Reducing HIV Vulnerability Through a Multilevel Life Skills Intervention for Adolescent Men: The iREACH

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INTRODUCTION AND PURPOSE:

From 2000-2010, the annual number of new HIV diagnoses among MSM aged 13-24 years old more than doubled. There are stark racial and ethnic disparities in the incidence of new HIV infections among YMSM; 13-24 year old racial and ethnic minority MSM now represent a rapidly growing share of all new HIV infections. We developed a mobile-friendly WebApp intervention focused on life skills training (iCON) across 16 topics, ranging from stigma and discrimination to sexual health, with links to local resources. In the proposed activities, we will adapt iCON for four U.S regions heavily impacted by HIV, and revise the content to include materials that are age-appropriate for 13 to 18 year-olds. Given the role that stigma and social isolation plays in the lives of many AMSM, we also propose to embed a peer-to-peer motivational interviewing component to iCON, allowing participants to access motivational interviewing counseling via VSee video-chat. With a large and diverse sample (n=500), we will test the efficacy of the intervention, now referred to as iReach, on cognitive and behavioral HIV-related outcomes using a two-arm randomized control design. In addition, we examine whether structural characteristics in a region (e.g., race/ethnicity segregation, HIV prevalence) influence the efficacy of the proposed intervention.

OBJECTIVES:

We propose the following Specific Aims:
(1) Adapt a multilevel, online life skills intervention (iReach) to address HIV vulnerability among AMSM living in four heavily impacted regions constituting diverse racial/ethnic and geographic areas (Chicago to Detroit; Atlanta to Washington, DC; Memphis to New Orleans; San Francisco to San Diego) in the US.

(2) Test the efficacy of iReach, as compared to a delayed intervention condition, to improve cognitive (e.g., comfort discussing sexuality; HIV prevention attitudes, norms, self-efficacy, behavioral intentions) and behavioral (e.g., condom use, HIV testing, PrEP use) factors using a prospective RCT design

(3) Examine the differential efficacy of iReach in improving psychosocial mediators (e.g., personal competency) associated with our outcomes, and

(4) Examine how socio-ecological determinants at the individual (e.g., race/ethnicity, urbanity) and regional (e.g., socioeconomic disadvantage, HIV prevalence) level are associated with iReachs efficacy.

BACKGROUND:

From 2000-2010, the annual number of new HIV diagnoses among AMSM more than doubled. In 2010, adolescent and young adult MSM accounted for 72% of new infections among people ages 13 to 24, and 30% of all new infections among MSM. At present, however, there is a paucity of efficacious HIV interventions for AMSM. New HIV prevention tools are needed that can address the prevention needs of AMSM, and they need to be culturally and developmentally adapted for this population.

From the heterosexual adolescent literature, prior life skills interventions have indicated improved psychosocial outcomes (e.g., psychological well-being, academic performance, social assertiveness and improved interpersonal skills) and HIV-related outcomes (e.g., gains in HIV-related knowledge and risk reduction norms, delayed or reduced alcohol and substance use, fewer sexual partners and condomless intercourse occasions), with evidence indicating sustained risk reduction effects six years post-intervention for substance use and up to 10 years post-intervention for sexual risk behaviors. Furthermore, long-standing life-skill programs like Botvins Life Skills Training have been tested across diverse racial/ethnic and urban/rural adolescent populations and are endorsed by CDC and SAHMSA for the robust evidence suggesting their efficacy and effectiveness. Thus, there is clear evidence of proof of concept for using a life skills approach for positive change among diverse groups of adolescents. In the proposed intervention, we provide a life skills intervention to a diverse sample of AMSM: while we expect there to be overall improvements in knowledge and attitudes around HIV vulnerability, we also suggest that gains may be larger for disadvantages groups (race/ ethnicity, rural low SES) who have not had access to resources. We aim to test the differential efficacy of the proposed intervention across groups (see analysis).

CHARACTERISTICS OF THE STUDY POPULATION:

1. Target Population and Accrual:

Adolescent participants who express same-sex attractions between the ages of 13 and 18 years of age (inclusive) living in four heavily impacted regions constituting diverse racial/ethnic and geographic areas (Chicago to Detroit; Atlanta to Washington, DC; Memphis to New Orleans; San Francisco to San Diego) in the US.

