays in virtual reality pedestrian crossings

- Secondary Efficacy Endpoint(s):

Other pedestrian safety outcomes, as assess in virtual and real world assessments

8.2 SAMPLE SIZE DETERMINATION

Sample size is driven by Specific Aims 1 and 3 in the grant submission. In our previous study comparing 4 pedestrian training groups including the laboratory VR (Schwebel, McClure, et al., 2014a), we observed after 6 training sessions an adjusted mean change from post to pre of 280 milliseconds in start delay (after accounting for baseline value; field and VR trials averaged). To conclude the smartphone group is not inferior to the laboratory VR group with 80% power and type I error rate of 0.05, assuming a common SD of 0.50 (similar to that observed previously) and a non-inferiority margin of 0.12 (reflecting reduction in the gap before initiating crossing from post to pre of no less than 160 milliseconds, 50% of the more ecologically-valid field trial reduction of 320 milliseconds seen previously in VR group, and also the more conservative estimate between field vs lab assessment; Schwebel, McClure, et al., 2014a; 50% recommended by Mulla et al., 2012), we require a sample size of 216 per group (total N = 432) based on a two-sample test of difference in means. To account for attrition, estimated conservatively from our previous study's 9% attrition rate, we will inflate the sample size by 15%, recruiting a total N of 498.

We expect the hypotheses tested in Specific Aim 3 will be sufficiently powered also. Specific Aim 3 has two primary outcomes. For start delay, we expect sufficient power as: (a) the SD of start delay should be smaller than that for Specific Aim 1 given the larger number of training trials, and (b) as the SD decreases, the sample size required to declare noninferiority with the same margin will be smaller. For unsafe crossings, in the previous VR study we observed a mean of 0.20 (SD=0.20) for the follow-up mean percent of unsafe crossings. We assume that after additional training sessions, the mean percent of unsafe crossings will decrease and the variation will also decrease. With 216 per group, and assuming conservatively that the standard deviation decreases from 0.20 to 0.18, with alpha=0.025 and a non-inferiority margin of 5%, we have 82% power. In reality, we anticipate that the standard deviation will decrease further yet, which will result in increases in power for this hypothesis (SD=0.17 → power=86%; SD=0.16 → power=90%).

8.3 STATISTICAL ANALYSES

Descriptive statistics for participants randomized to each intervention will be summarized for each outcome using standard measures of central tendency and variability. Several covariates may impact the relation between the intervention and the outcome measures of interest, including age, gender, temperament, attention during intervention, pedestrian experience, and verbal intelligence. Because children will be randomized to the interventions, we expect these covariates to be balanced across intervention groups. To test this, we will assess the relation between each covariate and intervention group. If differences emerge, those variables will be included as covariates in primary analyses. Primary inferential data analyses will address the study's three objectives. Specific Aim 1 is to test whether immersive training in the smartphone VR improves children's street-crossing skills after 6 training trials at a rate not inferior to improvement seen in the semi-immersive kiosk VR. Given its relevance especially during the early stages of learning pedestrian safety, start delay will serve as the primary dependent measure and the hypothesis of interest for testing change, assuming that an improvement is reflected by a negative value (that is, a lower post-training value is better), is:

$$H_o: \Delta_{LVR} - \Delta_{IVR} \geq \delta \text{ vs. } H_A: \Delta_{LVR} - \Delta_{IVR} < \delta$$

where δ is the non-inferiority margin. We will perform ANCOVA to determine if the difference in change from post- to pre-intervention visits in the two groups falls below the non-inferiority margin, after adjustment for the baseline measure. If so, we will reject the null hypothesis and conclude training in the smartphone VR is not inferior to training in the kiosk VR. We will use similar methodology also to examine secondary outcome measures such as unsafe crossings and attention to traffic.

Specific Aim 2 is to (2a) demonstrate that most children achieve adult-level pedestrian functioning after 25 training sessions and (2b) demonstrate how many training sessions are sufficient to achieve this functioning. Because the safety of crossings is ultimately of greatest interest from a public health perspective, unsafe crossings will serve as the primary outcome for this aim; start delay will serve as a critical secondary outcome. Adult functioning will be estimated based on the performance of 311 healthy adults in four previous studies. Aim 2a will be evaluated via simple descriptive statistics to determine what percent of children achieve an unsafe crossings rate equivalent to adults in multiple simulated crossings. Aim 2b will also be evaluated descriptively, in this case by examining the average number of trials needed to achieve adult functioning across the sample, as well as the trajectory and distribution of that variable.

Specific Aim 3 is to test whether training in the smartphone VR improves children's street-crossing skills after 25 training trials, or fewer if adult functioning is achieved earlier, at a rate not inferior to improvement seen in the semi-immersive kiosk VR. Two dependent variables will be primary, start delay and unsafe crossings (other measures will be considered secondarily) and we will test the aim with the same hypothesis, analyses, and assumptions as in Specific Aim 1. Two sets of analyses will be conducted, one to test change from baseline to post-intervention and the second to test change from baseline to follow-up visits 6 months later.

