



[reviewer notes-]

**Provide a short title for this study** (200 characters or less):

**Cluster-Randomized Trial of a Middle School Coach Gender Violence Prevention**

T1.0

**Select the type of application:**

New Research Study

T2.0

**Is the proposed research study limited to the inclusion of deceased individuals?**

\* No

T2.1

**Are any research activities being conducted at the VA Pittsburgh Healthcare System or with VA funds?**

\* No

[reviewer notes-]

T3.0

**What is the anticipated risk to the research participants?**

Minimal Risk

T3.1

**Why do you feel that all aspects of this research study, including screening and follow-up, involve no more than minimal risk to the research subjects?**

The study procedures are limited to surveys, questionnaires, observations, focus groups and interviews, and the only potential risks are breach of confidentiality and mild discomfort when answering personal questions.

T4.0

**Does the proposed study qualify for 'exempt' IRB review or for a determination of either 'not research' or 'no human subject' involvement?**

\* No

T5.0

**Does the proposed research study qualify for 'expedited' IRB review status?**

\* Yes

[reviewer notes-]

**CS1.0 What is the reason for this submission?**

New Research Protocol Submission

**CS1.1 Has this research study been approved previously by the University of Pittsburgh IRB?**

\* No

**CS1.1.1 Has this research study (or a substantially similar research study) been previously disapproved by the University of Pittsburgh IRB or, to your knowledge, by any other IRB?**

\* No

[\[reviewer notes-\]](#)**CS2.0****Title of Research Study:****Cluster-Randomized Trial of a Middle School Coach Gender Violence Prevention Program****CS2.0.1****Requested approval letter wording:****CS2.1****Research Protocol Abstract:**

The proposed cluster-randomized school-based study will examine the effectiveness of a program for the primary prevention of perpetration of teen dating violence (TDV) and sexual violence (SV) among middle school male athletes. Engaging men and boys in preventing violence against women and girls is recognized by major global health organizations as a critical public health strategy. "Coaching Boys into Men" (CBIM) is a theory- and evidence based program intended to alter gender norms that foster TDV/SV perpetration, promote bystander intervention (i.e., give boys skills to interrupt disrespectful and harmful behaviors they witness among peers), and reduce TDV/SV perpetration. Coaches receive a 60-minute training and biweekly check-in from a violence prevention advocate to administer the intervention to their athletes via 12 mini-lessons conducted weekly throughout a sport season. In a randomized trial of program effectiveness among high school athletes (CDC CE001561-01, PI Miller), male athletes receiving the program demonstrated increased positive bystander intervention behaviors and less verbal abuse perpetration compared to controls. This proposal seeks to test the effectiveness of this program with younger male athletes in grades 6-8 (ages 11-14). The innovations are three-fold: (1) testing the efficacy of a novel TDV/SV prevention program for middle school male athletes; (2) training athletic coaches in TDV/SV prevention thus implementing primary prevention that does not rely on teachers or classroom time; and (3) integrating the goal of changing gender norms with the technique of a bystander intervention approach to reduce TDV/SV prevention. This study is significant because we have too few evidence-based TDV/SV prevention programs for any age, there is only one other evidence-based TDV/SV prevention program for middle-school age youth, and we have no evidence-based TDV/SV programs for youth that take place outside of the classroom setting. The experimental design involves a 2-armed cluster randomized- controlled trial in 26 middle schools in Pennsylvania. Schools will be randomly assigned to either intervention or control (standard coaching) condition. Coaches in intervention schools will receive CBIM training. Baseline surveys will be collected for all intervention and control site athletes entering grades 6-8 at the start of each sports seasons across Year 1 (Time 1; N=2200 athletes). Follow up surveys will be collected at the end of each sports season (Time 2). All participating athletes will be re-surveyed 12 months after baseline (Time 3; final N =2000). Utilizing linear mixed models to account for clustering arising from randomizing at the level of schools, intervention effects on outcomes at Time 2 and at Time 3 will be assessed. The primary outcome is positive bystander behavior; secondary outcomes include increases in a) knowledge of what constitutes abusive behavior, b) gender-equitable attitudes regarding relationship behaviors, and c) intentions to intervene when TDV/SV-related peer behaviors are witnessed. At Time 3, self-reported TDV/SV perpetration behaviors of athletes will also be assessed.

**CS2.2****Select the category that best describes your research:**

Social, behavioral, educational, and/or public policy research

[\[reviewer notes-\]](#)**CS3.0****Name of the Principal Investigator:**

[Elizabeth Miller](#)

Note: Adjunct faculty of the University, including lecturers and instructors, are not permitted to serve as a PI or Faculty Mentor but may serve as co-investigators. Refer to [Chapter 4](#) on the HRPO website for more information.

**CS3.1 Affiliation of Principal Investigator:**

UPitt faculty member

If you chose any of the **Pitt options**, please indicate the specific campus:

[Main Campus - Pittsburgh](#)

If you chose the UPitt faculty member option, provide the PI's **University Faculty Title:**

Chief, Division of Adolescent Medicine

**CS3.2 Address of Principal Investigator:**

3420 Fifth Ave.  
Pittsburgh, PA 15217

**CS3.3 Recorded Primary Affiliation of the Principal Investigator:**

U of Pgh | School of Medicine | Pediatrics

**CS3.4 Identify the School, Department, Division or Center which is responsible for oversight of this research study:**

[U of Pgh](#) | [School of Medicine](#) | [Pediatrics](#)

**CS3.5 Telephone Number of Principal Investigator:**

412-692-8504

**CS3.6 Recorded Current E-mail Address of Principal Investigator to which all notifications will be sent:**

elizabeth.miller@chp.edu

**CS3.7 Fax Number:**

412-692-5145

**CS3.8 Does this study include any personnel from Carnegie Mellon University, and/or use any CMU resources or facilities (e.g., Scientific Imaging and Brain Research Center (SIBR))?**

\* No

**CS3.9 Is this your first submission, as PI, to the Pitt IRB?**

\* No

[reviewer notes-]

**CS4.0****List of Co-Investigators:**

Last	First	Organization
Abebe	Kaleab	U of Pgh   School of Medicine   Medicine

[reviewer notes-]

**CS5.0****Name of Primary Research Coordinator:**

Lisa Ripper

**CS5.1****Address of Primary Research Coordinator:**

3414 Fifth Avenue, 2nd floor, Room 203  
Pittsburgh, PA 15213

**CS5.2****Telephone Number of Primary Research Coordinator:**

**412-692-6313**

**CS6.0****Name of Secondary Research Coordinator:****CS6.1****Address of Secondary Research Coordinator:****CS6.2****Telephone Number of Secondary Research Coordinator:****CS6.3****Key Personnel/Support Staff (Only list those individuals who require access to OSIRIS):**

Last	First	Organization
Anderson	Jocelyn	Other
Bamwine	Patricia	U of Pgh   School of Social Work   Graduate Program
Bee	Courtney	U of Pgh   School of Medicine   Pediatrics
Boateng	Adwoa	U of Pgh   School of Medicine   Pediatrics
Chugani	Carla	U of Pgh   School of Medicine   Pediatrics
Cirba	Benjamin	Other
Copperman	Ethan	U of Pgh   School of Medicine   Pediatrics
Coulter	Robert	U of Pgh   Graduate School of Public Health   Behavioral and Community Health Sciences
Feinstein	Zoe	U of Pgh   School of Medicine   Pediatrics
Feliz	Nayck	U of Pgh   Graduate School of Public Health   Infectious Diseases and Microbiology
Jaime (formerly Virata)	Maria Catrina	U of Pgh   School of Medicine   Pediatrics
James	Jordan	Other

Last	First	Organization
Jones	Kelley	U of Pgh   Associate Vice Chancellor of Human Resources   All Temps
Landowski	Allison	Other
Macak	Justin	U of Pgh   School of Medicine   Pediatrics
Massof	Michael	UPMC   Hospital Divisions   Children's Hospital of Pittsburgh
Mehta	Saumil	U of Pgh   Other
Miller-Walfish	Summer	U of Pgh   Graduate School of Public Health   Behavioral and Community Health Sciences
Morrow	Sarah	U of Pgh   School of Medicine   Pediatrics
Mulbah	Paul	U of Pgh   Other
Mulwa	Zabi	U of Pgh   School of Medicine   Pediatrics
Paglisotti	Taylor	U of Pgh   School of Medicine   Pediatrics
Richter	Rachael	U of Pgh   School of Medicine   Pediatrics
Ripper	Lisa	U of Pgh   Graduate School of Public Health   Behavioral and Community Health Sciences
Schmulevich	Ali	Other
Simenson	Ashley	Other
Talis	Janine	U of Pgh   School of Medicine   Pediatrics
Van Dusen	Courtney	U of Pgh   School of Medicine   Pediatrics

[\[reviewer notes=\]](#)

**CS7.0 Will this research study use any Clinical and Translational Research Center (CTRC) resources?**

No

[\[reviewer notes=\]](#)

**CS8.0 Select the entity responsible for scientific review.**

**Department Review** - (a dean, department chair, division chief, or center head)

Note: **DoD funded studies** require departmental review

**CS8.1**

**Select the school, department or division which is responsible for scientific review of this submission.**

[U of Pgh](#) | [School of Medicine](#) | [Pediatrics](#)

[reviewer notes=]

**CS9.0** Does this research study involve the administration of an investigational drug or an FDA-approved drug that will be used for research purposes?

\* No

**CS10.0** Is this research study being conducted under a University of Pittsburgh-based, sponsor-investigator IND or IDE application?

\* No

*If YES, you are required to submit the IND or IDE application and all subsequent FDA correspondence through the Office for Investigator-Sponsored IND and IDE Support (O3IS). Refer to applicable University policies posted on the O3IS website ([www.O3IS.pitt.edu](http://www.O3IS.pitt.edu)).*

[reviewer notes=]

**CS11.0** Use the 'Add' button to upload one or more of the following:

- the sponsor protocol (including investigator initiated studies) and/or other brochures
- the multi-center protocol and consent form template, *if applicable*

Name Modified Date

**Is this research study supported in whole or in part by industry? This includes the provision of products (drugs or devices).**

\* No

**Is this a multi-centered study?**

\* No





- 15. Lakeview
- 16. Mercer
- 17. Montour
- 18. New Kensington-Arnold School District
- 19. Plum

**\* For research being conducted at non Pitt or UPMC sites, upload a site permission letter granting the researcher permission to conduct their research at each external site:**

Name	Modified Date
<a href="#">Pittsburgh Public Schools IRB Approval Letter</a>	2/2/2015 10:36 AM
<a href="#">LOS - Montour</a>	5/25/2016 1:56 PM
<a href="#">LOS - Sharon SD</a>	3/5/2014 9:30 AM
<a href="#">LOS - McKeesport SD</a>	3/5/2014 9:29 AM
<a href="#">LOS Shadyside Academy</a>	5/1/2015 4:07 PM
<a href="#">LOS -Ringgold SD</a>	8/18/2015 4:47 PM
<a href="#">LOS - Pittsburgh Public</a>	3/5/2014 11:23 PM
<a href="#">LOS - Belle Vernon Area SD</a>	3/5/2014 9:29 AM
<a href="#">LOS - New Kensington-Arnold SD</a>	5/25/2016 1:57 PM
<a href="#">LOS - Lakeview</a>	5/25/2016 1:55 PM
<a href="#">LOS - Hempfield Area SD</a>	8/18/2015 4:47 PM
<a href="#">LOS - Mercer</a>	5/25/2016 1:56 PM
<a href="#">LOS- West Mifflin</a>	10/20/2015 1:23 PM
<a href="#">LOS Steel Valley</a>	5/1/2015 4:07 PM
<a href="#">LOS St. Edmunds Academy</a>	5/1/2015 4:08 PM
<a href="#">LOS - Elizabeth Forward SD</a>	3/5/2014 9:29 AM
<a href="#">LOS - Plum</a>	5/25/2016 1:58 PM
<a href="#">LOS South Allegheny</a>	5/1/2015 4:07 PM
<a href="#">LOS- Highlands</a>	5/25/2016 1:55 PM
<a href="#">LOS - Clairton</a>	10/20/2015 1:24 PM
<a href="#">LOS - Allegheny Valley SD</a>	3/5/2014 9:28 AM
<a href="#">LOS Community Day School</a>	5/1/2015 4:06 PM

**CS15.1 Have you, [Elizabeth Miller](#) , verified that all members of the research team have the appropriate expertise, credentials, and if applicable, hospital privileges to perform those research procedures that are their responsibility as outlined in the IRB protocol?**

\* Yes

**CS15.2 Describe the availability of resources and the adequacy of the facilities to conduct this study:**

\* Dr. Miller's research office is located in the Oakland Medical Office Building, next to the research offices of the Division of General Pediatrics, Children's Hospital of Pittsburgh, University of Pittsburgh Medical Center. Research coordinators, analysts, research assistants, statisticians are all co-located in these research offices, with shared resources between the Division of Adolescent Medicine and the Division of General Pediatrics.

