MySTYLE: Online family-based HIV prevention for non-heterosexual Black adolescent males in the South

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SPECIFIC AIMS

In the United States, HIV/AIDS has disproportionately affected men who have sex with men (MSM).[1] In recent years, the highest rates of HIV have been concentrated among increasingly younger MSM, especially those of color in the Southern US.[1-4] Jackson MS, site of this study, has the highest prevalence of HIV among urban MSM in the US (39.5 per 100 MSM) and the third highest rate among Black MSM under the age of 25.[3, 5] Unfortunately, there is no evidenced-based prevention program for adolescent MSM (ages 13 to 18), who are the youngest, most vulnerable group.[6] Of 84 CDC-classified evidence-based interventions, only 9 were specifically designed for MSM, minorities were not adequately represented, and only 2 included MSM less than 18 years of age.[6] A prevention program specifically designed for this vulnerable adolescent group needs to be tested for efficacy and made available for widespread use, especially in the South. Providing early intervention to this population of adolescents may foster their early adoption of protective practices (e.g., safer sex, linkage to care for HIV/STD testing and treatment, PrEP use).

Parents may exert the most significant, longitudinal influence in the lives of adolescents and research with heterosexual youth indicates that family-based interventions can be efficacious. Parents of non-heterosexual youth have not generally been included in research because of the perceived difficulty of gaining their consent or because of adolescents' fears of engaging parents.[7] Fortunately, parents of non-heterosexual youth may be more accessible than commonly thought and they can be included safely. Elze, for example, found that 48% of non-heterosexual adolescents were willing to have caregivers contacted for study enrollment and all caregivers contacted provided consent.[8] In addition, four other recent pilot trials suggest that some parents of non-heterosexual youth may want help with their child's sexuality, and that a short video (without in-person contact) can positively impact parent attitudes.[9-12] Drs. Brown and Crosby have successfully conducted a NIMH-funded HIV prevention study.[13-16] known as Project STYLE. This randomized controlled trial successfully enrolled 721 racially and ethnically diverse heterosexual adolescent parent/caregiver dyads in three U.S. cities with a participation rate of 94%. This family based intervention was efficacious and evidence from the RCT and a subsequent DVD version tested among Black adolescents shows that parental involvement is highly protective.[13] MySTYLE has been designated as a "best evidence" intervention for risk reduction by the CDC. This success, and similar research, supports the utility of including parents in programs designed to promote sexual health among adolescents.[17, 18] The proposed project will adapt key elements of STYLE and its DVD to create on online HIV intervention program (MySTYLE) that will be delivered to non-heterosexual Black adolescent males (nHBAM), ages 13 to 18, and their parents/caregivers in Jackson, MS. We recognize the inherent risks to nHBAM of disclosing their sexual desires/activities to parents/caregivers. Therefore, the intervention program will occur in a two-stage sequence. We plan that nHBAM will first be enrolled under waivers of parental consent, unless they are willing to have parents contacted to provide consent and possibly join the study. A key aspect of the eight-week online intervention program for nHBAM is provision of motivation and skills needed to discuss sex and sexuality with parents/caregivers. Furthermore, MySTYLE will teach nHBAM how to evaluate and enhance the safety of disclosing to parents/caregivers who initially may not be accepting about same sex desires/behaviors. By the middle of the eight-week program, nHBAM who have not previously done so will be asked to consider inviting their parents/caregivers into the program. Online materials for enrollment and intervention will be provided to parents/caregivers.

The project will use formative work to adapt the family-based Project STYLE to the needs of nHBAM and their parents/caregivers. Working with an advisory board, an iterative development process will refine and tailor the online intervention. We recognize the inherent risks to adolescents of disclosing their sexual desire/activities to parents/caregivers. We will enroll those who indicate interest in a program to support healthy adolescent relationships and acceptance of straight and gay adolescents. Adolescents will not need to reveal their sexual

behavior or attitudes, although we expect that the majority of youth who participate will be non-heterosexual. In preparation for this project, we conducted two focus groups in Jackson MS and recruited 17 youth, and their caregivers from agencies, clinics and schools; 94% (16/17) of the teens self-identified as non-heterosexual. These same recruitment strategies will be used in this proposed project.

The Year 1 formative phase will consist of: 1) interviews of adolescents, 2) interviews of parents/caregivers, and 3) interviews of stakeholders such as staff from LGBT organizations, schools, churches, and state agencies. Findings from the interviews will inform the Year 2 iterative development and refinement phase between the investigators, the media company (MEE Productions, see Facilities), and workgroups (composed of youth, parents, stakeholders, investigators). It will culminate in the creation of MySTYLE, which is proposed to use an engaging online novella to increase motivation and skills to support healthy sexual behavior, communication, and family processes (connectedness and parent practices) for nHBAM and their parents/caregivers. MySTYLE will be tested in a small Randomized Trial Phase in Year 3 with 72 adolescents. This trial will compare the eight-week family-based HIV prevention intervention program to a waitlist control. All participants assigned to the waitlist control will receive the MySTYLE intervention after the active treatment group.

Aims: 1) To use interviews with youth, parents/caregivers, and other stakeholders to identify the relevant elements needed for a family-based intervention for Black adolescent males who do not identify as heterosexual and their parents/caregivers. 2) To use the ADAPT-ITT Model in an iterative approach between investigators, an advisory board, and a media company to refine and tailor MySTYLE. 3) To conduct a preliminary efficacy test of MySTYLE to assess effect size differences in HIV-related knowledge, attitudes, sexual behavior, and in acceptance of HIV testing, as well as parental attitudes and behavior. 4) To examine the overall perceptions of youth as to how each module could be improved for greater appeal to other young males of a similar age and background and the attributions of youth regarding which modules (if any) had an impact on their sexual risk behaviors. This aim uses in-depth, post-test interviews of adolescents and parents. These data will be used to inform adaptation of the intervention to be tested in a larger sample.

SIGNIFICANCE

Overview and Premise: Because parents and other caregivers are a significant, longitudinal influence on their adolescents, we propose to adapt an efficacious family-based HIV prevention intervention (STYLE) for use by Black adolescent males who do not identify as heterosexual. For the purposes of this application, we will refer to this group as non-heterosexual Black adolescent males (nHBAM). While we fully recognize that nHBAM are a larger population than Black adolescent men who have sex with men (MSM), our intent is to develop an online intervention program that avoids any stigma from a program that assumes participants are sexually active with other males. Recent work, reviewed below, suggests that parents of many nHBAM are more open and available for interventions than previously thought and that including parents/caregivers can be safe and beneficial. We will enroll adolescents and parents/caregivers who indicate interest in healthy adolescent relationships and acceptance of straight and gay adolescents. Adolescents will not need to reveal their sexual behavior or attitudes, although we expect that the majority of youth who participate will be non-heterosexual, due to enrollment community and clinic venues that serve nHBAM and with recruiters familiar with the LGBT community. The intervention adaptation will occur through detailed, comprehensive, formative work conducted with nHBAM, their parents/caregivers, and community stakeholders in Jackson, MS. The investigators have experience in developing and tailoring interventions with the target population and relevant stakeholders using community collaborations. In addition, a sophisticated media company (MEE productions, with whom they have previously worked) will help adapt the STYLE DVD intervention, which uses novella and

interactive elements to engage adolescents and parents, into an online intervention tailored for nHBAM (to be called MySTYLE). MySTYLE will be tested for feasibility and effect sizes in a small, randomized trial with 72 nHBAM and their parents/caregivers in Jackson MS.

The HIV epidemic in young MSM: Men who have sex with men (MSM) are dramatically more likely to be infected with HIV than any other population in the U.S. Of all males diagnosed with HIV during 2009-2013, 22% of those were ages 13-24 years and 91% of the infections in those were attributed to male-to-male sexual contact.[1] African American MSM account for 58% of all new HIV infections among MSM aged 13-24 years, respectively.[1] Adolescent MSM (AMSM) under the age of 19, are increasingly at risk for HIV, with a 22% increase in incidence between 2008 and 2010[1] yet there are no evidenced-based interventions (EBIs) specifically designed for them. Jackson MS, the site of this proposed project, has the highest prevalence rate of HIV among urban MSM in the US (39.5 per 100 MSM). [2, 3, 5]Jackson also has the second highest AIDS rate and the 3rd highest rate of HIV infection for Black men under age 25.[3] An ever-expanding number of young Black MSM in the U.S. are becoming infected, and evidence suggests that the age of infection for these men is becoming progressively younger.[4] In a recent study of 600 young Black MSM (ages 15 through 29) conducted by Crosby and Mena in Jackson, MS, 23.3% tested positive for HIV (n = 140) and nearly one third were 21 years of age or younger. Given the crisis of HIV/AIDS among young Black MSM in South, this study will focus on its youngest members, including those who may not yet identify as MSM (i.e., nHBAM).

Growing evidence suggests that non-heterosexual adolescent males have increased rates of sexual risk and face unique risk factors such as discrimination, internalized homophobia and disconnection from families and social networks. Longitudinal studies find that adolescent (MSM) AMSM were likely to have experienced homophobia and sexual/social/racial discrimination and these experiences are significantly associated with substance use and HIV sexual risk behaviors.[19, 20] Also, analyses of the Youth Risk Behavior Survey indicate that non-heterosexual adolescent males report higher rates of sexual risk.[21] Other research, supports the relevance of stigma, heterosexual expectations of masculinity by others and internalized homophobia.[26-33] Addressing these factors during adolescence, and with the family members of adolescents, may prove beneficial. Evidence suggests that nHBAM experience disapproval, discrimination, and homophobia in every arena of their lives (e.g., families, peers, racial/ethnic groups, faith communities).[22-28] Connectedness with family has been found to be highly protective against drug use, HIV and other risky behaviors among young people in general, [29, 30] Often nHBAM feel a sense of disconnection and isolation from their families because of their sexuality.[22-24, 31-33] Further, nHBAM may resist disclosure of their sexuality out of fear of rejection by peers or family members.[22, 31, 32, 34] Family reactions to disclosure can range from anger or withdrawal, [25, 35-37] to tolerance or active support.[38] An intervention is needed that will increase positive connections with family members so that the adolescent can improve and strengthen supports. **An engaging and safe family-based intervention may promote and sustain a healthier trajectory for many nHBAM, who will continue to need support from a parent/caregiver.**

Interventions for at-risk youth can be effective if they are theory-based, tailored, and impact multiple domains. Despite the lack of EBIs for adolescent MSM (AMSM), there is substantial evidence that adolescents, even those at greatest risk, will reduce their risk for HIV and increase condom use in response to theory-driven interventions. A review of STI/HIV interventions for adolescents[39] found that two important ingredients of effective interventions: a direct link to theory and intervention tailoring. Interventions that include a broader content, such as improving family patterns, improving peer support, and enhancing gender and ethnic pride, have also had a significant behavioral impact.[40] MySTYLE will incorporate these attributes.

Parents and other caregivers can be a source of support and resilience for non-heterosexual adolescent males and may be available for interventions. Parental support

and acceptance is associated with better sexual health for hetero and non-heterosexual youth,[7] and lack of support is associated with poor health outcomes.[41, 42] Cross-sectional studies indicate that positive family connections are advantageous and even small improvements may be beneficial.[43] Two recent studies of AMSM found an association between disclosure of same-sex sexual activity to parents and safer sex behaviors.[44, 45] Another study of AMSM found that parent – teen discussion about same-sex sexual behavior was associated with greater HIV testing.[46] In addition, parental involvement may be more possible than previously thought. For example, Elze found that 48% of non-heterosexual adolescents under the age of 18 were willing to have parents contacted for study enrollment and all parents contacted provided consent.[8] Because parents/caregivers continue to be involved after the intervention, a sustained impact may occur.[8]

Family-based interventions can be effective, even for families in stress, and may prevent internalized homophobia. Fortunately, data from many parent and family-based prevention programs that target diverse adolescents health risks, including substance use, mental health and violence, suggest that interventions can be effective. Programs can be efficacious even in distressed and at-risk families. Family-based interventions, including Project STYLE, are effective in reducing sexual risk in at-risk (largely heterosexual) adolescents by improving in emotional connectedness, communication about sex, and monitoring.[13, 47-53] These interventions identify areas of common agreement for each family to promote connection and shared values. Even for distressed families who are facing the challenge of adolescent mental health, stigma, and substance use disorders, interventions can establish a common, collaborative framework. Intervention during adolescence, when self-esteem and family dynamics are not yet entrenched, may help prevent internalized homophobia and family alienation that is commonly reported later by adult MSM.[54]

Pilot trials with non-heterosexual adolescents suggest that online interventions can be effective and that parents are interested and can be engaged. Four recent published pilot trials are relevant to this project [two open trials from the 1990s are not summarized [55, 56]]. An online 100-minute multimedia intervention for non-heterosexual youth was associated with improved safer sex and sexual orientation attitudes at posttest.[9] The online intervention was highly acceptable to youth and, although the study lacked a comparison condition, the results suggest that an online intervention can impact relevant attitudes. Unfortunately, behavior was not assessed and families were not enrolled. Hidalgo [10] conducted a pilot RCT with 101 young MSM (mean age 18) and found that the group intervention resulted in less sexual activity while using substances. Although the group format was “moderately acceptable,” only half of the sample attended at least 50% of the sessions. Huebner reported on a 35-minute video designed to improve caregiver behaviors towards LGB youth.[11] It was made available online and was viewed by 1,865 parents or caregivers. Most reported that they had not received any formal support in dealing with their child’s sexuality and they found the video to be helpful. Unfortunately, adolescents were not targeted and behavior change was not assessed. In a clinical intervention, Diamond adapted a family-based treatment for suicidal non-heterosexual adolescents to address parental concerns and reactions to their child’s sexual orientation.[12] The small study found that intervention with adolescents and their parents reduced depressive symptoms. Parents were engaged, retained, and their anxiety about sexual orientation reduced. The studies suggest that some parents of non-heterosexual adolescents may want help with their child’s sexuality and can be engaged safely; a short video can positively impact parent/caregiver attitudes; and online interventions are effective. Given the HIV/AIDS crisis among Black Americans in the southern US, having such a program available to willing parents and their non-heterosexual sons is an important prevention initiative.