We propose to enroll 600 AMSM and maintain a sample of 500 AMSM. We will use census information of population structure by race/ethnicity for each region to inform our recruitment goals. We will calculate the number of men in the eligible age group and by race/ethnicity in each region, and use data from the Youth Behavioral Risk Factor Surveillance System (YRBS) to estimate the proportion of AMSM in each age group who could meet eligibility criteria (based on same sex behavior, identity, or attraction), and apply that age-specific proportion to the estimated total AMSM population by race in each region. This will result in an estimated number of eligible AMSM per region and racial/ethnic group. Based on these calculations, to recruit a sample that is diverse in terms of race/ethnicity, we will need to oversample some racial/ethnic subgroups substantially. We will enroll a total of 150 AMSM from each of the 4 regions listed above. As noted, these regions were selected to represent variations in socioeconomic status, HIV prevalence, and rurality. Based on our estimates, we propose to sample such that at least 50% of our sample is a racial or ethnic minority, and at least 35% of participants being from rural areas across the regions. We recognize the challenge of recruiting early adolescents, especially because same sex attraction and same sex sexual experience become more commons with age. Therefore, we realistically expect to include a greater number of participants in older age groups. These procedures will provide power for an analysis of efficacy stratified by age and race/ethnicity. Our expected sample size for analyses across both conditions is N=500 (Intervention, n=250; Control, n=250), assuming a 15-20% loss to follow-up. We estimated the minimum detectable effect sizes at 80% power, for comparisons of the two groups for the continuous primary cognitive (e.g., behavioral intentions, attitudes, norms, self-efficacy) outcomes, as well as the difference in the proportion of AMSM who report increased behavioral in the outcomes (e.g., condom use, HIV testing) to engage in HIV prevention services and behaviors in our treatment arm (iReach) vs. our attention-control arm. For mean differences, our sample size calculations are based on a two-sample t-test assuming equal variance using a two-sided significance of 0.05. At 80% power, we are able to detect a between-arm difference of d=0.22 at the final follow-up. For repeated measure analyses, assuming a within-person correlation of 0.25, we would be able to detect a difference of 0.08. A less favorable within-person correlation of 0.75 allows us to detect an effect size of 0.11. For proportions, our sample size calculations are based on a two-sample test of proportions using a two-sided significance of 0.05. To have 80% power to compare active treatment to the control group, we require at least 500 participants to find a 12.5% difference between treatment and control in cross-sectional analyses. Assuming within person correlation of 0.25, we can detect an 8.8% difference. A less favorable within-person correlation of 0.75 allows us to detect an 11.3% difference

March 2020 Update:
In consultation with the NIMHD, in March 2020 the Investigators expanded the recruitment area to include the entire United States in order to assist with meeting recruitment targets by age and race/ethnicity.

2. Key Inclusion Criteria:

Inclusion criteria for enrollment into the study include:

1. being assigned a male sex at birth and identifying as male at time of enrollment,
2. being between the ages of 13-18 (inclusive),
3. speaking and reading English,
4. reporting same-sex attractions and/or behaviors,
5. have access to the internet,
6. living in and the United States
7. self-report as HIV-negative at time of enrollment.

Additionally, given that this is an online intervention, in order to be considered enrolled in the study, individuals must complete enrollment procedures which include

- providing and verifying contact information, and
- passing fraud checks described in the screening and data management sections of this protocol.

After these criteria have been met, participants will be randomized into a study arm and considered enrolled into the study.

Eligibility will close as goals are filled.

Justification. Socially disadvantaged populations in the United States (e.g., individuals who identify as racial/ethnic and/or sexual minorities, live in poverty, and/or reside in underserved communities) are more vulnerable to HIV infection and account for a substantial proportion of new HIV cases in the United States. These HIV disparities are further exacerbated when individuals are part of multiple minorities (e.g., Latino and MSM), as they may experience marginalization from both their racial/ethnic *and* sexual communities. These processes of marginalization may impact individuals' social mobility, create stress and social isolation, promote the adoption of negative coping behaviors (e.g., substance use), and disrupt access to community resources and social capital. Marginalization may also affect their sexual networks by limiting access to HIV prevention services, hindering their ability to enact safer sex practices when meeting partners, and shaping norms regarding risks. Youth, in particular, may experience further marginalization if they encounter structural policies that limit their development (e.g., absence of comprehensive sex education; no condoms in school settings). Together, these multilevel processes exacerbate HIV vulnerability among AMSM.

This research will involve children 13-18 years old. The age range is critical for this research because rates of HIV-related risk behaviors being in adolescence and peak as youth transition into adulthood, and interventions delivered during this time can have the potential to prevent future escalation and consequences associated with HIV. Thus, there is substantial potential public health impact. It is important to study this "vulnerable population" because they are at risk for negative cognitive, behavioral, and health outcomes. The development and testing of interventions targeted to this age group has the potential for significant gains in health for this age group. All ethnicities and races will be included in the proposed study, to the extent that they agree to participate in the study.