[reviewer notes-]

**CS16.0 Special Research Subject Populations:**

Categories

Children (age &lt; 18 years old)

[reviewer notes-]

**CS17.0 Does your research involve the experimental use of any type of human stem cell?**

\* No

[reviewer notes-]

**NIH Definition of a Clinical Trial**

***A research study<sup>1</sup> in which one or more human subjects<sup>2</sup> are prospectively assigned<sup>3</sup> to one or more interventions<sup>4</sup> (which may include placebo or other control) to evaluate the effects of those interventions on health related biomedical or behavioral outcomes.<sup>5</sup>***

<sup>1</sup> See Common Rule definition of research at [45 CFR 46.102\(d\)](#) .

<sup>2</sup> See Common Rule definition of human subject at [45 CFR 46.102\(f\)](#) .

<sup>3</sup> The term "prospectively assigned" refers to a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial.

<sup>4</sup> An intervention is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies.

<sup>5</sup> Health-related biomedical or behavioral outcome is defined as the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects' biomedical or behavioral status or quality of life. Examples include: positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); positive or negative changes to psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and /or information retention); positive or negative changes to disease processes; positive or negative changes to health-related behaviors; and, positive or negative changes to quality of life.

**CS18.0 \* Based on the above information, does this study meet the NIH definition of a clinical trial?**

Yes  No

If Yes, click Save and then [Click Here For Study Team's CITI Training Records](#) . Please ensure all personnel's training is up to date

[reviewer notes-]

**1.1 Objective: What is the overall purpose of this research study?** (Limit response to 1-2 sentences.)

This study seeks to test the effectiveness of a violence prevention program via a cluster randomized controlled trial, engaging 26 middle schools in Southwestern Pennsylvania and collecting survey data among middle school aged boys.

**1.2 Specific Aims: List the goals of the proposed study (e.g., describe the relevant hypotheses or the specific problems or issues that will be addressed by the study).**

Aim 1: To test, via a 2-arm cluster-randomized trial in Pennsylvania middle schools (N=26 schools; baseline N of athletes =2200), the effectiveness of a TDV/SV prevention program for male athletes delivered in the context of coaching middle school boys. At the end of the 12 week sports season (Time 2), compared to athletes in the control condition, athletes receiving CBIM will demonstrate:

Hypothesis 1.1: Increased positive bystander intervention behaviors (Secondary Outcome)

Hypothesis 1.2: Increased recognition of abusive behaviors (Secondary Outcome)

Hypothesis 1.3: Increased gender-equitable attitudes (Secondary Outcome)

Hypothesis 1.4: Increased intentions to intervene (Secondary Outcome)

Aim 2: To examine whether CBIM results in sustained improvements in these same outcomes assessed at 12 months after baseline (Time 3; anticipated final N = 2000 athletes), as well as reductions in self-reported perpetration of abusive and controlling behaviors toward girls (Primary Outcome) from baseline to Time 3 when compared to control athletes.

Aim 3: To explore whether demographics, athletes' pre-intervention risk and protective factors (e.g., history of TDV/SV, dating, school connectedness), and coaches' attitudes and behaviors may interact with the intervention to predict changes in outcomes of interest related to perpetration of TDV/SV (i.e., how intervention outcomes may differ across groups).

**1.3 Background: Briefly describe previous findings or observations that provide the background leading to this proposal.**

Teen dating violence (TDV, physical and sexual violence and psychological aggression in adolescent dating relationships) and sexual violence (SV, sexual harassment, sexual assault, and rape) are not uncommon among younger adolescents. In a study of over 5000 6th graders, 42% of dating students (about half the sample) reported being victimized by a boyfriend/girlfriend and 29% reported TDV perpetration, with youth reporting high acceptance of TDV. (Simon, Miller et al. 2010) In a national online survey, 1 in 5 tweens (ages 11-14) said their friends have been victims of TDV; almost 50% who are in relationships know friends who are verbally abused (Teenage Research Unlimited for Liz Claiborne Inc and The National Teen Dating Abuse Helpline 2008). A survey of 7th graders found that 35% of boys and 24% of girls reported being a victim of physical dating violence in the past year, and 21% of the boys and 25% of the girls reported perpetrating physical violence in a dating relationship in the past year. (Swahn, Simon et al. 2008) The alarmingly high rates of TDV/SV reported among younger adolescents point to the need to target TDV/SV prevention among middle school-age youth.

As youth age, the prevalence of TDV/SV increases (Wolitzky-Taylor, Ruggiero et al. 2008). Our own data collected from over 2000 male high school athletes demonstrated that among 9th grade boys who ever dated, 14% reported being abusive (physical, sexual or verbal) towards a female partner in the preceding 3 months, and this figure increased to 32% among 12th graders. Similarly, 68% of 9th grade athletes compared to 81% of 12th grade athletes reported witnessing abusive behaviors perpetrated against girls by their male peers. Evidence that such behaviors are prevalent in adolescence, and appear to increase as youth age, strongly supports the need for early primary prevention efforts targeting middle school students.

**1.4 Significance: Why is it important that this research be conducted? What gaps in existing information or knowledge is this research intended to fill?**

The middle school years represent a critical stage for TDV/SV education and prevention, as many youth start establishing romantic or sexual relationships for the first time(Stein 1995; Noonan and Charles 2009). Sexual harassment increases during middle school,(Pellegrini 2001; McMaster, Connolly et al. 2002; Bentley CG, Galliher RV et al. 2007; Manganello 2008) with studies identifying experiences of dating violence and sexual harassment as early as the 6th grade (Eaton, Kann et al. ; O'Keefe 1997; Callahan, Tolman et al. 2003). Increased interactions with the opposite-sex during the middle school years correlate with increasing rates of opposite-sex aggressive encounters in middle school (Pellegrini 2001). Even though younger adolescents have less experience with formal dating relationships, early gender based conflicts occur.(Noonan and Charles 2009; Mulford and Giordano 2008)

The middle school years are different developmentally from high school. Our data from the high school implementation of CBIM indicates that even by 9th grade, boys are frequently witnessing and perpetrating abusive behaviors towards girls, suggesting that prevention needs to occur earlier. Yet despite the high prevalence of TDV/SV reported by younger adolescents, only three school-based prevention programs are considered effective to stop perpetration of TDV/SV,(Foshee, Bauman et al. 1998; Wolfe, Crooks et al. 2009; Taylor, Stein et al. 2011) all of which involve classroom instruction. Only one of these programs focuses on middle school (Taylor, Stein et al. 2011); none of these programs utilize adults such as coaches outside the classroom setting, and none explicitly combine promoting gender equitable attitudes with a bystander behavior approach. Thus, the proposed study is significant because it addresses several substantive gaps in TDV/SV prevention utilizing a rigorous approach grounded in theory.

[reviewer notes-]

**2.1 Does this research study involve the use or evaluation of a drug, biological, or nutritional (e.g., herbal or dietary) supplement?**

\* No

[reviewer notes-]

**2.2 Will this research use or evaluate the safety and/or effectiveness of one or more devices?**

\* No

[reviewer notes-]

**2.3 Summarize the general classification (e.g., descriptive, experimental) and methodological design (e.g., observational, cross-sectional, longitudinal, randomized, open-label single-blind, double-blind, placebo-controlled, active treatment controlled, parallel arm, cross-over arm) of the proposed research study, as applicable.**

This is a cluster-randomized school based trial to examine the effectiveness of "Coaching Boys into Men" (CBIM) a program for the primary prevention of teen dating violence (TDV) and sexual violence (SV) among middle school athletes. Data collection will be through surveys and qualitative interviews and focus group discussions with coaches and middle school students.

**2.3.1 Does this research study involve a placebo-controlled arm?**

\* No

[reviewer notes-]

**2.4 Will any research subjects be withdrawn from known effective therapy for the purpose of participating in this research study?**

\* No

[reviewer notes-]

**2.5 Will screening procedures (i.e., procedures to determine research subject eligibility) be performed specifically for the purpose of this research study?**

\* No

[reviewer notes-]

**2.6 Provide a detailed description of all research activities (e.g., all drugs or devices; psychosocial interventions or measures) that will be performed for the purpose of this research study.**

This description of activities should be complete and of sufficient detail to permit an assessment of associated risks.

At a minimum the description should include:

- **all research activities**
- **personnel (by role) performing the procedures**
- **location of procedures**
- **duration of procedures**
- **timeline of study procedures**

Personnel performing the procedures:

Principal Investigator

Study Coordinator

Research Assistants

School-Liaison/CBIM Trainer/Violence Prevention Advocate

Location of procedures:

30 middle schools in Western Pennsylvania

Duration of procedures:

Student and coaches baseline surveys 15 minutes

Coaches "Coaching Boys Into Men" training session 60 minutes (intervention schools only)

Student and coaches follow up surveys 15 minutes

Coach interviews 30 minutes (intervention schools only)

Administrator interviews 30 minutes (intervention schools only)

Student focus group sessions or student interview duration of approximately 5-15 minutes (intervention schools only)

Student 12-month follow up survey 15 minutes

Tracking of fidelity to intervention: two in-person observations (conducted by the research team) of coaches delivering the intervention during the sports season (observations will be audio-recorded by the research team), 1 follow-up phone call (conducted by the research assistants), and completion of a delivery tracking tool (by coaches) to track the quality of the intervention delivery by the coaches.

Timeline of study procedures:

Collect baseline, self-administered computer-assisted surveys (or back up paper surveys if computers are not available or fail), from intervention and control middle school student athletes, with prior informed consent, at the start of each sports seasons across Year 1 (Time 1).

Collect baseline surveys via email or in-person from intervention and control middle school coaches (both men and women) with prior informed consent, at the start of each sports seasons across Year 1 (Time 1).

Provide intervention coaches with a 60-minute training session (training to be conducted by the school-liaison violence prevention advocate) to administer the intervention to their student athletes via 12 lessons across a sport season (Time 1).

Collect follow-up, self-administered computer-assisted surveys (or back up paper surveys if computers are not available or fail), from intervention and control middle school student athletes, at the end of their sports season (Time 2). In addition, contact information for 8th grade students (who will be moving on to high schools) will be collected at Time 2.

Conduct student athletes focus group sessions at the end of their sports season (Time 2).

Conduct coach interviews at the end of their sports season (Time 2)

Conduct administrator interviews with principals, superintendents, and athletic directors (Spring and Summer of 2016).

Collect 12-month follow-up, self-administered computer-assisted survey(or back up paper surveys if computers are not available or fail), from intervention and control middle school

student athletes, at 12 months after Time 1 to examine the longer term effects of the CBIM intervention (Time 3). In addition, contact 8th grade students to follow up with them at their high schools (Time 3).

