Schools Championing Safe South Africa: An Intervention Engaging Teachers and Students in Adolescent Prevention of HIV risk and Intimate Partner Violence

NCT to be assigned

Study Protocol and Statistical Analysis Plan

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Executive summary

Adolescence presents an ideal developmental transition period for an integrated intervention targeting prevention of HIV risk behaviors and intimate partner violence (IPV) including sexual violence. Adolescent boys in particular, are at high risk for HIV and perpetration of IPV. Yet, few behavioral interventions integrate HIV-IPV prevention and are tailored for the unique developmental needs of adolescent boys. Educational environments play a vital role in shaping behavioral choices among adolescent boys. Specifically, teachers and student peers serve as agents of change for adolescent boys' HIV and IPV prevention needs in four important ways. First, teachers and student peers influence community norms for appropriate adolescent male behaviors relating to dating, relationships, and sexual violence within the school ecology. Second, teachers and student peers have persistent contact with adolescents and thus, can play an influential role in adolescents' lives as role models for healthy norms. Third, teachers and student peers substantively motivate and reinforce protective behaviors relating to prevention of HIV and IPV. Fourth, teachers are ideally prepared to deliver age- and developmentally-tailored preventive interventions to adolescents because they are professionally trained to engage with adolescents in age and developmentally appropriate teaching. Despite the important role of teachers and student peers in promoting the health of adolescents, there are currently no HIV-IPV interventions in global priority settings for these epidemics that target teachers and student peers in school environments. In this study, we will develop and then investigate the acceptability and feasibility of *Schools Championing Safe South Africa*, an integrated HIV-IPV intervention where teachers and student peers engage adolescent boys in a developmentally-tailored approach to prevent adolescent HIV risk behavior and IPV using a social norms approach. We work in South Africa, a country with the largest HIV epidemic and some of the highest rates of IPV in the world.

Aim

This study explores the acceptability and feasibility of a school-based intervention called *Schools Championing Safe South Africa* that engages teachers and students in an integrated approach for preventing risk behavior related to acquisition of HIV and perpetration of IPV among adolescents in South Africa. Teachers and students are agents of change who can transform the school social environment to promote HIV and IPV prevention behaviors for adolescents.

Methods

To develop the intervention, we will gather behavioral and social norms data from teachers and students (aiming for 75% of students) relating to student-level prevention of HIV and IPV in 3 public high schools in poor, Cape Town communities, to inform the social norms campaign content for *Schools Championing Safe South Africa*; (2) We will refine the content of the intervention (which will comprise a social norms poster campaign and other intervention components) using n=5-10 interviews with teachers and k=3-6 focus groups with students in School #1 (poster campaign refinement school). We will measure the acceptability and feasibility of the intervention by conducting a randomized controlled pilot trial of the social norms campaign comparing School #2 (experimental intervention school) versus School #3 (wait list control school) with 1- and 6-month follow-up to measure change

among students at high risk for sexual risk behavior and IPV perpetration (e.g., adolescent boys 15-17 years), and to assess the acceptability and feasibility of the intervention for a future fully-powered efficacy trial.

Outcome

In this study, we will develop, and then examine the acceptability and feasibility of an intervention that substantively involves teachers and student peers in supporting male adolescents in prevention of human immunodeficiency virus (HIV) and intimate partner violence (IPV) in South Africa. South Africa faces some of the highest global rates of HIV and IPV with sustained high incidence of HIV and alarming rates of IPV among adolescents and thus, is an ideal site to advance prevention science to tackle these urgent public health priorities. Developing school-based interventions that involve teachers and students in promoting healthy decisions among adolescent boys can support optimal health for young people, their future partners, and society. Findings will advance preventive intervention science for young people at elevated risk for HIV and IPV in a global priority setting for HIV and violence prevention.

Intended feedback

In addition to peer review papers and conference presentations, we will develop research briefs and hold in-person meetings for adolescents, school stakeholders, and policy makers. This involves dissemination of study progress as the study activities proceed including regular updates to ensure continued stakeholder buy-in and to ensure a feedback loop for the project. This also involves early dissemination of study results to gather data that may guide directions for future grant plans. Finally, this involves dissemination of study final results to stakeholders. A letter of support for the study from Dr. Whittle, Deputy Director-General of the Dept. of Basic Education demonstrates a need for school-based HIV-IPV intervention interventions for adolescent boys (Appendix A). We will provide feedback to Dr Whittle and other stakeholders in the Department of Basic Education at the national level. We will also provide feedback to the provincial, Western Cape Education Department and to the three schools in which the study is implemented.

Specific Aims

South Africa is a global priority site for the overlapping HIV and IPV epidemics, and an ideal site for advancing prevention science for these urgent public health problems. South African adolescents face exponentially greater risk for human immunodeficiency virus (HIV) and intimate partner violence (IPV). South Africa has the largest country population of individuals living with HIV and adolescents represent the largest share of new infections, with 88,400 adolescents newly infected each year.[1] Adolescents engage in high risk sexual behavior with 58.8% reporting condomless last sex and 17.4% reporting two more sexual partners.[2] Rates of IPV – defined as physical, emotional or sexual violence by a current or former partner) and sexual violence – are also among the highest in the world. For example, in a population-based survey of South African men 18-49 years, 1 in 3 men (31.9%) perpetrated rape[3] with the majority (75%) perpetrating their first rape before age 20, with the average age of first rape at 17.[4,5] Empirical data on adolescent IPV in South Africa, especially perpetration of sexual violence are rare. A study in Cape Town identified a 10% prevalence of sexual violence perpetration (defined as 'forced' sex by/of a partner or non-partner) among eighth graders.[6] In a school-based HIV and IPV prevention study, 13% of adolescents reported perpetrating IPV.[7] Our HIV prevention study with South African adolescents 13-15 years (in a community with 33.1% HIV prevalence[8]) indicated high rates of forced oral sex (15%), sexual touching (14%), anal sex (8%), and vaginal sex at (6%); with perpetration more common among boys than girls (34.5% vs. 20.5%).[9] As engagement in IPV often persists over the lifespan, integrated primary prevention of HIV and IPV during adolescence offers opportunities to transform the life trajectory of the next generation of adults.

Biological and behavioral synergies between HIV risk and IPV perpetration require an integrated preventive intervention approach. Yet, in our recent systematic review, only six interventions concomitantly address HIV risk and IPV among adolescents in Sub-Saharan Africa. None focused on school community-level prevention of HIV and IPV using a social norms approach.[10] Social norms exert a powerful influence on behavioral choices in favor of, or against, prevention outcomes. Problematic norms are amplified by individuals engaged in problem behavior – who are often in the minority – and erroneously believe that their problem behavior is normative and supported by others.[11] In contrast, misperceptions of problem behaviors as the norm by healthier individuals – who are often in the majority – can pressure healthy individuals to engage in inappropriate behavior.[12] When healthy individuals falsely believe that they are alone in their opposition to inappropriate behavior they are less likely to speak up against it.[13] Social norms marketing campaigns repeatedly expose individuals to positive, data-based messages about true norms, and in so doing, correct misperceived problematic community norms that promote HIV risk, violence, and increase the number of individuals who act in accordance with healthy community standards.[14,15] Given the salient role of social influence during adolescence, interventions that promote healthy behavior by targeting misperceptions in peer norms are ideally suited to the developmental stage of this age group. Because adolescents are required to attend school, schools offer a well-defined community space to shape healthy norms that reinforce preventive behaviors. Our *long-term goal* is to prevent risk behaviors relating

to HIV and STIs, and IPV perpetration using developmentally-tailored interventions. In this R34, *our overall objective* is to develop, and then test the acceptability and feasibility of ***Schools Championing Safe South Africa***, an integrated HIV-IPV intervention that uses a social norms campaign to engage teachers and student peers in preventing HIV risk and IPV perpetration among male adolescents 15-17 years. *Schools Championing Safe South Africa* focuses on school community-level prevention; if promising, it will complement the existing individual-level prevention, *Safe South Africa* that our team developed and tested. Our *rationale for this study* emerged from stakeholder feedback and preliminary data showing the need to engage teachers and students in changing norms around HIV and IPV. We propose 3 aims:

1. **Development Aim: Formulate content for a data-driven social norms poster campaign that is the foundation for *School Championing Safe South Africa*** by collecting behavioral and social norms data from teachers and students (75% student coverage in 3 schools) relating to adolescent-level HIV and IPV.
2. **Refinement Aim: Refine components of the school community-level intervention** by refining messages and visuals delivered in the social norms poster campaign, as well as the other intervention components (teacher lunch- and-learn sessions, teacher workbook, and student intercept activities) via n=5-10 interviews with teachers and k=3-6 student focus groups in School #1 (campaign refinement school).Together, these intervention components are designed to transform poster campaign messages into prevention behaviors.
3. **Acceptability and Feasibility Aim: Assess the acceptability and feasibility of the intervention** by comparing School #2 (experimental school) versus School #3 (wait list control school) in a randomized pilot trial with 1- and 6-month follow-up focusing on outcomes for students at high risk for sexual risk behavior and IPV perpetration (adolescent boys aged 15-17 years). As an exploratory secondary aim, we examine preliminary evidence for hypotheses that the intervention, relative to the control, will produce in adolescent boys: (1) reductions in actual or intended HIV risk behaviors; (2) reductions in IPV frequency and decreased endorsement of IPV supportive attitudes; and (3) increased proactive bystander intentions.

The *expected outcomes* of this R34 include acceptability and feasibility data that will inform a future fully-powered RCT to test the efficacy of *Schools Championing Safe South Africa* for preventing acquisition of HIV and IPV perpetration among adolescent boys aged 15-17 years. Our research is aligned with the Trans-NIH Plan for HIV, NIMH, and NIAID strategic priorities including “eliminating disparities across the globe”, and a focus upon behavioral and social interventions that address “community norms and practices influence individuals’ behaviors”.

Significance

South Africa sits at the global epicenter of overlapping HIV and IPV epidemics, and is an ideal site to develop primary prevention science for adolescents most at risk for these urgent public health problems. The bi-directional relationship between human immunodeficiency virus (HIV) and intimate partner violence (IPV) indicates the need for an integrated preventive intervention. Several systematic reviews and meta-analyses identify causal and non-causal mechanisms linking HIV and IPV. Causal mechanisms linking increased HIV risk with sexual IPV – one form of IPV – include increased genital or anal tissue trauma associated with increased infection risk. Non-causal mechanisms include positive correlation between HIV infection and those who perpetrate IPV[16] and higher rates of HIV risk behaviors among IPV perpetrators including decreased condom use,[17,18] concurrent and/or multiple sexual partners,[17,19] alcohol and substance use, and higher rates of HIV and other sexually transmitted infections (STIs).[20,21] HIV acquisition risk is significantly higher among individuals who have experienced IPV. For example, a global systematic review and meta-analysis of 28 studies with N=331,468 women (including 4 South African studies), indicated that any type of IPV was significantly associated with HIV infection.[22] A preventive intervention to address IPV perpetration naturally addresses sexual risk reduction and can yield HIV prevention benefits for potential perpetrators, and current or future partners. Adolescence offers an ideal developmental transition point for prevention.

South Africa has the largest HIV epidemic of any country in the world,[1] with adolescents accounting for the majority of new HIV infections.[23] Adolescents are naturally at increased risk due to normal developmental milestones.[24] Initial sexual experiences frequently occur at this age, corresponding to increased risk for acquisition of HIV, other STIs, and IPV. Adolescent males are engaging in HIV risk behavior at higher rates than females: 67.7% of adolescent males reported condomless last sex compared to 49.8% for females, and 25.5% of adolescent males reported two or more sexual partners compared to 9% among females.[2] South Africa also has a high global burden of IPV. Globally, the sub-Saharan African region, including South Africa, has the highest prevalence for both intimate partner and non-partner sexual and/or physical violence at 65.6% (95% CI: 53.6-77.7%)[25] and 21% (95% CI: 4.5-37.5%) respectively.[26] While violence occurs across the lifespan, preventive interventions are urgently needed during adolescence, especially in South Africa because 75% of adult perpetrators commit their first rape before the age of 20.[4,5] Although all genders perpetrate violence, the vast majority of sexual violence is perpetrated by males; in South Africa, 1 in 3 men (31.9%) reported rape perpetration.[3] In our HIV prevention study with South African adolescents 13-15 years (in a community with 33.1% HIV prevalence[8]) male adolescents were more likely to engage in forced sexual touching, oral, vaginal, and anal sex compared to females (34.5% vs. 20.5%). Alarmingly, 14% of boys from our preliminary study engaged in repeat perpetration.[9] These data indicate that boys would especially benefit from integrated HIV-IPV perpetration prevention.

Adolescents have unique prevention needs and tailoring interventions to this age group allows us to better leverage developmental milestones for large prevention gains early in the lifecourse. The ideal age range for targeting adolescent boys most at risk for HIV and IPV perpetration is aged 15 to 17 years. In a large longitudinal prospective cohort study of South African adolescents, the median age of penetrative sexual debut was 15 years,

with 38.2% of males engaged in penetrative debut at this age);[27] in a large representative sample of rape perpetration among males in South Africa, participants reported an average age of 17 years for first rape perpetration.[4,5] Alignment of age of sexual debut with age of perpetration underscores the need for interventions during adolescence. Our intervention approach integrates prevention of both HIV risk and IPV perpetration, with a purposive focus on male adolescents. A focus on preventing IPV perpetration (focused on males) in relation to HIV, as opposed to reducing risk for IPV victimization (most often focused on females), is central to our effort to expand intervention approaches for HIV-IPV.

Limited Evidence for Adolescent-tailored HIV-IPV Interventions - Only six intervention studies have taken an integrated approach to HIV-IPV in sub-Saharan Africa, with only two specifically tailored to South African adolescents. Our systematic review on integrated HIV and IPV interventions for adolescents in sub-Saharan Africa identified only six interventions concomitantly address HIV and IPV among adolescents and none utilized a social norms approach.[10] Four interventions occurred in South Africa: *PREPARE, IMAGE, Stepping Stones,* and Kalichman's unnamed intervention. Only Kalichman's intervention exclusively targeted IPV perpetration and was male-focused but did not include adolescents under 18 years. Kalichman et al.'s quasi-experimental study recruited male participants 18 years and older to compare the effects of a trial IPV/HIV intervention with an HIV/alcohol intervention on IPV perpetration and risk of STI. The intervention was delivered in five 3-hour integrated IPV and HIV risk-reduction group sessions. The intervention group did not show any differences for increased condom use, decreased number of sexual partners, or decreased occurrence of unprotected sex. At the six-month follow-up, the intervention group showed decreased perpetration of past-month physical IPV (OR 0.3, 95% CI 0.2-0.4).[28] The other three interventions in South Africa either examined risk reduction or a mix of perpetration and risk reduction and only two included adolescents in the age range of this proposed R34; notably only two interventions (*PREPARE* and *Stepping Stones*) specifically targeted adolescents.[10] *PREPARE* led by Dr. Mathews (M-PI of this proposed R34 study) was a multi-component school-based intervention designed to decrease IPV and HIV risk behavior among adolescents. *PREPARE* was tested in a cluster RCT in 42 schools, targeting Grade 8 adolescents. The 21-session group-based intervention was accompanied by school health and school safety components. At the 12 month follow-up, intervention participants were less likely to report IPV victimization (35.1 vs. 40.9 %; OR: 0.77; 95 % CI 0.61–0.99) but had no changes in HIV risk.[29] There are 6 key differences between *PREPARE* and our proposed intervention: (1) *PREPARE* focused on all genders, while *Schools Championing Safe South Africa* focuses specifically on boys. (2) *PREPARE* focused on younger adolescents 13-14 years, most who have not had intimate partnerships. Our intervention focuses on older adolescents 15-17, who are more likely to have experience with intimate partnerships and sex. (3) *PREPARE* focused on changing the adolescent's "own" attitudes to the acceptability of IPV and rape but did not use a social norms approach for IPV or HIV. (4) *PREPARE* did not involve teachers in any classroom activities. (6) In *PREPARE*, there were no in-school classroom activities. All interactions with students took place after school, between students and facilitators employed by the research team; there was large attrition in attendance over time in *PREPARE* – and in a *PREPARE* publication (DOI 10.1186/s12889-015-1963-3), Mathews described this missed opportunity for reaching those at risk – which our intervention addresses. *IMAGE* RCT included 14-35 year olds,

and investigated whether a microfinance intervention delivered over 6-9 months providing economic stability and complemented with education on male gender norms, domestic violence, sexuality and HIV could reduce IPV among adults. After two years, intervention participants reported lower risk of past-year physical or sexual violence by an intimate partner (adjusted risk ratio=0.45; 95% CI: 0.23-0.91) but no changes in HIV incidence.[30] *Stepping Stones* RCT was a participatory intervention designed to reduce HIV, herpes simplex type 2 (HSV-2) among young men and women 15-26 years old living in the Eastern Cape province of South Africa. The group-based intervention was delivered in weekly sessions for 6-8 weeks. *Stepping Stones* was not associated with reduced HIV incidence, but demonstrated 33% reduction in Type 2 herpes simplex virus (aIRR 0.67, 95% CI 0.46-0.97). A lower proportion of male participants reported IPV perpetration at two-year follow-up in the intervention group compared to the control (adjusted odds ratio [aOR] 0.62, 95% CI 0.38-1.01).[31] Our review demonstrates an urgent need for interventions tailored for adolescents, targeting the school environment, and focusing on primary prevention of violence integrated with HIV.