The proposed research study focuses on the delivery of a HIV/STI prevention intervention for adolescent young men. Although intervention participants will identify as male at enrollment, we recognize that some may identify as transgender women or gender non-conforming during the trial. Additionally, participants who report acquiring HIV during study participation will not be withdrawn from the study.

3. Key Exclusion Criteria:

Exclusion criteria for enrollment into the study include:

1. being assigned a sex other than male at birth,
2. identifying as a gender other than male at time of enrollment,
3. being younger than 13 or older than 18 years of age,
4. not speaking and reading English,
5. reporting no same-sex attractions and/or behaviors
6. living outside the United States
7. not having access to the internet, and/or
8. self-reporting as HIV positive at time of screening.

Please see Section 2. Key Inclusion Criteria for justification of inclusion/exclusion criteria.

4. Subject Recruitment and Screening:

Social Media

We will reach the population using social media ads on sites including Facebook, Tumblr, Instagram, Reddit, Twitter, and Spotify. Ad targeting within social media sites allows us to specify the age range and other socio-demographic characteristics of individuals who will see the ads based on the information they provide in their online profiles. We will develop ads that promote our target populations interest by including diverse images of youth (i.e., images of different ages, portraying diverse race/ethnicity), as well as using ad-targeting specific to socio-demographic characteristics (e.g., delivering Facebook/Instagram ads only to youth living based on their age, race/ethnicity and sex) and interests (e.g., TV shows with LGBT themes).

Social Media Influencers

We will pursue reaching out to social media influencers to assist in posting recruitment ads on their various platforms to their followers. This can be done through tweets, videos, or messages on Facebook/Instagram. These influencers will be those popular among LGBT youth. We will contact them in various ways including social media (twitter, facebook, etc…) or through sites such as Cameo. Messages recorded by influencers will be posted with recruitment ads and on current social media platforms used in the study. Instructions on what to include in the messages will be provided to the influencers prior to recording. An example of a recorded message would be: "What's up, this is Todrick Hall and I just wanted to encourage young men to sign up for the research study called iReach. It's a web app that can help young men with same sex attractions deal with topics relating to their sexuality during their adolescent years. It's an awesome program, please look it up and tell them Todrick sent you."

Community Organizations and Universities

We will also seek approval from individual LGBT and youth-serving organizations to post advertisements on their websites and Facebook/Instagram pagesPhysical recruitment materials will be developed and distributed among organizations that serve and support LGBTQ+ youth (such as homeless youth organizations, community LGBTQ+ centers, HIV resources, etc.). Likewise, we will seek opportunities to distribute recruitment materials at colleges and universities.

Community Events

Physical recruitment materials will also be distributed during large community events, including Pride festivals . Individuals will also be given the opportunity to take a shortened eligibility screener using a study tablet or laptop, or to provide their contact information if they do not want to take the screener, but would like to have a screener link sent to them. Non-monetary giveaways (flags, buttons, etc..) equaling no more than $5 may be available to potential participants who take the screener. Both the shortened eligibility screener and the contact information form will be hosted on the same Alchemer (formerly named Survey Gizmo) platform as the standard screener and surveys, using the same security features described in sections 4 and 7 of this document.

At pride festivals or community event locations, we may recruit graduate students from universities where there are CFAR entities to assist with on-the-ground participant recruitment. These students will be paid a stipend for training and assisting with recruitment at events. These students will be required to either already be CITI certified in social and behavioral research ethics or attain this certification prior to the event training. The CFARs will assist in advertising to students and making the connections to the iReach team. These students will be trained and coordinated at events by iReach staff.

Referral of potential participants from other studies conducted at iReach study sites
We will send invitations to complete the eligibility screener to individuals who have consented to be contacted and screened for research opportunities at iReach study sites (University of Pennsylvania Program on Sexuality, Technology, and Action Research; Emory PRISM Health; University of Michigan Center for Sexuality and Health Disparities).

Referrals from current participants
Though we will not seek out peer referrals to the study, if a participant contacts us and asks if a peer of theirs can participate, we will provide study contact information which the participant can pass on. If the individual does indicate interest in participating, we will provide them with a link to the study screener.

Materials will avoid identifying candidates as AMSM in the recruitment text to avoid unintended disclosure. Ads will link interested individuals to the study site where they may verify their eligibility, email the team, or locate a toll-free number if they want to talk to a team member about the study. AMSM will click on viewed social media advertisements and be taken to a homepage containing basic study information including a short description of study activities. The homepage will not identify the study as a site for MSM.