Tracking of fidelity to intervention: The school-liaison violence prevention advocate will be responsible for checking with the coaches every two weeks to ensure the coaches are not having difficulty with delivery of the intervention. In addition, the research team will be responsible for conducting additional procedures to ensure delivery of the intervention as intended. We are adding two in-person observations of coaches delivering the intervention and a follow-up call to the coaches (all conducted by the research assistants). Qualitative data for the research study will be collected during these observations. The research assistants will be using an observational tracking tool to document overall card delivery (See Attachment - Other Documents). Additionally, research assistants will conduct one follow-up call and all intervention coaches will complete a delivery tracking tool throughout the season. Both the follow-up call and tracking tool are intended to track the progress and quality of the intervention delivery by the coaches.

Description of study procedures:

Randomization Process:

Prior to coach training, the 30 participating middle schools will be randomized under the direction of the study statistician to either the intervention or control condition. Randomization will involve the sites being alphabetized and matched to a computer-generated random sequence of numbers 1 through 30. Fifteen of the sites will be allocated to the intervention, while the remaining will be allocated to the control condition based on a systematic method (i.e. odd versus even numbers, numbers 1-15 versus 16-30, etc).

Student Athletes Surveys:

Time1: Time 1 involves one self-administered computer-assisted survey (or back up paper surveys if computers are not available or fail). Surveys are offered in English and are completed in the school's media lab on designated computers. Research assistants provide participants with instructions on using online survey tool. Participants enter their responses directly onto the computer. Surveys take approximately 15 minutes to complete. All survey questions are closed-ended multiple choice questions. Athletes will produce a self-generated personal code based on 7 non-identifiable questions (e.g., "Please enter the first letter of your biological mother's first name or N/A if you don't know or this is not relevant to you.") to ensure responses will remain as anonymous as possible and can be matched from baseline to follow up. The athletes receive giveaway gifts (such as a bracelet or water bottle) for participation in the baseline surveys (giveaways to students will follow policies specific to each participating school).

Time 2: The Time 2 computer-assisted survey involves a single, self-administered survey completed by athletes who completed the Time 1 survey (Back up paper surveys will be used if computers are not available or fail). Time 2 surveys will also be offered in English, and will be completed in the school's media lab on designated computers. Time 2 survey is similar to the survey administered in Time 1 and aims to assess intervention effects on knowledge, attitudes, self-efficacy, and behaviors regarding addressing disrespectful behaviors toward women and girls among male athletes. Remuneration for survey completion will again be a giveaway (such as a bracelet or water bottle).

Time 3: The Time 3 survey will be administered in 12 months after Time 1 (i.e., 12 months after the baseline survey, anticipated N =2000). Respective athletic departments and school administrators will facilitate reconvening participating athletes at 12 months post-intervention (Time 3). School administrators have agreed to convene these groups of athletes (regardless of whether they have continued athletic involvement). In addition, contact information for 8th grade students (who will be moving on to high schools) will be collected at Time 2. In order to maximize continuing interest, participants completing the Time 3 survey will receive \$20 remuneration (again following school policies).

In rare instances, if youth are unable to return to the site to complete the survey (for example, if they have moved and are no longer attending a participating school district), we will arrange for the survey to be completed via email as long as the participant can confirm that they have a safe and private computer/tablet on which to take the survey (verified via phone and email with participant, prior to sending survey link). We have used this option for survey completion in several of Miller's adolescent health studies.



### Non-Athlete surveys

At the request of one school partner, the research team will conduct baseline surveys with all students who have signed parental permission and not only those participating on a sports team. The school would like to have the baseline data from all students. Anonymous baseline survey information will be given to the school. For the purposes of the research study, the research team will only be using the baseline data from athletes and will only be conducting time 2 and time 3 surveys with athletes. The data from non-athletes will not be analyzed by the research team.

### Coach Surveys at Time 1 and Time 2

Coaches in both intervention and control arms will complete baseline surveys prior to the intervention period and a post-intervention survey at the end of the respective sports seasons. The surveys will be completed via email or in-person, depending on the preference of coaches. Coaches will produce a self-generated personal code based on 7 identifiers (e.g., first letter of mother's first name) to ensure responses will remain as anonymous as possible (given small numbers of coaches within any site) and can be matched across data collection points. Coaches will receive \$25 to thank them for their time taking the survey. Coaches in intervention schools will also be contacted biweekly by the school-liaison violence prevention advocate during program implementation to assess progress and unanticipated challenges.

### Coaches Training Session

As part of the CBIM Coaches Training, all coaches receive the Coaches Kit ([www.coachescorner.org](http://www.coachescorner.org)) to support their implementation of the CBIM intervention among their male athletes. The Playbook included in the kit provides examples of "teachable moments" on how to react with specific scripts when witnessing disrespectful or harmful speech or behaviors. The Training Cards (see Attachment - Other Documents) helps coaches integrate the lessons of the Playbook into 12 weekly mini-lessons throughout their athletic season. Coaches are guided to address all aspects of the program hypothesized to increase athletes' likelihood of positively intervening in cases of male peers' disrespectful or violent behaviors towards females, and to decrease the likelihood that male athletes will engage in such behaviors themselves.

The training of coaches at each school will be led a Violence Prevention Advocate with Center for Victims. Each of the 13 intervention schools will receive their own training at the start of each sports season (fall, winter and spring). The timing of the training will be arranged with the schools' athletic directors and coordinated by the trainer, at a time convenient for the coaches to meet at the school. Each 60-minute training with coaches will be timed to take place approximately one to two weeks prior to the start of the sports season. Each coach will receive their own Coaches Kit. Training content includes: an introduction to CBIM and rationale for the program, review of the content of the Kit, discussion of two common vignettes and how to use the Teachable Moment card, and an opportunity to ask questions. The training will emphasize the importance of following the pre-determined order for the training cards and ensuring that regular weekly sessions are provided to athletes. The trainers will be available throughout the sports season to assist coaches if difficult situations should arise (such as an athlete seeking advice about a friend in an abusive relationship). The trainer will review the Coach Activity Tracking Tool for coaches to record the date they used each card with their team and time spent (see Attachment - Other Documents). No data for the research study will be collected at these sessions.

Please note that the advocate who will serve as the school-liaison violence prevention advocate will be responsible for training the coaches to deliver the intervention. They will not be involved in recruitment of coaches and athletes, which will be conducted by the research team. They will, however, assist with tracking fidelity to intervention by checking in with the intervention coaches biweekly to ask about the progress with delivery of the program.

### Student Focus Groups and Interviews

A random convenience sample of student athletes who participated in the Year 1 intervention arm (all sports seasons) will be recruited by their school's athletic department to participate in one discussion (8-10 participants at each of 15 intervention schools, anticipated N = 130) about their relationships with their coaches, whether they've discussed



respectful behaviors towards women and girls, and their impressions of CBIM. Athletes from intervention schools who have participated in Time 1 and Time 2 waves of data collection will be eligible to participate. The research team will contact the athletic directors from each school to assist in recruiting eligible athletes in Year 2 to participate in this group discussion. Interested students will receive the consent form to review with their parent(s)/caregiver. Parents will have the option to call the PI to discuss any questions or concerns. If willing to have their child participate in the focus group, they will sign the consent form and give to their child to bring to the focus group.

The focus group will take place at the student's school location within a quiet and private space. Youth will receive the assent form, review and sign; they must have a signed parental consent form in order to participate. Youth will be reminded not to share personal information during the focus group discussion. The limits of confidentiality will be reviewed including mandated reporting if a youth discloses that they are in danger of hurting themselves or others, or of being hurt themselves. The focus group will be audiotaped to assist the investigator in capturing salient quotes. The audiotape will be destroyed once the investigator has reviewed the transcript of the focus group for accuracy. Youth will receive a \$10 gift card for their participation in the focus group.

In the case that, due to school structure or school administration wishes, focus groups with athletes are not feasible, there will be an option for students to participate in a one-on-one interview with a member of the research staff, using the focus group questions. Participants will be asked about their relationships with their coaches, whether they've discussed respectful behaviors towards women and girls, and their impressions of CBIM. Athletes from intervention schools will be eligible to participate. The research team will contact coaches, athletic directors, or school administration to assist in recruiting athletes. Interested students will receive the opt out consent form to review with their parent(s)/caregiver. Parents will have the option to call the PI to discuss any questions or concerns. If willing to have their child participate in the interview, parents will opt in and will not need to return the form to the school. If parents do not want their child to participate in the interview, they will sign the form and return it to the school. Participants who have signed opt out letters will not participate.

The interview will take place at the student's school location within a quiet and private space. Youth will verbally assent to the interview; a parent letter will have been sent home with the youth informing parents about the interview with the option to opt out. If youth do not return the letter with a parent signature, they will be eligible to participate in the interview. Youth will be reminded not to share personal information during the interview. The limits of confidentiality will be reviewed including mandated reporting if a youth discloses that they are in danger of hurting themselves or others, or of being hurt themselves. The interview will be audiotaped to assist the investigator in capturing salient quotes. The audiotape will be destroyed once the investigator has reviewed the transcript of the interview for accuracy. Youth will receive a \$10 gift card for their participation in the interview.

#### Coach interviews

The interviews will be scheduled by research staff based on the coaches' availability and preference. Interviews will be approximately 30-45 minutes and take place in a quiet and private space. Research staff will present and explain the interview consent form. If the coach signs and agrees after review of the informed consent process then he/she can participate. Coaches will be reminded not to share personal information during the interview. The interviews will be audio-taped to assist the investigator in capturing salient quotes. The audiotape will be destroyed once the investigator has reviewed the transcript for accuracy and any identifying information will be removed from the transcript.

#### Administrator Interviews

The research team will conduct interviews with middle school principals, superintendents, and athletic directors to survey the implementation of CBIM within their respective school districts. The interviews will be scheduled by research staff based on the administrators' availability and preference. Interviews will be approximately 30-45 minutes and take place in a quiet and private space. Administrators will be verbally consented by the research staff. If the administrator agrees to participate, he/she will be reminded not to share personal information during the interview. The interviews will be audio-taped to assist the investigator in capturing salient quotes. The audiotape will be destroyed once the

investigator has reviewed the transcript for accuracy and any identifying information will be removed from the transcript.

#### Tracking of fidelity to intervention

The research team will conduct two in-person observations of coaches delivering the intervention and one follow-up call to track the quality of the intervention delivery by the coaches. All of these procedures will be conducted by the research assistants. The research assistants will observe the coach delivering a training card, and note the amount of time spent on the card, the number of athletes present, and the length of discussion, as well as summarize the discussion (this will include the use of audio-recorders to assist the research team with note taking; recordings will be destroyed once notes are completed and deidentified). During delivery, the coaches will complete a delivery tracking tool to document when each training card was delivered. At the end of the season, research assistants will complete one follow-up call with each intervention coach to track the quality of the delivery and their feedback about the program. Additionally, research assistants will ask coaches to participate in one 30 minute semi-structured interview after the conclusion of the sport season in order to get coach feedback on the program and how card delivery went with the athletes.