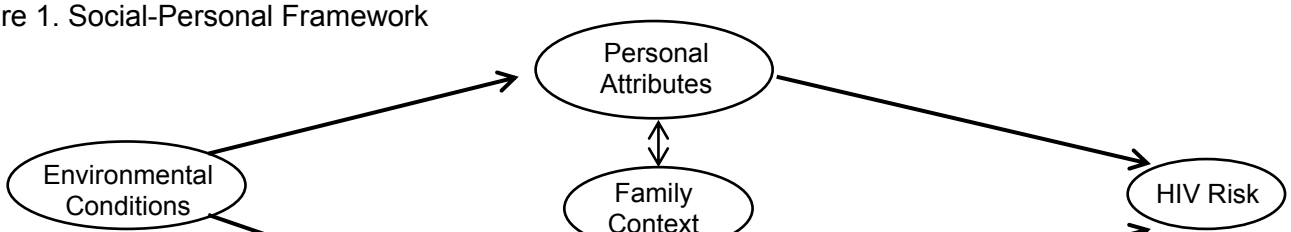
INNOVATION

This test of an online, family-based HIV prevention program for nHBAM will be the first of its kind. The adaptation of STYLE into MySTYLE is highly innovative: it will be designed through qualitative research to strengthen adolescent – parent relationships, involve parent/caregivers in a design that is safe for nHBAM adolescents, and it will be comprised of a sample of nHBAM experiencing a citywide epidemic of HIV that is one of the worst in nation. Additionally innovative is 1) that this is an online program thereby transcending pragmatic barriers to dissemination and making it readily scalable for use by community-based organizations and youth-serving organizations; 2) the adaptation for nHBAM is valuable given the ever-decreasing age of HIV acquisition among MSM. The addition of parent/caregiver involvement to improve family connectedness will further protect nHBAM against HIV; 3) it can be applied to all nHBAM (regardless of sexual behavior or age). This intervention takes a developmentally sensitive and broader approach to sexuality, rather than focusing exclusively on adolescents identifying as MSM; 4) parent/caregiver involvement will be optimally safe – the project will not require adolescents to reveal their sexual behavior to others; 5) in contrast to other online interventions for AMSM,[9] nHBAM will be enrolled in-person or digitally via HIPAA-compliant video conferencing platform thereby boosting internal validity because the sample and its SES and geographic distribution can be assured.

PRELIMINARY STUDIES

STYLE is an efficacious, theory-based, face-to face family-based HIV prevention intervention (R01 MH63008) and has been designated as a "best evidence" intervention for risk reduction by the CDC. We propose to adapt STYLE to be tailored specifically for nHBAM and their parents/caregivers. STYLE was developed to reduce HIV risk among adolescents by improving motivation, relevant knowledge, family communication, and behavioral skills. Some activities were separate for adolescents and parents, and others were joint. The project promoted positive family connections as a basis for improved sexual communication and monitoring. The intervention was based on the **Social Personal Framework (SPF),** which expands on Social Learning Theory by adding important psychosocial, contextual risk and protective factors.[13, 57] This framework specifies relationships that can be targeted to reduce HIV risk (see Figure 1). It proposes that adolescent risk behavior is a function of personal attributes (e.g. knowledge, attitudes, self-esteem), psychological functioning (e.g. depressive symptoms, substance use, PTSD), family context and parenting practices of communication and monitoring of adolescent's activities, peers and whereabouts, relationship concerns (e.g. peer and partner influence), and community factors. Adolescent HIV risk is most distally influenced by environmental factors (i.e., crime, poverty). Family factors contribute to the development of adolescents' sexual attitudes, behaviors and values, while also influencing adolescent peer and partner relationships through monitoring and parent-adolescent communication. Personal attributes and peer/partner relationships are two proximal factors that can directly influence adolescent HIV risk. The SPF, which was used for STYLE, is a broad framework that can incorporate attitudes relevant for any intervention population and any health behavior. Any factor found to be relevant by prior research or formative work can be included. For example, homophobia (a personal attribute of the teen, and an attitude of the parent) can be addressed by targeting adolescent internalized homophobia and parental acceptance of sexual orientation. Psychological factors of both adolescents and parents were significant areas of attention in STYLE. The SPF was a useful framework to organize formative material and guide intervention development. Psychological trauma, depressive symptoms and substance use (i.e. Personal Attributes) are possible risk factors for some nHBAMs. For parents, anxiety about their teen's sexuality and consequent difficulty with parent – child communication (i.e. Family Context) would likely be found in formative work and become intervention targets.

Figure 1. Social-Personal Framework



STYLE reduced sexual risk in a sample of distressed, stigmatized youth. Its efficacy was evaluated in a multi-site (Providence RI; Atlanta GA; Chicago IL) randomized clinical trial that included 721 adolescents **(60% Black)** in mental health treatment and their caregivers. [13] STYLE, compared to a time and attention matched general health promotion condition, resulted in fewer unsafe sex acts (adjusted rate ratio=0.49, p=.01), greater frequency of condom use (adjusted relative change=59%, p=.01), a greater likelihood of avoiding sex (adjusted odds ratio=1.44, p=.05), improved HIV knowledge (p<.01) and greater HIV prevention self-efficacy (p<.05) three months after the intervention and the effect was not moderated by race. There were also improvements, by report of the adolescents, in effective parenting practices: more parental monitoring (p<.01), less parental permissiveness (p=.05) and more parent-teen sexual communication (p<.01). Subsequent analyses demonstrated that the improvements in family functioning were evident six months after the intervention and that even highly distressed caregivers with mental health symptoms showed improvements in their parental functioning.[58]
STYLE reduced adolescent risk behavior and improved important parenting practices and connectedness in families under stress. Many caregivers were fearful, ashamed and openly hostile with their adolescent. STYLE was successful in helping caregivers find areas of agreement and connectedness with their adolescent as a foundation for change. Fifteen percent of the participating caregivers were not the parents or legal guardians. Non-guardian caregivers were nominated by the family. Caregivers included highly trusted family relatives (e.g. aunt, grandmother) or stable family friends. We propose to use this procedure with MySTYLE.

A Video DVD of STYLE (R44MH082103) was effective for Black community adolescents. Techniques and principles from STYLE formed the basis for the development of a targeted, interactive DVD ("Work it Out Together") to reduce HIV risk among Black adolescents by improving motivation, relevant knowledge, and behavioral skills. Similar to STYLE, it focused on improving family communication, connectedness, and parental practices. The intervention was introduced by a 35 minute Novella, which can be viewed at https://www.youtube.com/watch?v=GUjDLDNZYJY. It was developed in conjunction with MEE Productions, which will develop the online multimedia content for this project. MEE is a minority-owned media company specializing in the development of culturally appropriate learning videos for adolescents. The engaging novella provided a context in which to embed the intervention content. The vignettes involved a teen couple, their close friends, and parents and examined healthy and unhealthy behaviors. Adolescents and parents were shown the same film to become engaged in the story and outcomes. Scenes were replayed to emphasize points and to allow for personal reflection. Suggestions for "practice" were made to participants but they decided on when and what they practiced. On average, participants spent about 120 minutes viewing the DVD. The DVD for Black adolescents addressed both delay of sex/ return to abstinence and

condom use and health concerns in the Black community. All teens received important basic information about sex and protection and were directed to more detailed information based on their interest and experiences. Adults were provided with information on adolescent development, motivation to enhance positive connections with adolescents, techniques fostering trust, and tools to improve parenting practices (including assertive communication and parental monitoring). In addition, parents were shown techniques on how to engage their adolescents in discussions about safer sex; both prior to and after adolescents have become sexually active. In the trial, 94% of adolescents (41% sexually active) and their caregivers were retained at three months post-intervention. The program resulted in greater adolescent HIV prevention self-efficacy (42.58 vs. 40.35, t (158) = 2.28, p =.02,) and greater condom use self-efficacy (49.10 vs. 45.84, p =.04). Adults reported more effective parenting practices: discussions with adolescent (21.11 vs. 19.89, p =.04) and parental monitoring (23.81 vs. 22.50, p =.04), with adolescents also tending to report greater parental monitoring (20.90 vs. 19.24, p =.06).

Methods for recruitment of nHBAM and parents have been tested in Jackson, MS and preliminary input on the intervention obtained. In preparation for this proposed project, two focus groups with 16 of 17 identifying as nHBAM (mean age 16) and their parents/caregivers were conducted. Seven of the adults were extended relatives or close family friends, which emphasizes the need to include other caregivers in the intervention, with approval from parents (similar to STYLE). Participants said that HIV was a "huge problem" and parents said that they were very worried about their sons' health and problems all of their relationships. Parents and teens thought that a mobile phone intervention with brief novella videos similar to the STYLE DVD was novel and could easily reach participants. They suggested that the program be called "Family Table Talk: Building Healthy Relationships for Straight and Gay Teens," to emphasize the acceptance of sexual diversity and to include material on improving non-sexual relationships, which is needed by families. Participants thought that even if straight teens enrolled that they would benefit because "accepting yourself helps you accept others," and "we all need families to understand us more," and "even if a guy thinks he is straight, he could still end up having sex with another guy later." Focus group participants were easily recruited by a research assistant familiar with the local MSM community, a school guidance counselor, and staff in the Adolescent Medicine Clinic. We will use similar recruitment methods in the proposed project, in addition to participant referral and response driven sampling, peer ambassadors, flyers in CBOs and schools, and through targeted advertisements posted on various social media platforms (such as SnapChat, Instagram, and/or Twitter). **These methods will not result in sample that is perfectly representative of all nonheterosexual adolescent males, since enrolled parents and teens will be amenable to the intervention. However, it will provide valuable data on the feasibility and acceptability of a media-based intervention for families who desire assistance in protecting their sons against HIV acquisition.**

APPROACH

Please note: In the Approach section, we use the term **parent** to refer to the legal guardian of the adolescent and **caregiver** to refer to any family member or trusted, involved adult.

Overview. The project will use formative work to adapt the family-based Project STYLE and its media material to the needs of non-heterosexual Black adolescent males (nHBAM) and their parents/caregivers in Jackson MS, the urban area with the highest prevalence rate of HIV among MSM in the US (39.5 per 100 MSM).[2, 3, 5] In preparation for this project, we recruited 16 nHBAM and their caregivers for two focus groups from community-based agencies, adolescent medicine clinics and a school in a high HIV-prevalence neighborhood of Jackson, MS. Recruitment will also occur through our Advisory Board and two HIV clinics directed by our Jackson-based co-investigator, Dr. Mena. As suggested in our focus groups in Jackson, the

project will be called "Family Table Talk: Building Healthy Relationships for Straight and Gay Teens," or something similar, so that we will enroll adolescents and parents/caregivers who indicate interest in healthy adolescent relationships and acceptance of straight and gay adolescents. The project will not require adolescents to reveal their sexual behavior or attitudes. We expect that the majority of youth who participate will be non-heterosexual, similar to our focus groups.

