

# **AN INTERACTIVE WEB PLATFORM TO TEACH CHILDREN HUNTING, SHOOTING AND FIREARMS SAFETY**

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**National Clinical Trial (NCT) Identified Number: NCT04622943**

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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

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| <b>Title:</b>                             | An Interactive Web Platform to Teach Children Hunting, Shooting and Firearms Safety  |
| <b>Study Background:</b>                  | <p>Firearms injuries are a significant pediatric public health challenge in the United States. The Centers for Disease Control (CDC) estimates 803 children ages 0-15 were killed by firearms in the United States in 2018, and an additional 2,422 children visited emergency rooms for treatment after a firearms injury. Roughly half of children who are hospitalized for a firearm-related injury leave the hospital with a disability, creating long-term health, medical system, financial, family, and societal burden.</p> <p>About one-third of firearms injuries to children under age 15 are due to unintentional causes rather than suicide or homicide. Those injuries tally over 80 child deaths and 1200 serious injuries every year in the United States and represent the current focus.</p> <p>The present study implements a randomized clinical trial to evaluate ShootSafe, an interactive, engaging, educational website to teach children firearms safety.</p> |
| <b>Objectives:</b>                        | The research will evaluate whether ShootSafe achieves 3 goals: (a) teach children ages 10-12 basic knowledge and skills needed to hunt, shoot, and use firearms safely; (b) help children learn and hone critical cognitive skills of impulse control and hypothetical thinking needed to use firearms safely; and (c) alter children's perceptions about their own vulnerability and susceptibility to firearms-related injuries, the severity of those injuries, and their perceived norms about peer behavior surrounding firearms use.   |
| <b>Study Population:</b>                  | Children ages 10-12 years who have exposure to firearms  |
| <b>Phase:</b>                             | I-II   |
| <b>Description of Study Intervention:</b> | Interactive, engaging, and educational website   |

## 2 INTRODUCTION

### 2.1 STUDY RATIONALE

Firearms injuries are a significant pediatric public health challenge in the United States. The Centers for Disease Control (CDC) estimates 803 children ages 0-15 were killed by firearms in the United States in 2018, and an additional 2,422 children visited emergency rooms for treatment after a firearms injury. Roughly half of children who are hospitalized for a firearm-related injury leave the hospital with a disability, creating long-term health, medical system, financial, family, and societal burden.

About one-third of firearms injuries to children under age 15 are due to unintentional causes rather than suicide or homicide. Those injuries tally over 80 child deaths and 1200 serious injuries every year in the United States and represent the current focus.

The present study implements a randomized clinical trial to evaluate ShootSafe, an interactive, engaging, educational website to teach children firearms safety.

### 2.2 BACKGROUND

#### Children and Firearms

American children are routinely exposed to firearms in their homes. A study of 314 parent-child dyads seeking treatment at a rural health clinic in Alabama found that 201 of the homes (64%) had firearms present in their home. Among those 201, 73% of children ages 5-10 and 79% of children ages 10-14 knew where the guns were stored. An equal number of children – 36% – in both age groups reported they had handled the firearms, including 52% of boys. Our laboratory's research with 1561 fifth-graders in the Birmingham metropolitan area found that 31% of families reported having firearms in the home, with higher rates among families with Non-Hispanic White children than those with African-American or Hispanic children. Just under half of the 440 families in that study with firearms in their homes (47%) stated they used the firearms for hunting.

Recognizing the methodological limitations of self-report data concerning firearms ownership and usage, a different study by our research team used home inspections to evaluate risk to Birmingham children.<sup>7</sup> In a study of 42 Birmingham-area families who agreed to have their homes inspected for broad child safety risks (mean child age = 15 years), 38% had a firearm present and 29% had a firearm present and unlocked. Among the 23% of families with rifles present, 79% stored the rifle unlocked, 61% stored ammunition in the same place as the rifle, and 15% stored the rifle unlocked and loaded with ammunition.

Online forums suggest children as young as age 5 and 6 sometimes start hunting and shooting with their parents. Most United States state laws permit children of any age to hunt legally under supervision by an adult. In many states, children can legally hunt unsupervised by an adult at any age if they complete a hunter education training program; the remaining states usually limit unsupervised hunting to children over age 10 or 12 years. Anecdotal reports widely cite the fact that children typically begin shooting and hunting during the elementary school years and often hunt and shoot alone or with peers and siblings by age 10 or 12, whether legal in their state or not.