### 2.6.1

#### Will blood samples be obtained as part of this research study?

\* No

\* If submitting a protocol for expedited review, it should be clear that the planned blood draws are within the parameters described here:

<http://www.hhs.gov/ohrp/policy/expedited98.html> (see Expedited Research Category #2)

If **Yes**, address the frequency, volume per withdrawal, the total volume per visit, and the qualifications of the individual performing the procedure:

#### Study Flow Chart:

Name

[CBIM Middle School Study Flow Chart](#)

Modified Date

2/24/2014 12:39 PM

[\[reviewer notes-\]](#)

**2.7 Will follow-up procedures be performed specifically for research purposes? Follow-up procedures may include phone calls, interviews, biomedical tests or other monitoring procedures.**

\* Yes

See study flow chart in question 2.6

The Time 3 survey will be administered in 12 months after Time 1 (i.e., 12 months after the baseline survey). Respective athletic departments and school administrators will facilitate reconvening participating athletes at 12 months post-intervention (Time 3). School administrators have agreed to convene these groups of athletes (regardless of whether they have continued athletic involvement). In addition, contact information for 8th grade students (who will be moving on to high schools) will be collected at Time 2. In order to maximize continuing interest, participants completing the Time 3 survey will receive \$20 remuneration (again following school policies).

In rare instances, if a student is no longer attending a participating school, the research staff will contact the participant via phone to schedule a follow-up survey. If the participant cannot complete the survey at a school site, the research assistant will confirm the participant has a quiet, private and safe space to complete the survey via computer or tablet. If so, a survey link will be emailed to the participant.

[\[reviewer notes-\]](#)**2.8 Does this research study involve the use of any questionnaires, interview or survey instruments?**

\* Yes

**Upload a copy of all materials except for the SCID or KSADS which are on file at the IRB. The use of all instruments must be addressed in question 2.6 and/or question 2.7 (except for an exempt submission where they should be addressed on the appropriate uploaded exempt form).**

Name	Modified Date
<a href="#">Student Athlete Baseline</a>	8/21/2015 11:17 AM
<a href="#">Coaches Follow Up - End of the Season</a>	5/27/2015 3:13 PM
<a href="#">Student Athlete Follow Up - 1 YEAR</a>	8/21/2015 11:16 AM
<a href="#">Administrator Interview Guide</a>	6/4/2016 8:08 AM
<a href="#">Athlete Demographic Sheet</a>	2/2/2015 10:03 AM
<a href="#">Student Athlete Follow Up - End of the Season</a>	8/21/2015 11:17 AM
<a href="#">Contact Information Questionnaire</a>	5/1/2015 3:34 PM
<a href="#">Discussion Guide for CBIM Middle School Research Study Participants.docx</a>	3/8/2018 4:43 PM
<a href="#">Coach Interview Topic Questions</a>	5/27/2015 3:15 PM
<a href="#">Coaches Baseline</a>	8/21/2015 11:16 AM

**Previously the name and publisher for commercially available materials were listed in the textbox below but effective 9/1/2015, all materials (except for the SCID and KSADS) must be uploaded using the Add button above.**

[\[reviewer notes-\]](#)**2.9 If subjects are also patients, will any clinical procedures that are being used for their conventional medical care also be used for research purposes?**

\* n/a

If **Yes**, describe the clinical procedures (and, if applicable, their frequency) that will be used for research purposes:

**2.10 The blood sample question was moved to 2.6.1.**[\[reviewer notes-\]](#)**2.11 What is the total duration of the subject's participation in this research study across all visits, including follow-up surveillance?**

\* 12 months

[reviewer notes-]

**2.12 Does this research study involve any type of planned deception?**

If Yes, you are required to request an alteration of the informed consent process (question 4.7)

\* No

[reviewer notes-]

**2.13 Does this research study involve the use of UPMC/Pitt protected health information that will be de-identified by an IRB approved "honest broker" system?**

\* No

[reviewer notes-]

**2.14 Will protected health information from a UPMC/Pitt HIPAA covered entity be accessed for research purposes or will research data be placed in the UPMC/Pitt medical record?**

\* No

**2.14.1 Will protected health information from a non-UPMC/Pitt HIPAA covered entity be obtained for research purposes or will research data be placed in the non-UPMC/Pitt medical record?**

\* No

[reviewer notes-]

**2.15 Does this research study involve the long-term storage (banking) of biological specimens?**

\* No

[\[reviewer notes-\]](#)

**2.16 Will research participants be asked to provide information about their family members or acquaintances?**

\* Yes

**2.16.1**

**Describe what information about the third party will be obtained from the participant:**

For the 8th graders, at the time of initial consent, they will be asked to provide contact information (at least 3 different ways to reach them) in order to find them for the Time 3 survey, which may include a parent's cell phone number or other contact information about their adult caregiver (such as an email address), as well as information about which high school they expect to attend in the subsequent academic year.

**2.16.2**

**If the information about the third party is of a private nature, can the identity of the third party be readily ascertained or associated with this information?**

\*

Not applicable - The information about the third party is not of a private nature

[\[reviewer notes-\]](#)

**2.17 What are the main outcome variables that will be evaluated in this study?**

The primary outcome is positive bystander behavior; secondary outcomes include increases in a) knowledge of what constitutes abusive behavior, b) gender-equitable attitudes regarding relationship and sexual behaviors, and c) intentions to intervene in cases where TDV/SV related peer behaviors are witnessed as compared to male athletes attending control schools at Time 2 and Time 3. In addition at Time 3, we will assess self-reported TDV/SV behaviors among intervention athletes as compared to control athletes.

Athlete Outcome Assessments:

1) Bystander intervention behaviors (secondary): Investigator-developed items were piloted in a previous mixed-methods study intended to identify commonly witnessed behaviors among high school-age athletes such as "spreading rumors about a girl's sexual reputation, like saying she's 'easy'." (Miller, Heisterkamp et al. 2008) For each of a list of nine abusive behaviors they may have witnessed among peers or friends in the past three months, participants report how they responded to the behavior (if witnessed), by selecting all applicable responses from a list with two negative behaviors ("I didn't say anything" and "I laughed and went along with it") and four positive behaviors ("I told the person in public that acting like that was not okay;" "I told the person in private that acting like that was not okay;" "I talked to our coach about it privately;" "I talked to another adult (not coach).") In the high school study, witnessing specific behaviors ranged from 7.4% (witnessing physical TDV) to 59% (making disrespectful comments about a girl's body), with 75% reporting witnessing at least one such behavior. (Miller, Tancredi et al. Submitted) For each abusive behavior, separate binary indicators (for any positive and for any negative intervening behavior) are created. If an abusive behavior is not witnessed, both indicators are coded zero. The nine positive and nine negative indicators are summarized separately to create positive and negative bystander intervention behavior scores. For the proposed study, the primary outcome is positive bystander behavior.

2) Recognition of abusive behavior (secondary): A scale developed by Rothman et al. (Rothman, Decker et al. 2006) to assess perceptions of the degree of abusiveness of specified relationship behaviors such as "telling them which friends they can or can't see or talk to" and "telling them they're ugly or stupid," using a 5-point Likert-like scale ranging from "not abusive" to "extremely abusive" (Cronbach's alpha=0.93), modeled as a mean of responses to 12 items.

3) Gender equitable attitudes (secondary): This scale includes questions modified from Barker's Gender-Equitable Norms Scale, (Pulerwitz and Barker 2007) such as "if a girl is raped it is often because she did not say no clearly enough" and "a boy/man will lose respect if he talks about his problems." Responses range from "strongly agree" to "strongly disagree" on a 5-point scale (Cronbach's alpha = 0.80), modeled as a mean of responses to 11 items.

4) Intentions to intervene when witnessing abusive behaviors (secondary): These investigator-developed items were pilot tested in a previous study, (Miller, Heisterkamp et al. 2008) and utilized in the high school study with high internal consistency and face validity. For each item representing abusive behaviors (e.g., witnessing a peer make derogatory comments about a girl's appearance), participants report how likely they would be to say something to stop the behavior from "very unlikely" to "very likely" (Cronbach's alpha = 0.87), modeled as a mean of eight items.

5) Abuse perpetration (primary): Athletes are asked about perpetrating any of ten abusive behaviors (including physical, sexual, and emotional abuse) towards a female in the past three months, modified from the Conflict Tactics Scale-2 (Straus, Hamby et al. 1996) with additional items created and tested during a separate pilot study. (Miller, Heisterkamp et al. 2008) A summary abuse perpetration score is utilized for analysis.

#### Coach Assessment:

Coaches surveys (completed at Time 1 and 2), include the gender attitudes scale, recognition of abusive behaviors, and intervention behaviors as above, as well as investigator-developed items about confidence talking to their athletes about stopping violence against women.

## 2.18 Describe the statistical approaches that will be used to analyze the study data.

\* Addressed below:

The proposed study is a 2-arm cluster-randomized trial of 2200 students across 30 schools. Generalized linear mixed models will be used to account for the correlation between students from the same school as well as the correlation between observations from the same student.

Descriptive statistics will be utilized to summarize the sample with regard to baseline characteristics of interest. Means and standard deviations will be presented for continuous variables, while sample proportions will be provided for categorical variables. 95% confidence intervals will accompany all sample statistics. Primary assessment of intervention effects will be based on intent-to-treat estimates. As-treated effect parameters will be estimated in secondary analyses and reported as exploratory.

[reviewer notes-]

**2.19**

**Will this research be conducted in (a) a foreign country and/or (b) at a site (e.g., Navajo Nation) where the cultural background of the subject population differs substantially from that of Pittsburgh and its surrounding communities?**

\* No

Note that copies of training records, licenses, certificates should be maintained in the study regulatory binder and are subject to audit by the Research Conduct and Compliance Office (RCCO).

In addition, individuals planning to conduct human subject research outside the United States must complete an optional module on the CITI training website: International Studies. [Click here](#) to access the instruction sheet for accessing optional CITI modules.

[reviewer notes-]

**2.21**

**Will this research study be conducted within a nursing home located in Pennsylvania?**

\* No



[\[reviewer notes-\]](#)

## Section 3 - Human Subjects

### 3.1 What is the age range of the subject population?

Student male athletes in grades 6th or above (aimed for ages 11-14; but athletes participating in middle school sports who are older than 14 will also be included)

Coaches of male athletes in grades 6th through 8th (ages 18 and older)

### 3.2 What is their gender?

\* Males only - Provide a justification for limiting enrollment to only one gender.

Provide a justification if single gender selected:

The Coaching Boys into Men program is specifically focused on training coaches to talk to their male athletes about respect, non-violent, and equitable gender norms. While the program does not exclude female athletes, per se, but also is not targeting females; if there are female athletes on the team, they will not be refused participation.

Coaches can be either male or female.

### 3.3 Will any racial or ethnic subgroups be explicitly excluded from participation?

\* No

If **Yes**, identify subgroups and provide a justification:

### 3.4 For studies conducted in the U.S., do you expect that all subjects will be able to comprehend English?

\* Yes

[\[reviewer notes-\]](#)

### 3.5 Participation of Children: Will children less than 18 years of age be studied?

\* Yes

#### 3.5.1 Specify the age range of the children to be studied.

(Check all that apply below:)

\*

Choices

7-13 years of age

14-17 years of age

#### 3.5.2 Provide a rationale for the specific age ranges of the children to be studied:

Teen Dating Violence (TDV) and Sexual Violence (SV) occur among younger adolescents and increase during the adolescent years. The evidence shows such TDV/SV are prevalent in adolescence, and appear to increase as youth age, strongly supports the need for early primary prevention efforts targeting middle school students. Middle school is also a critical and overlooked developmental stage for TDV/SV prevention. The middle school years are also distinctly different developmentally from high school. Our data from the high school implementation of CBIM indicates 9th grade boys are frequently witnessing and

perpetrating abusive behaviors towards girls, suggesting that prevention needs to occur earlier. Yet, despite the high prevalence of TDV/SV reported by younger adolescents, there is limited number of prevention programs effective to stop perpetration of TDV/SV within this age group. Therefore it is critical to study if "Coaching Boys into Men" is an effective prevention program for middle school aged adolescents.