Year 1 will include formative work using three focus groups interviews with approximately 15 nHBAM, 15 parents/caregivers, and 15 interviews of stakeholder from staff such as schools, LGBT-friendly organizations, churches and state agencies. Using **the ADAP-ITT model**[59] and other models of digital intervention adaptation,[60] findings from the Year 1 interviews will inform the **Year 2 iterative development and refinement phase**. This phase involves iterative cycles of program development and refinement between the investigators, a Community Advisory Board, and the media development company (MEE Productions, see Facilities and Other Resources). Year 2 will culminate in the creation of MySTYLE, an 8-session online intervention program that will use an engaging novella to increase motivation and skills that support healthy sexual behavior, communication, and family processes (connectedness and parent practices) for nHBAM and their parents/caregivers. MySTYLE will be tested for feasibility and effect size in a small **Randomized Trial Phase in Year 3** and compared to a waitlist control. At the completion of the study, up to 30 interested participants (youth and parents) will be asked to participate in a qualitative interview or focus group to provide additional feedback on the MySTYLE intervention videos. Participants must have completed intervention activities in order to participate in the qualitative interview or focus group. Youth and parent focus groups will be conducted separately.

Research team. Dr. Brown (mPI)**,** is Professor in the Department of Psychiatry at Brown University. He has used qualitative methods to tailor and then test HIV prevention interventions for adolescents in five NIH-funded RCTs and several multi-site trials. One intervention outcome paper, with an impact lasting for up to 9 months, received the Reiger Award for Scientific Achievement from the American Academy of Child and Adolescent Psychiatry.[61] **Dr. Crosby** (mPI) is a Professor at the University of Kentucky School of Public Health and was an investigator on Project STYLE with Brown.[13] He is the PI of three efficacy trials of a safer sex program for young Black men,[62, 63] including a current NIMH-funded trial for adolescent and young adult Black MSM in Jackson. **Dr. Mena** (co-investigator) is a Professor of Medicine at the University of Mississippi Medical Center. He is the medical director of the Crossroads Clinic and the Open Arms Clinic, the only publicly funded HIV clinics in the state. This team is multidisciplinary, experienced in collaborative community-responsive adolescent and MSM research, and have previously collaborated in Jackson.

Research partner - A **Community Advisory Board (CAB)** will inform our project and will be essential members of our workgroup in Year 2. It will meet at least quarterly (monthly or as needed in Year 2) and it will be composed of 4 nHBAM, 4 parents/caregivers, and 4 community members. Four nHBAM from our recent Focus Groups have agreed to join our CAB and others will be solicited from Focus Groups in Year 1.

Research partner - Media Company: MEE (Motivational Educational Entertainment) Productions, Inc., has 20 years of HIV prevention experience. MEE is committed to developing cost-effective, cutting-edge and culturally relevant messages for low-income and underserved audiences. [www.meeproductions.com]. MEE has worked with Dr. Brown on two previous projects, including the development for the media content of the STYLE adaptation described above. The introductory novella that they created for the STYLE adaptation can be viewed at https://www.youtube.com/watch?v=GUjDLDNZYJY. MEE creates digital ads, radio and television public service announcements and advertising, small print and large outdoor media, online training tools and a wide array of educational videos with accompanying discussion guides. MEE focuses on delivering culturally relevant/specific

messages across the many communications platforms that are now available. The company has also developed new uses of e-health technologies, including text messaging and interactive DVDs, to deliver critically important health and behavior messages to youth and young adults. MEE has received national and international recognition, including Freddie, Telly and Regional Emmy Awards, for its research-based multimedia productions.

Eligibility criteria. Eligibility criteria for adolescents in all phases of the project will be: 1) at least 13 years of age but no more than 20; 2) stably-housed (have resided with the same adult caregiver for the past 6 months and no plans to leave the city or caregiver in the next 8 months). We understand that this will preclude homeless youth who may be at risk for HIV but MySTYLE will not be designed to address the numerous structural need of chronically homeless youth; 3) the ability to read and speak English; 4) identify as a male; 5) and identify racially as Black African American. Exclusion criteria will be: a) not able to provide meaningful assent as determined by research staff, b) known HIV-infection (staff will facilitate entry into care if needed). Although we expect that most enrolled youth with be nHBAM, heterosexual youth who enroll will be able to complete all intervention activities. Eligibility criteria for **Parents/caregivers** for all phases of the project will be: 1) parent/caregiver or trusted adult of an adolescent who is potentially eligible for enrollment into the study; and 2) English speaking. In addition to the aforementioned criteria, participants who have completed the MySTYLE intervention activities will be invited to participate in an exit interview or focus group (via a video conferencing platform or in-person, if safe to do so). These methods will not result in sample that is perfectly representative of all nonheterosexual adolescent males, since enrolled parents and teens will be amenable to the intervention. However, it will provide valuable data on the feasibility and acceptability of a media-based intervention for families who desire assistance in protecting their sons against HIV acquisition. It will reflect the population that would become recipients of MySTYLE once it has demonstrated efficacy and is being used in practice.

Recruitment. Our team has successfully recruited and retained at-risk adolescents and MSM and these methods will guide our project. The severity of the HIV epidemic among the Black community in Jackson has fostered an unprecedented level of willingness on the part of the community to fully support and direct youth and parents to the proposed study (see letters of support). As suggested in our focus groups in Jackson, the project will be called "Family Table Talk: Building Healthy Relationships for Straight and Gay Teens," or something similar. We will enroll adolescents and parents/caregivers who indicate interest in healthy adolescent relationships and acceptance of straight and gay adolescents. The project will not require adolescents to reveal their sexual behavior or attitudes. The project will use two experienced community recruiters with close ties to adolescent and LGBT relevant CBOs (My Brother's Keeper, the Teen Program of Mississippi First, GSA of Jackson, see Resources), agencies / clinics (adolescent health, HIV and STI clinics, and schools (via referral from school health and guidance counselors). Recruiters will publicize the project to youth at agency functions and with flyers/social media announcements. The agencies and schools will also direct potentially at-risk youth to the project. We will also utilize targeted advertisements posted on online social media platforms (e.g. SnapChat, Instagram, and/or Twitter) to recruit nHBAM. Referrals and advertisements will provide the contact information of the study project director, who will promptly initiate contact and seek parent consent if the youth is interested. Our Advisory Board, peer ambassadors and currently enrolled participants will also assist in recruitment. Currently enrolled participants will be incentivized to recruit up to five new participants and will receive an additional $10 for each referral that is enrolled in the study. The Jackson urban area has a population of 574,998; 26% are under the age of 18, 48% are male, half are adolescents, and 5% will identify as non-heterosexual.[64] Based on these estimates, we will be recruiting a total of 97 non-heterosexual Black adolescent males (nHBAM) for all phases of the project from a pool of at least 1,794 non-heterosexual adolescent males in this urban area. In other projects, Dr. Brown has enrolled 1,923 at-risk adolescents with parental consent by similar methods in 5 NIH-

funded RCTs, with 1-year retention from 75 to 86%.[13, 61, 65, 66] His enrollment has targeted diverse youth including youth in mental health treatment, in alternative school settings, in community-based organizations, or in juvenile justice facilities. Drs. Mena and Crosby have enrolled 600 young Black MSM into a 12-month RCT in Jackson, MS.[63, 67, 68]

Enrollment. For both the formative phase and the RCT we will enroll balanced numbers of participants by age (≤16, >16).

In the Formative phase, interested nHBAM will be asked to give our study team permission (and contact information) to enroll their respective parents/caregivers to: 1) provide written informed consent for those under 18 and 2) to also participate in the project. The project will be described as an intervention developing healthy relationships in Black adolescent males and to increase acceptance for hetero and hetero teens; **it will not disclose the adolescent's private behaviors or attitudes; and will not require adolescents to disclose any sexual behavior.**

In the Formative phase, Parents will be contacted by phone and written informed consent for obtained in person. If the parent (legal guardian) agrees to their son's participation in the project but does not want to participate, the parent and adolescent can nominate "someone important in the life of the adolescent such as other family, teacher, religious leader, or social worker" who will be contacted for enrollment. Caregivers will not be enrolled in lieu of a parent unless the parent agrees. This option of involving a caregiver, rather than a parent, worked well in Project STYLE, and involving a non-parental adult was recently recommended as an intervention option for non-heterosexual adolescents.[69] Even if a parent/caregiver never participates in the intervention, MySTYLE, may improve the family climate by focusing on healthy family communication, similar to other studies finding an impact without all family members attending sessions.[70]

See **RCT Phase** for details on enrollment for that phase.

Formative phase (PY01). Aim 1: To use interviews with nHBAM, parents/caregivers, and other stakeholders (e.g. staff from schools and relevant organizations) to identify the relevant elements needed for a family-based intervention for nHBAM and their parents/caregivers. [**Appendix 1]** Focus groups with nHBAM, caregivers, and stakeholders will address the relevant elements needed to adapt our family-based intervention. Themes will be identified as to how the family and community environments of nHBAM have influenced their HIV-related knowledge, attitudes and behavior (KAB). All data will be organized using the Social Personal Framework allowing the impact of family/community influences to be examined in relation to KAB. In addition, focus groups (of nHBAM, caregivers, and stakeholders) will be designed to elicit insights on the design, content, and tailoring of MySTYLE. The findings will inform Aim 2 (development of MySTYLE) and will also solicit interest in becoming a member in the intervention development Work Groups.

Focus groups of nHBAM. The three focus groups with ≈15 total nHBAM will begin with a screening of segments of our MEE-developed videos, as a prompt to explore factors relevant to nHBAM in each scene. Scenarios will deal with all of the preliminary, draft content area such as the spectrum of adolescent sexual development, relevance of HIV, stigma and poor self-esteem, assertive communication and privacy concerns with parents and peers, challenges with parental/caregiver support, sexual safety, and coping with personal challenges of substance use, depression, and trauma (see Intervention Conditions in RCT Phase below). The MEE video clips are primarily heterosexual but address all of these topics in relation to a group of Black teenagers with different families, areas of conflict, and types of support. Group members will be asked: "Is the topic you just saw relevant to the typical Black teen male who may be gay (or not fully heterosexual)?" and "What other things could be added?" and "Did the characters sound realistic?" Because teens are not speaking personally, this technique can create trust and rapport. Next, an informal version of the nominal group process will be used to increase

participation. The group will consider how the content is influenced by the Social Personal Framework factors (personal attitudes, family, peers / partners, and community /structural) in relation to their KAB. Each adolescent will receive four color-coded cards that will signal whether they believe a topic area is a product of: a) their personal thinking (blue card), b) influenced by parents (red card), c) influenced by peers or dating/sex partners (green card) or d) influenced by life in their community (yellow card). Adolescents may hold up one, or more cards at a time. Probes will explore race, stigma, culture, and age interact with family, peers and the community in all content area. For instance, if several teens indicate that families "have influence over the overall mental health and happiness" of nHBAM, then further probes could include: "How could parents show gay teens support?" and "What are gay or undecided teens, afraid of the most in talking with parents?" "How is it different depending on age? Or if you have an older friend that your parent does not trust?" This final segment will assess the priorities for intervention content (especially as influenced by age and sexual experience), additional needed topics, and the best methods for intervention delivery. We will also solicit ideas as to the most effective methods for recruitment and retention.

Focus groups of parents/caregivers. Three focus groups with ≈15 total parents/caregivers will assess their views and personal perceptions regarding: 1) Intervention content that is relevant and acceptable, 2) preferred formats of intervention delivery, and 3) effective recruitment methods for parents/caregivers. Staff will solicit feedback in two broad areas – the needs of nHBAB and the needs of their parents. Similar to the adolescent focus groups parents will begin with a modified theatre testing exercise prompted by MEE-produced video clips. We will use the same techniques and questions as with adolescents. Questions will be designed to elicit responses in three categories: 1) what parents want most from this type of program, 2) fears or concerns they have about being part of the program, and 3) suggestions on specific content for parent-related and teen-related aspects of the program. Probes will examine parents' sexual norms, sexual knowledge, their perception of community sexual/social/racial discrimination, and areas of conflict, acceptance, and support in the family. A closing segment will ask parents about their thoughts on how we can optimize our recruitment and retention methods.