Social Norms Campaigns Constitute a Novel Theoretical Approach for Community-level HIV-IPV Prevention - No existing HIV-IPV intervention studies in sub-Saharan Africa utilized a social norms approach for integrated prevention of HIV and IPV.[10] Social norms are differentiated from personal attitudes in that they convey ideas about behavior that is (mis)perceived to be normal and socially accepted.[32] While social norms marketing campaigns have not yet been tested for integrated primary prevention of HIV-IPV, social norms marketing campaigns have shown promise in preventing bullying, problem alcohol use, and dating violence, as well as mosquito nets for malaria prevention in Southern Africa.[12,33-35] Social norms create a potentially powerful risk or protective pathway for interlinked risks of HIV and IPV. Dr. Berkowitz (expert consultant) and others have described four theoretical assumptions in how social norms theory can be applied to promote positive change in the community norms that sustain sexual risk behavior, IPV, and sexual violence:[36,37] 1) community norms influence behavior; 2) positive community norms aligned with prevention can be reinforced; 3) community norms are often misperceived (i.e., they are over- or under-estimated) and misperceptions encourage individuals to adjust their attitudes and behaviors to conform to what they incorrectly perceive to be true;[38] and 4) correcting misperceptions allows individuals to act in accordance with their actual beliefs, which are most often positive and health promoting.[38] Positive behavior is generally the norm, but individuals tend to believe that problem behavior is more common.[12] Changing norms contributes to prevention of HIV and IPV.[39]

Using Social Norms Campaigns in Prevention – The social norms approach is ideally suited for the developmental stage of adolescence in well-defined communities such as schools. Early experiences around relationships, sexual behavior, and violence during adolescence can uniquely shape young people's social norms around what is healthy/unhealthy norms for future relationships.[40] Schools constitute important community environments for social norms formation; adolescents spend a large segment of their day in school and social interactions with student peers and teachers are critical to identity development and health behaviors.[41-45] Thus, leveraging the school ecology (including teachers and student peers) to establish healthy norms among adolescents just as they are establishing attitudes towards sex, relationships, and violence may help to shape patterns of healthy behavior across the lifespan. This R34 proposal will advance the science of community-level primary prevention

by rigorously evaluating a comprehensive data-driven social norms marketing poster campaign designed to promote school environmental change for HIV-IPV perpetration prevention. Over the long term, we intend to combine the school community-level primary prevention intervention being piloted in this R34 (*Schools Championing Safe South Africa*) with a parallel line research, the individual-level intervention (*Safe South Africa* described under Preliminary Evidence) that was previously piloted by our team and is moving towards efficacy testing. Evaluating the promise of a stand-alone social norms marketing campaign in reducing sexual risk behavior relating to HIV and STIs, and sexual violence is a vital first step in understanding whether this community-level intervention strategy should be incorporated into more comprehensive combination prevention approaches that target multiple levels of the social ecology. If both the community- and individual-level interventions are efficacious, their pairing would create a comprehensive combination prevention for HIV-IPV.

Preliminary Evidence Indicating Need for Schools Championing South Africa Intervention

Our team recently completed 6-month follow-up for a R34 testing *Safe South Africa* (R34MH113484-01), an intervention that targets individual-level behavior change for N=80 adolescents boys aged 15-17 years who are at risk for HIV and IPV perpetration. Boys regardless of HIV, sexual status, or previous perpetration behavior were eligible for inclusion. In brief, the *Safe South Africa* intervention was adapted to integrate HIV prevention, and the South African context based on the existing *Safe* Intervention (tested previously in the USA by co-I Orchowski and consultant Dr. Berkowitz);[46-53] *Safe* is a gender- and developmentally-tailored intervention designed to reduce actual or intended HIV risk behaviors; reduce IPV perpetration frequency and decrease endorsement of IPV supportive attitudes; and increase proactive bystander behavior. The final *Safe South Africa* intervention is a group-based, facilitated behavioral intervention for HIV risk and IPV perpetration comprised of 2-hour sessions, held weekly for two weeks. The intervention is based on two individual behavior change theories: (a) the HIV risk prevention components were based on the Information-Motivation-Behavioral (IMB) theory; and (b) the IPV perpetration prevention components were based on a conceptual model called the Integrated Model of Sexual Assault and Acquaintance Rape (a conceptual model original proposed by Dr. Berkowitz, expert consultant).[54,55] This model proposes interventions to prevent IPV, interpersonal violence, and sexual aggression are most salient when adolescent males must consider their own potential for intimate and interpersonal violence (i.e., attitudes, beliefs and socialization experiences) and take a stand against violence perpetrated by others.[56]

Our preliminary data from the existing R34 on *Safe South Africa* clearly indicate a need for developing the school community-level intervention (*Schools Championing Safe South Africa*). We focus on baseline, feasibility and acceptability data, and exploratory data analysis on preliminary evidence of intervention on outcomes.

> **HIV and STI risk behaviors are high, IPV frequent:** 89% of boys aged 15-17 years at baseline had engaged in lifetime vaginal and/or anal sex. 16% of sexually active boys at baseline had never used a condom. 4% reported being HIV positive. 64% had ever been tested for HIV (testing does not need parental consent and is free). 56% of boys at baseline had engaged in or attempted to engage in IPV.
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> **High risk in-school youth can be reached in school settings.** The above HIV and STI risk behaviors, and IPV perpetration were reported by in-school youth. In South Africa, learners in grades 8 and 9 are

required by law to be in school. While there is some drop-out in grades 10 and 11, a significant number of high risk youth can still be reached in school settings.[57]

Misperceived social norms in South Africa are tied to problematic HIV and IPV behaviors. Correcting misperceived social norms is a promising approach for HIV-IPV prevention in South Africa. There was a positive correlation of 0.34 between misperceived norms score regarding a partner's satisfaction during sex and anal sex perpetration (p-value = 0.002). Adolescent boys who agreed that "a man should know what his partner likes during sex" but believed their friends disagreed were more likely to force someone to have anal sex than both adolescent boys whose perception was similar to peers and adolescent boys who perceived their peers to agree more strongly with the statement than they did. There was a similar positive correlation between misperceived norms score regarding a partner's satisfaction during sex and number of reported attempts or completed perpetration in the past 12 months (0.28; p-value = 0.012), any oral sex perpetration attempt (0.28; p-value = 0.013), and lifetime number of vaginal or anal sex partners (0.28; p-value = 0.018). There was a negative correlation of -0.25 between misperceived norms score regarding whether one could demand sex and any forced vaginal sex perpetration attempt (p-value = 0.028). Adolescent boys who disagreed with the statement "girls should have sex with their boyfriend or the guy they are dating when he wants" but believed their friends would approve of having sexual intercourse with many women during the year were more likely to attempt to force someone to have vaginal sex than both adolescent boys who perceived their peers to respond equally and adolescent boys who agreed but perceived their peers to disapprove.

***Safe South Africa* is highly feasible:** First, we captured feasibility by coding fidelity in a random selection of 20% of all sessions. Fidelity was captured through live fidelity coding, where a neutral observer coded skills and adherence to protocol in the facilitators' delivery using rankings ranging from 1 to 3. The ranking of "1" was equivalent to low demonstration of skills <25% of the time and "3" was equivalent to high demonstration of skills >75%. Safe South Africa was implemented with rigorous fidelity. The intervention facilitators exhibited skilled delivery of the intervention, with an average ranking of "3" for seven of the 11 skills, including active engagement with participants; active listening; respectful, positive communication; warmth, concern, confidence, professionalism; building participant confidence; ending all activities with positive prevention; and consistency with the emphasis on consent. The intervention facilitators were scored an average of 2.75 on the remaining four skills evaluated. Second, we examined feasibility by tracking recruitment and retention data. We were able to recruit at a rapid pace, successfully finding enough participants over 5 weeks, and this informs are current timeline estimates. We achieved 100% retention at the 1-month follow-up and 97% retention at the 6-month follow-up for all in spite of a challenging scientific environment including working around school schedules, tracking and tracing students with no street names or home addresses, no postal service, few landline phones, and migration.

***Safe South Africa* is highly acceptable:** 100% rated the quality of the program as "good" or "excellent", would recommend the program to a friend, and felt information would help address important life issues.

Safe South Africa was not powered for efficacy and thus underpowered to examine study outcomes between trial arms. However, we saw promising differences between arms, and direction of effects in the intervention arm. At six months post-intervention, those in the intervention arm were significantly less likely than the control group to have perpetrated vaginal sex in the past five months (0% vs. 13%, p-value = 0.04). There was an increase in the proportion of adolescents who reported ever having refused sex because they did not have a condom (85% at M6 vs. 48% at BL; p-value = 0.005). Furthermore, there was a significant reduction in both vaginal and anal sex perpetration comparing prevalence prior to baseline and prevalence in the past five months, despite a significant and expected increase in the average number of lifetime anal/vaginal sex partners from 6.7 at baseline to 13.8 six months post-intervention. Specifically, 23% and 20% of adolescents at baseline reported ever having perpetrated vaginal and anal sex, respectively; none reported vaginal or anal perpetration in the past five months (p-value = 0.006 and 0.01, respectively). Finally, there was an increase in equitable gender norms (GEM score: 53.5 at BL, 57.0 at M6; p-value = 0.01) and a reduction in rape myth acceptance (RMA score: 22.5 at BL, 18.6 at M6; p-value = 0.03)

While highly feasible and acceptable, Safe South Africa intervention does not address school community-level factors that influence adolescent boys' risk for HIV and IPV perpetration: The existing *Safe South Africa* only addressed individual-level behavior change and only involves adolescent boys 15-17. This R34 proposal would introduce *Schools Championing Safe South Africa Intervention* to directly address school community environmental factors that contribute substantively to HIV risk and IPV perpetration among adolescent boys 15-17 years of age and engage teachers and peers into prevention efforts given that they are important influencers of HIV and IPV perpetration behaviors for adolescent boys.

School stakeholders provided strong feedback that they wanted to be directly involved in changing the school community-environment to support prevention of HIV-IPV among the target group of adolescent boys: We engaged in stakeholder meetings with the school principals, teachers, and school staff prior to study launch and as the study progressed. We are currently engaging in meetings focused on dissemination of findings. In these school stakeholder meetings, we received strong feedback that schools wanted teacher and student peers be directly involved in creating a school environment that supports prevention change among the target group of adolescent boys. A letter of support from the National Department of Education reinforces a desire for this approach towards school-based HIV-IPV intervention (Appendix A).

We also present preliminary data from Dr. Orchowski's (co-I's) studies that demonstrate the powerful role teachers and peers have in shaping norms and the strong promise of a social norms approach for prevention of IPV perpetration in the USA, complementing the South African preliminary data above. In an evaluation of perceived norms among high school students and (N = 7673) and teachers (N = 986) in 27 high schools in the United

States, teachers consistently misperceived the norm among students, notably underestimating healthy behavior and overestimating negative behavior to a greater extent than students. For example, whereas 94.1% of students reported that it was wrong to pressure someone to have sex, teachers estimated that only 53.4% of students would believe this to be wrong; whereas students estimated that only 78.5% of their peers would believe this to be wrong. In summary, preliminary data provide a compelling case that an intervention addressing school community-level factors (i.e., *Schools Championing Safe South Africa Intervention*) would be the logical next step for developing interventions targeting primary prevention of HIV-IPV in a priority population and setting.

Overview of the proposed *Schools Championing Safe South Africa* Intervention:

The foundation of the proposed intervention - ***Schools Championing Safe South Africa*** - is a social norms marketing poster campaign. We have specifically chosen this low-tech approach (rather than apps, websites, other media) for South Africa with future sustainability and scalability in mind. The impoverished communities and public schools where we work have students who may not own phones and limited/no web data, schools have intermittent electricity, and there is limited or no access to internet and computers for students. Whereas social norms media campaigns are often viewed as "poster campaigns", this campaign is more comprehensive in nature in that messaging is linked to a variety of other compatible and synergistic activities in the community designed to create immersive exposure to poster messaging. Research shows these components complementing the poster campaign are necessary to support behavior change. Specifically, posters are complemented by careful messaging to correct misperceived norms to support prevention, implementation of concurrent efforts to engage the audience in conversations about accurate norms messaging and techniques for bystander intervention, and training of teachers and students to serve as active bystanders in the process for adolescents boys at high risk for HIV risk behaviors and IPV perpetration (e.g., the intervention target group).[36,58-60] This process will take place over several months in each school. The core components of the intervention are detailed in **Table 1** and summarized below the table. Although intervention components involve the entire school community (e.g., teachers and student peers), intervention elements come together to support behavior change targeting adolescents at highest risk for HIV and perpetration of IPV, e.g., adolescent boys aged 15-17 years.

Table 1. Core Intervention Components

Target Member of the Community	Intervention Activity
Students	Participate in Normative School Survey (all 3 schools)
	Participate in Focus Groups to Refine Posters (school #1 – refinement school, exclusion of schools #2 and 3 to avoid contamination)
	Receive Targeted Poster Messaging (school #2 – intervention school; school #3 as wait list control)
	Receive Classroom Activities (from Teacher Workbook) (school #2 – intervention school; school #3 as wait list control)
	Participate in Intercept Activities to Deepen Behavioral Change Goals of Poster Campaign (school #2 – intervention school)
Teachers	Participate in Normative Survey (all 3 schools)
	Participate in Interviews to Refine Posters (school #1 – refinement school, exclusion of schools #2 and 3 to avoid contamination)
	Receive Lunch and Learn Teacher Training (school #2 – intervention school; school #3 as wait list control)
	Receive Teacher Workbook Guiding Student Intercept Activities) (school #2 – intervention school; school #3 as wait list control). Team provides ongoing technical assistance to help teachers engage in activities around the campaign.

Step 1: Engaging Stakeholders: As a school community-level change strategy, the goal of the proposed social norms marketing poster campaign is to change community mind-set. Given the widespread reach of misperceived norms, some key stakeholders in a community may display resistance to the approach. Therefore, the

first step in implementation is to educate key stakeholders about the model, and the plan for implementation. Stakeholder resistance will be addressed prior to the implementation of the campaign through stakeholder meetings with school administrators and teachers. A school champion (e.g., principal, teacher, counselor) will also be nominated to coordinate the campaign and engage other teachers in the initiative.

Step 2: Identifying Misperceptions: Individual communities may hold a range of false beliefs relating to HIV and STI risk, sexual risk behaviors, dating relationships, and sexual violence. Student and teacher participation in a normative school survey of perceived norms around these behaviors will identify core misperceptions in community norms within schools. To increase the credibility of the survey, it is essential that the survey have reach. As such, we aim to include a minimum of 75% of the target intervention school community.