### 3.5.3

#### **Describe the expertise of the study team for conducting research with children within this age range:**

Elizabeth Miller is the Chief of Adolescent Medicine at University of Pittsburgh. She is a nationally and internationally recognized expert in teen dating abuse and gender-based violence. Trained in medical anthropology as well as Internal Medicine and Pediatrics. Dr. Miller's research has focused on the impact of teen dating abuse on adolescent health, in particular the relationship between dating abuse and teen pregnancy. She has extensive experience working with marginalized youth populations, including pregnant-parenting teens, gang-involved youth, youth in foster care, and homeless youth.

Maria Catrina D. Virata is a clinical research coordinator for the University of Pittsburgh, department of Adolescent Medicine. Subsequent to this employment she worked 6 years in health and clinical research at University of California, Davis. She is continuing her doctoral program at the Graduate School of Public Health and completed her training in a Masters in Public Health. She served as the previous project manager for the evaluation of "Coaching Boys into Men" program with high school aged student athletes. Currently, she is the project manager for the CBIM Adaptation Study in the Pittsburgh region and works with Dr. Miller in the adaptation and implementation of the CBIM in Southwestern PA.

### 3.5.3.1

**Have you obtained the following clearances from all research staff who may have direct contact with children under the age of 18? Direct contact under the law includes face-to-face, and telephonic or electronic, contact with minors. Please see the [Child Clearances](#) guidance document for further explanation?**

**Pennsylvania Department of Public Welfare Child Abuse History Clearance;  
Pennsylvania State Police Criminal Record Check; and  
FBI Criminal Background Check**

Yes

**Note:** If No, once all clearances are obtained, a modification must be submitted.

**If you selected N/A, please explain:**

It is important to note that "direct contact" refers not only to face-to-face meetings but also extends to communication via phone (including text messaging), social media or internet. Direct contact also includes the care, guidance, supervision or control, or routine interaction with, minors. Conversely, a participating investigator or support staff member who does not have direct contact, either electronically or in person, with children does not need to obtain clearances (e.g., statistician, non-clinical laboratory personnel, etc.). If your research study provides babysitting services, the babysitters must have the required child clearances.

**\* Note:** It is the responsibility of the principal investigator to ensure that all research staff have these clearances prior to any interaction with children. Contact Human Resources at 412-624-8150 for assistance with this process.

### 3.5.4

**Describe the adequacy of the research facilities to accommodate children within this age range:\***

Not applicable; research will be conducted in the child's normal environment.

### 3.5.5

**Permitted Categories of Research: The Federal Policy and FDA regulations governing human subject protections specify that research involving children must fall into one of the following permitted categories.**

\*

The research does not involve greater than minimal risk [45 CFR 46.404/21 CFR 50.51].

#### **45 CFR 46.406**

- The risk represents only a minor increase over minimal risk.
- The research procedures present experiences to the subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations.
- The research procedures are likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for understanding or amelioration of the subjects' disorder or condition.

#### **45 CFR 46.407**

- The risk is justified by the anticipated benefit to the subjects; and the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches.

Provide a justification which **must address all considerations** related to the designated category of research:

This study is of minimal risk to participants.

The athlete surveys are anonymous. That is, athletes produce a self-generated personal code based on 7 non-identifiable questions (e.g., first letter of mother's first name) to ensure responses will remain as anonymous as possible and can be matched across data collection points. No names or linking information will be connected to the surveys.

The focus groups and interviews with students will be confidential, i.e., no names will be associated with the data collected.

[reviewer notes=]

### 3.6 Does this research study involve prisoners, or is it anticipated that the research study may involve prisoners?

\* No

[reviewer notes=]

### 3.7 Will pregnant women be knowingly and purposely included in this research study?

\* No

[reviewer notes-]

**3.8 Does this research study involve neonates of uncertain viability or nonviable neonates?**

\* No

[reviewer notes-]

**3.9 Fetal Tissues: Does this research involve the use of fetal tissues or organs?**

\* No

[reviewer notes-]

---&gt;

**3.10**

**What is the total number of subjects to be studied at this site, including subjects to be screened for eligibility?**

Note: The number below is calculated by summing the data entered in question 3.11. Any additions or changes to the values entered in 3.11 will be reflected in 3.10.

\* 2448

**3.11**

**Identify each of the disease or condition specific subgroups (include healthy volunteers, if applicable) that will be studied.**

Click on the "Add" button and specify for each subgroup:

1) how many subjects will undergo research related procedures at this site; and

2) if applicable, how many subjects will be required to undergo screening procedures (e.g., blood work, EKG, x-rays, etc.) to establish eligibility. **Do Not include subjects who will undergo preliminary telephone screening.**

\*

Subgroup	Number to undergo research procedures	Number to undergo screening procedures
<a href="#">View</a> Administrators	40	0
<a href="#">View</a> Athletes	2200	0
<a href="#">View</a> Coaches	208	0

**3.12**

**Provide a statistical justification for the total number of subjects to be enrolled into this research study at the multicenter sites or this site.**

\* Described below:

We expect to enroll 2200 athletes and 208 coaches at baseline.

Sample sizes for each of the athlete outcomes were based on clinically meaningful differences between treatment groups with respect to changes in the outcomes across time (i.e. intervention effect). For the primary outcome in Aim 1, the necessary sample size per arm was calculated based on traditional methods that assumed a fixed number of clusters. (Hemming, Girling et al. 2011 ) If we assume 15 schools randomized per arm with a within-school correlation of 0.02 (in the high school study within-school correlations ranged from 0.018 to 0.029), we would need 1100 students per arm (N=2200) to detect a standardized effect size of 0.20. If we achieve our anticipated enrollment of 2200 students across 30 schools, our detectable difference for the primary outcome is 0.18.

[reviewer notes-]

**3.13 Inclusion Criteria: List the specific criteria for inclusion of potential subjects.**

Student Athletes:  
Grade 6th and above  
Participating in middle school athletics  
English speaking

Coaches:  
Age 18 or older  
Coaching an athletic team at one of the participating middle schools  
English speaking

Schools Included:  
Participating middle schools from Pittsburgh  
The ethical justification to exclude non-English Speaking Subjects is due to the fact that the study questionnaires have not been validated in a language other than English.

**3.14 Exclusion Criteria: List the specific criteria for exclusion of potential subjects from participation.**

Student Athlete Excluded:  
Grades 5 and younger  
Not participating in middle school athletics  
Non-English speaking

Coaches Excluded:  
Under the age of 18  
Non-English speaking  
Not coaching an athletic team at one of the participating middle schools

Schools Excluded:  
Not a participating middle school from Pittsburgh area

**3.15 Will HIV serostatus be evaluated specifically for the purpose of participation in this research study?**

\* No

If **Yes**, provide a justification:

[reviewer notes-]

- 4.1** Select all recruitment methods to be used to identify potential subjects:  
Recruitment Letters and/or Scripts

<b><u>Recruitment Letters and Scripts</u></b>	
Upload recruitment letters/scripts/text:	
Name	Modified Date
<a href="#">Administrator Information Letter</a>	6/4/2016 8:22 AM
<a href="#">Coaches Intake Form</a>	2/27/2014 6:02 PM
<a href="#">Parent Letter for Focus Groups and Interviews (had previous consent) with opt out option</a>	11/8/2017 4:17 PM
<a href="#">Parent Checklist</a>	8/31/2016 4:00 PM
<a href="#">Parent Information Letter</a>	8/31/2016 5:00 PM
<a href="#">Parent Information letter with opt out option</a>	9/1/2016 11:20 AM
<a href="#">Parent Letter for Focus Groups and Interviews (used for previous opt-out schools) with opt out option</a>	11/8/2017 5:16 PM
<a href="#">Coaches Information Letter</a>	2/27/2014 6:02 PM

- 4.2** **Provide a detailed description of your recruitment methods, including identifying and initiating contact with participants:**

**School Recruitment:**

The Principal Investigator and research staff have approached superintendents and principals from various school districts in Pittsburgh in Winter 2015. Several school districts agreed to participate at the time the grant proposal was submitted (see attached letters of support) and the first 30 schools who confirm participation will be included in the study. Research staff will work with each school's athletic director and approach coaches of male and co-ed sports at their middle schools to participate each season (spring, fall, winter). Recruitment with coaches and student athletes will be conducted by the research team at each individual school.

**Coaches Recruitment:**

Athletic directors will provide an introduction and/or contact information in order to recruit coaches of male and co-ed sports each season. The research assistants (RA) and trainer will follow up to schedule in-person or phone contact to discuss the research study. During in person contact, the RA will present coaches the consent form to review and sign in order to participate in the coach's survey. At the time of consent, RA will confirm eligibility with

coaches via verbal assessment of the following inclusion criteria: 1) Over the age of 18 and 2) participating in school athletics.

#### Student Athlete Recruitment:

Student athletes from all 30 schools currently participating in middle school athletics will receive a letter notifying parents of the study and research consent form from their athletic department. The informational letter to parents (in languages relevant for the participating school districts) will clearly state that participation in the research study is voluntary and will not have an impact on the athlete's participation on the team.

For schools that agree to the waiver of signed parental permission, parents will have the option to opt out their child from participating in the study on this informational letter or by calling/emailing the research team to decline their child's participation.

For school partners who wish to use electronic communication, the parent information letter and IRB approved permission form will be available via a Qualtrics survey. Schools may email the link to parents and have them grant or decline permission for their child to participate in the research study electronically.

For schools who choose to continue with signed parental permission, only those athletes with parental permission will provide assent, and complete a baseline survey. The research assistants (RA) and school-liaison violence prevention advocate will work with the athletic departments to confirm that the parental information letter and permission forms are distributed to 6th to 8th grade athletes. At the time of the baseline survey, RA will confirm eligibility with potential participants with signed consent forms via verbal assessment of the following inclusion criteria: 1) In 6th grade or above 2) participating in school athletics.

Note: Questions jump from 4.2 to 4.6 as questions 4.3-4.5 have been removed and the information is now captured in 4.1

[reviewer notes-]

**4.6 Are you requesting a waiver to document informed consent for any or all participants, for any or all procedures? (e.g., a verbal or computerized consent script will be used, but the subjects will not be required to sign a written informed consent document. *This is not a waiver to obtain consent.***

\* Yes

**4.6.1 Identify the specific research procedures and/or the specific subject populations for which you are requesting a waiver of the requirement to obtain a signed consent form.**

Addressed below:

**If not all**, identify the specific procedures and/or subject populations for which you are requesting a waiver:

We are requesting a waiver to document written permission for participants who attend schools who have requested an online parental permission process. A few participating schools have requested this online permission process to decrease burden on parents.

We are also requesting a waiver to document written consent for the administrator interviews. These interviews are minimal risk and will not include sensitive topics. All participants will be 18+ years of age.

**4.6.2 Indicate which of the following regulatory criteria is applicable to your request for a waiver of the requirement to obtain a signed consent form.**



**45 CFR 46.117(c)(2)**

**45 CFR 46.117(c)(1)** That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

**45 CFR 46.117(c)(2)** That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

**4.6.2.1**

**Address why the specific research procedures for which you are requesting a waiver of the requirement to obtain a signed consent form present no more than minimal risk of harm to the research subjects:**

All aspects of this research study including athlete surveys and focus groups, and administrator interviews, involve no more than minimal risk. All athlete surveys are completely anonymous, with no names or identifying information attached to any of the surveys (baseline, post season and one year follow-up surveys). The athlete focus groups and administrator interviews are confidential. The primary risk is breach in confidentiality

**4.6.2.2**

**Justify why the research listed in 4.6.1 involves no procedures for which written informed consent is normally required outside of the research context:**

All surveys are anonymous and the focus groups and interviews are confidential. There are no procedures involved for which written informed permission is normally required outside of the research context.

**4.6.3**

**Address the procedures that will be used and the information that will be provided (i.e., script) in obtaining and documenting the subjects' verbal informed consent for study participation:**

Enrolled schools that requested an online permission process for parents will email a link to the Parental Permission and Contact Info Qualtrics survey. The survey is uploaded as a script below. The survey shows the IRB approved consent form and asks parents to agree or decline permission for their child to participate.