Individual and group interviews of stakeholders. Whereas the focus group sessions with teens and parents will be quite similar in structure and content, interviews with stakeholders will be much different. Because we are defining "key stakeholders" as people who are directly providing sexual health services to teens in Jackson, the 15 people we interview will have a wealth of ideas and opinions as to the intervention content (for both teens and parents), intervention methods, and recruitment/retention methods. Thus, the interview guide for stakeholders will be centered on eliciting views and ideas regarding the primary socio-sexual issues that nHBAM face in Jackson. Questions will be generic at first and progressively become more specific. For instance, an early question will be: "Please tell us about levels of acceptance of non-heterosexual males in high schools in Jackson and in the community." A later question would be: "Can you also please describe your thoughts or experiences with parents as an influence on prejudice or discrimination about not being fully heterosexual?" Other items item would be: "Are some parents highly accepting of a son's non-heterosexual orientation?" and "What factors influence parents' degree of acceptance?" Because stakeholders are community professionals, we anticipate that they will be very eager to offer ideas and thus we hesitate to overly-structure the sessions (as doing so would constrain the otherwise in-depth value of the interview).

Interview reliability. Interview guides will contain detailed protocols for administration. Two trained staff members will conduct each focus group. They will be trained by Dr. Brown to use skills such as reflective listening, probing, and the use of vignettes to promote thought and discussion. This training will also involve techniques from theatre testing such as eliciting dialogue pertaining to content, message presentation and its framing. Consistency will be

maintained by weekly calls with Drs. Brown, Crosby and Mena to discuss the interview details and unexpected events. All interviews will be audio-recorded and Dr. Brown or Crosby will listen to each focus group for adherence to procedures and to inform analyses.

Analysis Plan (Aim 1). Identify factors relevant to HIV prevention and family-based intervention delivery. Interviews will be audio-recorded and transcribed. We will use the Rapid Approach to examining all interview data, which is appropriate when interview topics are focused.[71] The data will be aggregated using the Social Personal Framework (see Preliminary Studies) thus allowing the impact of family, peer and structural community influences to be examined in relation to adolescent attitudes and behavior. The data will suggest the ways in which family, peers, and community influence sexual safety for nHBAM and how the healthy influences can be augmented and unhealthy ones lessened. The data will guide the final content development of MySTYLE and the novellas. Also, we will examine whether any sample composition factors (e.g. age) require attention; identify pragmatic issues such as how to best recruit and retain nHBAM and their caregivers; and the best methods to deliver the intervention. Drs. Brown and Crosby have experience in this area. For example, Brown completed a mixed methods study of a culturally tailored STI/HIV prevention campaign for African American teens with a TV/radio media component (IMPACCS, U01 MH066785)[72] and the methods are similar to that used to create the STYLE DVD with the media company.

Program Development (Year 2). Aim 2: To use the **ADAPT-ITT Model** in an iterative approach between our **investigators, the Community Advisory Board, and a media company** to refine the family-based MySTYLE and its media material. The **ADAPT-ITT model** is specifically designed for adapting HIV-prevention programs. [59] Briefly, the model begins with a qualitative phase (Aim 1) and proceeds to the intervention development workgroup. The workgroup will consist of our **Community Advisory Board** (4 nHBAM, 4 parents/caregivers, and 4 community members, see above in **Research Partners**) and the three investigators. The workgroup will use the interview findings to inform the language, approaches, interactive components, and contextual details of the intervention. A nominal group process will be employed to facilitate balanced decision-making; consensus building will be the priority of each meeting. Workgroup meetings will be held monthly or more frequently to use themes from interviews to build storyboards (i.e. video production draft) that will be used for the development of brief video novellas by MEE Productions for MySTYLE. Dr. Brown has used this process successfully in adapting two efficacious interventions into digital media self-guided interventions that completed the formative work and the video production in less than two years (R44MH082103; R44MH102140).

Pilot Trial to determine intervention acceptability. The full "beta" version of MySTYLE sessions will be tested with a new cohort of 10 nHBAM and 10 parents/caregivers for acceptability and relevance of content and feasibility of the procedures. The Workgroup members will view and rate the full "beta" version of MySTYLE sessions. Participants and Workgroup members will complete the Session Evaluation Form [73] and the Client Satisfaction Questionnaire[74] to assess the clarity, relevance and appeal of the activities and their reactions to the sessions (Appendix 2). Mean scores of 24 on the CSQ and 30 on the SEF will be deemed as acceptable for each complete session. Refinement will continue until all sessions meet these criteria.

RCT Phase (Year 3) Aim 3: To conduct a preliminary test of the efficacy of MySTYLE compared to a waitlist control on knowledge, attitudes and behaviors of 72 nHBAM and their parents/caregivers.

Procedures: This two-arm randomized controlled trial will have an 8-week intervention period followed by a post-test and a later follow-up (baseline, 2, and 4-month assessments) to

compare MySTYLE to a waitlist control condition. Participants assigned to the waitlist control will receive the 8-week MySTYLE intervention after the active treatment group. Waitlist participants who participate later in the MySTYLE intervention will also complete assessments at 6 and 8 months. This will provide a test of feasibility and it will assess effect size differences to inform an ensuing R01 application that will provide a formal test of MySTYLE.

nHBAM Enrollment: In the RCT phase, a waiver of parental consent will be requested for those under 18 and youth aged 18 or older will be able to provide their own consent. A waiver of parental consent for those under 18 produces a sample that is more diverse in terms of the extent to which nHBAM have disclosed their sexual attitudes to others, their degree of perceived stigma and discrimination, and their perceived support from, and engagement with, parents. Recruitment procedures for the RCT will be similar to those employed during the formative phase of the project. Community recruiters will publicize the project to youth at agency functions and with flyers/social media announcements. The agencies and schools will also direct potentially at-risk youth to the project. We will also continue to utilize targeted advertisements posted on online social media platforms (e.g. SnapChat, Instagram, and/or Twitter) to recruit nHBAM. Our Advisory Board, peer ambassadors and currently enrolled participants will also assist in recruitment. Currently enrolled participants will be incentivized to recruit up to five new participants and will receive an additional $10 for each referral that is enrolled in the study. Referrals and advertisements will provide the contact information of the study project director, who will promptly initiate contact with the youth and use the waiver of parental consent to enroll the youth if he is interested.

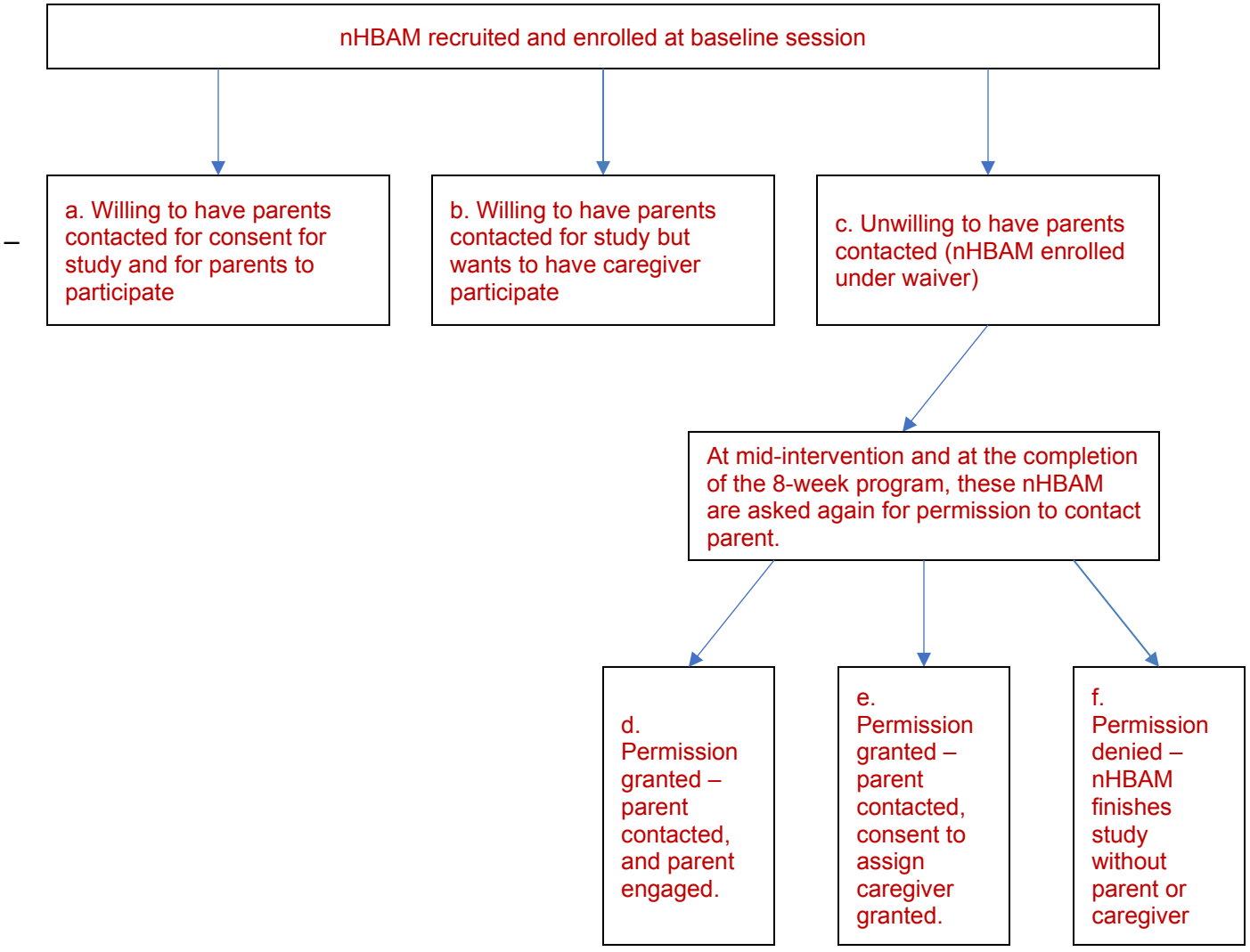
Digital consent, enrollment, and follow-up: In light of the COVID-19 outbreak, several of our recruitment sites (i.e. CBOs, clinics, and schools) have either closed or are limiting non-essential visits. This limitation severely impacts our ability to recruit and enroll potential participants in-person for the RCT phase of this project. We are proposing to offer digital consent and enrollment via HIPAA-compliant platforms (i.e. DocuSign, HIPAA-compliant video conferencing platforms). nHBAM identified as eligible, based on an online REDCap screener, will be asked if they would like to be contacted by study staff. Those that indicate they would like to be contacted will then be asked to provide their name, email address, and phone number. UMMC research assistants will follow up with interested parties by phone or email. Those who wish to participate will receive a DocuSign consent form via email from the UMMC research assistant and will be given the opportunity to participate in a video conference call (via HIPAA-compliant video conferencing platform with the UMMC research assistant to review the consent form. The DocuSign consent form will outline study aims and procedures and contains language regarding the risks/benefits of participating in a research study. The online survey data will be de-identified and kept in a password-protected participant log on a secure server. Participants will be given ample time to consider risks of participation and will have the opportunity to ask questions during the video conference. Participants will also be reminded that study participation is voluntary and that refusing to participate or withdrawing from the study at any time will not result in any negative consequences. For the remaining follow-up appointments (at 2- and 4-months, and additionally at the 6- and 8-month appointments for waitlist control participants) participants will be emailed their online REDCap surveys and will receive online gift cards for each completed survey. At the 4-month appointment, nHBAM will be offered a home HIV testing kit, that will be mailed to them by UMMC, in lieu of an in-person HIV test.

Parent or caregiver enrollment: The RCT allows nHBAM into the program before parent/caregiver involvement is requested (with a waiver of parental consent for those under 18) and then prepares nHBAM to safely involve their parent, if possible. More detailed information on the process is shown in the schematic below. nHBAM aged 18 or older

will be able to provide their own consent, although we will ask for permission to enroll parents/caregivers, if possible and safe for the youth. The project will be described as a general sexual health intervention for adolescent males; it will not disclose the adolescent's private behaviors or attitudes and will not require adolescents to disclose any personal information.

Parent/Caregiver involvement may begin at study entry, at the middle of the intervention or immediately after the 8-week intervention, after the nHBAM has had more time to consider it. Parents/caregivers will be assigned to the same condition as their adolescents.

RCT Phase



a.) These adolescents are likely to have highly supportive parents who enroll as well. nHBAM will give consent for their study enrollment and permission for the study to contact parents for their participation.
b.) These adolescents may nominate up to 4 caregivers – the project director may then obtain parental consent and parent engagement (less likely than "a') or parental consent and parental agreement for caregiver to enroll in place of the parent. nhBAM aged 18 or older will be able to give consent for caregivers to enroll but caregiver enrollment is not required.
c.) We will not pressure these adolescents to allow us to make this contact – their reticence is a clear sign that a waiver of parental consent is warranted for safety reasons.
d.) As a result of intervention efforts nHBAM from "c" are asked again at mid-intervention and at the end of the intervention for permission to contact a parent – those agreeing may then have that parent become engaged in the study.
e.) As a result of intervention efforts nHBAM from "c" are asked again at mid-intervention and at the end of the intervention for permission to contact a parent – some may agree only for the purpose of gaining parental permission to involve one of four nominated caregivers in the study. nHBAM aged 18 or older will be able to give consent for caregivers to enroll but caregiver enrollment is not required.
f.) These adolescents will continue under a waiver of parental consent if under 18 and do so without a parent or caregiver being engaged. Adolescents aged 18 or older continue under their own consent.