Step 3: Selecting/Testing the Message and Visual Poster Media Development: The social norms marketing poster campaign is data-driven. We focus on two sets of data for the targeted poster messaging to be used in the poster media campaign. First, we focus on items with a discrepancy between the actual and perceived norms. Second, in cases where engagement in problematic behavior is high, and norms correspond to this, we focus on changing norms relating to mechanisms of behavior change. For example, if problem behavior such as rates of HIV risk behavior are high, we focus on increasing protective behavior and decreasing risky behavior by challenging pluralistic ignorance (where the majority of the group privately rejects a problematic norm, but incorrectly assumes that most others accept it) and by addressing false consensus (were positive norms show individuals engaging in problematic behavior that their actions are not normative and that the group does not support them). In order to be salient, only messages endorsed by >75% of the community will be selected for inclusion in the campaign. Potential messages will be discussed within focus groups consisting of students and individual interviews with teachers. Interviews with teachers and focus groups with students will also be utilized to determine a unifying and recognizable theme, and to identify appealing and clear presentation.

Step 4: Readying the Community by Training Teachers in How to Support the Campaign Through Classroom Activities and Engage Students in Conversations that Facilitate Norms Change: Teachers can be critical "carriers of community misperceptions". As such, they represent important targets in a social norms messaging campaign. We engage teachers in three ways. First, we train teachers to be effective in their role of amplifying the campaign using meetings with teachers (i.e., via Lunch and Learn Teacher Trainings). The goal of this is to facilitate wide-spread diffusion of the messaging. Second, we provide teachers with an activity toolbox that they can use in the classroom to support the campaign. This Teacher Workbook has activities grounded in social norms theory designed to coach them through supporting corrections of misperceived norms for students (and in so doing, themselves). Examples of student activities from prior social norms marketing campaigns include: 1) fostering discussions as questions arise from students; 2) integrating school data into "Life Orientation" health classes; and 3) distributing handouts on school norms. The Workbook will be refined in consultation with Drs. Berkowitz and Sikeyiya. Third, we support teachers in engaging students in conversations about the campaign that challenge "kick-back" (i.e., the disbelief that naturally occurs when a salient norm is challenged); this will take the form of a FAQ about the campaign and ways to facilitate discussion about "kick-back" with examples

of student activities. These activities have been utilized in Co-I Dr. Orchowski's administration of school-based social norms campaigns in U.S. middle and high schools to successfully train and engage teachers.

Step 5: **Implement Social Norms Poster Media.** A total of 6-12 posters will be developed for each school (the control group will receive the posters as a wait list, after all trial activities have been completed). Each poster will address an identified misperception for the community. Posters will address the following themes: 1) social pressures to be sexually active or engage in HIV and STI risk behavior; 2) (mis)perceived acceptability of dating and sexual violence; 3) gender role beliefs that facilitate aggression or submissive behavior; 4) (mis)perceived embarrassment regarding sexual communication and consent; 5) community support for victims; and 6) perceived support for proactive bystander intervention. Care will be taken to ensure that poster messaging is relevant to all genders since posters have the potential to affect all in the school community, but posters will also include specific messaging that targets the priority adolescent group for the intervention (boys 15-17 years). For example, posters will include specific messaging addressing masculinity and its connection with violence. All posters will include a description of survey methods to enhance believability that the data was derived from the majority of the school community. Posters will be placed in each classroom and in high traffic areas of the school. Posters will remain up for 2 weeks, and then be rotated in order to avoid habituation. Intervention materials will be provided to the school so they can be incorporated into newsletters, presentations, and programs for school events.

Step 6: Addressing Criticism (a.k.a. "Kick-Back"). Given that social norms marketing attempts to change community culture, it is vital to plan for "kick-back" from the community. Addressing issues relating to the believability of the social norms marketing campaign requires having someone within the community who is trained to facilitate conversations about these issues. Towards this goal, the school randomized to receive the campaign (school #2) will have study staff involved in conducting intercept activities with students (modeling this for teachers will support teachers in their own intercept activities) to monitor believability and "kick-back" to the campaign. Intercept activities will take place during 3 visits, facilitated by our team. In the first visit, intercept activities address: 1) whether students/teachers see the message; 2) whether students/teachers believe the message; and 3) whether students/teachers think their friends/colleagues believe the message. If the messaging is not deemed credible, follow-up questions will ascertain why not. In cases where messaging is not believed, the study staff will challenge the source of disbelief using techniques developed by Dr. Berkowitz and Dr. Orchowski in similar campaigns. Prior work in this area suggests that messages are sometimes not believed because teachers are making negative comments about a campaign, or because students believe that their peers were not honest in their survey responses. Students may also utilize extreme examples of behavior (i.e., graffiti, newsworthy events) to discredit the campaign. In these cases, opportunities for teacher training can be provided, interoffice messages can be sent to teachers, and classroom discussions can be implemented to educate students on how the most visible behavior (although most extreme) is not typically the norm. Study consultant Dr. Alan Berkowitz will be available throughout the study to consult with the study staff in developing and implementing strategies for assessing and addressing "kick-back". In the second visit, intercept activities will address: 1) whether students/teachers have talked about the message with their peers/colleagues/students; 2) whether students/teachers had challenges in that discussion and how to overcome those challenges. In the third visit, intercept activities

will address: 1) whether students/teachers want to develop skills as active bystanders; 2) and skills development in active bystander intervention techniques for HIV risk behavior and violence prevention. We will train the school champion (described in Step 1) to address “kick-back” to promote sustained implementation.

Step 7: Evaluate. Formal outcome assessments will be conducted with target adolescents (boys 15-17 years) at pre- (baseline) and post-intervention (1- and 6- months), and with teachers as baseline and post-intervention. The teacher champion will monitor the posters to ensure visibility and that the campaign maintains intensity.

Innovation

Our study offers several innovations. **First**, we develop our scientific understanding of developmentally appropriate preventive interventions to address the adolescent intersection of HIV behavioral and IPV perpetration risk. Based on our recent systematic review detailed previously, this will be the first intervention to prevent adolescent HIV risk and IPV perpetration in an integrated manner, using a social norms approach to transform community-level environments in a high priority global setting where prevalence of HIV and IPV is high. **Second**, our approach is differentiated from general "social marketing" campaigns; social **norms** marketing campaigns convey messages about positive community norms in a very different way. Specifically, the messaging of social marketing campaigns is generally broad and non-specific, whereas the messaging of social norms marketing campaigns is data-based and community-specific[61-63]. Messages in social norms marketing campaigns are chosen to correct under-endorsement of specific beliefs in a community (e.g., "**98%** of men in this community believe it is important to treat women with respect"). By repeatedly exposing individuals to a variety of positive, **data-based** messages about the true norms in their community, social norms marketing campaigns aim to reduce the misperceptions that sustain problem behavior and increase the proportion of individuals who are likely to act in accord with the actual, prosocial community norms of health, and safety[14,15]. Research has yet to rigorously test the efficacy of social norms marketing campaigns to address dating and sexual violence. **Third,** the present study advances the science of HIV and sexual violence prevention research by addressing several of the existing limitations in prior implementation of social marketing campaigns in general, and social norms marketing campaigns in particular. A weakness of social marketing campaigns is that they use "stock" or "prefabricated" posters to spread positive norms messages. Although standard posters are easy to implement in a community, specifically-tailored messages are likely to be more personally and culturally relevant than generic media. As a result, social norms marketing campaigns—which are distinguished by the provision of community-specific data within messaging—are likely to be more powerful than social marketing campaigns. Our study overcomes several weaknesses observed in existing social norms marketing programs that have received empirical evaluation[33,64] by newly incorporating a plan for addressing "kick-back". Efforts to change community norms are apt to evoke cognitive dissonance among community members; as a result, expecting kick-back and being proactive to assess and address it is a vital component of "best practice" in social norms marketing. We do so through a comprehensive campaign that involves teachers and students in the development of messaging and by working directly with these "carriers of misperceived norms" through activities as summarized in Table 1. **Fourth**, if found to be efficacious, this intervention offers immediate prevention promise for adolescent males, as well as community benefits for teachers and other students, and the long-term promise for current and future partners of these male adolescents by preventing negative consequences of HIV and IPV. Finally, our **fifth** innovation is that our intervention is directly policy-relevant, consistent with the government policy encouraging structured in-school and after-school health-related activities as part of Integrated School Health Policy. We purposively choose to test acceptability and effectiveness of this HIV-IPV preventive intervention in school settings because a systematic review has shown numerous challenges to reaching youth for sexual health services within health

facility settings[65] and because this intervention strategy is scalable with support in the policy realm given South Africa's commitment to integrating health interventions and services into school settings.[66]

Approach and methods

In this proposed R34 Grant, we will focus on testing the acceptability and feasibility of *Schools Championing Safe South Africa* in preparation for a future R01 efficacy trial. We are underpowered to gather biomarker data on HIV and STI incidence may have limited utility given the acceptability and feasibility focus of this study; we plan to collect biological data on HIV and STIs – as aligned with NIH HIV research strategy – in a future RCT.

Language. All study materials and procedures will be conducted in English or isiXhosa. Study materials will be translated by a professional translator. Multi-lingual research assistants (RAs) will conduct procedures in the preferred language. We draw from our established research networks to hire a team experienced in HIV and violence preventive intervention development and testing research with adolescents.

Site Selection. We build on our team's extensive experience conducting school-based interventions, adolescent HIV and IPV interventions, and prevention research in South Africa. We select schools in high HIV prevalence communities in Western Cape where we have previously worked with success in our school-based intervention trials with this age group.[29,67-69] See **letter of support from the Department of Basic Education (Appendix A)**.

Specific Aim 1 (Development Aim) – Formulate content for a data-driven social norms poster campaign that is the foundational content for the intervention *School Championing Safe South Africa*

Goals. In the **Development Phase (Aim 1)** we begin with a survey of teachers (Appendix B), as well as student peers (Appendix C) to evaluate community-level social ecology of HIV and IPV risk. This survey data will generate evidence-based social norms messages to create a poster campaign tailored to address specific social-ecological risk and protective factors for HIV and IPV. We gather social norms from teachers and all student peers on adolescent-level HIV and IPV. It is vital to include teachers and all students, not just the target group most at risk (adolescents boys aged 15-17 years) because social norms theory suggests that individual misperception of community norms are shaped by the extent to which others in a community endorse and reinforce misperceived norms. Teachers and student peers may convey acceptance of coercive dating behavior through indirect remarks and may be "carriers of the (mis)perception" in adolescent boys' lives that inadvertently reinforce unhealthy behavior.[70]

Survey of Social Ecology. In preparation for Aims 2 and 3, we conduct school surveys to understand the social ecology of the school community. We aim for 75% coverage of all teachers and students in schools (school size varies, but we estimate this will be N=1500 students and N=120 teachers across three schools). For the teacher survey, we will recruit all teachers in the school. Interested teachers will speak privately with the study team to be screened for eligibility. Inclusion criteria includes: (1) any teacher in the school. We will include teachers regardless of what age group they teach. For teachers interested in participation, our team will then proceed with the consent process. Study staff will provide a signed written informed consent form (Appendix D) from each teacher who is eligible and interested in participating for them to review and then complete the survey. The brief

school social ecology climate survey assesses: (1) predicted prevalence of adolescents' IPV and sexual behaviors in their school; (3) norms and attitudes of teachers around adolescent's sex, HIV, gender, and IPV.

For the student survey, we will recruit student peers by visiting all classrooms, briefly explaining the purpose of the anonymous survey. Then we will follow the subsequent consent and assent process, which we have given careful consideration based on our own research of the most appropriate consent procedures for low-risk research with adolescents in school settings.[71] Our team will visit classrooms to describe the survey to students. We will provide parents/legal guardians a letter about the nature of the research and a consent form seeking their permission for their child's participation (Appendix E), and we will provide a period of 1-2 weeks to return the form which includes our teams' contact details to answer questions and concerns. Then we revisit high school classes 1-2 weeks later. For adolescents with parental consent forms, we will verify eligibility for adolescent surveys. Inclusion criteria include: (1) adolescents attending the high school. We include adolescents attending the school regardless of gender and age (anticipating a range of 12-19 years) to get a full assessment of social ecology (rather than just focusing on the target group of the intervention, males aged 15-17 years). Interested and eligible adolescents go through assent procedures using a consent form (Appendix F). Then we provide a brief survey assessing: (1) IPV and HIV behavior data (students only); (2) predicted prevalence of IPV and sexual behaviors in their school; (3) norms and attitudes around sex, HIV, gender, and IPV.

Reimbursement. For the brief school social ecology climate survey, students and teachers will receive a small token (e.g., keychain, stationary) as appreciation.

Analysis. We will check all forms for missing data in field and during entry. We will examine key variables for skewness, variability, missing data, and outliers, with transformations to achieve normality if needed. We will conduct chi-square, Fisher's exact and t-tests to examine associations between participant demographic characteristics, social norms, and actual or predicted IPV behaviors. We look for differences between perceived norms and actual norms/behaviors. Findings inform social norms messages for the campaign.

Development of draft social norms posters and complementary intervention elements. First, we will work as a team to select the initial draft messages and visuals for poster media development (to be tested for refinement in Aim 2). We will target norms where there is a salient discrepancy between the actual and perceived norm in the school. We will ensure representation of norms that are addressing IPV and HIV as well as the intersection of these 2 targets. Not all norms need to be positive in the school environment for the campaign to be applicable; even when problem behavior is present in a community, it is useful to correct the misperception of positive norms held in the community, to facilitate change in negative problem behavior. Final drafts of 6-12 posters for each school (described in Step 5 of the intervention overview above) will be developed by Glad Works, a creative agency with over 25 years of experience in visual media, communications strategy and management, copywriting, technology, and multimedia production; Glad Works has worked successfully with Drs Orchowski and Berkowitz in their social norms interventions including Dr. Orchowski's school-based interventions. We will combine Glad Works specialized experience in the production of materials with in-house expertise of the South African Medical Research Council's experienced communications team which consists of designers

and marketing specialists familiar with media used in behavioral interventions in the South African context. Second, we will draft materials for the Teacher Workbook (described in Step 4 of the intervention overview above). This workbook includes a teacher-friendly manual, walking them through the classroom intercept activities grounded in social norms theory that coach them through supporting corrections of misperceived norms for students (and in so doing, themselves). Third, we will develop an intervention facilitator for 3 types of intercept activities with students to monitor believability and "kick-back" to the campaign (described in Step 6 above) including how to engage students and teachers in challenging kickback, supporting teachers and students in engaging each other to change norms, and active bystander behavior. Finally, we draft materials for the Lunch and Learn Teacher trainings, focused on mechanisms of change for social norms, and to prepare teachers to talk with students to address kick back and facilitate activities that support the curriculum in their classrooms.

Specific Aim 2 (Refinement Phase) – Refine components of the school community-level intervention

Goals. In the **Refinement Phase (Aim 2)** we showcase drafts of the social norms posters developed by the scientific team during Aim 1 (based off data in Aim 1 that generated these initial drafts) to teachers and students to refine the final messages and visuals to be delivered in the social norms poster campaign. In addition to the social norms posters which are the foundation to the community-level intervention, we also gather feedback on the other core intervention components (e.g., Teacher Lunch and Learn sessions, Teacher Workbook, and Student Intercept activities) designed to transform poster campaign messages into prevention behaviors. We will gather refinement data using n=5-10 interviews with teachers and k=3-6 focus groups with students. We will implement refinement activities in School #1 (the campaign refinement school) to avoid contamination of the teachers and students being targeted in the pilot randomized controlled trial in Aim 3 in Schools #2 and #3.

Teacher recruitment, eligibility, and informed consent. We will recruit all teachers in the school for n=5-10 interviews to further refine our initial poster messages/visuals and the other teacher components (Teacher Lunch and Learn sessions, Teacher workbook to guide classroom intercept activities). Interested teachers will speak privately with the study team to be screened for eligibility. Inclusion criteria includes: (1) any teacher in the school. We will include teachers regardless of what age group they teach but begin sampling with the teachers who teach 15-17 year olds. For teachers interested in participation, our team will then proceed with the consent process. Study staff will obtain a signed consent form (Appendix G) from each teacher who is eligible and interested in participating for them to review and then schedule an interview time.