Screening: Interested individuals will be asked to consent to and complete an online screening survey. We will use this approach as one of our strategies for filtering fraudulent or duplicate entries (see Measures to protect against fraud and hacking below). Individuals who do not meet the eligibility criteria will be thanked for their interest and automatically routed to the Google home page. We will not indicate why they were ineligible to avoid unintentional disclosure and to protect against fraud. In order to meet recruitment sub-targets (e.g. by race/ethnicity), the eligibility screener programming will be modified to exclude groups as recruitment sub-targets are met. Participants who are part of these now-excluded groups and would otherwise be eligible to participate will be offered the opportunity to provide their contact information and be put on a study “waitlist.” Individuals on this list may be re-contacted if recruitment targets are re-evaluated in the future. Consent: If they are screened eligible, they will be taken to the study consent form (a waiver of parental consent has been obtained for minor participants). To optimize AMSMs active understanding of the consent process, we also include a video with subtitles and key concepts from the consent form at the bottom of the video screen. The video will be followed by the full consent form, which AMSM will be prompted to read and then either consent to or reject participation. AMSM will also have the ability to download a complete version of the consent form. AMSM who do not consent will be taken to a screen thanking them for their interest (which will also include information on HIV testing). AMSM who consent to participate will be directed to continue through the registration process.

We note several advantages and disadvantages of conducting online and mobile-based research and interventions. An advantage of online research is data validity; a growing number of studies indicate higher reporting of sexual risk and substance-using behaviors with computer-based surveys compared to mail, phone, and in-person surveys. However, compared to the gold standard (in-person interviewing), a limitation of online research like mail and phone surveys is the challenge of verifying a respondent’s identity. Based on our prior work, we will use best practices to reduce the likelihood of online fraud by keeping compensation sufficiently low (i.e., balance incentives with the effort required from respondents) to reduce the chances of respondents participating solely to gain incentive payments, and verifying contact information using multiple verification methods, including email, cell phone, and mailing address. The validation, or verification, of participant contact information is the "gold standard" for fraud prevention. This process is commonly used in online research and will prevent multiple submissions as well as help ensure that the intended participant fills out the responses. We will verify participant information using two forms of personal information, including their mobile phone, to ensure that the participant’s mobile phone number is unique in the study database. We will also run duplicate detection software continually (i.e., respondent creates a fake user profile to gain incentives) until recruitment is complete and all subjects are verified. Responses from the screening survey will be checked against responses in the baseline survey to ensure consistency, and IP addresses, email addresses, and phone numbers will be reviewed to check for multiple registrations. Proxy IP addresses will be flagged for further scrutiny, and reviews of the baseline survey data will be conducted to check for suspicious response patterns and realistic completion times. Within 48 hours after verifying the baseline survey, participants will be sent an email confirmation. Within 24-48 hours after verifying their email, participants will receive their login credentials for the iReach WebApp and subsequently their incentive payment for completion of the baseline survey. Prior to receiving the login credentials, participants are assigned into a 1:1 ratio using a stratified randomization by race and region into the Intervention or Attention-Control condition. Screener and baseline data will be used by iReach to inform personalized, tailored content for AMSM assigned to the intervention condition.

5. Early Withdrawal of Subjects:

Participants are told in the consent form that they can withdraw from the study at any time without penalty. Participants are told that they can withdraw from the study by contacting Dr. José Bauermeister at the University of Pennsylvania by email (bjose@nursing.upenn.edu).

Participants may also be withdrawn by study PIs for the following reasons:

1. A participant is flagged to have a duplicate or fraudulent registration during the fraud detection process. Fraudulent entries will not be counted towards study recruitment totals.
2. Failure to follow study instructions
3. Other circumstances in which a PI determines that continued study participation is not in the best interest of a participant.

6. Vulnerable Populations:

Children are enrolled in this study. Please see the Vulnerable Populations – Children form attached to the initial IRB application for more information.

7. Populations vulnerable to undue influence or coercion:

Using online recruitment methods and consent processes where the intervention is not pitched by a recruiter minimizes the risk of potential coercion. Instead, AMSM will be able to choose and click on the recruitment advertisement and decide if they wish to learn more or not. Consent documents will fully explain the study procedures, potential risks, and potential benefits. Participants will also be reminded that the study participation is voluntary and that refusing to participate in the study or withdrawing from the study is an option at any time.