Randomization: Immediately after completing baseline assessment, small block randomization (via REDCap) will create groups balanced on age and on the proportion who identify as nHBAM. We estimate that 90% of those enrolled will be nHBAM. **72 participants** will provide sufficient power for the analyses (see Data Analysis). **Recruitment will continue until 72 nHBAM are enrolled**.

Format: Immediately after randomization, participants (adolescents and parents/caregivers) in the active (MySTYLE) condition will receive two secure, HIPAA compliant texts or emails to their mobile phones or preferred indicated device each week for eight weeks and each text/email will contain a link to new media content (overall, at least 120 minutes of multimedia time is planned, not including participant replays, which is comparable to our interactive DVD and to an online RCT conducted by Mustanski and colleagues).[9] The weekly content, as well other content and interactive materials, will be available on their condition's secure website. All nHBAM and enrolled parents/caregivers will each have their own links with separate, but parallel, content (see Figure below in Intervention Conditions). Those participants assigned to the waitlist will be eligible to participate in MySTYLE after they have completed their 2- and 4-month assessments. They then will receive two secure, HIPAA compliant texts or emails to their mobile phones or preferred indicated device each week for eight weeks and complete further assessments at 6 and 8 months. If those enrolled in the waitlist choose to participate in MySTYLE, they will have the opportunity to include their parent mid-intervention. During the 4 months that the participant is on the waitlist, study staff will not engage with the parent.

Intervention fidelity and usage: The twice-weekly video/graphic content will be embedded in the participant's unique REDCap link, providing data on the number of videos viewed by each participant. The participant will not proceed to the next web page (containing options for their weekly practice, etc.) until the video has fully played, but it may be paused and resumed later. The videos/graphics will be posted on the website for repeat viewing. Analytics will be collected on the number of minutes enrolled nHBAM spend viewing project materials, the content accessed, and the number of times any one video was re-played.

Retention: Collectively, our research team has 1-year retention rates greater than 80% for young MSM and adolescents. In an on-going RCT in MS, Crosby and Mena have recruited 600 Black MSM (ages 15 to 29) and 3-month retention for those under 20 is 98% and Dr. Brown's 1-year have ranged from retention rates have ranted 75 to 86%.[13, 61, 65, 66] Formative work and prior experience will inform our retention strategies. Effective techniques include (1) collecting primary and secondary phone/text numbers, e-mail addresses, and social media names at all assessments, (2) maintaining a primary staff contact with interim contacts, (3) a convenient assessment location, and (3) assessment reimbursements appropriate to the community standards. Retention efforts will be aided by use of a locally developed Access tracking database, including (1) specification of visit schedule, (2) generation of target dates for assessment based on protocol, (3) tracking of assessment instruments completed by visit, (4) linkage of participants with research assistant staff, (5) specification of completed and missed visits, (6) notes attached to each participant and visit, and (7) generation of customizable reports. All data in the tracker are easily exported to statistical packages, for easy linkage with other study data, which supports efficiency in data management activities.

MySTYLE Intervention Condition

MySTYLE is online, brief and encourages parent-adolescent communication about sex and HIV prevention. The formative research phase will determine the final content/format of MySTYLE but the earlier projects of STYLE and the interactive DVD will inform the proposed intervention aims, content, and techniques. Qualitative work from these projects suggested the intervention should be easily accessible (online), brief (each segment lasting only a few minutes), and encourage personal practice. Adolescents and parents want the topics to be personally relevant ("I'm worried my son is into drugs and sex but I can't talk to him because we fight all the time." Or "My parents don't need to know my business!") **MySTYLE will have three main targets:** (1) **Improved sexual health** (with relevant information, motivation, skills); (2) **increased acceptance of non-heterosexuality** by nHBAM and parents/caregivers; (3) **Improved parent – adolescent relationships** based on improved communication, connectedness and parenting practices. **MySTYLE will have many factors to sustain its impact:** (1) Multilevel approach which engages parents/caregivers; (2) Online for ease of access and repeat viewing; (3) Novella to enhance relevance for youth and parents/caregivers; (4) Behavioral practice to improve self-efficacy; (5) Social media elements to improve social supports; (6) Access to local resources; (7) Easily updated if new information or resources become available.

Session 1 will be a 7-10 minute novella introducing participants to an ongoing story that will be continued for 8 weeks. The engaging story, created with a sophisticated health media company (MEE productions; http://www.meeproductions.com/, see above or Facilities) will show interactions between three Black adolescent males, their families, friends and potential sexual partners. Novellas will feature communication, relationships and behavior that are healthy and unhealthy. Novellas will be relevant to participants, seek to improve social support, and to provide motivation for, and modeling of, healthy behaviors. The novella will be suitable and engaging for both nHBAM and parents/caregivers, so the intervention provides a common ground for both. Content will be tailored for the adolescents and also for the parents/caregivers. Adolescents and parents/caregivers will have similar content (e.g. HIV/AIDS facts), but also content that is specifically for them (e.g. Peer pressure for adolescents and Effective parenting practices for parents). The online intervention can be viewed and completed by the adolescent and parent/caregiver on their own. Some novella content will encourage communication in the family, which we will assess at follow-up assessments.

The first text each week will be a continuation of the novella. The relevance of the topics

for that week and their healthy/unhealthy aspects will be shown in the novella. The second text will provide follow-up content to reinforce and amplify the message and allow time for personal reflection. Material will emphasize the knowledge, attitudes and behavioral message of the novella (the "take home messages"), which will be narrated by the novella characters. A brief novella clip will emphasize the point and/or the character will explain their thoughts, feelings or the anticipated consequences of their action. Each week, participants will chose a behavior ("practice exercise") that they can do in the next week. Practice choices of participants and their subsequent utility ratings may be tabulated and viewed online to reinforce "practice" and group participation.

Content and format in interventions will be guided by our formative work. MySTYLE is proposed to include topics consistent with the Social Personal Framework and are shown in the figure below and in Table 1. The novella will introduce HIV as personally relevant to one of the characters, while others are unconcerned "because it can be treated." Variations in sexual interest and development will be portrayed, as well as common family and community reactions. Parents will explore ways to "find common ground and areas of acceptance" with their adolescent even when upset with their teen's sexuality. Parents will identify their personal concern, find their own supports and refocus the ways they can immediately support their child. Parents will also see examples of effective **parenting practices in supportive communication and monitoring**, which includes setting expectations, tracking activities and companions, and providing consequences. Both parents and nHBAM will view material on condom use, HIV/STI testing and treatment, and pre-exposure prophylaxis. Characters in the novella will experience fear of infection and find that STI testing is an essential element in self-care and also a "teachable moment" that heightens awareness of risk and protective behaviors. Several novella episodes will demonstrate health and unhealthy parent-adolescent communication. nHBAM will be encouraged to pick topics with parents that are meaningful and safe, and to use the assertive techniques that they are learning. Parents will see families in the novellas that are able to move from fear and disengagement to support of their adolescent and being an "ally in health." Stigma, trauma, mental health issues and substance use will be topics in the novella episodes. Their impact on health and behavior will be demonstrated so that the topics are personally relevant. The texts will provide novella examples of effective coping and the use of social support to build resilience. Links will be provided to local resources for nHBAM-relevant support, mental health / substance use treatment, medical care (e.g. routine care, STI/HIV testing, PrEP), family support (e.g. PFLAG), and vocational/educational assistance. Parents/caregivers and nHBAM will contemplate their life and family goals early in the intervention and then return to those goals to update them and plan for the future. All of the material will be online after the participant has viewed it (along with supplemental materials and links) so that it may be reviewed anytime. [Appendix 3 contains the STYLE adolescent and parent DVD workbooks to suggest relevant topics and techniques. This project will not construct workbooks, but it will have online supplemental material.]

Potential Challenges. The pilot study of 72 nHBAM in Year 3 will be monitored and treated as if it were a large-scale trial. This will optimize our ability to learn from the pilot study and thereby prepare for the ensuing definitive, efficacy trial. Three points will be prioritized: (1) Recruitment will be closely monitored, thus emerging issues, such as less than 90% of nHBAM in sample, will be identified and recruitment will be addressed. (2) Delivery of online content to be confidential. Participants will receive the text/link to their personal phone or email address and the links will not be able to be forwarded and content will not be downloadable. Adolescents could let others view the content on their device or show them the intervention's password protected website, leading to mild contamination. Thus, we will assess exposure to intervention content at follow-up to account for it. (3) Cell phone and email access is nearly universal [(75)] but if a nHBAM does not have this access, we will provide a smartphone and service plan at no

cost. (4) The RCT timeline is ambitious. The intervention is conducted using texts, which can be automated, so the limiting factor is recruitment. Our revised protocol does not have specific criteria for sexual behavior or orientation, so recruitment will be easier, as evidenced by our focus group success. Also, we will begin the RCT earlier (last quarter of PY02) to optimize the time available for its completion in PY03.

Measures for the Randomized Trial

Nonheterosexual orientation: Because youth are enrolling in a project to promote Straight – Gay Acceptance, we anticipate that nearly all will be nonheterosexual, that is they will identify with at least one of the following categories: a) have had at least one non-coercive intimate sexual experience (e.g., prolonged kissing, oral sex, anal sex) with a male, b) expect to someday have a male sex partner, c) sexually aroused by and attracted to males, or d) self-identify as gay, bisexual, gender-queer, or other term that is not heterosexual.
In addition to determining feasibility and acceptability of MySTYLE, the purpose of the small RCT conducted is to determine effect size differences in knowledge, attitudes, and behaviors. Given the reality of effect decay and the constraints of the R34, we will use only two follow-up assessments at 2 and 4 months after baseline. Participants assigned to the waitlist control condition will also complete assessments at 6 and 8 months. **Scale score outcomes** include relevant knowledge (e.g. HIV/ STIs), attitudes (e.g. internalized stigma, condom attitudes) and behavior (e.g. prevention self-efficacy, parental monitoring of teens' activities and companions, and practice exercises) (see Appendix 2). Scales will be adapted for nHBAM from those used in STYLE or by our investigators. Table 1 summarizes our central measures, as a function of the Social Personal Framework, and others may be added as needed based on our formative work. **Behavioral outcomes** are: (1) the number of condomless sex acts during the follow-up period, (2) the rate of onset of sexual activity and (3) the acceptance of an HIV test. Sexual behaviors, HIV testing history and STI history will be assessed in a computer-assisted self-interview designed specifically for use with adolescents and using branching logic so that they only answer items that are relevant. [76-78] As a dependent variable, adolescents will be offered a free point-of-care (POC) HIV test at 4. Also, self-report of prior HIV and STI testing will be assessed. Those who are not yet sexually active may decide against HIV testing and we will analyze the differences in testing rates separately based on self-report of sexual activity. Our outcome is testing, rather than the HIV or STI results because rates of infection will likely be low at this age, although the study will provide data on this issue in our high-prevalence city of Jackson, MS. **Intervention content acceptability**: At 2 or 6 months, depending on assigned condition, adolescents will complete the CSQ (see Year 2) to assess relevance and utility of the content and to aid in refinement of the intervention, if needed, prior to a subsequent, larger RCT.

Location: Assessments of adolescents at baseline, 2 months, 4 months, and 6 months (waitlist only) and 8 months (waitlist only) will occur in person in a safe, convenient location at the Jackson Medical Mall or the Jackson Medical Tower. Both locations are easily accessible and used by the entire community, which avoids stigma. **Mode**: REDCap is a CASI system that is HIPPA-compliant and meets HITECH security and privacy requirement (Appendix 4).

Parent/Caregiver Outcomes. All assessments for parents/caregivers will occur online, using the same REDCap software provided to adolescents. Parents will complete a parental version of all eight Family and Relationship scales in Table 1 (there is separate adolescent version of each scale), as well as measures of acceptability at 2 or 6 months (CSQ) depending on assigned condition.