Teacher interview procedures. We will conduct a total of n=5-10 interviews with teachers, with final qualitative interview numbers dependent upon data saturation. We will begin each interview by answering questions regarding the consent form, and then obtain written consent. Then we will administer a brief socio-demographic survey to gather details on age, gender, race/ethnicity, primary language, years of teaching experience, teaching subject areas, and age of students. Each interview will last approximately 45 minutes to 1 hour. Interviews will follow a semi-structured agenda exploring the following themes: 1) perceptions of adolescent-level HIV and STI

behaviors in the school, and barriers/facilitators to engaging in protective behaviors; 2) perceptions of adolescent-level IPV behaviors in the school including attitudes and norms around gender roles, relationships, and violence with exploration specific to the target adolescents (boys aged 15-17 years); 3) exploration of school community, and broader community factors relating to HIV and IPV behaviors including social norms; 4) feedback on visual appeal, and clarity and appropriateness of content of messages on draft posters; 5) anticipated barriers/facilitators of the teacher and student intervention components including logistics regarding delivery preferences; and 6) suggestions for optimizing teacher recruitment, data collection, and retention procedures. The interview guide is appended (Appendix H). All interviews will take place in a private room in the school setting. Interviews will be recorded using a digital voice recorder (DVR). Audio files will be stored in the password-protected project drive. Audio files will then be translated and transcribed verbatim. A RA will compare 10% of transcripts to audio files for accuracy.

Teacher Reimbursement. At the close of the interview, we will thank participants and provide reimbursement. Each participant will be provided with reimbursement of 75 Rand.

Student recruitment, eligibility, and informed consent/assent. We will recruit male and female adolescents for k=3-6 focus groups to further refine our initial poster messages/visuals and the other student components (three stage student intercept activities described previously). We will recruit a convenience sample of any race of adolescents, but stratifying by gender (for separate groups) and age (trying to get a 50% mix of those 12-15, and 16-19, the split guided by average age of sex) through flyers providing contact details for study staff in the school setting and recruit in-person. All interested adolescents who are under 18 years will be sent home with written parental consent (Appendix I) and adolescent assent forms (Appendix J). Parents/legal guardians will have a chance to ask questions or discuss concerns using the contact details provided to them via study information sheet and consent form. For adolescents who return signed consent forms, study staff will assess eligibility for adolescent focus groups. Inclusion criteria include: (1) adolescent who attends the school. We will include adolescents regardless of sexual activity, HIV, or IPV status because prevention may alter the trajectory of possible engagement in new (not yet experienced) risk behaviors, or risk for those already engaged in unsafe behaviors. We are not specifically screening for intimate partnerships in our eligibility because South African data shows by age 15, approximately half engaged in penetrative sexual debut, with large portion of younger adolescents having engaged in sexual foreplay prior to 15 years.[27] We also include adolescents of any age range in this refinement stage (anticipating age to vary from 12-19 years) so long as they attend the school. We include any gender. The broad range of ages and genders is vital for this refinement stage because norms are set for the target group of boys 15-17 years by a wider group of peers.

Student focus group procedures. We will conduct a total of k=3-6 adolescent focus groups with final focus group numbers dependent upon data saturation. Each focus group will contain a minimum of 4, and maximum of 8 participants. We will begin each group by confirming receipt of consent forms from parents/legal guardians, and verbally go over assent procedures followed by written voluntary adolescent assent (or consent for those 18 or 19 years old). Then we will administer a brief socio-demographic survey to gather details on age, gender, race/ethnicity, primary language, family situation, and behavioral data relating to HIV and IPV to contextualize

focus group data. Each group will last approximately 1.5 hours; when combined with informed consent procedures and the demographic questionnaire, we anticipate that each participant will spend approximately 2 hours involved in the study. Two members of the study team will facilitate each group with one study team member directing the flow of discussion, and the other taking notes and prompting with additional questions as needed. Focus groups will follow a semi-structured agenda (Appendix K) exploring the following themes: 1) perceptions of adolescent-level HIV and STI behaviors in the school, and barriers/facilitators to engaging in protective behaviors; 2) perceptions of adolescent-level IPV behaviors in the school including attitudes and norms around gender roles, relationships, and violence with exploration specific to the target adolescents (boys aged 15-17 years) specifically probing for developmental age differences and gender differences based on how we stratify focus groups; 3) exploration of school community, and broader community factors relating to HIV and IPV behaviors including social norms; 4) feedback on visual appeal, and clarity and appropriateness of content of messages on draft posters; 5) anticipated barriers/facilitators of the student intervention components (student intercept activities led by both teachers using the Teacher Workbook and planned interventionist led intercept activities) including logistics regarding delivery preferences; and 6) suggestions for optimizing recruitment, data collection, and retention procedures for the boys involved in the intervention outcome surveys (e.g., boys aged 15-17 years). All focus groups will take place in a private room in the school setting. Food and refreshments will also be offered during the focus groups. Focus group discussions will be recorded using a digital voice recorder (DVR). Audio files will be stored in the password-protected project drive, translated and transcribed verbatim, with “cleaning” purging information that could identify a participant personally. A RA will compare 10% of transcripts to audio files for accuracy.

Adolescent Reimbursement. At the close of the focus group, we will thank participants and provide reimbursement. Each participant will be provided with reimbursement of 75 Rand (approximately $7.50) comprised of 50 Rand for time and 25 Rand for travel. This reimbursement may be provided in the form of a voucher. If the focus group is under-enrolled, we still offer a reimbursement for travel of 25 Rand.

Analyses of Teacher/Student Data. We will conduct ongoing saturation analyses, based on iterative coding during data collection.[72] Specifically, after each focus group, we will examine content to see what sort of repetitive data is emerging. Data themes that are consistently repeated will be dropped from latter focus group discussion agendas so we can spend time probing more deeply for other new and emergent data themes. Each audio recording is transcribed word-for-word and translated if necessary. Transcriptions are checked for accuracy and entered into NVivo. We will enter all observational notes as memos. We will use a grounded theory approach in conjunction with ‘sensitizing concepts’ to guide analyses.[73-75] Sensitizing concepts provide a general reference point to guide interpretation of empirical data/themes while maintaining the use of inductive analysis. Combining sensitizing concepts with a grounded theory approach will allow us to use social norms theory as a starting off point for data analysis and interpretation, while also allowing for codes/themes to arise from the data that may not fit directly into social norms theory, but which contribute a comprehensive picture of adolescent boys lived experience from the perspective of a variety of genders and ages. Data analysis is iterative including techniques

of open and axial coding.[74] Dr. Mathews will double-code the transcripts, aiming for >80% agreement and discussing discrepancies. We will also discuss transcripts in regular meetings with Drs. Orchowski, Berkowitz, and Sikweyiya to analyze themes and compare interpretations. The focus of analysis is to connect themes between participants with a particular focus on the context that frames motivations and decision-making around risk and protective behaviors relating to HIV, IPV, and bystander behavior. We also want to gain understanding of common experiences between participants, and to understand the context of how social norms are developed, reinforced, and challenged effectively to prepare us for an effective social norms intervention. We will also compare data for similarities and differences based on the stratification of our groups (gender and age) to appropriately guide messaging that speaks to the developmentally specific experiences, and to feature differential gender perspectives as necessary to effectively change our target populations behavior. We will distill qualitative intervention components into thematic categories to guide refinement of the intervention for Aim 3.

Specific Aim 3 (Acceptability and Feasibility Phase) – Assess the acceptability and feasibility of the intervention School Championing Safe South Africa in a pilot randomized controlled trial.

Goals. In **Acceptability and Feasibility Aim 3** our primary goal will be to assess acceptability and feasibility of the school community-level preventive intervention, *Schools Championing Safe South Africa*, among N=282 male adolescents aged 15-17 years who are the primary targets of the community-level school environment intervention. This sample will be split in a 1:1 ratio (n=141 boys in the intervention school, n=141 boys in the wait-list control school). The goal of this school community-level intervention is to prevent HIV risk, IPV perpetration, and increase bystander behavior) among boys at high risk for HIV and STI risk behaviors and IPV perpetration (e.g., male adolescents aged 15-17 years). In this aim, we will also explore preliminary evidence for hypotheses that the intervention, relative to the control, will produce the following outcomes: (1) reductions in actual or intended HIV risk behaviors; (2) reductions in IPV frequency and decreased endorsement of IPV supportive attitudes; and (3) increased proactive bystander intentions. We also survey N=80 teachers to assess whether teacher (mis)perceptions have been corrected (e.g., whether teachers perceive student attitudes and behaviors more accurately) and whether they intend to engage in more bystander intervention.

Training Intervention Facilitators for Roll-out of Intervention Activities in Aim 3. Our investigative team will train an intervention facilitator in preparation for the core intervention activities that include teacher and student interactions (Lunch and Learn Teacher Training, Classroom activities supported by the Teacher Workbook, and student intercept activities). We will recruit a facilitator through our pool of experienced adolescent HIV and IPV intervention facilitators used in our previous trials including our current *Safe South Africa* trial, supplemented by advertising, community-flyers, and outreach with NGOs/CBOs, community meetings, clinics, and schools. Training will involve 5 modules. Module 1 includes: 1) introductions and ice-breakers, 2) project overview, 3) education regarding prevention of HIV and IPV perpetration, communication, gender roles and social norms particularly in regards to sexual relationships. Module 2 focuses on intervention delivery skills: 1) public speaking and 2) communication of sensitive topics, 3) engagement of teachers and students. Module 3 involves training in use of the intervention posters, Lunch and Learn Teacher Training and Teacher workbook including (a) demonstrations of these intervention components, (b) education on core intervention elements, and (c) role-play. Module 4 involves

training in use of the intervention posters and the student intercept activities including (a) demonstrations of intercept activities to evaluate whether students see the poster messages; whether students believe the message; whether students/think their friends believe the message; and (b) role-play. Module 5 involves: 1) testing implementation skills in short mock scenarios, 2) feedback from the investigative team. We incorporate challenges that may arise during implementation including inter-personal interactions to assess facilitator mastery of core skills and performance. We rank performance using the fidelity forms (explained further in Aim 3). If the facilitator is not deemed qualified, additional training will be provided.

Overview of Randomized Pilot Trial. We will recruit N=282 male adolescents who are the primary targets of the school community-level intervention. We will also recruit N=80 teachers (numbers are average estimates of 40 teachers/school), randomly selecting from a full list of teachers from the school. Data from this pilot trial will help prepare us for a future R01 full-scale efficacy trial that will take the form of a cluster randomized controlled trial where schools will be randomized to an intervention or control arm. In this trial, we will pilot in two schools (School #2 will receive the experimental intervention, and School #3 will serve as a wait-list control). The assignment to the experimental intervention will be randomly determined. For future trial feasibility, the first set of assessments will reflect the outcome questionnaire used at baseline, 1- and 6-months for N=282 boys (Appendix L); we also gather baseline outcomes from N=80 teachers (prior to Teacher Lunch and Learn sessions) and at post-intervention (end of the school year). The teacher instrument is in Appendix M. We will track recruitment and retention strategies and success rates. A second set of assessments for future trial feasibility will evaluate fidelity, ranking integrity and competency of our team's delivery of Teacher Lunch and Learn, Student Intercept activities in real time. These fidelity assessments follow recommendations issued by the Treatment Fidelity Workgroup of the NIH Behavior Change Consortium to ensure rigorous coding of fidelity based on a standardized monitoring checklist (Appendix N).[76] For acceptability data, we will gather intervention satisfaction forms from male adolescents (Appendix O) and teachers (Appendix P) randomized to the intervention, and gather opinions on content, clarity and appeal of materials, delivery, and format.

Sample Size and Power Considerations. The primary objective of this pilot is to test the feasibility and acceptability of the intervention and to generate meaningful effect size estimates for a future fully-powered RCT. We considered sample size needed to demonstrate increased condom use at last sex, reduced sexual violence perpetration, and increased active bystander behavioral intentions. To measure significant change in the three objectives, a total of N=282 adolescent boys will be enrolled, with n=141 in the intervention arm and the same number (n=141) in the control arm. The power calculations are based on a McNemar's test for paired proportions, 80% power, and type 1 error rate (alpha) of 5%. These calculations were generated by findings of the R34 testing *Safe South Africa* (R34MH113484), which included 80 male adolescents aged 15-17 years (**1.** Akande, M., Kuo, C., Orchowski, L., Berkowitz, A., Harrison, A., Abrahams, N., Mathews, C. (2019). Leveraging Positive Social Norms for Preventing Sexual Violence among South African Adolescents. Oral presentation for the American Public Health Association Conference, November 2-6, 2019; Philadelphia, Pennsylvania, USA. **2.** Akande, M., Orchowski, L., Harrison, A., Berkowitz, A., Kuo, C., Mathews, C. (2020). Prevention of HIV Risk and Intimate

Partner Violence among Adolescents in South Africa. Submitted abstract on January 30, 2020 for poster presentation for the International Women's and Children's Health and Gender Group Conference. **3.** Akande, M., Orchowski, L., Harrison, A., Abrahams, N., Berkowitz, A., Kuo, C., Mathews, C. (Under review). Examining perceptions of peer norms relating to sexual violence among adolescents in South Africa. Submitted November 2020 to *Journal of Interpersonal Violence*). **Condom use:** We assume that in the *Schools Championing Safe South Africa* pilot trial, 88% of male adolescent participants will have ever had sex at baseline, and 63% of those will report at baseline that they used a condom at last sex. The sample size required to detect changes between baseline and 6-months in condom use ranging from 3% to 17% at six months at 80% power and a type 1 error rate of 5%. To detect changes of 15% or greater in condom use at last sex between baseline and 6 months in the intervention arm, assuming 0.20 correlation between paired observations, 135 adolescent boys are required in the intervention arm. To account for a 3% dropout rate (observed in the *Safe South Africa* study), a total of 141 per arm will be enrolled. **Sexual violence perpetration:** We assume that at baseline, 56% of male adolescent participants will have perpetrated sexual violence in the past 6 months. To detect changes 16% or greater in sexual violence perpetration of sexual violence between baseline and 6 months in the intervention arm, assuming a 0.20 correlation between paired observations, a total of 125 adolescent boys are required in the intervention arm. The planned sample size of 141 per arm will account for greater than 3% dropout rate. **Active bystander behavior:** We assume at baseline, 60% of male adolescent participants will have intentions to engage in active bystander behavior. To detect changes 15% or greater in active bystander intentions between baseline and 6 months in the intervention arm, assuming 0.20 correlation between paired observations, 125 adolescent boys are required in the intervention arm. (**See details of calculations in section below: Statistical Design and Power.)**

Recruitment. We will recruit N=282 male adolescents using similar procedures as Aim 1. Inclusion criteria include: (1) male adolescent that attends Schools #2 or #3; and (2) 15-17 years of age inclusive. We will include adolescents regardless of sexual activity, HIV, or IPV status. Male adolescents are excluded if parents do not provide informed consent or adolescents do not provide informed assent. These adolescents will complete outcomes assessment, and the n=141 male adolescents assigned to the intervention school will complete satisfaction assessments. We will also recruit N=80 teachers (N represents estimates, with final N determined based on final buy-in of school sites) to complete outcome assessments at baseline and post-intervention, and intervention satisfaction assessments, (similar to the boys, n=40 teachers will complete intervention satisfaction assessments if assigned to the intervention). Inclusion criterion includes: (1) any teacher in the school.

Consent and Assent. For N=282 adolescent boys, consent and assent will occur at the first point of contact, after screening for eligibility and prior to gathering baseline assessment. Consent and assent will cover all outcome assessments at baseline, 1- and 6-months as well as satisfaction assessment for the intervention group. The parental consent and student consent/assent form are attached (Appendix Q and R). The assent process will involve an enrollment session which includes a method of obtaining meaningful informed participation by discussing pros and cons of trial participation, detailed at the NIH Randomized Behavioral Clinical Trials Institute

(attended by M-PI Kuo);[77] this method serves to optimize recruitment and offers a platform for thoroughly discussing ethical considerations. For N=80 teachers interested in participating in outcome and satisfaction assessments, our team will then proceed with the consent process using the consent form attached (Appendix S). Study staff will obtain written consent from each teacher who is eligible and interested in participating for them to review and sign.