STUDY DESIGN:

The research activities involve a two-arm prospective RCT enrolling a sample of 600 AMSM with the aim of maintaining a randomized sample of approximately 500 online-recruited AMSM (13-18), assuming 15-20% attrition. After consent and completion of the online baseline survey, AMSM are randomized to either the control or experimental condition (Intervention, n=300; Control, n=300). Participants in the control arm will receive access to only the resource locator function of iReach, allowing them to search for local resources. Participants recruited nationally will receive a list of national resources. Participants in the experimental arm will receive access to all iReach functions, including life skills education, goal setting, local/national resource directory, a discussion forum related to life skills and goal setting, and the ability to link to a Peer Mentor through the VSee video-chat function. After consent and a baseline survey, AMSM are randomized to either the attention control or intervention condition. Self-completed study assessments are conducted online every three months across the intervention and attention-control follow-up time points, with a total follow-up period of 12 months for participants initially randomized into the intervention group, and 15 months for participants initially randomized into the control group. In months 12 to 15, we will make the intervention accessible to AMSM in the attention-control condition. The primary outcomes are cognitive (e.g., HIV prevention attitudes, norms, self-efficacy, behavioral intentions); behavioral outcomes are secondary (e.g., condom use, HIV testing, PrEP use). The proposed study design thus tests the impact of an e-delivered life skills intervention with an embedded video-chat peer motivational interviewing function on cognitive and behavioral HIV-related outcomes on a large (n=600) sample of AMSM.

The study is funded for approximately 5 years (Project Period: 07/28/2016 to 02/28/2021). Once consented, participants randomized into the intervention group will be active in the study for 12 months. Participants randomized into the control group will be active in the study for 15 months.

METHODS:

1. Study Instruments:

Participants will complete 5 or 6 online surveys during the trial (baseline, followed by 3, 6, 9, and 12 month follow-up surveys for participants in the intervention group; baseline, 3, 6, 9, 12, and 15 month follow-up surveys for the control group). Assessments will take 30-45 minutes to complete. Primary Outcomes: Consistent with our theoretical framework, we will assess AMSMs psychosocial correlates predicted to engage in HIV prevention behaviors as our primary outcome. We will measure AMSMs HIV knowledge using a recently updated measure of the HIV-KQ for AMSM, an internally consistent and stable HIV knowledge scale shown to be appropriate for low-literacy populations. We will also use Bouris et al.s assessment of AMSMs discussion of sexuality-related topics, which measures frequency of communication (1=Never; All of the Time) in seven domains: (1) puberty, biology and human sexuality; (2) sexual orientation disclosure; (3) how to resist sexual