Table 1. Social Personal Framework Factors, Intervention Targets, Measu

Social Personal Framework factors		Intervention	Measures
	HIV Knowledge	HIV Facts	HIV Knowledge Scale[79]

Personal Attributes	PrEP Knowledge	PrEP Facts	PrEP Knowledge Scale
	Internalized Stigma, Homophobia, Transphobia	Information, Motivation	Homophobia Scale (Wright et al., 1999) Genderism and Transphobia Scale (Tebbe, Moradi, & Ege 2014)
Risk Behaviors	Youth Risk Behaviors	Motivation, Skills	YRBSS (CDC 2017)
	Substance Use	Motivation, Skills	ASSIST[91];
	Sexual Risk Behaviors	Motivation, Skills	ARBA[76-78]
Family* A=adolescent P=parent	Acceptance of Sex/Gender	Self-safety Evaluation, Motivation	Acceptance Items[92]
	Parenting Practices	Information, Skills (e.g. monitoring of peers)	Silverberg Scale (PPM) [94, 95] **A/P** Intervention Practice exercises **A/P**
	Communication about Sex	Assertive Skills	Parent-Adolescent Sexual Communication Scale[97] **A/P**
	PrEP Items for Parents	Motivation	Parent Knowledge of PrEP item; Acceptance of son taking PrEP item **P**
Relationship Concerns A=adolescent P=parent	Family Support	Motivation, Assertive Skills	MSPSS[98] **A/P**
	Significant Non-family Adult Support	Motivation, Assertive Skills	Social Support[83] **A/P**
Community	a. Stigma	Knowledge, Coping Skills	Cultural Stigma[99]
	b. Healthy Resources	Knowledge, Assertive Skills	Resources Checklist

***The measures for this construct include both parent (P) and adolescent (A) forms**

POST-TEST INTERVIEWS

Post-test Interviews will examine the overall perceptions of participants as to how each module could be improved for greater appeal to other young males of a similar age and background as well as the attributions of youth regarding which modules (if any) had an impact on their sexual risk behaviors

In the final year, we will conduct interviews or focus groups of up to 30 participants (youth and parents) from the RCT phase. These data will be used to inform later adaptation of the intervention. Participants that have completed the intervention will be invited to complete a remote or in-person (if safe to do so) individual interview or focus group. Dr. Brown, Crosby, Mena or a trained senior research associate, who has experience with post-intervention interviews, will do all interviews. Interviews will be not audio-recorded. Instead, as a structured interview, the staff member(s) conducting the interview will take copious notes, on paper, during the one-hour session. These paper records will not be photocopied, scanned, or transcribed to a digital system in any way whatsoever. **Participant interviews or focus groups** will target

Intervention characteristics (e.g. "What module content or storylines did you find important/unimportant?" "What were your overall perceptions of how each module could be improved for greater appeal to other young males who you know?", "What impact did the specific module content have on your sexual risk behaviors, including intentions to have sex?"). We will use the Rapid Approach methodology to examine these data, which is appropriate when topics are focused.[67] This methodology organizes the major themes and identifies their strong or weak associations.[68]

DATA ANALYSIS PLAN

Data will be collected using the electronic data capture portal **REDCap**, and extracted for entry to statistical programs (e.g., SPSS). Syntax will be developed to arrange the data for analysis. Data will be extracted and archived on a monthly basis. Routines for assessing data integrity will be developed, with procedures established for accepting, correcting, or rejecting data. All data will reside on servers behind firewalls (with access restricted to study personnel) and on computers with hospital security enabled. All servers are routinely backed daily (to off-site locations). Transfer of data will be done using secure methods (e.g., secure FTP).

Analysis Plans for Aims 1 and 2 – see Formative Work earlier in this application.

Analysis Plan (Aim 3). Enrollment will continue until 72 nHBAM are randomized Hypothesis**:** Among the 72 families enrolled with nHBAM, those in the MySTYLE will have fewer condomless sex acts (CSAs), a less onset of sexual activity, and greater HIV testing rates, compared with those in the waitlist control by the 4-month assessment. Further, those randomized to MySTYLE will have significantly greater levels of HIV prevention knowledge, more favorable attitudes toward HIV prevention, greater HIV prevention self-efficacy, and more effective family practices at 2- and 4-month assessments. Data will be aggregated across follow-up assessments and analyzed using generalized linear models. CSAs will be analyzed using a negative-binomial model, which will account for over-dispersion due to zero-inflation. HIV testing during the follow-up period will be assessed using a logistic model. Knowledge, attitude, and HIV risk scores will be evaluated at baseline, 2, and 4 months using linear mixed-effect models, which will account for the three assessments being nested within individuals, and will help mitigate bias due to missing data.[100, 101] We will test for differences in linear change over time between groups on each outcome variable. For HIV testing outcome, we will evaluate difference between conditions in the proportion of participants who engaged in HIV POC test. Propensity scores (i.e., inverse probability of treatment weighting) will be used to account for any imbalance in baseline characteristics between conditions. [102] Note that the research uses small block randomization based on age and sexual experience to reduce group imbalance. Intervention acceptability will be determined at the 2-month assessment using the Aim 2 criteria of mean scores ≥ 24 on the CSQ and ≥30 on the SEF.

Power. Although pilot studies are not typically powered for significance testing,[103] the RCT of 72 will nonetheless provide a "signal" of impact regarding major outcomes – e.g. CSAs, HIV testing, parenting practices. We conservatively assume that retention of 72 participants over 4 months is 85%, based on previous trials. Power analyses for knowledge, attitudes, and family practices were run with Optimal Design 3.01[117] and assumed 3 assessments nested within cases. The HLM analyses with alpha of 0.05 and power 0.80 will be able to detect an effect size .41 SD for change in the scale score outcomes. If the alpha is 0.1 (as is appropriate in exploratory research), then power is 0.80 to detect an effect size of .36 SD, so this study should detect meaningful "signals" of impact. Power estimates for the behavioral counts were estimated using Mplus simulation utility using estimates from Dr. Brown's previous prevention trials with adolescents. As expected, the study will be powered to detect medium to large effect sizes (rate-ratios/odds ratios ranging from 2.67 to 6.05). These combined data (scale scores, behavior outcomes, acceptability) will be used to revise intervention content and procedures, as indicated, and to prepare for a larger, definitive efficacy trial.

Protection of Human Subjects and Safety Monitoring Plan

Please note: In the Human Subjects section, we use the term **parent** to refer to the legal guardian of the adolescent and **caregiver** to refer to any family member or trusted, involved adult. Parent engagement in the RCT phase is desirable; however, caregiver engagement is also acceptable to meet the needs of the intended intervention (MySTYLE).

Human Subjects Involvement, Characteristics and Design
The program will be described in recruitment and advertisements as building healthy adolescent relationships and acceptance of straight and gay adolescents. Parents will be approached for consent after the teens have indicated an interest in the project, which will not reveal the adolescent's sexual orientation or behavior, only an interest in participating.

The proposed research study is comprised of two phases, a formative phase to develop the intervention and a trial phase to test the intervention. In the **formative phase** of the project (years 1-2), the online family-based HIV prevention intervention will be adapted and refined to the needs of non-heterosexual Black adolescent males (nHBAM) and their parents/caregivers. Interviews will be conducted with approximately 15 non-heterosexual adolescent males, 15 parents/caregivers and 15 stakeholders to inform development of the intervention. The investigators and our media partner, MEE Productions will iteratively refine digital material and ensure its relevance. Beta versions of the intervention, to be called MySTYLE, will be tested in an open trial to assess clarity, relevance and appeal of activities with approximately 10 non-heterosexual Black adolescent males and their parents/caregivers.

In the **trial phase** (year 3) a randomized control trial of MySTYLE will be conducted to compare to waitlist control condition among 72 nHBAM and their parents/caregivers. The 8-week online intervention conditions will be delivered via text message or posted privately on a HIPAA compliant, password protected site. At the completion of the study, interested participants will be asked to participate in a one-hour interview or focus group (in-person or via a video conferencing platform). Youth and parent focus groups will be conducted separately.

Inclusion Criteria. Eligibility criteria for **adolescents** in all phases of the project will be: 1) at least 13 years of age but no more than 20; 2) stably-housed (have resided with the same adult caregiver for the past 6 months and no plans to leave the city or caregiver in the next 6 months). 3) the ability to read and speak English; 4) identify as a male; and 5) and identify racially as Black African American. Exclusion criteria will be: a) not able to provide meaningful assent as determined by research staff, b) known HIV-infection (staff will facilitate entry into care if needed). Adolescents age 18 will be able to provide their own consent. We will enroll those who indicate interest in a program to build healthy adolescent relationships and the acceptance of straight and gay adolescents. Adolescents will not need to reveal their sexual behavior or attitudes, although we expect that the many of youth who participate will be non-heterosexual. Eligibility criteria for **Parents/caregivers** for all phases of the project will be: 1) parent/caregiver of an adolescent who is potentially eligible for enrollment into the study; and 2) English speaking. For the exit interview or focus group, in addition to the aforementioned criteria, participants (youth and parents) will have had to already completed the MySTYLE intervention.

Participants will be recruited by two experienced community recruiters with close ties to adolescent and LGBT relevant CBOs (My Brother's Keeper, GSA of Jackson, Mississippi First), agencies / clinics (adolescent health, HIV and STI clinics, and schools (via referral from school health and guidance counselors). Recruiters will publicize the project to youth at agency

functions and with flyers. The agencies and schools will also direct youth to the project. Our Advisory Board, peer ambassadors, and currently enrolled participants will also assist in recruitment. Currently enrolled participants will be incentivized to recruit up to five new participants and will receive an additional $10 for each referral that is enrolled in the study. There will not be overlap between subjects in the formative phase and the randomized control trial.

Rationale for Including Special Classes of Subjects. The age of our participants is dictated by the need for research in the area of HIV prevention for nHBAM because of the high prevalence of HIV in young Black men who have sex with men.

Sources of Material

Research Material Obtained from Living Human Subjects
Research material obtained from participants includes: 1) questionnaire data; 2) audio-tapes from individual or group, interviews with nHBAM, parents/caregivers and stakeholders; and 3) Point-of-Care HIV test results. For the formative phase, participants (adolescents, parents/caregivers, stakeholders) will partake in interviews and will be asked questions regarding their knowledge, attitudes, and beliefs relative to HIV prevention among nHBAM. Interviews will generate themes that participants feel should be the focal points of MySTYLE. These interviews will take place in private offices controlled by Dr. Mena and located on the third floor of the Jackson Medical Mall. The audio-taped interview and written surveys of their reactions to possible intervention content will be the sources of material for this phase.

During the pilot trial, adolescents and parents/caregivers will complete the Session Evaluation Form and Client Satisfaction Questionnaire to assess the clarity, relevance, and appeal of the activities and their reactions to the sessions. The adolescents in the pilot trial will also complete questionnaires about their demographic information, HIV related knowledge/attitudes/beliefs, substance use, sexual behavior, self-efficacy for HIV prevention, stigma, social support, parental involvement and parental-adolescent communication about sex. Pilot trial adolescent questionnaires will be completed in person at entry to the study and 6-months post-enrollment. These assessments will occur in a safe, convenient location at the Jackson Medical Mall or the Jackson Medical Tower.

For the randomized trial phase of the intervention adolescents will complete questionnaires about their demographic information, HIV related knowledge/attitudes/beliefs, substance use, sexual behavior, self-efficacy for HIV prevention, stigma, social support, parental involvement and parent-adolescent communication about sex. Trial phase adolescent questionnaires will be completed in person or remotely at entry to the study entry, 2- months, 4-, 6- and 8-months post-enrollment. Assessments at 6 and 8 months will only be completed by those assigned to the waitlist control condition who choose to participate in MySTYLE after their 4-month assessment. At the completion of the study, interested participants will be asked to participate in a one-hour interview or focus group, either in-person or via a video conferencing platform. Due to the COVID-19 outbreak, medical clinics and clinical spaces are limiting non-essential visits, which severely limits our ability to complete in-person study appointments. We are proposing to complete assessments and exit interviews/focus groups remotely using HIPAA-compliant electronic signature and video conferencing platforms. This service would be available for the assessments at study entry, at the 4-month, and the exit interview/focus group. UMMC staff will be available via video conference for these assessments to complete enrollment and study completion activities. In-person assessments will occur in a safe, convenient location at the Jackson Medical Mall, the Jackson Medical Tower. Remote assessments will occur in a location

of the participant's choosing. Participants will receive REDCap survey links via email. Once a survey has been completed, participants will receive an online gift card. Biological measures (collected via POC HIV test) will be obtained at the in-person 4-month follow-up assessment or participants may opt to receive a home HIV testing kit, which will be mailed to them by UMMC. Adolescents who agree to take a no-cost POC HIV test will be provided this based on standard-of-care at the Crossroads Clinic. Positive test results will be reported to Dr. Mena who will conduct confirmatory testing and follow-up using standard treatment and reporting protocols.