Reimbursement. In the pilot trial, N=282 adolescents (baseline, 1-, 6-months) and N=80 teachers (baseline, post-intervention) will receive 75 Rand at each time point. N=141 boys and n=40 teachers in the intervention group will receive 50 Rand for the satisfaction assessments.

Assessments. Outcome assessments evaluate changes at 1- and 6-months post-intervention, relative to control for these primary outcomes: Do male adolescents report a higher prevalence of condom use at last sex (for those who have debuted) or anticipated risk behaviors (for those who have not debuted) relating to HIV and STI risk acquisition or transmission?; Do male adolescents report fewer experiences of sexual violence perpetration or attempts to perpetrate sexual violence?; and Do male adolescents report increased intentions for active bystander intervention? All measures utilized in the current study are well established, and tested in our prior studies including the complementary *Safe South Africa* trial. We collect self-reported outcome assessments using audio-computer assisted self-interviewing software which limits social desirability bias.[78] See **Table 2**.

Table 2: Outcome Measures and Satisfaction Assessment

Outcome	Measures	Baseline	After Intervention	1-month	6-month
Teachers and Adolescent Boys					
Acceptability	Client Satisfaction Questionnaire[79]		✓		
Teachers					
Teacher intervention for negative adolescent sexual and IPV behaviors	The Perceptions of School Personnel Helping Scale[80,81]	✓	✓		
Active Bystander Behaviors	Miller Likelihood to Intervene, Miller Positive and Negative Bystander Behavior[82]	✓	✓		
Sexual aggression norms relating to HIV transmission and IPV; endorsement rape myths, traditional gender roles; social norms regarding sex and violence; norms around HIV transmission including condom attitudes, HIV stigma	Illinois Rape Myth Acceptance Scale [83]; Boeringer's Social Norms Measure[84]; Gender Equitable Mens Scale[85]; AIDS Related Stigma Scale and Internalized AIDS-Related Stigma Scale; Condom Attitudes Scale - Adolescents	✓	✓		
Adolescent Boys					
HIV Risk Behavior & Intentions: HIV and STI status; HIV testing; frequency sex; number and type of partners; use of condoms	• Items taken from South African trials & NIH's Adolescent Medicine Trials Network for HIV/AIDS Interventions	✓		✓	✓
IPV Perpetration Behaviors: type, frequency and severity of IPV; sexual perpetration and aggression, dating violence	• Sexual Experiences Survey Short Form Perpetration[86]	✓		✓	✓
Bystander Intervention Behaviors: proactive bystander behavior; bystander efficacy and readiness	• Sexual Social Norms Inventory[87] • Bystander Behavior Scale[88-90] • Intent to Help Scale [88,90] • Bystander Efficacy Scale[89,90]	✓		✓	✓

Co-variates: socio-demographics; economic status; household characteristics	• Items from the South African 2011 Census Questionnaire & World Health Organization Food Security Questionnaire [91] • Verbal Autopsy for AIDS orphanhood[92]	✓		✓	✓
Mechanisms & Moderators: • Norms relating to HIV transmission including condom attitudes, HIV stigma; HIV knowledge; self-efficacy, and skills • Resilience; mental health; substance use • Sexual aggression norms relating to both HIV transmission and IPV; endorsement rape myths, traditional gender roles; social norms regarding sex and violence	• South African HIV Knowledge[93]; AIDS Related Stigma Scale and Internalized AIDS-Related Stigma Scale[94,95]; Condom Attitudes Scale - Adolescents[96]; Condom Use Self-Efficacy Scale[97]; Condom-use skills checklist[98] • Connor-Davidson Resilience Scale[99]; Center for Epidemiologic Studies Scale[100,101]; Alcohol Use Disorders Identification Test[102]; Drug Use Disorders Identification Test[103] • Illinois Rape Myth Acceptance Scale[83]; Boeringer's Social Norms Measure[84]; Gender Equitable Mens Scale[85]	✓		✓	✓

All administration systems (paper forms scanned to digitized data) and data software come with rigorous human Subjects' protections and worked well in our previous collaborative USA-South African trials.

Analysis and Further Intervention Refinement. We will check all forms for missing data in field and during entry, with at least 2 telephone calls to participants to collect missing data. We will examine key variables for skewness, variability, missing data, and outliers, with transformations to achieve normality if needed. For our acceptability data (satisfaction assessments), we will set 80% reporting positive ratings as a marker of acceptability and examining process data on satisfaction with format, length, etc. For our fidelity data, we will assess fidelity of facilitator implementation, setting 80% as acceptable fidelity, and using data to make final adjustments to training. For our feasibility data, we will also evaluate feasibility in regards to recruitment ease, and retention during outcome timepoints. For trial outcomes, preliminary analyses will include studies of patterns of missing data , dropout rates, and correlations effect size estimates with small samples have large standard errors so we use pilot data to assess hypothesized intervention effects.[104] We will examine key variables for skewness, variability, missing data, and outliers, with transformations to achieve normality if needed. We will examine descriptive statistics for main outcomes and mediators with extreme scores or deviations from normality to be addressed in subsequent analyses. Baseline differences between groups on demographic variables will be examined using t-tests or the Chi-square test, where appropriate, and variables that show differences will be included as covariates in outcome analyses. McNemars test, for paired binary variables, will be used to determine whether the follow-up measurements significantly differ from baseline measurements in the intervention and control arm, separately. Generalized linear mixed (random effects) models, will be used to compare intervention and control group, via treatment by time interaction terms, following intention-to-treat principles. In exploratory analysis, we will look at directions of hypothesized effects. While we are underpowered to test mediation effects directly, we will explore differences between study arms. Effect sizes observed will be used to inform a larger adequately powered RCT. We also examine exposure to other interventions to see how this may be affecting outcomes.

Rigor, Reproducibility, and Transparency

To ensure research rigor and reproducibility of *Schools Championing Safe South Africa*, this pilot study is a careful and rigorous progression to prepare for a future cluster randomized controlled trial. The design of this pilot study is focused on development of a school community-level intervention that is distinct but complementary to the existing line of intervention research on the individual behavior-level intervention *Safe South Africa* described above. If both lines of intervention research show promise, they will be brought together into an existing combination intervention approach that comprehensively tackles multiple levels of socio-ecological risk for boys

at risk for HIV and IPV perpetration. This school-based intervention is potentially sustainable. The choice to deliver a preventive intervention targeting the school as the community-level environment is purposive, perfectly aligned with South Africa's recent commitment to integrating health services into school settings and outlined in their national Integrated School Health Policy.[66] Our team has a strong reputation in the community, and a tried and true process of gaining buy-in prior to the study, delivering updates during the course of the study that provide opportunity for course correction in study rigor, and in providing prompt dissemination that offer opportunities to hear feedback that is directly relevant to developing future phases of research in a manner that prioritizes the needs of the target population and stakeholders.

Inclusion of Individuals Across the Lifespan

For Aims 1 and 2, components that are not the pilot randomized clinical trial, eligibility is as follows. Aims 1 and 2 - School survey with students & Aim 2 qualitative focus groups with students, inclusion criteria includes: (1) adolescents attending the high school. Aims 1 and 2 - School survey with teachers & Aim 2 qualitative interviews with teachers, inclusion criteria includes: (1) any teacher in the school. For these Aims, students and teachers will be included regardless of biological sex, gender identity, and race and ethnicity. Based on average school age in South Africa for high school students, we anticipate that students will range from 12 to 19 years of age. Based on the required retirement age for government employees, which includes teachers, we anticipate that the range of age for teachers will range from 18 to 65 years of age. We select public high schools in high HIV prevalence communities. Although participants will NOT be excluded based on racial or ethnic group, we do expect that school sites with high HIV prevalence are likely have a mix of black African and Afrikaans teachers and adolescents in our study, and reflecting the historical consequences of Apartheid in which geographical segregation of racial and ethnic groups in South Africa continues to occur. We select from public health high schools in the highest HIV risk communities in Western Cape Province. Reflecting the most recent HIV epidemiological data from South Africa, we expect that these communities will be primarily black African, isiXhosa populations or Afrikaans populations.[105]

For Aim 3, the pilot randomized clinical trial, eligibility is as follows: (1) male adolescent; and (2) 15-17 years of age inclusive. For the randomized pilot trial component that focuses on adolescents, the target population for evaluation of outcomes will be adolescent boys 15-17 years of age who are a disproportionate age and gendered risk for HIV, STIs, and perpetrating IPV. As such, exclusion of girls is scientifically justified because of the gender-disparities in IPV perpetration with males much more likely to perpetrate violence globally[106] and in South Africa specifically.[3-5] The inclusion of children is necessary to achieve the scientific objectives of the study. We recognize that children may be a vulnerable group, and extreme care is required to ensure protection and empowerment amongst participants but that exclusion of this group would significantly prohibit scientific development in topic areas of great importance to the health and wellbeing of this group. To ensure informed consent and assent, we will clarify what information will be kept confidential and what will be disclosed to another party. We also build

upon our team's extensive research and clinical experience working with adolescents living with HIV in South Africa as well as our team's experience conducting HIV behavioral research with vulnerable populations affected by HIV in South Africa and other international settings. We provide additional protections in consent and assent procedures. All informed assent forms will be read aloud in participants' chosen language and participants will also be provided copies. To ensure that children do not feel obliged to participate in the research, emphasis will be placed on their ability to refuse to participate, or to cease participation at any point during the research. As has been the practice in our previous studies with this vulnerable population, our research team is trained to recognize that any avoidance by children of the research will be taken as evidence of failure to assent. For adolescents, we emphasize that all information shared with us will remain confidential except for life-threatening disclosures or disclosures regarding age-differential partners, exploitative sex, perpetration with identifiable rape victims, being a victim of rape, sexual abuse or physical abuse which falls under legally mandated reporting to police, social services, and IRB.

The clinical trial portion of the study will also include teachers. Inclusion criteria is as follows: (1) any teacher in the school. For this Aim 3, teachers will be included regardless of biological sex, gender identity, and race and ethnicity.

Recruitment and retention plan

Aim 1: Cross-Sectional Survey

In the **Development Phase (Aim 1)** teachers and student will participate in a cross-sectional survey to evaluate community-level social ecology of HIV and IPV risk. The primary goal of this survey data is to create evidence-based social norms messages to include in the poster campaign tailored to address specific social-ecological risk and protective factors for HIV and IPV.

We conduct school surveys in all three schools to better understand the social ecology of the school community. We aim for 75% coverage of all teachers and students in these schools (school size varies, but we estimate this will be N=1500 students and N=80 teachers across three schools). For the teacher survey, we will **recruit all teachers** in the school. Interested teachers will speak privately with the study team to be screened for eligibility. Inclusion criteria includes: (1) any teacher in the school. We will include teachers regardless of what age group they teach but begin sampling with the teachers who teach 15-17 year olds. For teachers interested in participation, our team will then proceed with the consent process. Study staff will provide a signed written informed consent form from each teacher who is eligible and interested in participating for them to review and then complete the survey. **Retention of teachers** for follow-up does not apply for this one-time cross-sectional survey.

For the student survey, we will **recruit a convenience sample of student peers (all ages, genders, races)** attending our chosen intervention school by visiting classrooms, briefly explaining the purpose of the anonymous

survey. Then we will follow the subsequent consent and assent process, which we have given careful consideration based on our own research of the most appropriate consent procedures for low-risk research with adolescents in school settings.[71] Our team will visit classrooms to describe the survey to students, explaining parents/legal guardians need to indicate in writing whether they do not want their child to participate. We will provide parents/legal guardians a letter about the nature of the research seeking their permission for their child's participation, and provide a period of 1-2 weeks to return the form with our teams contact details to answer questions and concerns. Then we revisit high school classes 1-2 weeks later. For adolescents with consent forms, we will verify eligibility for adolescent surveys. Inclusion criteria include: (1) adolescents attending the high school. We include adolescents attending the school regardless of gender and age (anticipating a range of 12-19 years) to get a full assessment of social ecology (rather than just focusing on the target group of the intervention, males aged 15-17 years). Interested and eligible adolescents go through assent procedures of if 18 years and older, consent procedures. Adolescents under 18 years of age are excluded if parental consent and adolescent assent are not obtained. Then we provide a brief school social ecology climate survey assessing: (1) IPV and HIV behavior data (students only); (2) predicted prevalence of IPV and sexual behaviors in their school; (3) norms and attitudes around sex, HIV, gender, and IPV. **Retention of students** for follow-up does not apply for this one-time cross-sectional survey.

Aim 2: Qualitative Interview and Focus Groups

In the **Refinement Phase (Aim 2)** we showcase drafts of the social norms posters developed by the scientific team during Aim 1 to teachers and students to refine the final messages and visuals to be delivered in the social norms poster campaign. In addition to the social norms posters – which are the foundation to the community-level intervention – we also gather feedback on the other core intervention components (e.g., Teacher Lunch and Learn sessions, Teacher Workbook, and Student Intercept activities) designed to transform poster campaign messages into prevention behaviors. We will gather refinement data using n=5-10 interviews with teachers and k=3-6 focus groups with students. We will implement refinement activities in School #1 (the campaign refinement school) so as not to contaminate the population of teachers and students being targeted in the pilot randomized controlled trial in Aim 3 in Schools #2 and #3. We will use FileMaker Software to pre-program school allocation to the three options (School#1, 2 or 3) using a computerized randomization procedure. This computerized program eliminates any investigator bias in assignment of schools to various conditions.

We will **recruit all teachers in the school for n=5-10 interviews** to further refine our initial poster messages/visuals and the other teacher components (Teacher Lunch and Learn sessions, Teacher workbook to guide classroom intercept activities). Interested teachers will speak privately with the study team to be screened for eligibility. Inclusion criteria includes: (1) any teacher in the school. We will include teachers regardless of what age group they teach but begin sampling with the teachers who teach 15-17 year olds. For teachers interested in participation, our team will then proceed with the consent process. Study staff will provide a signed written informed consent form from each teacher who is eligible and interested in participating for them to review and then schedule an interview time. **Retention of teachers** for follow-up does not apply for these one-time qualitative interviews.

We will **recruit male and female adolescents for k=3-6 focus groups** to further refine our initial poster messages/visuals and the other student components (three stage student intercept activities described previously). Participant recruitment will follow procedures used previously in our research on best ethical procedures with adolescents in South Africa.[107] We will recruit a convenience sample of any gender, age, and race of adolescents through flyers providing contact details for study staff in the school setting and recruit in-person with permission of the school principal and teachers. All interested adolescents will be sent home with written parental consent and adolescent assent forms. Parents/legal guardians will have a chance to ask questions or discuss concerns using the contact details provided to them via study information sheet and consent form. For adolescents who return signed consent forms, study staff will assess eligibility for adolescent focus groups. Inclusion criteria include: (1) adolescent who attends the school. **Retention of students** for follow-up does not apply for these one-time qualitative interviews.

Aim 3: Pilot Randomized Controlled Trial

In the **Acceptability and Feasibility Aim 3** our primary goal will be to assess acceptability and feasibility of the school community-level preventive intervention, *Schools Championing Safe South Africa*, among N=282 male adolescents aged 15-17 years who are the primary targets of the community-level school environment intervention. This sample will be split in a 1:1 ratio (n=141 boys in the intervention school, n=141 boys in the wait-list control school). The goal of this school community-level intervention is to prevent HIV risk, IPV perpetration, and increase bystander behavior) among boys at high risk for HIV and STI risk behaviors and IPV perpetration (e.g., male adolescents aged 15-17 years). In this aim, we will also explore preliminary evidence for hypotheses that the intervention, relative to the control, will produce the following outcomes: (1) reductions in actual or intended HIV risk behaviors; (2) reductions in IPV frequency and decreased endorsement of IPV supportive attitudes; and (3) increased proactive bystander intentions. As a secondary aim, we also survey N=80 teachers to assess whether teacher (mis)perceptions have been corrected (e.g., whether teachers perceive student attitudes and behaviors more accurately) and whether they intend to engage in more bystander intervention.