#### Firearms Injuries while Hunting and Shooting

Among adults, between 25-33% of unintentional firearms injuries occur while hunting. In one case series of serious hunting injuries over a 2-year period, 10 of the 68 (15%) shooters were under age

15 and an additional 12 shooters (18%) were between the ages of 15-17. Half of the 22 children who unintentionally shot a person while hunting were being supervised by an adult while hunting, and half were not. 28% of the cases in the series were fatal.

Data on injuries and fatalities related to recreational shooting are less readily available, but one report suggests about 3% of unintentional firearms fatalities from 2003-2006 in selected US states were known to be the direct result of an incident during target shooting activities. An additional 21% occurred during hunting, 11% while cleaning or loading the firearm, and 5% while carrying or handling it. A large portion (15%) were due to other or unknown causes and may also have been associated with hunting or shooting.

### **Previous Research on Firearms Safety Programs for Children**

A large portion of existing child firearms safety programs focus on changing adult behavior through strategies such as safe firearms storage rather than on changing children's behavior with firearms. Two recent systematic reviews, which identified 12 and 10 studies respectively targeting children (and 9 others targeting adolescents in the Ngo et al. review), suggest most existing programs to teach children firearms safety are ineffective. A surprising number of published empirical trials yield either null results or results that document capacity to teach children basic knowledge but not translate that knowledge into safer behavior.

Despite the discouraging results of previous research, a smattering of studies offer promising results to guide the current study. Perhaps most influential is a series of studies by Miltenberger and colleagues that test the use of active learning strategies, generally delivered in small-group or classroom settings, to teach children firearms safety. In all cases, these studies use small sample sizes (largest N = 45 and many Ns < 10). The findings generally suggest children exposed to theory-based active-learning activities involving behavioral strategies like modeling, rehearsal and feedback successfully learn both relevant firearms safety skills as well as displaying appropriate behavior in role-play scenarios following the training. We adopt these active-learning behavioral strategies into an internet-based delivery system for ShootSafe.

## **2.3 RISK/BENEFIT ASSESSMENT**

### **2.3.1 KNOWN POTENTIAL RISKS**

Psychological risks include slight possibility that children may believe they are more safe using firearms after participating in the study (iatrogenic effects) and slight risk that children might become more excited about shooting, hunting, and using firearms after participating in the study, increasing risk of injury through exposure.

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).

There are no known physical, economic, or legal risks involved in study participation.

### **2.3.2 KNOWN POTENTIAL BENEFITS**

Study results may provide valuable information to society concerning ways to reduce risk of firearms injuries to children. Study participants may learn about firearms safety (intervention group) or nutrition (control group).

### 3 STUDY DESIGN

#### 3.1 OVERALL DESIGN

A randomized controlled trial with two arms will be conducted.

### 4 STUDY POPULATION

#### 4.1 INCLUSION CRITERIA

- Child ages 10-12
- Live within driving distance of laboratory in Birmingham, Alabama
- Child has exposure to firearms through personal experience with firearms in the home or engagement in hunting or shooting activities

#### 4.2 EXCLUSION CRITERIA

- Inability to complete study protocol in English
- Physical or mental disability that prohibits valid participation in the study

### 5 STUDY INTERVENTION

#### 5.1 STUDY INTERVENTION(S) ADMINISTRATION

##### 5.1.1 STUDY INTERVENTION DESCRIPTION

All intervention activities will occur in a laboratory setting where we can monitor usage and control exposure to the intervention. Children in both intervention groups will use the randomly-assigned websites during two 45-minute sessions.

The active ShootSafe intervention offers a wide range of stories, games and videos for children to experience in a sequential manner, such that children step through the website in a prescribed order. The comparison group will visit nourishinteractive.com, a website that provides educational games and activities relevant to child nutrition and exercise. Of similar size/scope to ShootSafe, nourishinteractive.com offers extensive games, stories, and interactive activities for children in a range of age groups, including our target age. Children in the comparison group will self-direct to their preferred activities on the website.

#### 5.2 MEASURES TO MINIMIZE BIAS: RANDOMIZATION

Randomization to condition will be achieved using a 1:1 allocation ratio. The research team will determine randomized assignment through a random number generator and randomized order list concealed to all parties prior to assignment. Children will be assigned to a condition upon arrival to the first training visit, following all baseline data collection.

## 6 STUDY INTERVENTION DISCONTINUATION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL

### 6.1 DISCONTINUATION OF STUDY INTERVENTION

The intervention will be discontinued if participants request it or 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 scheduled visits and/or are unable to be contacted by the study site staff.

## 7 STUDY ASSESSMENTS AND PROCEDURES

### 7.1 STUDY ASSESSMENTS

The primary study outcome will be children's behavior with firearms, as assessed through three strategies: (a) a basic written "quiz" concerning firearms safety; (b) a series of photographs showing various safe and unsafe situations, in which children respond whether the situation is safe or not; and a role-play simulation.