Parents/caregivers in the pilot and randomized trial phases will complete questionnaires about their demographic information, parenting practices, parental monitoring, parent-teen communication about sex, acceptance of another's non-heterosexual orientation, social support, and measures of acceptability. During the trial phases, all assessments for parents/caregivers will occur online.

Linkages to Subjects and Access to Subject Identities

For each stage of the research study, participant names and contact information will be maintained in a recruitment/enrollment database. Once individuals enroll in the study, names will be linked to a participant ID number in this database, which will be kept in a restricted access folder on a secure server. All name/ID number files will be assigned a code name unrelated to the name of the study. Signed consent and assent forms will also be kept in a locked file cabinet, separate from any other project data. Once data collection is completed, the corresponding recruitment/enrollment database will be deleted as it is unnecessary to maintain the link between participant identity and study data. Destruction of these databases must be witnessed and documented on the Master List Verification of Destruction document, which will be maintained in a regulatory file. Furthermore, any information collected as part of this study will be accessible only to research staff that has completed mandatory training in the protection of human subjects.

Potential Risks

The risks for this study are considered minimal. Every effort will be made to ensure that study participants are protected from risks. The risks are as follows: 1) potential coercion; 2) loss of confidentiality; 3) emotional discomfort during the assessments and/or intervention activities; 4) risk associated with learning they have HIV, if that is diagnosed during the course of the study; and 5) adverse reactions from parents/caregivers if participant discloses sexual attitudes or behavior (disclosure is not a study requirement). The protection against each risk is described in detail below under Adequacy of Protection Against Risk.

Adequacy of Protection Against Risk

Recruitment and Informed Consent. The program will be described in recruitment and advertisements as building health and acceptance for Black young men of all backgrounds (sexual, economic, and family). Parents will be approached for consent after the teens have indicated an interest, which will not reveal the adolescent's sexual orientation or behavior, only that they are interested in greater health and acceptance of all teens and the tolerance of diversity. The project will use two experienced community recruiters with close ties to adolescent and LGBT relevant CBOs (My Brothers Keeper, GSA of Jackson, Mississippi First), agencies / clinics (adolescent health, HIV and STI clinics, and schools (via referral from school health and guidance counselors). Recruiters will publicize the project to youth at agency functions and with flyers/social media announcements. The agencies and schools will also

direct potentially at-risk youth to the project. Referrals and advertisements will provide the contact information of the study project director, who will promptly initiate contact either in-person or by phone or email.

Recruitment of adolescents for all phases of the project (formative phase, pilot trial and randomized trial phase) will involve completing a preliminary eligibility screener and parents/caregivers of a potentially eligible youth will be approached for consent. Community recruiters will publicize the project to youth at agency functions and with flyers/social media announcements. The agencies and schools will also direct potentially at-risk youth to the project. We will also continue to utilize targeted advertisements posted on online social media platforms (e.g. SnapChat, Instagram, and/or Twitter) to recruit nHBAM. Referrals and advertisements will provide the contact information of the study project director, who will promptly initiate contact with the youth and use the waiver of parental consent to enroll the youth if he is interested. Recruitment of stakeholders (i.e. staff members at community-based organizations that serve LGBT youth, schools, faith-based organizations, and relevant state agencies) in the formative phase of the study will involve being contacted by site investigators to participate in interviews. Exit adolescent/parent interviews or focus group will be conducted with those that have already completed the intervention.

The risk of possible coercion will be minimized by following standard procedures for obtaining informed assent/consent from non-heterosexual Black adolescent males. In March 2020, the COVID-19 outbreak created significant barriers to recruiting and enrolling participants in person. In situations where the COVID-19 outbreak has not affected recruitment and informed consent, assent will be obtained using the same process applied to obtaining written informed consent in studies of adults (e.g., a research staff member will verbally explain the assent/consent document on a paragraph-by-paragraph basis). Study personnel will fully explain the study procedures, risks, benefits, and alternatives to adult participants and ask for their written informed consent. Participants will also be reminded that study participation is voluntary and that refusing to participate or withdrawing from the study at any time will not result in any negative consequences.

Formative phase and pilot trial adolescent enrollment: adolescents will be consented and enrolled with written parental consent. After hearing the description of the study and asking any questions they may have, adolescents who are interested in participating will be assented. Those interested will be asked to give our study team permission (and contact information) to enroll their respective parents/caregivers to: 1) provide written informed consent for those under 18 and 2) to also participate in the project. The project will not disclose the adolescent's private behaviors or attitudes; and will not require adolescents to disclose any sexual behavior.

Formative phase and pilot trial parent or caregiver enrollment: Parents will be contacted by phone and written informed consent for a son's participation obtained in person. If the parent (legal guardian) agrees to their son's participation in the project but does not want to participate, the parent and adolescent can nominate "someone important in the life of the adolescent such as other family, teacher, religious leader, or social worker" who will be contacted for enrollment. Caregivers will not be enrolled in lieu of a parent unless the parent agrees. This option of involving a caregiver, rather than a parent, worked well in Project STYLE, and involving a non-parental adult was recently recommended as an intervention option for non-heterosexual adolescents.[69] Even if a parent/caregiver never participates in the intervention, MySTYLE, may improve the family climate by focusing on healthy family communication, similar to other studies finding an impact without all family members attending sessions.[70]

RCT enrollment: For the RCT phase a waiver of parental consent will be utilized for those under 18 and youth aged 18 or older will be able to provide their own consent. A waiver of parental consent for those under 18 produces a sample that is more diverse in terms of the extent to which nHBAM have disclosed their sexual attitudes to others, their degree of perceived stigma and discrimination, and their perceived support from, and engagement with, parents.

The RCT allows nHBAM into the program before parent/caregiver involvement with a waiver of parental consent for those under 18 and then prepares nHBAM to safely involve their parent, if possible. nHBAM aged 18 or older will be able to provide their own consent, although we will ask for permission to enroll parents/caregivers, if possible and safe for the youth. The project will be described as a general sexual health intervention for adolescent males; it will not disclose the adolescent's private behaviors or attitudes and will not require adolescents to disclose any personal information. **Parent/Caregiver involvement may begin at study entry or at mid-intervention, after the nHBAM has had more time to consider it.** After the adolescent provides permission to contact their parent/caregiver for enrollment, we will follow the parent/caregiver consent procedures described above in the formative and pilot trial phases. Parents/caregivers will be assigned to the same condition as their adolescents.

RCT digital consent, enrollment, and follow-up: In light of the COVID-19 outbreak, several of our recruitment sites (i.e. CBOs, clinics, and schools) have either closed or are limiting non-essential visits. This limitation severely impacts our ability to recruit and enroll potential participants in-person for the RCT phase of this project. We are proposing to offer digital consent and enrollment via HIPAA-compliant platforms (i.e. DocuSign, video conferencing software). nHBAM identified as eligible, based on an online REDCap screener, will be asked if they would like to be contacted by study staff. Those that indicate they would like to be contacted will then be asked to provide their name, email address, and phone number. UMMC research assistants will follow up with interested parties by phone or email. Those who wish to participate will receive a DocuSign consent form via email from the UMMC research assistant and will be given the opportunity to participate in a video conference call (via HIPAA-compliant video conferencing platform, such as Zoom) with the UMMC research assistant to review the consent form. The DocuSign consent form will outline study aims and procedures and contains language regarding the risks/benefits of participating in a research study. The online survey data will be de-identified and kept in a password-protected participant log on a secure server. Participants will be given ample time to consider risks of participation and will have the opportunity to ask questions during the video conference. Participants will also be reminded that study participation is voluntary and that refusing to participate or withdrawing from the study at any time will not result in any negative consequences. For the remaining follow-up appointments (at 2- and 4-months, and additionally at the 6- and 8-month appointments for waitlist control participants) participants will be emailed their online REDCap surveys and will receive online gift cards for each completed survey. At the 4-month appointment, nHBAM will be offered a home HIV testing kit, that will be mailed to them by UMMC, in lieu of an in-person HIV test.

Protections Against Risk

Breach of Confidentiality. Potential risk will be minimized by strictly adhering to the guidelines for research outlined by the site IRB, state laws, the Federal Health Insurance Portability and Accountability Act of 1996 and its regulations ("HIPAA"), and the DHHS Federal Policy for the Protection of Human Subjects (45 CFR Part 46 Subpart D). This will include identifying participant research data by numeric ID only and maintaining any records containing potentially-identifying information separate from any research data. All research data (written records and audiotapes of program sessions) will be kept in a locked file and electronic data will be

password-protected. All of these study-related materials will only be accessible to research staff. No names, only identification codes, will be used in presenting data in lectures, seminars, and papers. Information will be released only with written consent of the parent/guardian.

Participant confidentiality will be breached only to protect the safety and welfare of research participants and only in accordance with state and federal law. If child abuse or neglect is reported, a report will immediately be filed with the appropriate state department or agency. See "Emotional Distress" below for more details on the available clinical services.

All data collection (ie. Baseline, 2 months, 4 months, 6 months and 8 months for the RCT phase for adolescents) will take place in secure and supervised settings, if possible. The REDCap online survey software suite will be utilized for the collection of data from both participants through computer-assisted survey interviewing (CASI) as well as from relevant staff for project-specific data collection (e.g., recording/transferring of lab results, forms for rating and coding of intervention fidelity, site information), from which data are easily extracted for entry to statistical programs (e.g., SPSS). The research team will develop documentation for each survey measure, including appropriate branch and skip logic, as well as a codebook with documentation for each variable. Project managers will program surveys using the REDCap survey platform. Basic survey content will be programmed first and then survey flow and logic will be programmed after content has been reviewed and edited. Survey-based reporting mechanisms will be programmed, including automated invitation and reminder emails for participants as well as triggered emails to staff for the purposes of monitoring and reporting. Usability testing by trained staff will be conducted and will include checks for basic grammar, spelling, sequence, and comprehension. Further advanced testing will be conducted in order to test the survey's logic and flow; this advanced testing phase will include the generation of test data to ensure all branch and skip logic works as planned within the variable codebook. Throughout the course of the project, regular data downloads will be conducted to check the quality and accuracy of the data, to ensure no data are missing, and to regularly report on the sample characteristics. REDCap meets or exceeds all HIPAA and HITECH requirements for security and privacy**.** Following data transfer, syntax will be developed to arrange the data for quantitative analysis. Directories describing data files, variable label codebooks, and data routines will be developed during the year-2 pilot trial. Following that, data will be extracted and archived on a monthly basis. Routines for assessing data integrity will be developed, with procedures established for accepting, correcting, or rejecting data. All data will reside on servers behind firewalls (with access restricted to study personnel) and on computers with hospital security enabled. All servers are routinely backed daily (to off-site locations), and the project will create its own weekly backups on secure external drives kept both on and off site. Transfer of data among the study sites will be done using secure methods (e.g., secure FTP).

All study personnel names on this application have completed training and received certification in Human Subjects Research Protection (CITI Program) and HIPAA regulations. They will continue to renew this training in compliance with hospital policies.

For the formative interviews in PY01 and exit interviews in PY03, participants will be asked to provide informed written consent to audiotaping at the time of study entry, whether they are participating in the individual or group interviews. To assure confidentiality and protection of the participants during audiotaping, all tapes will be stored in a locked file cabinet in a secured office. Only research staff will have access to the audiotapes so that ongoing guidance can be provided as to the conduct and design of the study.. Notes taken by the interviewer will be identified by a study ID only and will be stored in a locked cabinet in a locked room at the University of Mississippi Medical Center.

Completion of online intervention activities will involve the use of a phone or computer. This introduces the risk of unintended disclosure if the participant is seen completing the activities by other individuals who may not be aware of their sexual orientation. Participants will be encouraged to use password protected devices and to complete study activities in a private, secure setting to minimize the risk of unintended disclosure.

Emotional Distress. We will minimize distress by presenting questions/program techniques in a supportive manner, assuring participants that they may refuse to answer any questions that make them uncomfortable, and may terminate participation in the intervention at any time. All subjects may receive medical or mental health treatment at any time during the study. Clinical need will determine whether it is appropriate for the participant to stop continuation in the study.

Another potential risk associated with conducting research among non-heterosexual Black adolescent males is unintentional disclosure of sexual desires/behaviors to family, friends and others. To minimize risks, we will enroll those who indicate interest a program to support healthy adolescent relationships and acceptance of adolescents of all backgrounds (e.g. sexual). Adolescents will not need to reveal their sexual behavior or attitudes to parents or to staff.