We will **recruit N=282 male adolescents** who meet study inclusion criteria and who are the primary target group for HIV risk and IPV perpetration prevention for the *Schools Championing Safe South Africa* intervention. Inclusion criteria include: (1) male adolescent that attends Schools #2 or #3; and (2) 15-17 years of age inclusive. We will include adolescents regardless of sexual activity, HIV, or IPV status. Male adolescents are excluded if parents do not provide informed consent or adolescents do not provide informed assent. These adolescents will complete outcomes assessment, and the n=141 male adolescents assigned to the intervention school will complete satisfaction assessments. For N=282 adolescent boys, consent and assent will occur at the first point of contact, after screening for eligibility and prior to gathering baseline assessment. Consent and assent will cover all outcome assessments at baseline, 1- and 6-months as well as satisfaction assessment for the intervention group. The assent process will involve an enrollment session which includes a method of obtaining meaningful informed participation by discussing pros and cons of trial participation, detailed at the NIH Randomized Behavioral Clinical Trials Institute (attended by M-PI Kuo);[77] this method serves to optimize recruitment and offers a platform for thoroughly discussing ethical considerations prior to randomization, intervention, and assessments.

We will also **recruit N=80 teachers** (N represents estimates, with final N determined based on final buy-in of school sites for School #2 and #3) to complete outcome assessments at baseline and post-intervention, and intervention satisfaction assessments, (similar to the boys, n=40 teachers will complete intervention satisfaction assessments only if they were assigned to the intervention school). Inclusion criterion includes: (1) any teacher in the school. For N=80 teachers interested in participating in outcome and satisfaction assessments, our team will then proceed with the consent process. Study staff will provide a signed written informed consent form from each teacher who is eligible and interested in participating for them to review and sign.

To **retain participants**, our team will gather robust details for tracking and tracing 1) at baseline, documenting multiple participant contact details and three individuals who know how to contact the family; 2) monthly contact via telephone or text; 3) follow up at least five times using different days, times, and methods. These strategies were successful in maintaining 100% retention at 1-month and 99% retention at 6-months in Dr. Kuo and Mathews' recent acceptability and feasibility trial with adolescents of the same age and setting for the parallel *Safe South Africa* trial.

Study timeline

Table 3. Study Timeline	Year 1				Year 2				Year 3			
3 month quarters	1	2	3	4	5	6	7	8	9	10	11	12
Development Phase (Aim 1)												
Translation and programming of school survey measures	✓											
Training of survey study team	✓											
Survey of school social ecology with students in the school community	✓	✓										
Survey of school social ecology with teachers in the school com-	✓	✓										
Analysis to draft poster campaign content and visuals		✓	✓									
Refinement Phase (Aim 2)												
Draft poster campaign content and finalize other intervention components			✓	✓	✓							
Translation of qualitative protocols					✓							
Training of qualitative interviewers and focus group facilitators					✓							
Focus group discussions with students						✓	✓					
Qualitative interviews with teachers						✓	✓					
Qualitative analysis to finalize intervention							✓	✓				
Refine poster campaign content and finalize other intervention components								✓				
Acceptability and Feasibility Phase – Pilot RCT (Aim 3)												
Interventionist training and supervision							✓	✓	✓			
Pilot RCT recruitment, eligibility screening, consent/assent, and baseline for boys and teachers						✓	✓	✓	✓			
1-month follow-up for boys								✓	✓			
6-month follow-ups for boys; teacher follow-up									✓	✓	✓	
Analysis of feasibility and acceptability data; analysis of outcome, mediation and moderation analysis											✓	
Manuscripts and Future Study Preparation												
Preparation of manuscripts					✓	✓	✓	✓	✓	✓	✓	✓
Preparation of follow-up grant applications											✓	✓

Ethical Considerations related to the protection of human subjects

This research meets the definition of a clinical trial. This is not a Phase III clinical trial. We will seek IRB approval for all study procedures.

Risks to Human Subjects

a. Human Subjects Involvement, Characteristics, and Design

Human Subject Involvement. Human subject involvement is needed to accomplish Specific Aims 1-3 and includes the following procedures:

Aim 1: Cross-Sectional Survey: In the **Development Phase (Aim 1) N=80 teachers** and **N=1500 students** will participate in a cross-sectional survey to evaluate community-level social ecology of HIV and IPV risk. The primary goal of this survey data is to create evidence-based social norms messages to include in the poster campaign tailored to address specific social-ecological risk and protective factors for HIV and IPV.

Aim 2: Qualitative Interview and Focus Groups: In the **Refinement Phase (Aim 2)** we showcase drafts of the social norms posters developed by the scientific team during Aim 1 to teachers and students to refine the final messages and visuals to be delivered in the social norms poster campaign. In addition to the social norms posters – which are the foundation to the community-level intervention – we also gather feedback on the other core intervention components (e.g., Teacher Lunch and Learn sessions, Teacher Workbook, and Student Intercept activities) designed to transform poster campaign messages into prevention behaviors. We will gather refinement data using **n=5-10 interviews with teachers** and **k=3-6 focus groups with students (size of focus groups will range from n=4-8 participants per group).** We will implement refinement activities in School #1 (the campaign refinement school) so as not to contaminate the population of teachers and students being targeted in the pilot randomized controlled trial in Aim 3 in Schools #2 and #3.

Aim 3: Pilot Randomized Controlled Trial: In the **Acceptability and Feasibility Aim 3** our primary goal will be to assess acceptability and feasibility of the school community-level preventive intervention, *Schools Championing Safe South Africa*, among **N=282 male adolescents aged 15-17 years** who are the primary targets of the community-level school environment intervention. This sample will be split in a 1:1 ratio (n=141 boys in the intervention school, n=141 boys in the wait-list control school). The goal of this school community-level intervention is to prevent HIV risk, IPV perpetration, and increase bystander behavior) among boys at high risk for HIV and STI risk behaviors and IPV perpetration (e.g., male adolescents aged 15-17 years). In this aim, we will also explore preliminary evidence for hypotheses that the intervention, relative to the control, will produce the following outcomes: (1) reductions in actual or intended HIV risk behaviors; (2) reductions in IPV frequency and decreased endorsement of IPV supportive attitudes; and (3) increased proactive bystander intentions. Outcomes will be collected at baseline, 1- and 6- months. As a secondary aim, we also **survey N=80 teachers** to

assess whether teacher (mis)perceptions have been corrected (e.g., whether teachers perceive student attitudes and behaviors more accurately) and whether they intend to engage in more bystander intervention. Teacher surveys will be collected as baseline (prior to the Teacher Lunch and Learn Sessions) and at follow-up (end of the school year).

Characteristics. We anticipate the following characteristics for study subjects in terms of age and number (see **Table 4**).

Table 4: Anticipated Subject Numbers* and Age

	Adolescents	Total Participants*
Aim 1	**Any gender adolescents, ages 12-19**	**1500**
Aim 1	**Any gender teachers, ages 18-65**	**120**
Aim 2	**Any gender adolescents, ages 12-19***	**48**
Aim 2	**Any gender teachers, ages 18-65***	**10**
Aim 3	**Male adolescents, ages 15-17**	**282**
Aim 3	**Any gender teachers, ages 18-65**	**80**

* maximum enrollment targets have been included, final sample sizes will be based on saturation analyses

Collaborating Sites. All primary data collection occurs in South Africa, based out of the South African Medical Research Council (SAMRC) via a contractual arrangement with Brown University. Dr. Mathews, M-PI is based at SAMRC. Data will be obtained, managed, and protected through a data agreement between Brown University and SAMRC. M-PI's Drs. Kuo and Mathews will oversee all standard operating procedures including study protocols including ethics; quality control and assurance; and data collection, management, and analyses procedures. In regards to data collection, our trained South African team will collect all data. For school site selection, we build on our team's extensive experience conducting school-based interventions, adolescent HIV and IPV interventions, and prevention research in South Africa. We work off our established network of 40 school research sites in Western Cape Province of South Africa, focusing on high schools in high HIV risk communities. We select schools in high HIV prevalence communities in Western Cape where we have previously worked with success in our school-based intervention trials with this age group.[29,67-69] In each of these schools, we have established relationships with school stakeholders including principals and other educators. These relationships allow us to run our HIV-IPV prevention program on school premises.

b. Study Procedures, Materials, and Potential Risks

Research Material and Data Obtained from Human Subjects. The following primary data will be obtained from subjects for Aims 1-3. Data will be collected in isiXhosa or English, depending on participant preference. When data is collected in isiXhosa, data will be transcribed and translated.

Aim 1 will generate data from a cross-sectional survey from N=1500 adolescents and N=120 teachers to evaluate school climate. From students, this survey will focus on: (1) IPV and HIV behavior data (students

only); (2) predicted prevalence of IPV and sexual behaviors in their school; (3) norms and attitudes around sex, HIV, gender, and IPV. From teachers, this survey will focus on: (1) predicted prevalence of adolescents' IPV and sexual behaviors in their school; (3) norms and attitudes of teachers around adolescent's sex, HIV, gender, and IPV.

Aim 2 will generate qualitative data from k=3-6 focus groups (n=4-8 people per group) with adolescents. Focus groups will follow a semi-structured agenda exploring the following themes: 1) perceptions of adolescent-level HIV and STI behaviors in the school, and barriers/facilitators to engaging in protective behaviors; 2) perceptions of adolescent-level IPV behaviors in the school including attitudes and norms around gender roles, relationships, and violence with exploration specific to the target adolescents (boys aged 15-17 years); 3) exploration of school community, and broader community factors relating to HIV and IPV behaviors including social norms; 4) feedback on visual appeal, and clarity and appropriateness of content of messages on draft posters; 5) anticipated barriers/facilitators of the student intervention components (student intercept activities led by both teachers using the Teacher Workbook and planned interventionist led intercept activities) including logistics regarding delivery preferences; and 6) suggestions for optimizing recruitment, data collection, and retention procedures for the boys involved in the intervention outcome surveys (e.g., boys aged 15-17 years). All focus groups will take place in a private room in the school or community setting. Food and refreshments will also be offered during the focus groups. Focus group discussions will be recorded using a digital voice recorder (DVR). Audio files will be stored in the password-protected project drive. Audio files will then be translated and transcribed verbatim by a transcriptionist. After transcription, the study team will edit out any information that might be used to identify a participant personally. A bilingual RA will compare 10% of transcripts to audio files for accuracy.

Aim 2 will also generate qualitative data from n=5-10 interviews with teachers. Interviews will follow a semi-structured agenda exploring the following themes: 1) perceptions of adolescent-level HIV and STI behaviors in the school, and barriers/facilitators to engaging in protective behaviors; 2) perceptions of adolescent-level IPV behaviors in the school including attitudes and norms around gender roles, relationships, and violence with exploration specific to the target adolescents (boys aged 15-17 years); 3) exploration of school community, and broader community factors relating to HIV and IPV behaviors including social norms; 4) feedback on visual appeal, and clarity and appropriateness of content of messages on draft posters; 5) anticipated barriers/facilitators of the teacher and student intervention components including logistics regarding delivery preferences; and 6) suggestions for optimizing teacher recruitment, data collection, and retention procedures. All interviews will take place in a private room in the school setting. Interviews will be recorded using a digital voice recorder (DVR). Audio files will be stored in the password-protected project drive. Audio files will then be translated and transcribed verbatim by a transcriptionist. After transcription, the study team will edit out any information that might be used to identify a participant personally. A bilingual RA will compare 10% of transcripts to audio files for accuracy.

Aim 3 will generate data from a RCT pilot with n=282 male adolescents aged 15-17 years. Data emerges from several sources. We conduct a set of assessments to evaluate acceptability using paper forms with automated scanning to turn into computerized data using our TeleForm Software. These include are session satisfaction and intervention program satisfaction forms. These satisfaction forms gather opinions on content, material, delivery, format, length, time, and location. We conduct a second set of assessments to evaluate feasibility. For this feasibility data we track recruitment, retention, and attrition data using FileMaker Software to inform future studies. This will include gathering characteristics on who is eligible (from baseline data) but does not attend the enrollment session; data on who fills out baseline, post-, and 3 month assessments; as well as who attends scheduled intervention sessions. We also conduct exit questionnaires for early exiters and full completers probing for 1) intervention drop out/facilitators including logistical, job or family related barriers, 2) perceived burden of intervention and assessment, 3) satisfaction with interactions with the research team in scheduling, etc. For early exiters who we are unable to identify at intervention sessions, we will attempt to get these early exit assessments at the time of exit, then we will complete these by phone. We conduct a third set of assessments for our exploratory secondary aim, evaluating outcomes whether the intervention, relative to the control, will produce: (1) reductions in HIV risk behaviors including unprotected sex and frequency of sexual intercourse; (2) reductions in IPV frequency and decreased endorsement of IPV supportive attitudes; and (3) increased proactive bystander intentions. As a secondary aim, we also survey N=80 teachers to assess whether teacher (mis)perceptions have been corrected (e.g., whether teachers perceive student attitudes and behaviors more accurately) and whether they intend to engage in more bystander intervention. For these assessments we use an outcome questionnaire at baseline, 1- and 6-months. As a secondary aim, we also survey N=80 teachers to assess whether teacher (mis)perceptions have been corrected (e.g., whether teachers perceive student attitudes and behaviors more accurately) and whether they intend to engage in more bystander intervention.

Access to Individually Identifiable Information & Data Collection, Management, and Protections.

Only PIs, co-Is and other essential project staff will have access to project data. All data will be protected by unique research identification numbers (RINs). Identifiable data will be kept separate from documents containing other participant data. Paper documents relating to participant data will be kept in locked cabinets accessible only to essential study personnel. Data will also be backed up by the data enterer and transferred via two-way encryption via the nCrypted Cloud program for PIs and Co-I to oversee for quality control. Participants' names will never appear in any report resulting from the project. Electronic data, including digital voice recordings will have several protections. First, all data will be stored on password-protected computers and smartphones. Second, all files on project computers will be further protected by nCrypted Cloud software which offers two-way encryption with secure access controlled by PIs (who can turn on and off access to password protected files from a central location) and wipe all data from devices remotely in the case of staff leaving the project or in the unlikely event of theft of devices. NCrypted Cloud also enables the PIs to control who has access, who can move files from the secured and encrypted cloud server onto local hard-drives (including computers, phones, and external hard-drives), and whether and how files can be moved between computers,

thus providing absolute control over data management and monitoring. Third, all staff will be trained in procedures for maintaining confidentiality of participant information. Data analyses will only focus on data associated with RIN. All other identifiers will be expunged from transcripts. Any names or pseudonyms used during focus groups will be replaced with the RIN. In order to ensure data quality, we will implement several quality procedures. These include the following procedures: 1) transferring of digital files to computers checking of DVR recordings within 48 hours; 2) after transcriptions, a check of transcripts for accuracy and to facilitate cleaning of transcripts.

Potential Risks to Subjects.