Additionally, one of our school partners requested that all students be invited to complete the baseline surveys so there is a separate script uploaded for that school (Winchester Thurston Parental Permission and Contact Info Qualtrics Script). This survey also shows our IRB approved consent form but includes a small explanation on the welcome screen that explains why all students are being invited to participate.

For the administrator interviews, the research staff will verbally consent the participant before the start of the interview.

Upload Scripts:

Name	Modified Date
<a href="#">Winchester Thurston Parental Permission and Contact Info Qualtrics Script</a>	11/1/2015 12:55 PM
<a href="#">Administrator Interview Verbal Consent Script</a>	6/4/2016 8:42 AM
<a href="#">Parental Permission and Contact Info Qualtrics Script</a>	11/1/2015 12:55 PM

[reviewer notes-]

**4.7 Are you requesting a waiver to obtain informed consent or an alteration of the informed consent process for any of the following?**

\* Yes

**4.7.1 If Yes, select the reason(s) for your request:**

Parental permission and/or child assent

General Requirements: The Federal Policy **[45 CFR 46.116 (d)]** specifies in order for a waiver of consent to be approved, the request must meet four criteria. For each request, you will be asked to provide a justification addressing how each of these criterion is met.

**Parental Permission and/or Child Assent**

The research involves no more than minimal risk to the subjects; **[45 CFR 46.116 (d) (1)]** Athlete's participation in anonymous surveys and confidential focus group discussions will be of minimal risk, as the risk for emotional distress from any of the questions is highly unlikely and risks for breaches of confidentiality are minimized by using methods to protect participant anonymity. Given the minimal risk procedures proposed and to ensure that youth who wish to participate in the study do not experience barriers to participation, a waiver of parental permission is requested.

The waiver or alteration will not adversely affect the rights and welfare of the subjects; **[45 CFR 46.116 (d) (2)]** The parents will still receive information about the study and will have the option to opt their child out of participation by signing and returning the parent information letter or by calling the research team.

**[45 CFR 46.116 (d) (2)]** Minors interested in participating in the study will have the opportunity to review the consent information and to determine whether they want to participate or not.

The research could not be carried out without the waiver or alteration; **[45 CFR 46.116 (d) (3)]** Throughout data collection thus far, our participation rates have been very low due to only a small number of parental permission forms being signed and returned to school with the students. This also creates a bias in our study participants because we are excluding students who are not returning the forms. This will allow all student the opportunity to decide whether or not they would like to participate. In order to have a diverse participant group to strengthen the results of the evaluation, we will not be able to practicably carry out the research without a waiver.

**[45 CFR 46.116 (d) (3)]** Individual school districts, however, will be given the option to use the parent letter with an opt out method or continue to use signed parental permission form.

Whenever appropriate, Yes, if the student, parents or school district request information about the study after participation, they will be offered both description of the study

## Section: Section 4 - Recruitment and Informed Consent Procedures

the subjects as well as any aggregate reports developed as a result of the study. No individual, personally identifying information will be provided with anyone. additional pertinent information after participation.

**[45 CFR  
46.116 (d)  
(4)]**

#### 4.7.2 Under what circumstances (if any) will you obtain consent from some of these subjects?

There will be no circumstances where consent will be obtained for administrator interviews.

For student athletes, we will give school districts the opportunity to decide whether they would like to have signed parental permission in order for students to participate in the research or if they are comfortable with sending home a parent letter outlining the research activities and allowing parents who do not want their child to participate to either sign the letter and return it to school or to contact the research team.

[\[reviewer notes=\]](#)

#### 4.8 Are you requesting an exception to the requirement to obtain informed consent for research involving the evaluation of an 'emergency' procedure?

**Note:** This exception allows research on life-threatening conditions for which available treatments are unproven or unsatisfactory and where it is not possible to obtain informed consent.

\* No

[\[reviewer notes-\]](#)**4.9****Upload all consent documents for watermarking:**

Draft Consent Forms for editing:

Name	Modified Date
<a href="#">Student Athlete Survey Assent</a>	5/27/2015 4:04 PM
<a href="#">Parent Survey and Focus Group Permission Form</a>	8/31/2016 3:46 PM
<a href="#">Coaches Interview Consent Form</a>	5/27/2015 4:05 PM
<a href="#">Student Athlete Focus Group Assent</a>	8/26/2015 8:52 AM
<a href="#">Coaches Survey Consent</a>	5/27/2015 4:03 PM

Approved Consent Form(s):

Name Modified Date

[\[reviewer notes-\]](#)**4.10 Will all potential adult subjects be capable of providing direct consent for study participation?**

\*

Yes

[\[reviewer notes-\]](#)**4.11****At what point will you obtain the informed consent of potential research subjects or their authorized representative?**

Prior to performing any of the screening procedures

**4.11.2****Taking into account the nature of the study and subject population, indicate how the research team will ensure that subjects have sufficient time to decide whether to participate in this study. In addition, describe the steps that will be taken to minimize the possibility of coercion or undue influence.**

Research staff will ensure that subjects have sufficient time to decide their participation in the study by providing student athletes, their parents, and coaches up to 3 days to review the study information and consent and assent forms. Generally, with student athletes they are given up to 3 days to return the completed parent consent form at the next practice or scheduled survey administration, which gives student athletes and parents time to review the information letter, consent form, and assent form provided. Research staff contacts coaches prior to any study procedures and determines their interest in participating. Only coaches interested in participating are provided either a hand delivered, emailed, or mailed consent. Research staff arranges accordingly with the coaches to review and complete consent, offering at least 3 days to review the materials.

[\[reviewer notes-\]](#)

**4.12 Describe the process that you will employ to ensure the subjects are fully informed about this research study.**

\* Addressed below:

**This description must include the following elements:**

- who from the research team will be involved in the consent process (both the discussion and documentation);
- person who will provide consent or permission;
- information communicated; and
- any waiting period between informing the prospective participant about the study and obtaining consent

In addition, address the following if applicable based on your subject population:

- process for child assent and parental permission
  - continued participation if a child subject turns 18 during participation
- process for obtaining proxy consent and assent for decisionally impaired subjects
  - continued participation if subject regains capacity to consent

Research staff will first approach athletic directors and/or coaches to schedule a time to meet with the student athletes to provide them an overview of the study. School administrators will be given the option to use a written parental permission option or a parent information letter that includes an opt out option (in which all eligible athletes will be invited to participate unless their parents returns the parent information letter or contacts the research team and says they do not want their child to participate.

In schools using the written parental permission form, during this overview the research staff reviews page by page with the athletes the information on the consent form and explains that their parents must review and sign the consent form in order to participate. Once the overview is complete, only those student athletes interested in participating in the study are provided a parent consent form. At that point the student athletes take the consent home to review with their parents. Once the student athlete returns with completed signed parent consent forms then they are allowed to participate in the survey.

In schools using the parent information letter with the opt out option, the research staff will provide detailed information about the research study to athletes. Once information has been explained, the parent letter will be distributed to interested athletes. Student athletes will take the letter home to review with parents. Research staff will wait at least 3 days before administering surveys to ensure that parents have had enough time to review the information and return the letter/contact research staff if they do not want their child to participate in the research study.

Alternative consent process: At schools that have requested an online permission form for parents, school administrators will email the link to the Qualtrics Parent Permission and Contact Info survey (script uploaded in section 4.6.3). This survey includes the IRB approved parental permission forms that details all study activities and provides contact information for the PI if parents have any questions. Parents can either agree to have their child participate or decline permission for their child to participate. Only those athletes who parents gave permission will be asked to participate in the survey.

Prior to survey administration, the research staff reviews with each student athlete the student assent form. The research staff reviews page by page the information on the assent form and then allows the student athlete time to ask questions and make a decision to proceed with the survey. Same protocols take place with student athletes who decide to participate in the student focus group discussions.

Research staff will approach individual athletic directors and/or coaches in person, by phone or email prior to providing the consent form to participate in the study. A conversation takes place with the coach where the research staff provide an overview of the study and what is involved in participating. After this conversation, those coaches interested in participating are hand delivered, emailed or mailed the consent form to review. Once consent is signed and completed then the research staff provides the coach an option to

complete the survey via computer or on paper. An online survey link can be emailed to coaches.

**4.13****Are you requesting an exception to either IRB policy related to the informed consent process?**

- For studies involving a drug, device or surgical procedures, a *licensed physician who is a listed investigator* is required to obtain the written informed consent unless an exception to this policy has been approved by the IRB
- For all other studies, a *listed* investigator is required to obtain consent (Note: In order to request an exception to this policy, the study must be minimal risk)

\* Yes

If **Yes**, provide a justification and describe the qualifications of the individual who will obtain consent:

Dr. Miller's trained research staff will conduct the consent and assent processes as described above.

**4.14****Will you inform research subjects about the outcome of this research study following its completion?**

\* Yes

If **Yes**, describe the process to inform subjects of the results:

Once the study is complete, the results will be disseminated to all participating schools administrators and athletic directors. The research team will also plan an end of the study celebration and invite all participating school's athletic directors and coaches. At this celebration, information will be reported about the final outcomes of the program and the research study.

[\[reviewer notes-\]](#)

**5.1 Describe potential risks (physical, psychological, social, legal, economic or other) associated with screening procedures, research interventions/interactions, and follow-up/monitoring procedures performed specifically for this study:**

\*

<a href="#">View</a>	<p><b>Research Activity:</b> Administrator Interview</p> <p><b>Common Risks:</b> <i>No Value Entered</i></p> <p><b>Infrequent Risks:</b> It is possible that administrators may be uncomfortable answering the interview questions. There is a remote possibility of breach of confidentiality with connecting consents to audiofiles.</p> <p><b>Other Risks:</b> <i>No Value Entered</i></p>
<a href="#">View</a>	<p><b>Research Activity:</b> Athlete Interviews</p> <p><b>Common Risks:</b> <i>No Value Entered</i></p> <p><b>Infrequent Risks:</b> It is possible that some student athletes may find some of the discussion questions to sensitive or uncomfortable.</p> <p><b>Other Risks:</b> <i>No Value Entered</i></p>
<a href="#">View</a>	<p><b>Research Activity:</b> Audiorecording and Observation of Program Delivery in Intervention Sites</p> <p><b>Common Risks:</b> <i>No Value Entered</i></p> <p><b>Infrequent Risks:</b> There is a remote possibility of breach of confidentiality and it is possible that some coaches may feel uncomfortable being observed during card delivery</p> <p><b>Other Risks:</b> <i>No Value Entered</i></p>
<a href="#">View</a>	<p><b>Research Activity:</b> Coach Interviews</p> <p><b>Common Risks:</b> <i>No Value Entered</i></p> <p><b>Infrequent Risks:</b> It is possible that coaches may be uncomfortable answering the interview questions. There is a remote possibility of breach of confidentiality with connecting consents to audiofiles.</p> <p><b>Other Risks:</b> <i>No Value Entered</i></p>
<a href="#">View</a>	<p><b>Research Activity:</b> Focus Group Discussions</p> <p><b>Common Risks:</b> <i>No Value Entered</i></p> <p><b>Infrequent Risks:</b> It is possible that some student athletes may find some of the discussion questions too sensitive or uncomfortable. There is a remote possibility of breach of confidentiality with student athletes discussing what happened during the focus group discussion after the session is over and connecting consents to audio files.</p> <p><b>Other Risks:</b> <i>No Value Entered</i></p>
<a href="#">View</a>	<p><b>Research Activity:</b> Follow Up with Coaches</p> <p><b>Common Risks:</b> <i>No Value Entered</i></p> <p><b>Infrequent Risks:</b> There is a remote possibility of breach of confidentiality with coaches contact information as research staff calls, emails and any other follow ups related to coordinating research related activities.</p> <p><b>Other Risks:</b> <i>No Value Entered</i></p>