Another potential risk is associated with adolescents learning that they have HIV. All participants, regardless of reported history of sexual activity, may accept free, confidential HIV testing at the final assessment. Before testing participants it will be explained that the testing process requires a blood test before we can give them their HIV test results. HIV screening will be done using a finger stick to obtain a specimen for the HIV rapid test (Clearview Complete HIV 1/2, Alere or Insti HIV-1/HIV-2 Rapid Antibody Test, Biolytical). For those unwilling to provide a fingerstick sample we will offer the test using an oral fluid sample (with OraQuick Advanced HIV-1/2 – OraSure Technologies, Inc). HIV testing will only be done by the site project director, who will be certified in HIV testing and counseling procedures. If the rapid test results are inconclusive, invalid, or preliminary positive, when that happens, instead of receiving their results in few minutes, they may have to wait 1-2 days. Any adolescent testing positive will be navigated, by the project director and Dr. Mena, to confirmatory testing. They will be told that a blood test needs to be done because their rapid HIV test result was not diagnostic. Adolescents receiving HIV positive results will be linked to HIV care and to services such as mental health providers, social workers, and other support services to assist in linkage and retention in HIV care.
We anticipate very few adolescents will test positive for HIV; however, those who test positive may feel extreme distress when learning of their diagnosis. For those who test positive to HIV, they will be counseled in private by in accordance with CDC's HIV testing and counseling guidelines. The diagnosis and counseling provided will involve first reviewing the type of test that was administered to the youth, giving them their test results, explain the meaning of the test result, ask the youth if they have any questions, comments or concerns, talk about resources, discuss the adolescent's feelings and assess their readiness to leave the location, secure additional support and resources for the youth if necessary, and provide them with additional information if necessary. All youth will be taken to the University of Mississippi Medical Center HIV clinic to ensure they get confirmatory testing and that they are enrolled in HIV treatment services. If an appointment in the HIV clinic is not immediately available, then study staff will maintain contact with the subject until they have been evaluated by the HIV clinic. The result will be reported to the Department of Health as per state regulations. Dr. Mena and staff are expert HIV medical care providers and are experienced in assisting those newly diagnosed with HIV.
Minors may obtain STI treatment without consent of parents; accordingly, parents will not be notified of results. Our study staff cannot request identifying information about sex partners.

However, in all consent and assent documents, we will explicitly stipulate that per state statutes, we are required to notify the respective health department of all reportable HIV cases. HIV is also reportable to the State Health Department. Routine clinic procedures encourage infected individuals to inform their partners so that they can be tested and treated.

If a participant reports feeling distressed, or has any acute concerns, as a result of their involvement in any phase of the research project (i.e. consenting, baseline assessment, interview session, follow-up, collection of biological data), clinical resources will be offered on-site. The clinical location used in this study is ideal as it provides easy access to medical and mental health clinicians. If a participant contacts study staff because of distress or concern due to participation in the study or directed activities that occur away from the clinical space (such as a concern that phone use or activities led to a dispute with parents), he will be assessed first over the phone, and then, if needed, as described below.

During any phase of the study, if research staff determines that a participant is an acute medical or psychiatric risk, Dr. Mena or a licensed designee will meet with him individually for further assessment and notify the participants' parents of any clinical needs. Acute risks would include severe medical illness, or the development of any other severe psychiatric symptoms or disclosure of sexual or physical abuse. Any adolescent who exhibits acute risks will be evaluated immediately by emergency room clinical staff or if less acute, by an independent clinician that day. Less severe medical needs or distress can be managed by staff or Dr. Mena over the phone or with an individual interview. Dr. Mena and/or staff will meet with participants and/or families to review concerns and to make referrals for continuing care as needed. Of note, members of the proposed research team have substantial prior clinical (medical and psychiatric) and research experience in care of adolescent males as evidenced through their biographical sketches.

One final protection involves the disclosure by study participants ages 14 and under that they have had sex with partners who are at least 24 months older than the minor and 15 to 17 years old that they have had sex with partners who are at least 36 months older than the minor. Mississippi's law requires immediate reporting of these cases to the Mississippi Department of Human Services (MDHS). Dr. Mena has created a protocol that will be applied to this circumstance, should it arise. It is important to note that our assessment instruments do not ask study participants about the age of their sex partners. However, we do clearly recognize the possibility that young male study participants may volunteer such information to the study staff during interviews or in the course of the assessments. In brief, clinic policy requires that the person to whom the information was disclosed should immediately report to MDHS Child Protective Services the incident by calling the statewide toll free hotline (1-800-222-8000). The report is then screened by a MDHS supervisor to decide whether it should be investigated. Thus, if a minor in our study discloses having sex with an adult (at least 36 months older than the minor) this mandatory reporting protocol is activated. Any male study participant ages 17 and under will be told that the health department is obligated to report to the state any instance of sex with older men (if at least 24 months older than the minor for those 14 and under and 36 months older than the minor for youth ages 15-17). Dr. Mena employs three full-time case managers who are trained counselors and will be on-hand to handle instances where a 15-17 year old discloses sex with an adult to a member of the research staff. The case managers provide additional evaluation to assure the welfare of the minor.

Adverse Reactions from Parent/caregivers. The project will be described as an intervention developing as building healthy adolescent relationships and acceptance of straight and gay adolescents; it will not disclose the adolescent's private behaviors or attitudes; and will not

require adolescents to disclose any sexual behavior. However, it is possible that some parents/caregivers will discover their son is non-heterosexual during the course of the study. Many of the enrolled nHBAM will have previously disclosed their non-heterosexual identity to parents/caregivers thus we are primarily concerned here with those who have not done so in the past. Adverse reactions from this discovery may include verbal or physical threats or abuse, or various forms of physical neglect (asking the adolescent to move out) and abuse. Our plan is twofold: 1) avert disclosures that may be dangerous in any way, and 2) mitigate harm when signs of retribution first occur. To avert potentially risky disclosures we will guide non-heterosexual Black adolescent males through the completion of a **Self-Safety Evaluation tool** that we will create. This tool serves as a "best possible" method of helping non-heterosexual Black adolescent males make the decisions regarding what personal information to discuss with their parents, such as expressing their non-heterosexual identity. The tool helps participants anticipate likely reactions, based on past history, and identify trusted available social supports and safety resources, including project staff. Staff will be available to review the results of the Self-Safety Evaluation with the participant if needed and will follow-up with the participant if any adverse reactions are reported. If research staff learns of any verbal, emotional or physical abuse from a parent, he/she will immediately notify Dr. Mena who, in turn, will exercise any of several options: 1) initiate mandatory reporting as required by state law, 2) notify local child protective service authorities regarding the situation, or 3) withdraw the adolescent from the study as a safety precaution.

Potential Benefits of the Proposed Research to the Subjects and Others

Importance of Knowledge to be Gained. All phases of the proposed study will provide important information for the development of HIV prevention interventions for non-heterosexual Black adolescent males. We hope that our intervention will be successful in reducing HIV risk behavior among non-heterosexual Black adolescent males and think that the clear examination of these questions outweighs the previously mentioned risks. The effectiveness of a tailored, scalable, online HIV prevention intervention is severely understudied with this population. Given the significant risk of HIV infection among nHBAM and the lack of easily accessible prevention interventions tailored specifically to nHBAM, the knowledge to be gained from this research is significant. The risks to participants are reasonable in relation to the importance of the knowledge to be gained.

Reimbursement for Time and Effort. Participants (approximately 15 non-heterosexual Black adolescent males, 15 parents/caregivers) will be reimbursed $30 for focus group participation. Stakeholders will be reimbursed $50 for focus group participation. Community Advisory Board members (4 non-heterosexual Black adolescent males, 4 parents/caregivers, 4 community members) will be reimbursed approximately $50 for each meeting (12 CAB members x $50 x 4 meetings/year in Years 1-3). Participants in the Open Trial (10 nHBAM and their parents/caregivers) will be reimbursed $35 for the baseline and 2-month post-intervention assessments. Randomized Controlled Trial participants (72 nHBAM) will be reimbursed approximately $35 for the in-person assessments (baseline, 2-months, 4-months, 6-months and 8-months post-intervention). Only those assigned to the waitlist control condition will be eligible for the 6- and 8- month assessments. Randomized Controlled Trial parents/caregivers will be reimbursed $35 for each of the online assessments (baseline, 2-months, 4-months, 6-months and 8-months post-intervention). Only those assigned to the waitlist control will be eligible to complete the 6- and 8-month assessments. All online assessments will culminate in a screen that provides study participants with a code for an online purchase from Amazon.com. Currently enrolled participants will be incentivized to recruit up to five new participants and will receive an

additional $10 for each referral that is enrolled in the study (up to a total of $50). Exit interview or focus group participants will be reimbursed $100 for the one-hour interview/focus group.

Inclusion of Children, Women and Minorities

Children. In this family-based intervention approximately half of the participants will be youth ages 13-18 and the remaining will be their adult parents or caregivers. The content to be selected in the intervention will be designed and appropriate for children 13 and older. The Development phase of the study will ensure that all material is tailored to the developmental and cognitive level of adolescents and for their parents. Thus, the proposed program is appropriate for adolescent children.

Women. All of the adolescents in the study will be male. The target population for this project is adolescent non-heterosexual males, who are greatest risk for acquiring HIV in the U.S. The proposed project involves a family-based intervention, which provides the opportunity to include parents/caregivers who may be women. It is anticipated that approximately 80% of the sample of parents/caregivers and stakeholders will be females.

Minorities. The aim of our recruitment strategy is for the resulting program materials to be appropriate for Black non-heterosexual males because of their high risk for acquiring HIV. In terms of race, 100% of the enrolled adolescent participants will be Black/African American. Ethnically, 5% or fewer will self-identify as Hispanic or Latino.

DEPARTMENT OF HEALTH AND HUMAN SERVICES (DHHS) "REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS"

Since October 1, 2001, Lifespan has required that researchers and IRB members read Protecting Study Volunteers in Research (Dunn & Chadwick) and complete the related exam. This process has served as initial certification between 10/2001 and 5/2005. In June 2005, the Office of Research Administration contracted with CITI, a Collaborative Institutional (modular) Training Initiative program, for our Human Subjects protection and HIPAA training for all research personnel. Currently this program offers our researchers a basic human subject's protection course as well as a refresher course, which is required every three years. Documentation of successful completion is automatically generated and is printed directly by the researcher. For further information regarding Lifespan's Human Subject's Protection course go to: http://www.lifespan.org/research/IRB/MandatoryEdguidance.asp. Additional and continuing education opportunities for clinical researchers include the Office of Research Administration newsletter that is circulated to > 900 recipients every 6 weeks. Relevant information concerning research review is available on the ORA web page at www2.lifespan.org/research/. In addition to standard institutional research information, the web page contains links to other sites such as CenterWatch, NIH, PRIM&R/ARENA. Investigators and staff at all sites receive similar training and certification.

Data and Safety Monitoring Plan

The nature of the population warrants the development of a Data Safety and Monitoring Plan. To address the NIH policy for Data and Safety Monitoring, Drs. Brown and Crosby have developed a system for oversight of the proposed study and its participants. The Data and Safety Monitoring Plan for this application will begin by implementing standard procedures for day-to-day monitoring of the study. 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 outcome. Participant experiences with the study procedures and the rates of adverse events will also be reviewed to determine any changes in participant risk. The project will designate two Independent Safety Monitors (one in Jackson, MS and one in Rhode Island) will review all Adverse events with the PIs quarterly or more frequently as indicated. The Independent Study Monitors will be academic researchers with experience in psychosocial intervention trials with adolescents.

Reporting adverse events:

1. Serious Adverse Events: The PIs will immediately report any serious adverse events (SAEs) to the UMMC IRB and the Rhode Island Hospital IRB immediately by telephone and by written report within 24 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 Lifespan IRB, which then will grant or deny permission to make the requested change or amendment in protocol. Modifications to study aims or design will also be submitted to NIH for approval prior to instituting them. Finally, if significant medical or mental health risks occur during the study period evaluation by the site's hospital emergency department will be immediately initiated 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), the SAE is determined to be clearly unrelated to the study intervention, or the SAE results in death. Outcome of all SAEs will be periodically reported to NIMH. A summary of the SAEs that occurred during the previous year will be included in the annual progress report to NIMH.

2. Any moderate adverse event (e.g., causing interference with usual activities or requiring treatment) and which appears definitely, probably, or possibly related to study participation will be reported to the IRB as indicated under #1 above in writing within 20 working days.

3. Any mild adverse event will be summarized in the NIMH and IRB annual progress reports and will be reviewed by our Independent Safety Monitors quarterly.

We will inform the NIMH of actions, if any, taken by the IRBs, or changes in our protocols as result of any of the reviews.