This research includes sensitive topics. Thus, there are some risks due to participation in our study. Concerns include risk of retribution against perpetrators disclosing in these studies. The risk of retribution against boys disclosing perpetration is guarded against by using self-completion for disclosure of acts that are socially stigmatizing or involve violence. The other concern is psychological distress; those who have raped or perpetrated sexual assault can find discussing it makes them realise that it was wrong. For consent and assent procedures, we will spend significant time discussing what topics will be covered, particularly highlighting what questions will explore including HIV-status, perpetration behaviors. We will emphasize that adolescents can halt participation at any time without consequence. We will also emphasize that although study staff will protect confidentiality of participants, this is not guaranteed in group settings. We also highlight the legal norms that would require break in confidentiality, and who information would be reported to as laid out by South African law. We balance these legal norms from South Africa on protecting the best interests of the child. For some data, we collect it anonymously (as in the school climate survey in Aim 1), participants will be guaranteed that the information will be kept confidential with no reporting given the anonymized data. In other cases of data for our other Aims, we follow the limits to confidentiality detailed above. Although our study protocol does not specifically probe for identifiable victims of perpetration, we recognize that there is the small chance adolescents will disclose this, unprompted by our team and requiring reporting. In anticipation of any possibility of serious adverse events, we will work with Dr. Mathews and Dr. Kuo's affiliations with University of Cape Town's Department of Psychiatry to refer adolescents to appropriate HIV support, mental health, and social support services, via Groote Schuur and associated partner hospital and clinic services within South Africa's free public health service system. At the start of the study, we will establish a relationship with key officials in the Department of Social Development to ensure the appropriate referrals are made for at-risk adolescents and their families, and to facilitate the process of mandatory reporting of cases of child abuse. In addition, we will engage the services of a psychologist and social worker to ensure an effective referral system and mandatory reporting procedure. Furthermore, all adolescents (regardless of eligibility) will receive a list of resources of HIV, IPV, general health, and social services. We specifically promote access to information about Childline (for adults Lifeline), Stop GBV helpline, HIV helpline, FAMSA and the South African Depression and Anxiety Group (SADAG) helpline and dissemination of phone numbers to anyone who wants further support. In our weekly team meetings, we explicitly probe for any unanticipated ethical situations which do not need immediate emergency attention. All

ethical emergencies requiring urgent attention are reported to the PIs immediately. All procedures will be reviewed by institutional IRBs.

Participants will potentially be exposed to the risk of COVID-19 during the focus group discussions. To mitigate this risk, we will conduct such discussions in a large, well-ventilated classroom with all the windows open during the FGD. Each participant and facilitator will be supplied with a medical mask to use for the duration of the FGD. Sanitizer will be provided and upon arrival, they will be requested to sanitize their hands. Chairs for the participants and facilitators will be placed at least two meters apart, and participants will be requested not to move closer to other participants or the facilitators. At the end of the FGD, participants will be asked to leave the classroom one by one, in an orderly fashion, maintaining a distance of two meters between them.

Loss of Privacy or Confidentiality.

There is a small risk of loss of privacy or confidentiality of data, including sensitive data on HIV status, sexual behaviors, depending on what participants choose to disclose, particularly in the group discussion. We take this risk seriously, and we will take steps to protect participants' identities. As outlined in the previous section, we will ensure that all personal identifiers are removed from the data and any publications arising from the study. We will make clear prior to the start of the focus group discussion that we cannot guarantee the absolute confidentiality of participant statements made in the group setting, and we will encourage them to use aliases when referring to third parties in the group discussion. The informed consent and assent documents will highlight confidentiality risks. We will inform both adolescents and parent/legal guardians during the informed consent and assent process that we will not share information about anything disclosed in focus groups unless in a case of self or other harm and legally mandated reporting requirements.

Psychological Discomfort during Data Collection.

Participants may experience embarrassment or distress while providing data on HIV, IPV, and sexual behavior. For those who have raped or assaulted someone, they can find discussing the topic or responding to survey questions about it makes them realise that it was wrong. However, the scientific team has extensive experience in interviewing participants, including adolescents around these topics and rarely have participants reacted to these types of questions with more than temporary embarrassment or mild discomfort in group discussion because they can decide what to discuss. The scientific team will train and supervise the RAs in these procedures and techniques to gather data sensitively. If any such moments of sensitivity occur during the study, the M-PIs will be available for consultation. Further, if participants experience emotional discomfort, they will be given the option of taking a break or rescheduling the focus group discussion or other data collection for another date and time. Further, any distress will be minimized by assurances that participants can refuse to answer any particular question they do not feel comfortable addressing and withdraw from the study at any time without penalty.

Alternative Treatments.

Alternative treatments are not a consideration in this study given no existing rigorously tested HIV-IPV perpetration preventive interventions exist for adolescents in South Africa. This is not a treatment study but has a prevention focus. For any unexpected adverse event, we will follow reporting requirements as mandated by legal requirements in South Africa and link to appropriate support via South Africa's free public health service system. In our weekly team meetings, we explicitly probe for any unanticipated ethical situations which do not need immediate emergency attention. All ethical emergencies requiring urgent attention are reported to the M-PIs immediately. All procedures will be reviewed by IRBs.

Adequacy of Protection Against Risks

a. Informed Consent and Assent

For Aim 1 with adolescents, our team will visit classrooms to describe the survey to students, explaining parents/legal guardians need to indicate in writing whether they do not want their child to participate. For potential participants under 18 years of age, we will provide parents/legal guardians a letter about the nature of the research seeking their permission for their child's participation, and provide a period of 1-2 weeks to return the form with our teams contact details to answer questions and concerns. Then we revisit high school classes 1-2 weeks later. For adolescents with consent forms, we will verify eligibility for adolescent surveys. For Aim 1 for teachers interested in participation, our team will screen for eligibility and then proceed with the consent process. Study staff will provide a signed written informed consent form from each teacher who is eligible and interested in participating for them to review and then complete the survey.

For Aim 2 with teachers interested in participation, our team will then proceed with the consent process. Study staff will provide a signed written informed consent form from each teacher who is eligible and interested in participating for them to review and then schedule an interview time. For Aim 2 with adolescents, we will recruit a convenience sample of any gender, age, and race of adolescents through flyers providing contact details for study staff in the school setting and recruit in-person with permission of the school principal and teachers. All interested adolescents under 18 years of age will be sent home with written parental consent and adolescent assent forms. Parents/legal guardians will have a chance to ask questions or discuss concerns using the contact details provided to them via study information sheet and consent form. For adolescents who return signed consent forms, study staff will assess eligibility for adolescent focus groups.

For Aim 3 with adolescents, we recruit a convenience sample of male adolescents 15-17 years through flyers providing contact details for study staff in the school setting and recruit in-person with permission of school principals and teachers. Interested adolescents will speak privately with the study team to be screened for eligibility and then commence the parental/legal guardian consent process. All interested adolescents are sent home with written parental/legal guardian consent and adolescent assent forms We will provide parents/legal guardians a letter about the nature of the research seeking their permission for their child's participation, and

provide a period of 1-2 weeks to return the form with our teams contact details to answer questions and concerns. Then we revisit high school classes 1-2 weeks later. For adolescents with consent forms, a participant locator form will be filled out to help schedule the intervention. Adolescents have been given an assent form at the initial point of contact but go through assent procedures prior to the intervention to give additional time to consider assent. We begin enrollment into the trial by confirming receipt of consent forms from parents/legal guardians, and verbally go over assent procedures followed by written assent. Parents/legal guardians and adolescents will provide consent and assent for baseline data collection, and then again for intervention enrollment, randomization, intervention procedures (if randomized to the intervention arm) and follow-up outcome assessments at 1- and 6-months post intervention; intervention participants will also provide consent/assent for satisfaction assessments. For Aim 3 for teachers interested in participation, our team will screen for eligibility and then proceed with the consent process. Study staff will provide a signed written informed consent form from each teacher who is eligible and interested in participating for them to review and then complete the survey.

b. Protections against Risk

Planned Procedures for Protecting Against or Minimizing Potential Risks. For adolescents, during assent procedures, and for parents/legal guardians in the consent form, we highlight the legal norms that would require break in confidentiality, and who information would be reported to. For adolescents in focus groups, we will minimize loss of privacy by limiting access to individually identifiable information using unique RINs on all paper, electronic data, and analyses; we also emphasize limits of confidentiality in a group discussion. Electronic data, including digital voice recordings and digitally scanned paper data will have several protections for both teacher and student participants. First, all data will be stored on password-protected computers including smartphones and files. Second, all files on project computers and android smartphones will be further protected by nCrypted Cloud software which offers two-way encryption with secure access controlled by PIs (who can turn on and off access to password protected files from a central location) and wipe all data from devices remotely in the case of theft. NCrypted Cloud also enables the PIs to control who has access, who can move files from the secured and encrypted cloud serve onto local hard drives (including computers, smartphones, and external harddrives), and whether and how files can be moved between providing absolute control over data management and monitoring. Third, all staff will be trained in procedures for maintaining confidentiality of participant information. We are also prepared to address any distress that may arise by referring to South African's mental health care within their free public health systems. All serious adverse events will be reported to IRB and NIH. Overall internal monitoring of the safety of human subjects will be conducted by the M-PIs. For non-emergency issues, a weekly meeting will be held to address study progress, recruitment and retention, data collection, and other factors related to human subjects and meetings will be held more often if necessary.

c. Vulnerable Subjects Protections

Additional Protections for Children. We put into place additional protections for children. We recognize that children may be a vulnerable group, and extreme care is required to ensure protection and empowerment amongst participants, but that exclusion of this group would significantly prohibit scientific development in topic areas of great importance to the health and wellbeing of this group. To ensure informed consent and assent, we will clarify what information will be kept confidential and what will be disclosed to another party. We also build upon our team's extensive research and clinical experience working with adolescents living with HIV in South Africa as well as our team's experience conducting HIV behavioral research with vulnerable populations affected by HIV in South Africa and other international settings. We provide additional protections in consent and assent procedures. All informed assent forms will be read aloud in participants' chosen language and participants will also be provided copies. To ensure that children do not feel obliged to participate in the research, emphasis will be placed on their ability to refuse to participate, or to cease participation at any point during the research. As has been the practice in our previous studies with this vulnerable population, our research team is trained to recognize that any avoidance by children of the research will be taken as evidence of failure to assent. For adolescents, during the parental/legal guardian informed consent procedures and during the adolescent informed assent procedures, we emphasize that all information shared with us will remain confidential except for life-threatening disclosures or disclosures regarding age-differential partners, exploitative sex, perpetration with identifiable rape victims, being a victim of rape, sexual abuse or physical abuse which falls under legally mandated reporting to police, social services, and IRB.

Adverse Events. If an unanticipated Problem or a Serious Adverse Event occurs at the study site and is more likely than not related to the research activity, and places participants or others at a greater risk of harm than was previously known or recognized, the M-PIs will report the event in writing using the appropriate forms to IRB. The M-PIs will also report Serious Adverse Events in writing to the sponsor. The M-PIs will review the Adverse Event report with the entire study team and gather any information needed to investigate the event and to determine subsequent action. The M-PIs will document and report any subsequent action to IRBs. We will also generate a brief report of Adverse Events for the study record each year, and we will forward the report to Brown University IRB, South African Medical Research Council IRB and NIH.

Potential Benefits of the Proposed Research to Human Subject and Others

There may be little or no direct benefit to participants from the study. Some possible benefits may include informing HIV and IPV prevention science. Adolescent participants will be given information on HIV, IPV, general health, and social services and referrals if necessary. The risks associated with this research are reasonable in relation to the anticipated benefits of advancing empirical knowledge adolescent prevention approaches for this high priority population and setting.

Importance of Knowledge to be gained

To our knowledge, this will be the first intervention to prevent adolescent HIV risk and IPV perpetration in an integrated manner and in a high impact setting (South Africa) using a school community-level approach.

Data and Safety Monitoring Plan:

The study population warrants the development of a Data Safety and Monitoring Plan including a Data and Safety Monitoring Board. To address the NIH policy for Data and Safety Monitoring, the M-PIs (Drs. Caroline Kuo and Catherine Mathews), along with the co-Investigator, will be responsible for monitoring (Dr. Lindsay Orchowski). The team has developed a system for oversight of the proposed study and its participants. The Data and Safety Monitoring Plan focuses on protecting participants in the involvement in all three aims with primary data collection activities which occur in South Africa.

Potential risks to subjects are as follows. This research includes a number of sensitive topics. Thus there are some risks due to participation in our study. Concerns include risk of retribution against perpetrators disclosing in these studies. The risk of retribution against boys disclosing perpetration is guarded against by using self-completion for disclosure of acts that are socially stigmatizing or involve violence. The other concern is psychological distress; those who have raped or perpetration sexual assault can find discussing it makes them realise that it was wrong. For consent and assent procedures, we will spend significant time discussing what topics will be covered, particularly highlighting what questions will explore including HIV-status, perpetration behaviors. We will emphasize that all participants (teachers and adolescents, but especially adolescents) can halt participation at any time without consequence. We will also emphasize that although study staff will protect confidentiality of participants, this is not guaranteed in group settings such as the focus groups occurring with adolescents in Aim 2. We also highlight the legal norms that would require break in confidentiality, and who information would be reported to as laid out by South African law (abuse, neglect, victim of assault or rape, specific cases of sex in within certain age ranges). For some data, we collect it anonymously (as in the survey in Aim 1), participants will be guaranteed that the information will be kept confidential with no reporting given the anonymized data. In other cases of data for our other Aims, we follow the limits to confidentiality detailing limits to confidentiality in detail. Although our study protocol does not specifically probe for identifiable victims of perpetration, we recognize that there is the small chance adolescents will disclose this, unprompted by our team and requiring reporting. In anticipation of any possibility of serious adverse events, we will work with Dr. Mathews and Dr. Kuo's affiliations with University of Cape Town's Department of Psychiatry to refer adolescents to appropriate HIV support, mental health, and social support services, via Groote Schuur and associated partner hospital and clinic services within South Africa's free public health service system. Furthermore, all adolescents (regardless of eligibility) will receive a list of resources of HIV, IPV, general health, and social services. We specifically promote access to information about Childline (for adults Lifeline), Stop GBV helpline, HIV helpline, FAMSA and the South African Depression and Anxiety Group (SADAG) helpline and dissemination of phone numbers to anyone who wants further support.

We have several procedures in place to protect and minimize risks. For adolescents, during assent procedures, and for parents/legal guardians in consent documentation, we highlight the legal norms that would require

break in confidentiality, and who information would be reported to. For both adolescents in focus groups, we will minimize loss of privacy by limiting access to individually identifiable information using unique RINs on all paper, electronic data, and analyses. Electronic data, including digital voice recordings and data collected via paper and then scanned digitally, will have several protections. First, all data will be stored on password-protected computers. Second, all files on project computers will be further protected by nCrypted Cloud software which offers two-way encryption with secure access controlled by PIs (who can turn on and off access to password protected files from a central location) and wipe all data from devices remotely in the case of theft. NCrypted Cloud also enables the PIs to control who has access, who can move files from the secured and encrypted cloud serve onto local hard drives (including computers, and external harddrives), and whether and how files can be moved between providing absolute control over data management and monitoring. Third, all staff will be trained in procedures for maintaining confidentiality of participant information. We are also prepared to address any distress that may arise by referring to South African's mental health care within their free public health systems. All serious adverse events will be reported to IRB and NIH. Overall internal monitoring of the safety of human subjects will be conducted by the M-PIs. For non-emergency issues, a weekly meeting will be held to address study progress, recruitment and retention, data collection, and other factors related to human subjects and meetings will be held more often if necessary. We put into place additional protections for children. We recognize that children may be a vulnerable group, and extreme care is required to ensure protection and empowerment amongst participants but that exclusion of this group would significantly prohibit scientific development in topic areas of great importance to the health and wellbeing of this group. To ensure informed consent and assent, we will clarify what information will be kept confidential and what will be disclosed to another party. We also build upon our team's extensive research and clinical experience working with adolescents living with HIV in South Africa as well as our team's experience conducting HIV behavioral research with vulnerable populations affected by HIV in South Africa and other international settings. We provide additional protections in consent and assent procedures. All informed assent forms will be read aloud in participants' chosen language and participants will also be provided copies. To ensure that children do not feel obliged to participate in the research, emphasis will be placed on their ability to refuse to participate, or to cease participation at any point during the research. As has been the practice in our previous studies with this vulnerable population, our research team is trained to recognize that any avoidance by children of the research will be taken as evidence of failure to assent. For adolescents, during the parental informed consent procedures and during the adolescent informed assent procedures, we emphasize that all information shared with us will remain confidential except for life-threatening disclosures or disclosures regarding age-differential partners, exploitative sex, perpetration with identifiable rape victims, being a victim of rape, sexual abuse or physical abuse which falls under legally mandated reporting to police, social services, and IRB.