<a href="#">View</a>	<b>Research Activity:</b> Screening Procedure
	<b>Common Risks:</b> <i>No Value Entered</i>
	<b>Infrequent Risks:</b> Some coaches or student athletes may feel obligated to participate in the research study if they see their peers are interested or participate
	<b>Other Risks:</b> <i>No Value Entered</i>
<a href="#">View</a>	<b>Research Activity:</b> Survey Administration
	<b>Common Risks:</b> <i>No Value Entered</i>
	<b>Infrequent Risks:</b> It is possible that some coaches or student athletes may find some of the survey questions too sensitive or uncomfortable. There is a remote possibility of breach of confidentiality with coaches and student athletes completing the survey, particularly the back-up method of using a paper survey.
	<b>Other Risks:</b> <i>No Value Entered</i>
<a href="#">View</a>	<b>Research Activity:</b> Survey Administration at 1 Year follow up
	<b>Common Risks:</b> <i>No Value Entered</i>
	<b>Infrequent Risks:</b> There is a remote possibility of breach of confidentiality with student athletes contact information. Student athletes who graduate from 8th grade and will be in high school during 12month follow up survey will need to be contacted.
	<b>Other Risks:</b> <i>No Value Entered</i>

### 5.1.1 Describe the steps that will be taken to prevent or to minimize the severity of the potential risks:

#### Focus Group Discussions

Student participants in the focus group will be reminded that they can stop participating at any point and participation is completely voluntary. They will be encouraged to be as honest as possible with their responses and to respect each other's responses and privacy after the session is over. The focus groups with students will be confidential, i.e., no names will be associated with the data collected. Audiotapes from the focus groups will be destroyed after transcription is completed; transcripts from the focus groups will be completely de-identified. In addition, research staff will remind participants about the limits of confidentiality.

#### Student Athlete Interviews:

Student athlete participants in the one-on-one interview will be reminded that they can stop participating at any point and participation is completely voluntary. They will be encouraged to be as honest as possible with their responses. The interviews with students will be confidential, i.e., no names will be associated with the data collected. Audiotapes from the interviews will be destroyed after transcription is completed; transcripts from the interviews will be completely de-identified. In addition, research staff will remind participants about the limits of confidentiality.

#### Follow Up with Coaches

Coaches contact information will only be used to follow up with coaches regarding research related activities and only accessible to Dr. Miller and her research team. All of the contact information will be destroyed after coaches have been re-contacted to complete the follow up survey.

#### Screening Procedure

All coach and student participants will be reminded that participation is completely



voluntary and whether or not he/she participates will have no effect on their participation in sports and school athletics program.

#### Survey Administration

All coach and student participants will be reminded that they can stop participating at any point and participation is completely voluntary. All surveys will be administered via a web-based secure survey system (REDCap) created for this project, loaded on desktops available in the computer labs of participating schools. Paper surveys will only be used as backups if the computers are not available or fail.

All coach and student athlete surveys are anonymous. That is, coaches and student athletes produce a self-generated personal code based on 4 non-identifiable questions to ensure responses will remain as anonymous as possible and can be matched across data collection points. No names or linking information will be connected to the surveys.

For student athlete's anonymous surveys, they will be encouraged to be as honest as possible with their responses; all students will receive a research assistant 'check in' at the end of the survey to ensure the student is not displaying emotional distress, and provided with teen-relevant resource information. Should a student display signs of emotional distress, or disclose to the research assistant that they are in danger of hurting themselves, hurting others, or of being hurt, the research assistant will follow an established protocol to notify appropriate school personnel, and ensure that the student receives urgent evaluation.

#### Survey Administration at 1 Year follow up

Student athletes' contact information will only be used to follow up regarding 12 month follow up survey and only accessible to Dr. Miller and her research team. All of the contact information will be destroyed after student athletes have been re-contacted to complete the follow up survey. The contact information will be stored in a password-protected, encrypted file, on Dr. Miller's secure research drive, accessible only to the research team.

Audiorecording and Observations to Track Fidelity to Intervention -- no names will be associated with the Observational Tracking Tools that will be completed by research assistants, only the school and sport. The Observational Tracking Tools will be stored in a locked filing cabinet in Dr. Miller's secure office space. Only de-identified data will be shared with the stakeholders. Research assistants will arrange the observations to occur according to the coaches' preference and the RAs will remind coaches that their participation is voluntary. Audiotapes from the observations will be destroyed after notes are completed; notes from the focus groups will be completely de-identified. In addition, research staff will remind participants about the limits of confidentiality.

Coach and administrator interviews: The interviews with coaches and administrators will be confidential, i.e., no names will be associated with the data collected. Audiotapes from the interviews will be destroyed after transcription is completed; transcripts from the interviews will be completely de-identified. Participants will be reminded that the interviews are completely voluntary and they can stop the interview at any time.

## 5.2

**What steps will be taken in the event that a clinically significant, unexpected disease or condition is identified during the conduct of the study?**

\* **Not Applicable**

## 5.3

All the risk questions (screening, intervention/interaction, follow-up) have been merged into one question (5.1).

[\[reviewer notes-\]](#)

## 5.4

**Do any of the research procedures pose a physical or clinically significant psychological risk to women who are or may be pregnant or to a fetus?**

\* No

[reviewer notes-]

**5.5 Do any of the research procedures pose a potential risk of causing genetic mutations that could lead to birth defects?**

\* No

[reviewer notes-]

**5.6 Are there any alternative procedures or courses of treatment which may be of benefit to the subject if they choose not to participate in this study?**

\* No

If **Yes**, describe in detail:

[reviewer notes-]

**5.7 Describe the specific endpoints (e.g., adverse reactions/events, failure to demonstrate effectiveness, disease progression) or other circumstances (e.g., subject's failure to follow study procedures) that will result in discontinuing a subject's participation?**

\* Not applicable - There are no anticipated circumstances that would lead to discontinuing a subject's participation in this research study.

[reviewer notes-]

**5.8 Will any individuals other than the investigators/research staff involved in the conduct of this research study and authorized representatives of the University Research Conduct and Compliance Office (RCCO) be permitted access to research data/documents (including medical record information) associated with the conduct of this research study?**

\* No

**5.9 Has or will a Federal Certificate of Confidentiality be obtained for this research study?**

\* No

**5.10 Question has been moved to 5.17**

**5.11 Question has been moved to 5.16**

[reviewer notes-]

<b>5.12</b>	<b>Does participation in this research study offer the potential for direct benefits to the research subjects?</b>
-------------	--

No - Describe the general benefits to society (e.g., increased knowledge; improved safety; better health; technological advancement) that may result from the conduct of this research study.

Describe the benefit:

This is a rigorous evaluation of one of the only teen dating violence/sexual violence prevention program for middle school youth (already with demonstrated effectiveness among high school students). Thus the results may add to the number of evidence-based programs available to help youth (especially younger adolescents) reduce disrespectful and harmful behaviors toward women and girls.

**5.13 Describe the data and safety monitoring plan associated with this study. If the research study involves multiple sites, the plan must address both a local and central review process.**

**Data Security**

Responses to the anonymous computer-assisted on-line survey is entered by the participants themselves (coaches and students), and through this computer-based system, the data is automatically entered into a password protected data base accessible only to the investigative team. No names are connected to the survey data as each participant creates their own personal identification code as described above.

The only study documents that will contain unique personal identifiers are consent forms and the contact list of participants (youth and coaches) that are kept to assist with recontacting participants at the end of the sports season (Time 2) and in the subsequent academic year (Time 3). Signed consent forms will be stored in a secure file drawer inside the locked office of the PI whenever not in use. Consent forms will be stored separately from any survey data collected in this study (as all the survey data are collected via computer and immediately housed in a password-protected secure database). Note any paper surveys will also be stored separately from consent forms in a locked cabin in a password protected office space. The names of participants will be kept in an encrypted file on a password protected secure shared drive and on-line server called SharePoint (available to the research team through the University of Pittsburgh at no additional cost), and accessed only when needed to arrange the follow up data collection with each school's athletic department (Time 2 and Time 3). Please note that there are three layers of protection for the contact information: password protection to enter the University of Pittsburgh system, another password to enter SharePoint, and another password to decode the encrypted file. This information will be accessed only when needed to arrange the follow up data collection.

**Internal Data Safety and Monitoring Plan**

During the course of conducting the high school study with over 2000 athletes, we did not experience any adverse events, including no evidence of emotional distress among participants and no disclosures of abuse or violence. However, given the sensitivity of the questions being asked regarding violence perpetration, we are taking extra precautionary measures to have an internal data safety and monitoring plan in place. Dr. Miller (PI) will meet weekly by phone to monitor the data safety and review protocols with the research team to identify any challenges. A summary report of all data and safety monitoring activities will be provided to the IRB at the time of the annual review.

- a) Systematically review assessment materials to ensure that assessment is conducted appropriately and that participants disclosing abuse or violence during the course of taking the survey receive appropriate connection to violence-related services and that mandated reports are made by school personnel when appropriate.
- b) Systematically review notes from research assistants to ensure that participants experiencing distress are being connected directly with a school professional, receiving educational materials, and being referred appropriately; this includes ensuring that all research assistants document asking each participant about emotional distress after completion of the survey.
- c) Monitor staff performance with regard to protection of privacy, confidentiality, maintenance of secure data bases, and study procedures designed to reduce the risk of distress and potential breaches of confidentiality.
- d) Ensure that the PI (Miller), or a designated qualified individual, will be available by pager

in case research staff needs to confer regarding participants' behaviors or comments made during the survey.

e) Review and report any adverse events associated with the study.

[reviewer notes-]

## Section 5 - Potential Risks and Benefits of Study Participation

### 5.14

**What precautions will be used to ensure subject privacy is respected?** (e.g. the research intervention will be conducted in a private room; the collection of sensitive information about subjects is limited to the amount necessary to achieve the aims of the research, so that no unneeded sensitive information is being collected, drapes or other barriers will be used for subjects who are required to disrobe)

All surveys will be administered via a web-based secure survey system (REDCap) created for this project, loaded on desktops available in the computer labs of participating schools. (If online surveys cannot be administered due to computer availability or failure, back up paper surveys will administered as needed). Students in the computer lab will be positioned to maximize privacy when taking the survey; multiple data collection sessions will be scheduled for groups larger than 20 to allow such privacy during survey completion. Coaches have the option to complete in the computer labs at school or private office space.

This computer-based survey modality was used for data collection for the high school study. For this project, Dr. Miller and her Research Team will create an online survey program such that as data are collected these are entered directly into a secure database (REDCap).

### 5.15

**What precautions will be used to maintain the confidentiality of identifiable information?** (e.g., paper-based records will be kept in a secure location and only be accessible to personnel involved in the study, computer-based files will only be made available to personnel involved in the study through the use of access privileges and passwords, prior to access to any study-related information, personnel will be required to sign statements agreeing to protect the security and confidentiality of identifiable information, whenever feasible, identifiers will be removed from study-related information, precautions are in place to ensure the data is secure by using passwords and encryption, because the research involves web-based surveys, audio and/or video recordings of subjects will be transcribed and then destroyed to eliminate audible identification of subjects)

Coaches and athletes will produce a self-generated personal code based on 7 questions that only they will know (e.g., "Please enter the first letter of your biological mother's first name or N/A if this is not relevant to you."). This system of using a secret code (which has been used by Dr. Miller in previous studies, including the Iowa CBIM pilot study and the Sacramento CBIM randomized trial) helps to ensure that responses remain as anonymous as possible while maintaining the ability to match baseline and follow up data across the three waves of data collection. No names will be connected to any of the surveys, and there will be no linking of specific surveys to any identifiable information. The contact list of athletes who participated in each of the waves of data collection will be kept in an encrypted file on a password protected secure shared drive and on-line server called SharePoint (available to the research team through the University of Pittsburgh at no additional cost), and accessed only when needed to arrange the follow up data collection with each school's athletic department.