9 SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

9.1 REGULATORY, ETHICAL, AND STUDY OVERSIGHT CONSIDERATIONS

9.1.1 INFORMED CONSENT PROCESS

9.1.1.1 CONSENT/ASSENT AND OTHER INFORMATIONAL DOCUMENTS PROVIDED TO PARTICIPANTS

Consent forms describing in detail the study intervention, study procedures, and risks are given to the participants' parents and written documentation of informed consent is required prior to conducting study screening procedures. Verbal assent will be obtained from child participants.

9.1.1.2 CONSENT PROCEDURES AND DOCUMENTATION

Informed consent is a process that is initiated prior to the individual's agreeing to participate in the study and continues throughout the individual's study participation. Consent forms will be Institutional Review Board (IRB)-approved and the participant's parent or legal guardian will be asked to read and review the document. The investigator will explain the research study and answer any questions that may arise. A verbal explanation will be provided in terms suited to both the participant's and the child's comprehension of the purposes, procedures, and potential risks of the study and of their rights as research participants. Participants will have the opportunity to carefully review the written consent form and ask questions prior to signing. The participant will sign the informed consent document prior to engaging in any study procedures. Participants will be informed that participation is voluntary and that they may withdraw from the study at any time, without prejudice. The informed consent process will be conducted and documented in the source document (including the date), and the form signed.

9.1.2 STUDY DISCONTINUATION AND CLOSURE

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to regulatory authorities. If the study is prematurely terminated or suspended, the Principal Investigator (PI) will promptly inform study participants and the Institutional Review Board (IRB), will provide the reason(s) for the termination or suspension. Study participants will be contacted, as applicable, and be informed of changes to study visit schedule.

Circumstances that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants
- Demonstration of efficacy that would warrant stopping
- Insufficient compliance to protocol requirements
- Data that are not sufficiently complete and/or evaluable
- Determination of futility

The study may resume once concerns about safety, protocol compliance, and data quality are addressed, and satisfy the IRB.

9.1.3 CONFIDENTIALITY AND PRIVACY

Participant confidentiality and privacy is strictly held in trust by the participating investigators and their staff. Therefore, study documentation, data, and all other confidential information generated will be held in strict confidence. No information concerning data will be released to any unauthorized third party without prior written approval of the Principal Investigator.

Representatives of the Institutional Review Board (IRB) may inspect all documents and records required to be maintained by the investigator.

The study participant's contact information will be securely stored for internal use during the study. At the end of the study, all records will continue to be kept in a secure location for as long a period as dictated by the reviewing IRB and/or Institutional policies.

Study participant research data, which is used for purposes of statistical analysis and scientific reporting, will be stored securely. Individual participant research data will be identified by a unique study identification number.

9.1.4 DATA HANDLING AND RECORD KEEPING

9.1.4.1 DATA COLLECTION AND MANAGEMENT RESPONSIBILITIES

Data collection is the responsibility of the research under the supervision of the Lab Manager and Principal Investigator. The Principal Investigator is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.

9.1.4.2 STUDY RECORDS RETENTION

Study documents will be retained for a minimum of 3 years after the completion of the study or longer if required by local regulations.

9.1.5 PROTOCOL DEVIATIONS

A protocol deviation is any noncompliance with the clinical trial protocol requirements. The noncompliance may be either on the part of the participant, the investigator, or the study site staff. As a result of deviations, corrective actions will developed and implemented.

These practices are consistent with ICH GCP:

- 4.5 Compliance with Protocol, sections 4.5.1, 4.5.2, and 4.5.3
- 5.1 Quality Assurance and Quality Control, section 5.1.1
- 5.20 Noncompliance, sections 5.20.1, and 5.20.2.

It is the responsibility of the Principal Investigator to use continuous vigilance to identify and report deviations within 10 working days of identification of the protocol deviation. Protocol deviations must be sent to the reviewing Institutional Review Board (IRB) per their policies. The Principal Investigator is responsible for knowing and adhering to the reviewing IRB requirements.

9.2 ABBREVIATIONS

AE	Adverse Event
ANCOVA	Analysis of Covariance
CFR	Code of Federal Regulations
CONSORT	Consolidated Standards of Reporting Trials
CRF	Case Report Form
DHHS	Department of Health and Human Services
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
ICH	International Conference on Harmonisation
ICMJE	International Committee of Medical Journal Editors
IRB	Institutional Review Board
LSMEANS	Least-squares Means
NCT	National Clinical Trial
NIH	National Institutes of Health
OHRP	Office for Human Research Protections
PI	Principal Investigator
QA	Quality Assurance
QC	Quality Control
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SOA	Schedule of Activities
SOP	Standard Operating Procedure
UP	Unanticipated Problem
US	United States

10 REFERENCES

Much of this protocol was published in the following study protocol:

Schwebel, D. C., Severson, J., He, Y., & McClure, L. A. (2017). Virtual reality by mobile smartphone: Improving child pedestrian safety. *Injury Prevention, 23*, 357.

Other aspects are included in the study IRB protocol.