The Data and Safety Monitoring Plan for this application will begin by implementing standard procedures for day-to-day monitoring of the study. Also, we hold weekly meetings with the research team will be conducted to evaluate the progress of the trial and to review data quality, recruitment, study retention, and examine other factors that may affect safety. Participant experiences with the study procedures and the rates of adverse

events will also be reviewed to determine any changes in participant risk. The PI will report any adverse events (AEs) that are observed to the local site's IRB (South African Medical Research Council, Brown University, and to NIH. Serious adverse events (SAEs) will be reported to the local site's IRB by written report within 48 hours of our receipt of information regarding the event; SAEs will also be reported in writing to NIH. Actions taken by the IRB in response to SAEs will also be reported to NIH, as will reports of changes or amendments to the protocol as a result of an SAE. Reports of changes or amendments to the protocol in general must be requested first in writing to the IRB, which then will grant or deny permission to make the requested change or amendment in protocol. Modifications to study aims or design, if applicable as a response to SAEs, will also be submitted to NIH. Finally, if significant medical or mental health risks occur during the study period brought to the attention of the study team will be tracked as AEs; if significant medical or mental health risks occur during the study period that have a reasonable possibility of being related to the study will be referred for evaluation by the emergency department to determine whether hospitalization or urgent care is needed. In the event that a research participant either withdraws from the study or the investigator decides to discontinue a research participant due to SAE, the research participant will be monitored by the investigator via ongoing status assessment until either a resolution is reached (i.e. the problem requiring hospitalization has resolved or stabilized with no further changes expected or the SAE is determined to be clearly unrelated to the study intervention). Outcome of all SAEs will be periodically reported to NIH. A summary of the SAEs that occurred during the previous year will be included in the annual progress report to NIH.

Data and Safety Monitoring Board:

A Data and Safety Monitoring Board (DSMB) will be created when the project is selected for funding and has proceeded into the preparatory phase for Aim 3 (the randomized pilot trial). The DSMB shall determine safe and effective trial conduct and recommend termination of a trial if significant risks develop or the trial is unlikely to be concluded successfully. Specifically, the DSMB shall be responsible for the following:

1. Reviewing the research protocols and planning for data and safety monitoring.
2. Evaluating the progress of the trial during each phase during active enrollment and treatment. The DSMB will conduct assessments of participant recruitment, accrual and retention, data quality and intervention fidelity, and other factors that may affect study outcomes. They will also review all study adverse events (AEs) and serious adverse events (SAEs). Monitoring may also consider factors external to the study when interpreting the data, such as scientific or therapeutic developments that may have an impact on the safety of the participants or ethical issues related to the study.

3. Maintaining confidentiality during all phases of the trials.

4. Generating a report that will be provided to the investigators, IRBs (as needed), and NIH.

Membership. The DSMB will consist of three members including an expert in behavioral interventions, an expert in HIV and/or violence, and an expert in adolescents. None of the DSMB members will be on the study team. No member of the DSMB will have direct involvement in the conduct of the study. Furthermore, no member will have financial, proprietary, professional, or other interests that may affect impartial, independent decision-making by the DSMB. All DSMB members will sign a Conflict of Interest certification to that effect at the time they are asked to participate. At the beginning of every DSMB meeting, the investigative team will confirm that no conflict of interest exists for DSMB members and will again ask them to sign a Conflict of Interest certification. Meetings will be held by conference calls twice a year (every 6 months). The study team will help to develop the agenda in consultation with the DSMB. Procedures and protocols for notifying the IRBs and NIH Program Official concerning serious adverse events will be discussed at the first meeting.

Board Process. The first meeting will involve a discussion of the project, any modifications, and to establish guidelines to monitor the project. The DSMB members and the PIs will prepare the agenda to address reviews of the study, modification of the study design, initiation of the project, reporting of accrual, reporting of adverse events, stopping rules, preliminary analysis plan, etc. Meetings will be held twice a year.

Meeting Format. The format for DSMB meetings will be an open (with PIs) followed by closed session (if needed) where the PIs will be informed of recommendations made by the DSMB. The open sessions will include the PIs and study staff. Issues discussed at open sessions will include conduct and progress of the study,

including accrual, compliance with study design, and problems encountered. Only aggregate data, without any treatment arm comparisons, will be presented in the open session. The closed session will include only DSMB members. The DSMB may request others to attend part or all of the closed session, if needed. The discussion at the closed session is completely confidential. If there are differences among DSMB members regarding major study recommendations such as early termination, a vote of the DSMB will be required.

Reports from the DSMB. The meeting minutes containing the DSMB meeting summary and recommendations for continuation, modifications, or termination of the study is used as the meeting report. The draft meeting report will be reviewed and approved by the DSMB Chairperson. The final meeting report will be forwarded to DSMB members and the PIs. It will be the responsibility of the investigators to distribute the meeting report to all clinical sites, and to assure that copies are submitted to all the IRBs associated with the study (if needed).

Confidentiality. All materials, discussions and proceedings of the DSMB are completely confidential. Members and other participants in DSMB meetings are expected to maintain confidentiality.

Statistical design and power

Sample Size and Power Considerations.

The primary objective of this pilot is to test the feasibility and acceptability of the intervention and to generate meaningful effect size estimates for a future fully-powered RCT. We considered sample size needed to demonstrate increased condom use at last sex, reduced sexual violence perpetration, and increased active bystander behavioral intentions. To measure significant change in the three objectives, a total of N=282 adolescent boys will be enrolled, with n=141 in the intervention arm and the same number (n=141) in the control arm. The power calculations described below are based on a McNemar's test for paired proportions, 80% power, and type 1 error rate (alpha) of 5%. These calculations were generated by findings of the R34 testing *Safe South Africa* (R34MH113484-01), which included 80 male adolescents aged 15-17 years. **Condom use:** We assume that in the *Schools Championing Safe South Africa* pilot trial, 88% of male adolescent participants will have ever had sex at baseline, and 63% of those will report at baseline that they used a condom at last sex. **Table 5** shows the sample size required to detect changes between baseline and 6-months in condom use ranging from 3% to 17% at six months at 80% power and a type 1 error rate of 5%. For example, Table 5 shows a sample size in excess of 1000 (N=1138) is required to detect changes in condom usage that are less than 5 percent. To detect larger differences, for example 10% or greater, a maximum sample size of 276 participants is required. To detect changes of 15% or greater in condom use at last sex between baseline and 6 months in the intervention arm, assuming 0.20 correlation between paired observations, 135 adolescent boys are required in the intervention arm. To account for a 3% dropout rate (observed in the *Safe South Africa* study), a total of 141 per arm will be enrolled. **Sexual violence perpetration:** We assume that at baseline, 56% of male adolescent participants will have perpetrated sexual violence in the past 6 months. To detect changes 16% or greater in sexual violence perpetration of sexual violence between baseline and 6 months in the intervention arm, assuming a 0.20 correlation between paired observations, a total of 125 adolescent boys are required in the intervention arm (Table 5). The planned sample size of 141 per arm will account for greater than 3% dropout rate. **Active bystander behavior:** We assume at baseline, 60% of male adolescent participants will have intentions to engage in active bystander behavior. To detect changes 15% or greater in active bystander intentions between baseline and 6 months in the intervention arm, assuming 0.20 correlation between paired observations, a total of 125 adolescent boys are required in the intervention arm (Table 5).

Table 5: Sample Size Estimates

	Baseline proportion	6-month proportion	Change	Sample size
Sexual Violence Perpetration	0.56	0.38	-0.18	99
	0.56	0.4	-0.16	125
	0.56	0.42	-0.14	163
	0.56	0.44	-0.12	221
	0.56	0.46	-0.1	317
	0.56	0.48	-0.08	493
	0.56	0.5	-0.06	872

	0.56	0.52	-0.04	1953
Bystander Activity	0.6	0.66	0.06	816
	0.6	0.67	0.07	597
	0.6	0.68	0.08	455
	0.6	0.69	0.09	358
	0.6	0.7	0.1	289
	0.6	0.71	0.11	238
	0.6	0.72	0.12	199
	0.6	0.73	0.13	169
	0.6	0.74	0.14	145
	0.6	0.75	0.15	125
	0.6	0.76	0.16	110
	0.6	0.77	0.17	97
	0.6	0.78	0.18	86
	0.6	0.79	0.19	77
	0.6	0.8	0.2	69
Condom usage	0.63	0.66	0.03	3198
	0.63	0.67	0.04	1789
	0.63	0.68	0.05	1138
	0.63	0.69	0.06	786
	0.63	0.7	0.07	574
	0.63	0.71	0.08	437
	0.63	0.72	0.09	343
	0.63	0.73	0.1	276
	0.63	0.74	0.11	227
	0.63	0.75	0.12	190
	0.63	0.76	0.13	161
	0.63	0.77	0.14	138
	0.63	0.78	0.15	119
	0.63	0.79	0.16	104
	0.63	0.8	0.17	92

Management approach

Management approach, staff and scientific collaboration

This study will occur at two sites, the USA in Rhode Island where Dr. Kuo and Dr. Orchowski are based, and in South Africa were Dr. Mathews is based. All primary data collection occurs in South Africa.

Dr. Kuo will have oversight all activities including the subcontracts. At Brown University, she will oversee all data programming, protocol preparation, data receipt from South Africa, data cleaning, and data analysis. Dr. Mathews will have oversight over the South African Medical Research Council subcontract activities, in close collaboration with Dr. Kuo. This includes all primary data collection activities, institutional collaboration for IRB, transfer of data to the USA for cleaning and processing, and translation. Together, Drs. Kuo and Mathews will ensure adequate systems, training of the study team, enforcement of protocols, working with their experienced institutional financial and grants management teams, to ensure that grant activities are in compliance with US laws, and DHHS and NIH policies, including biosafety, the protection of Human Subjects, data and facilities, as well as parallel applicable laws and policies in South Africa. In the case of unanticipated serious adverse events, and with the permission of children and parents, we will refer to services by tapping into the extensive social service and clinical networks that we have worked with for adolescent health in South Africa including both Drs. Kuo and Mathew's respective affiliation with the Medical School at University of Cape Town. Project progress will be summarized weekly in order coordinate scientific, fiscal and administrative management of the project, setting priorities for allocation of resources and funds.

Our multidisciplinary team consists of highly qualified, accomplished personnel with extensive complementary experience in adolescent preventive interventions for HIV and IPV in South Africa and globally. Our investigative team has multiple projects in South Africa on adolescent HIV and IPV. Dr. Caroline Kuo (M-PI) will manage the overall grant and contribute social and behavioral expertise in adolescent HIV prevention and in mixed-methods formative intervention development research that will yield appropriately tailored interventions for adolescents. She has 5 ongoing studies in Cape Town as an investigator (NIH grants: R34 MH 113484, R01 NIMH 114843, R21 NICHD 089825, H70TI080569-01, D43 TW011308). Dr. Kuo directly collaborates with Dr. Cathy Mathews on 2 of these studies (R34 MH 113484, R01 NIMH 114843), and Dr. Orchowski on 1 study (R34 MH 113484); this R34 is the *Safe South Africa* intervention that complements this proposal. Dr. Cathy Mathews (M-PI) will manage the SAMRC sub-contract, including overseeing reporting, financial management, procurement of equipment and supplies and management of field activities. is a public health scientist with expertise in adolescent interventions for HIV and IPV, and specializing in school-based interventions. Her research is specifically focused on testing interventions for scale-up in school and health systems with an emphasis on informing national policies related to adolescent sexual and reproductive health in South Africa. Dr. Lindsay Orchowski (co-I) will bring her substantial expertise in the violence preventive *Safe* intervention being used as a foundation in the study. She has served as PI of two large-scale, CDC-funded evaluations of sexual assault prevention programming for high school and middle school boys; each of which included a social norms marketing campaign within the school (with Dr. Alan Berkowitz). She has also served as PI of an NIAAA R34

grant designed to evaluate the *Safe* program for men in the military, and has published extensively on sexual assault prevention. Dr. Alan Berkowitz (consultant) is an expert in social norms theory, bystander intervention, and engaging men in sexual assault prevention. He has conducted work in South Africa, Australia, Canada, Europe, and the USA. A collaborator on the design of the *Men's Workshop* (which forms the basis of the *Safe* program), he has worked with Dr. Orchowski in three evaluations of the model. He will contribute social norms expertise to the intervention development research. Dr. Yandisa Sikweyiya (consultant) is an expert in violence risk reduction and prevention in South Africa as well as gender norms and relationships. He brings significant content expertise in IPV and interpersonal violence research within South Africa with a specific focus on understanding men, masculinities, and HIV in relation to gender-based violence. He will contribute to the intervention development and the evaluation instruments. Dr. Kuo, Mathews, and Orchowski recently collaborated on an edited volume on sexual violence published by Elsevier entitled, "Sexual Assault Risk Reduction and Resistance: Theory, Research, and Practice."

Multiple principal investigators (PIs)

We propose a multiple PI leadership plan that involves sharing responsibility by two M-PIs, Dr. Caroline Kuo (Brown University) and Dr. Catherine Mathews (South African Medical Research Council). This scientific collaboration is stronger than a study conducted by either the USA-based or South African-based team alone. We are able to consolidate expertise with South African adolescents at risk for HIV and IPV. This collaboration also illustrates our philosophy of multidisciplinary and equitable international research partnerships. Dr. Kuo contributes significant expertise in behavioral and social risk. She also brings expertise in mixed-methods for intervention development and adaptation of empirically supported programs to the South African context as well as international data systems and mobile data collection in South African community contexts. Her experience will facilitate tracking and tracing of adolescents for collection of data in the community setting, and high quality data collection from adolescents on sensitive topics. Dr. Mathews contributes significant experience in school-based interventions including interventions that focus on the endpoint of adolescent health including adolescent HIV, sexual and reproductive health, and IPV. She brings vast expertise in intervention trial design, implementation, analyses, and dissemination for maximum health systems and policy impact.

Dr. Kuo will have oversight of Brown University activities including the subcontract to the University of Cape and submission of reports to NIH. This includes annual research performance progress reports, reporting for NIMH's recruitment milestones system, clinical trials registry reporting, and Brown University reporting. Dr. Mathews will have oversight over the South African Medical Research Council subcontract activities, in close collaboration with Dr. Kuo. Dr. Mathews will oversee coordination of stakeholder meetings in South Africa, as well as seeking permission to work with the South African Department of Education. Dr. Mathews will oversee the day to day management of the South African team, given the time difference between countries. However, Dr. Kuo will coordinate all weekly team meetings. Together, Dr. Kuo and Dr. Mathews will oversee project progress summarized weekly in order coordinate scientific, fiscal and administrative management of the project, setting priorities for allocation of resources and funds; Dr. Kuo will focus on summarizing the activities

occurring on the USA side (reporting, data systems, data analysis) and Dr. Mathews will focus on summarizing the activities occurring on the South African side (field-based primary data collection). Together, Drs. Kuo and Mathews will ensure adequate systems, working with their experienced institutional financial and grants management teams, to ensure that grant activities are in compliance with US laws, and DHHS and NIH policies, including biosafety, the protection of Human Subjects, data and facilities, as well as parallel applicable laws and policies in South Africa. In the case of unanticipated serious adverse events, and with the permission of children and parents, we will refer to services by tapping into the extensive social service and clinical networks that we have worked with for adolescent health in South Africa including both Drs. Kuo and Mathew's respective affiliation with the Medical School at University of Cape Town with Dr. Mathews taking specific charge of the immediate response needed given the time difference.

Authorship for peer-reviewed manuscripts, book-chapters, scientific conference presentations, policy and clinical briefs, and dissemination briefs resulting from project activities will be determined prior to creating drafts for these outputs. Authorship will be negotiated based on the relative scientific contributions of the PIs, Co-I, consultant, and key personnel, following international guidelines set by the International Committee of Medical Journal Editors (ICMJE). All decisions regarding the technical aspects of the project will be decided jointly in weekly Skype meetings by the M-PIs and Co-Is. In the unlikely case of conflicting opinions regarding the technical approach of the study, the M-PIs, Drs. Kuo and Mathews will consult with co-I and consultants (Drs. Orchowski, Sikweyiya, and Berkowitz).

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