pressure from partner; (4) sexual satisfaction and desire; (5) having sex with male, female, and transgender partners; (6) HIV/STIs, and (7) condom use. The existing assessment was developed to focus on the exchanges between mothers and AMSM in a racially and ethnically diverse sample of YMSM. We will extend it to include fathers and/or other trusted adults identified by the AMSM. Motivation to engage in condom use behaviors will be assessed using 3 scales from Fisher et al.s Teen Health Survey. We will measure motivation using 3 scales: attitudes (3 items; .60), social norms regarding peers and partners (6 items; .80), and behavioral intentions (3 items; .80). Motivation to adopt routine HIV testing (e.g., making a calendar for HIV testing or talking to partners about HIV testing) will be assessed with 3 subscales assessing AMSMs attitudes, social norms, and behavioral intentions that we have used in the past with this population. Each attitude item is measured with three five-point semantic differential scales (good-bad; worthless-valuable; pleasant-unpleasant). Social norms assess the extent to which participants felt that friends and family believed he or she should test for HIV on a 1 to 5 scale. Behavioral intentions items assess participants intention to adopt HIV testing, on a 1 (very unlikely) to 5 (very likely) scale. We will measure self-efficacy across three behaviors: condom-use self-efficacy (3 items; =.72), safer-sex negotiation self-efficacy with casual partners (5 items; =.94) and regular partners (5 items; =.91), and discussing HIV testing with partners (3 items; =.90), Finally, we will measure PrEP knowledge, awareness, and use of PrEP. The survey will contain a detailed description of PrEP to orient the participant. Questions related to PrEP uptake (i.e., willingness, awareness) are adapted from recent studies of PrEP attitudes with AMSM. PrEP awareness will be a single item measure of whether the participant has heard of PrEP (binary: yes/no). Among non-PrEP users, PrEP willingness will be measured using an existing 8-item scale (=.84) developed for YMSM (range 1-3) to gauge how willing they would be to use PrEP across different conditions (e.g., partner types; experiencing potential side effects). Secondary Outcomes: We will also examine the interventions efficacy among AMSM who engage in risk behaviors. Specifically, we will assess whether the intervention aided to (1) reduce sexual risk behaviors, (2) decreased ATOD (alcohol, tobacco and other drug) use, and (3) increase linkage to HIV prevention services. For incident HIV+ cases, we will assess AMSMs linkage and retention in care. Sexual risk behavior will be assessed using the Sexual Practices Assessment Schedule for Youths. We have adapted this assessment for use in previous online studies with YMSM. The assessments asks lifetime of sexual partners and types of sexual acts (e.g., kissing, touching, oral sex, penetrative sex) before proceeding any further. For behaviors reported, the assessment then explores the number of occasions of different sexual acts (oral, anal; receptive, insertive) with three different types of partners (romantic interest, casual partner [hookup] or friend with benefits), use of condoms during the past 3 months, and knowledge about partners HIV status. The assessment also differentiates between male and female partners. We will adapt the assessment to ascertain whether, to their knowledge, their sexual partners are on PrEP. HIV/STI testing and care: The baseline survey will include questions on lifetime HIV/STI testing history. Follow-up surveys will repeat the questions from the baseline, and will also include questions on HIV/STI testing in each 3-month period including test results. Among newly diagnosed HIV+ cases, we will assess their linkage and retention in care. We will also assess onset of ART initiation and viral suppression as exploratory indicators, as we recognize that our follow-up period may not be a sufficient amount of time to see these changes. PrEP use: At baseline and each follow-up assessment, we will measure whether eligible AMSM are using PrEP. ATOD (alcohol, tobacco, and other drug) use: We will assess frequency of ATOD use (as measured in National Survey on Drug Use & Health) over the past 3 months and past 30 days for alcohol, cigarettes, tobacco, marijuana, non-prescription drugs, cocaine, amphetamines, depressants, and heroin. We will also ask age of onset. If respondents indicate current smoking behaviors we ask how many cigarettes they smoke daily and past year attempts to quit smoking. If respondents indicate alcohol use, we will ask the Alcohol Use Disorders Identification Test (AUDIT) developed by the WHO. The AUDIT is a 10-item screening questionnaire with 3 questions on the amount and frequency of drinking, 3 questions on alcohol dependence, and 4 on problems caused by alcohol. Self-efficacy for managing triggers for substance use: We will administer a composite measure that assesses self-efficacy for managing triggers for alcohol or other drugs using the Situational Confidence Questionnaire 8 item version (SCQ-8) is a brief, validated measure of self-efficacy for managing internal (e.g., emotional) and external (e.g., situations) triggers for ATOD use. Psychosocial Mediators of Interest: As articulated in Figure 2, we will measure the following psychosocial mediators that result in the hypothesized intervention effects: Life skills will be assessed using several constructs. The Future Goals subscale of the Stanford Time Perspective Inventory assesses the degree to which participants were striving for future goals and rewards. The scale is made up of 13 items (.7032) rated on a 5-point scale (1=very untrue-5=very true). We will also use the Life Outcome Expectancies measure developed by the Adolescent Trials Network. The measure is divided into two conceptual domains, Outcome Expectations and Efficacy. The Life Outcome Expectancies questions measure participants perceived likelihood of reaching life milestones on a five-point scale (1=not at all-5=has already occurred; .70). The Efficacy questions measure participants perceived control over their life circumstances on a 4-point scale (1=poor-4=excellent; .80). Personal competency will be measured by answering 14 statements using a 4-point scale (1=Never True-4=Often True), indicating the degree of how much each statement applied to themselves in the past month. Examples are No matter what challenge I face, I always find a solution, I can handle unpleasant feelings, and I have realistic plans for the future. Identity Development will be assessed with a general self-esteem score as well as several measures to examine AMSMs sexual orientation and racial/ethnicity identity development that we have used in prior studies with YMSM of color. We will use the 10-item Rosenberg Self-Esteem, measured on 4-points (0=Strongly disagree-3=Strongly agree; .85). Sexual orientation identity will be assessed using Mayfields 23-item Internalized Homonegativity Inventory (IHNI), which uses a five-point scale (1=strongly disagree-5=strongly agree) to measure 3 subscales: Personal Homonegativity (11 items measuring negative emotions and attitudes towards ones own sexual orientation; .90), Gay Affirmation (7 items measuring positive attitudes and feelings that being gay is important, normal and fulfilling; ; .80), and Morality of Homosexuality (5 items measuring