In the role play simulation, we will arrange replicated hunting and shooting scenes in the laboratory and children will use toy firearms to engage in simulated hunting and shooting activities. They also will prepare for outings (e.g., select proper attire) and return to a different room to "store" their firearms safely. All behavior will be videotaped and subsequently coded for risk-taking using an objective coding scheme.

Several secondary measures will be assessed also.

### 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, 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, assessment of severity, relationship to study activities, 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 Endpoints: scores from the quiz, photograph, and role play simulation tasks

### 8.2 SAMPLE SIZE DETERMINATION

A power analysis was conducted to determine sample size using PASS 14 (Power Analysis and Sample Size) software. Based on previous work, we conservatively assumed change of 3 (SD = 2) in the ShootSafe website condition and 2 (SD = 2) in the comparison condition, yielding an anticipated medium effect size of 0.5. That is, we powered to detect a difference of 0.5 standard deviations between the ShootSafe website and control condition groups. Using 2 tails and  $\alpha = .05$  and assuming an independent samples t-test is conducted, a sample size of 70 per group provides 90% power to detect an effect size as small as 0.5. With the same assumptions and retaining  $n = 70$  per group, we estimate 95% power to detect an effect size of at least 0.56. As we are using a linear mixed model to assess the specific aims rather than a t-test, we will ensure that power is higher yet than that determined above since we will incorporate the observed correlation between the trials. Conservatively inflating 15% to account for attrition, we propose a sample size of 162, which is amply large to test our hypotheses.

### 8.3 STATISTICAL ANALYSES

Data analysis will be conducted with condition masked. Descriptive analyses will be conducted first to examine the distributions of key variables and identify any unusual cases or outliers. Most outcome variables are expected to be normally distributed, but variables with substantially skewed distributions will be appropriately transformed so that linear models may be applied without violating assumptions.

Following inspection and interpretation of descriptive statistics, primary inferential data analyses will address the study's specific aims. Primary analyses will be conducted with the full sample using an intention-to-treat analytic approach.

The primary aim is to evaluate whether the website improves children's safety with firearms. This aim will be measured through scores from the quiz, photograph, and role play simulation tasks. We will standardize each outcome variable and evaluate through correlation matrices and factor analysis to determine if they appear to be measuring the same underlying construct. If so, they will be aggregated. Otherwise, they will be assessed as independent outcome variables.

Linear mixed models will evaluate our primary hypotheses. Linear mixed models were selected primarily because they offer the ability to allow for correlation within each child based on all three of the child's measurements. Group differences will be tested by fitting the following model:

$$E[Y_{ij} | X, Z] = \beta_0 + \beta_1 X_{\text{group}} + \beta_2 X_{\text{time}} + \beta_3 X_{\text{group}} * X_{\text{time}}$$

where time will be entered into the model as a categorical variable (baseline vs post vs follow-up) utilizing effect cell coding so that we can determine whether changes in the outcomes between different time points differ by intervention group. Of greatest interest will be  $\beta_3$ , as this parameter will tell us whether the effect of the intervention group differs between baseline, post-intervention and follow-up time points. If we find that  $\beta_3$  is significant, we will perform orthogonal contrasts to determine which specific time points differ from each other. To increase statistical efficiency, we will use previous literature to identify covariates that may be highly associated with the outcome before statistical analysis, and those covariates will be included in the linear model.

Secondary aims will evaluate efficacy of the ShootSafe program to improve relevant cognitive skills in two domains, impulse control and hypothetical thinking, and to improve children's perceptions of vulnerability, susceptibility and severity of injury, plus their perception of normative peer behavior. Analyses will follow using similar linear mixed models.

We anticipate missing data among the dataset for various reasons, including attrition from the study, rare participant refusal to conduct particular tests or answer particular questions and rare equipment failure or experimenter error. The planned linear mixed models allow the use of all observed data, including data from participants with incomplete missing outcome measurement at follow-up, with the relatively mild assumption of missing at random. We will handle missing covariate data through multiple imputation or other appropriate analytic strategies.

## 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.

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#### 9.1.4 DATA HANDLING AND RECORD KEEPING

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##### 9.1.4.1 DATA COLLECTION AND MANAGEMENT RESPONSIBILITIES

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

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##### 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.

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#### 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 be 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., Long, D. L., Gowey, M., Severson, J., He, Y., & Trullinger, K. (2021). Study protocol: Developing and evaluating an interactive web platform to teach children hunting, shooting and firearms safety: A randomized controlled trial. *BMC Public Health*, 21, 308.

Other aspects are included in the study IRB protocol.