### 5.16

**If the subject withdraws from the study, describe what, if anything, will happen to the subject's research data or biological specimens.**

Any subject that withdraws from the study, before any data collection is completed, such as survey responses, consent and assent forms will be kept and filed with withdrawn/declined records.

**5.17** **Following the required data retention period, describe the procedures utilized to protect subject confidentiality.** (e.g., destruction of research records; removal of identifiers; destruction of linkage code information; secured long-term retention)

Once data collection and analysis is completed consent and assent forms are stored and archived. After a period of five years after the study is completed, then all research records will be destroyed.

[reviewer notes-]

**6.1**

**Will research subjects or their insurance providers be charged for any of the procedures (e.g., screening procedures, research procedures, follow-up procedures) performed for the purpose of this research study?**

\*

No

[reviewer notes-]

## 6.2 Will subjects be compensated in any way for their participation in this research study?

\* Yes

### 6.2.1

#### **Describe the amount of payment or other remuneration offered for complete participation in this research study.**

Coaches who complete baseline and follow up (3 month) survey will receive a \$25 gift card per survey.

INTERVENTION Coaches who complete the 60-minute CBIM Coaches Training session will receive a \$25 gift card. After the training, INTERVENTION coaches are eligible to receive an additional \$50 in remuneration by participating in the activities related to tracking the delivery of the intervention as intended (fidelity to intervention). These procedures include having a research assistant observe him/her deliver up to 2 different lesson cards and answering up a follow-up phone call with a research assistant and completing a training card delivery tracking tool (\$25), as well as, participating in a semi-structured interview (\$25) at the end of the sport season. These amounts will be added to the We Pay card at the end of the sports season, after they are completed. Thus, the total amount that an intervention coach can receive during a sports season is \$125 (including participation in baseline and follow up surveys) to thank them for participating in the training and intervention delivery as well as study procedures as described.

Student athletes receive remuneration for each survey completed: for completing a baseline or follow up (3month) survey he/she receives a giveaway gift (such as a bracelet or water bottle for each survey, and those student athletes who complete the 1 year follow up survey will receive a \$20 gift card.

Student athletes who participate in focus groups will receive a \$10 gift card.

Student athletes who participate in an interview will receive a \$10 gift card.

There will also be a drawing for one \$25 gift card for each sport team participating in the study. Each student athlete who returns a parent permission form will be entered into the drawing for their respective sport team and one student who was entered into the drawing from each team will receive a \$25 gift card.

Administrators will receive remuneration (\$25) for completing administrator interviews.

### 6.2.2 Describe the amount and term of payment or other remuneration that will be provided for partial completion of this research study.

Subjects receive a giveaway or gift card for each activity completed (i.e., survey or observation) as described above.

For example, if an athlete completes only a baseline survey, he/she will receive a giveaway (such as a bracelet). Similarly for the coaches, a coach who completes the baseline survey (\$25), receives the training (\$25) and completes the follow-up survey will receive \$75.

[\[reviewer notes-\]](#)

**7.1 Summarize the qualifications and expertise of the principal investigator and listed co-investigators to perform the procedures outlined in this research study.**

Elizabeth Miller is the Chief of Adolescent Medicine at University of Pittsburgh. She is a nationally and internationally recognized expert in teen dating abuse and gender-based violence. Trained in medical anthropology as well as Internal Medicine and Pediatrics. Dr. Miller's research has focused on the impact of teen dating abuse on adolescent health, in particular the relationship between dating abuse and teen pregnancy. She has a particular passion for working with marginalized youth populations, including pregnant-parenting teens, gang-involved youth, youth in foster care, and homeless youth. She was the lead investigator on the high-school version of this study (also a cluster-randomized controlled trial) which was conducted in Sacramento, CA.

Kaleab Abebe is a faculty member and biostatistician in the Center for Research on Health Care, and his research experience has included collaborations in a wide variety of areas such as depression, HIV, and emergency medicine. In addition, he is currently a co-investigator for a data coordinating center of a multisite clinical trial in chronic kidney disease. His primary contributions will be to the design, implementation, and statistical analyses of the proposed study.



[reviewer notes=]

**7.2 Indicate all sources of support for this research study.**

\*

Selections

Federal: Upload a copy of the entire grant application (**including the cover sheet**) if our site is the awardee institution; for federal contracts, upload a copy of the research plan

If **Federal** support, provide the sponsor information:

Federal sponsor	Grant Title	Grant number	Awardee institution	Federal grant application
<a href="#">View</a> CDC	A Cluster-Randomized Trial of a Middle School Violence Prevention Program	1R01CE002543-01	University of Pittsburgh	<a href="#">CDC CBIM Grant Submission(0.01)</a>

For projects not supported by a federal grant, upload the research plan that was submitted for funding:

Name Modified Date

If **Industry** support, provide the sponsor information and level of support:

If **Foundation** support, provide the sponsor information:

If **Other** support, provide the support information and level of support:

We are submitting this proposal to the Centers for Disease Control and Prevention. Given the younger age group that is the target for the prevention program and potential concerns about consent and assent, we would like to make sure that CDC is aware that this project has been appropriately reviewed by the IRB.

[reviewer notes=]

**7.3****Is this study funded in part or whole by a PHS Agency?**

\* Yes

**Does any investigator\* involved in this study (select all that apply):**

Name

**A.** Have a financial interest (aggregated value of equity and remuneration\*\* during the past or next twelve months) in a **publicly-traded entity** that either sponsors\*\*\* this research or owns the technology being evaluated or developed that exceeds **\$5,000 but not \$10,000?**

**B.** Have a financial interest (aggregated value of equity and remuneration during the past or next twelve months) in a **publicly-traded entity** that either sponsors this research or owns the technology being evaluated or developed that exceeds **\$10,000?**

## Section: Section 7 - Qualifications and Source(s) of Support

Name

- C.** Receive remuneration (during the past or next twelve months) from a **non-publicly traded entity** that either sponsors this research or owns the technology being evaluated or developed that exceeds **\$5,000 but not \$10,000?**
- D.** Receive remuneration (during the past or next twelve months) from a **non-publicly traded entity** that either sponsors this research or owns the technology being evaluated or developed that exceeds **\$10,000?**
- E.** Have equity in a **non-publicly traded entity** that either sponsors this research or owns the technology being evaluated or developed?
- F.** Receive reimbursement or sponsorship of travel expenses (for one trip or a series of trips during the past or next twelve months) by an outside entity that either sponsors this research or owns the technology being evaluated or developed that exceeds **\$5,000?**
- G.** Have rights as either the author or inventor of **intellectual property** being evaluated or developed in this research that is the subject of an issued patent or has been optioned or licensed to an entity?
- H.** Have an officer or management position\*\*\*\* with a **Licensed Start-up Company** overseen by the COI Committee that either sponsors this research or owns the technology being evaluated or developed?
- I.** Receive compensation of any amount when the value of the compensation would be affected by the outcome of this research, such as compensation that is explicitly greater for a favorable outcome than for an unfavorable outcome or compensation in the form of an equity interest in the entity that either sponsors this research or owns the technology being evaluated or developed?
- None of the above options apply and there are no other financial conflicts of interest in the conduct of this research.**

**\*Investigator** means the PI, co-investigators, and any other member of the study team, regardless of title, who participates in the design, conduct, or reporting of this research, as well as his/her spouse, registered domestic partner, dependents, or other members of his/her household. **The PI is responsible for ensuring that s/he and all other relevant members of the study team review the above questions describing Significant Financial Interests.**

\*\*such as salary, consulting fees, honoraria, or paid authorship

\*\*\*through the provision of funds, drugs, devices, or other support for this research

\*\*\*\*Such as serving on the Board of Directors or Board of Managers or a position that carries a fiduciary responsibility to the company (e.g., CEO, CFO, CTO, or CMO).

[\[reviewer notes-\]](#)

## Supporting Documentation Section

### References and Other Attachments

Additional documents:

Name	Modified Date	Version
<a href="#">CBIM Card Series Delivery of the Program</a>	1/29/2015 2:52 PM	0.02
<a href="#">CBIM ToolKit - Fan Pledge Day</a>	2/24/2014 1:19 PM	0.01
<a href="#">CBIM ToolKit - Getting Started</a>	2/24/2014 1:19 PM	0.01
<a href="#">CBIM ToolKit - Need Help</a>	2/24/2014 1:19 PM	0.01
<a href="#">CBIM ToolKit - Overview</a>	2/24/2014 1:19 PM	0.01
<a href="#">CBIM ToolKit - Sample School Radio Script</a>	2/24/2014 1:20 PM	0.01
<a href="#">CBIM ToolKit - Sample Sports Reporter Letter</a>	2/24/2014 1:20 PM	0.01
<a href="#">Coach Training Cards - Tracking Tool</a>	5/27/2015 4:14 PM	0.02
<a href="#">Dear Coach Letter</a>	2/27/2014 6:26 PM	0.01
<a href="#">Observational Tracking Tool</a>	5/27/2015 4:14 PM	0.03

*Please use the Add button to the left to upload additional documents if needed.*

[\[reviewer notes-\]](#)

***ClinicalTrials.gov is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world.***

"[Applicable clinical trials](#)" are required **by federal law** to be registered in [ClinicalTrials.gov](#).

Applicable Clinical Trials (ACTs) are studies that meet the following criteria:

- The study is an interventional study AND
- The study intervention is a drug, biologic, medical device, radiation or genetic AND
- The Study is not Phase 0 or 1 AND
- The study has at least one site in the United States or is conducted under an investigational new drug application or investigational device exemption

#### NIH Policy

Effective January 18, 2017, revised [NIH Policy](#) requires that all [clinical trials](#) funded in whole or in part by the NIH be registered and results information posted on [ClinicalTrials.gov](#).

As defined by the NIH, a [clinical trial](#) is:

*A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of*

*those interventions on health related biomedical or behavioral outcomes.*

The NIH Policy extends beyond the Food and Drug Administration Amendment Act (FDAAA 801) requirements in that it requires registration and results reporting of:

- clinical trials of behavioral, surgical and other types of health and medical interventions
- phase 1 studies of drugs and biological products
- small feasibility studies of device products

Failure to submit all required registration and results information requested on ClinicalTrials.gov can jeopardize University grant funding, the future funding of the grantee and subject the University of Pittsburgh to future monetary penalties.

In addition, to promote transparency of the clinical trials process, the [International Committee of Medical Journal Editors \(ICMJE\)](#) has established a policy requiring the entry of clinical trials in a public registry, such as ClinicalTrials.gov, prior to subject enrollment as a condition of consideration for publication of the trial results.

**\* Based on the above information, will this study be registered in ClinicalTrials.gov?**

Yes

**Who will serve as the Responsible Party?** UPMC/Pitt Investigator or IND/IDE Pitt Sponsor

**Why are you registering your study?** (Check all that apply)

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It is strongly encouraged by the NIH

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It is required for publication by the **International Committee of Medical Journal Editors** (*Registration is required in a publically available, searchable database system prior to informed consent being obtained from the first study participant*)

If you are not yet registered and need to establish an account for the PI or other research staff that may need to access the record, please send an email to the University of Pittsburgh PRS administrator at [ctgov@pitt.edu](mailto:ctgov@pitt.edu) with the following information for each individual:

- Full name
- Telephone number
- Pitt or UPMC email address

If you have any questions or concerns, please email us at [ctgov@pitt.edu](mailto:ctgov@pitt.edu).

To find out additional information about how to register your study go to:

<https://www.clinicaltrials.gov/ct2/manage-recs/how-register>