negative attitudes regarding the moral implications of same-sex attraction and behavior; ; .70). Racial/ Ethnic Identity will be assessed using the multi-group racial/ethnic identity measure (MEIM). The MEIM is a 14-item scale including three items that require the participant to choose a racial/ethnic group for himself as well as for each parent. We will use two subscales of the MEIM: Racial/Ethnic Identity Search (a developmental and cognitive component; .70) and Affirmation, Belonging, and Commitment (an affective component; .85). Participants answer items with a four-point scale (1=strongly disagree-4=strongly agree). Higher scores on each subscale indicate a stronger connection to ones racial/ethnic identity. All identity domains and subscales have strong convergent, discriminant and construct validity in a prior study with YMSM. Social Environment will assess perceived connectedness to the LGBT community, as well as enacted experiences of stigma and discrimination. AMSMs Connectedness to the LGBT community will be assessed with Frost & Meyers 8-item scale (1=Strongly Disagree-4-Strongly Agree; =.88). We will also measure AMSMs Sense of Belonging to measure participants involvement in environments considered to be LGBT (1=Strongly Disagree-4Strongly Agree; =.86). LGBT Discrimination will be measured with the Gay Bashing Scale, a 9-item scale (0=never; 4=more than three times) with strong reliability developed to assess the frequency of discriminatory events (e.g., verbal insults) due to someone knowing or assuming that the participant was gay or bisexual. We will also measure AMSMs sexual identity stigma (e.g., Most people in my community think less of a person who is gay/bisexual) using the Perceptions of Local Stigma Scale (0=Strongly disagree; 4=Strongly agree). LGBT Stigma: We will also measure internal LGBT stigma (homonegativity) and experienced LGBT stigma. Internalized homonegativity will be measured by the revised 10-item Reactions to Homosexuality Scale, which includes items like It is important for me to control who knows about my homosexuality, and answered on a 4-point scale (0=Strongly disagree; 4=Strongly agree). Experienced LGBT stigma will be measured using an 8-item scale to examine heterosexist harassment, rejection and discrimination (e.g., How often has a friend rejected you because of your sexual orientation? (0=Never-4=Many Times; .90). HIV Stigma: We will assess the abbreviated 7-item version of the Anticipated HIV stigma scale to measure internalization (e.g., I would feel I were not as good a person as others if I got HIV) and negative consequences of stigma (e.g., If I got infected men would not want to have sex with me). Items are rated on 4-point scale (1-Strongly Disagree-4=Strongly Agree; .80). Social Network characteristics will be measured as they relate to parents and peers. We will assess AMSMs disclosure (outness) to their social network. Participants will rate their comfort with disclosure to different members of their social network. For those who are not out, they will be asked to rate their social network members reaction where they to find out about his same-sex attractions. We will measure emotional support from parents and peers, respectively. Parental support is an abbreviated, 5-item version scale that assesses participants perceived emotional support from parents. Peer support from friends will be examined using the peer-equivalent version of the parent social support scale. For both scales, participants rate, on a scale from 1 (Not True) to 5 (Very True), how much each of the items describe their feelings and experiences in your relationships with your [parents/friends]. We will measure Peer sexual norms by adapting an existing 5-item measure that ascertains how many peers within participants social networks perceive that being sexually active makes someone cool or popular using a 4-point scale (0=None-3=All). We will assess perceived descriptive norms regarding peer sexual behavior with 4 items assessing whether AMSM perceive that their friends are engaging in risky sexual behavior (0=None-3=All). High scores indicate that participants perceive greater HIV risk in their networks. Based on our prior work with AMSM, dating behaviors will be assessed to examine whether they are in a relationship, and to note the gender of their partner, duration of their relationship, and satisfaction with the relationship. Covariates. We will also collect information of the following mediators and moderators for our analyses: Socio-demographic information will include questions on race/ethnicity, educational attainment, employment status, place of birth, year of immigration (when appropriate), housing status, history of incarceration, and engagement in transactional sex. Psychological distress will be measured using existing, well-validated scales. We will use subscales from the Brief Symptom Inventory to measure depressive symptoms and anxiety symptoms. Depressive symptoms include 6 items (.80) rated on a 5-point scale (1=never, 5 = very often). Items include feelings of loneliness, blue or sad, and having thoughts of ending ones life. Anxiety also includes 6 items (.90) measured on the same 5-point scale and includes reporting nervousness or shakiness, feeling fearful, or suddenly scared for no reason. We will also measure AMSMs Perceived Loneliness using the UCLA Loneliness Scale using a 4-point scale (1=Never;4=Often). In our prior work, reliability for this scale with YMSM was high (.90). To measure Stress, we will assess perceived stress through daily hassles. AMSM will rate their experiences of stress over the past month (e.g. how often have you found that you could not deal with all the things that you had to do), and rate the frequency with which they felt these ways on a scale from 1 (Never) to 5 (Very often). We have used these measures in prior studies, and have shown excellent psychometric properties consistently over time. Social Media Use: Given potential disparities in access to technology, we will include the PEW Internet Survey questions regarding use of different devices, the number of hours spent online through each device, the reasons for social media use, sites commonly frequented, and extent to which the Internet supplements face-to-face interactions. We will also measure AMSMs frequency of use of social media to look for HIV or sexual health-related information, and their online partner-seeking behaviors. Online health seeking competency will be measured using an adapted, 6item version of the eHealth Literacy Scale (eHEALS) that asks respondents on a 5-point Likert scale about their knowledge of online resources including where to locate them, how to find them, how to use information, and comfort with assessing the quality of online health information. In a recent trial, we had strong reliability when used with AMSM (=0.94). Intervention Acceptability and Satisfaction: At each follow-up, AMSM will report data on the acceptability of their assigned intervention. We will ascertain participants overall satisfaction with the intervention, using factors from the Information Systems Success Model (ISSM)288,289: perception of the information quality, system quality, and perceived usefulness of their intervention. Information quality refers to users perceptions of the quality of the information on the intervention; system quality refers to users perceptions of how easy the

intervention was to navigate and its technical responsiveness; and perceived usefulness reflects how the intervention was perceived by participants to impact their health behaviors. Scores range from 1 (Strongly Disagree/Very Unlikely) to 7 (Strongly Agree/Very Likely). Intervention Exposure, Fidelity & Dosage: We will measure intervention exposure using paradata from the intervention, including counts of user sessions, session lengths, pages visited and functions utilized. For the VSee peer counseling component, we will record the number and duration of VSee sessions, as well as the domains covered in these sessions. We will also include MITI fidelity scores across the sessions. This information will assist in examining whether intervention dosage influences the overall efficacy of the intervention, as well as inform the Secondary Aim regarding cost analysis and wider implementation and scalability.

2. Group Modifications:

Over the first year of the study, we will adapt existing measures to ensure that they are developmentally appropriate for our participants through our Adolescent Development and Clinical Medicine Working Group and our Technical Expert Group. The Adolescent Development & Clinical Medicine Working Group will be led by Dr. Bauermeister and will provide expertise regarding the psychosocial and clinical developmental milestones occurring during adolescence. Specifically, they will contribute to the adaptation of intervention measures and materials for early and middle-aged adolescents. The Working Group will include two leading HIV prevention and care clinicians who have devoted their career to the needs of AMSM, and two public health researchers, Dr. Marc Zimmerman and Dr. Sarah Stoddard. We have also convened a Technical Expert Group (TEG) who engage with youth and MSM in their roles as researchers (Keith Horvath, PhD & Katherine Elkington, PhD), HIV and LGBTQ clinical and social service providers (Rob Garofalo, MD), national advocates invested in AMSMs well-being (Moisés Rosario-Agosto from NMAC & Maureen Blaha from National Runaway Switchboard), and researchers who have experience in intervention/program development and evaluation with AMSM (Susan Kegeles, PhD; David Chae, PhD). The input of the TEG will be incorporated across all of our proposed activities, including reviewing the screening and assessment tools to ensure that they are culturally and linguistically appropriate for use with diverse groups of AMSM. Once we have reviewed our measures, we will pilot the HIPAA compliant online survey assessments to ensure that the survey layout works with different mobile devices (e.g., Android, iPhone) and browser platforms (e.g., Safari, Mozilla, Chrome, Explorer), that skip-patterns are correct, and that the server is saving the data appropriately. We have also taken several steps to ensure that the assessments are brief and also developmentally-appropriate. First, AMSM will not answer all listed constructs at every assessment. Identity-related constructs, for example, will be measured at 6-month intervals, whereas other constructs (e.g., comfort discussing sexuality) will be assessed at each follow-up. Second, consistent with best practices that we have used in prior HIV studies with pediatric and adolescent populations, we will use gate-keeping questions to decide whether participants should receive other probes within a domain. For example, a participant who has yet to become sexually active would receive cognitive assessments focused on HIV risk and awareness (e.g., attitudes, norms), but would not receive questions regarding behavioral intentions to engage in HIV prevention in next 3 months (e.g., HIV testing, PrEP) or questions regarding sexual risk behaviors (e.g., sexual behavior, HIV testing, PrEP use). Similarly, at each assessment, AMSM with no lifetime substance use will not be asked about additional substance use questions. Among sexually active participants, gate-keeping also provides opportunities to regulate how detailed the assessments will be. For example, we will assess sexual behaviors (yes/no) around kissing, touching, oral sex, vaginal and/or anal sex; if a participant notes only engaging in kissing and touching behavior, we will not ask any additional sexual behavior questions as they are not pertinent to HIV risk.

3. Method for Assigning Subjects to Groups:

Eligible participants will complete a baseline survey and subsequently assigned in a 1:1 ratio using a stratified randomization by race and region into the Intervention or Attention-Control condition. Participants recruited nationally will be assigned to a fifth “region” and randomized in a 1:1 ratio to the Intervention or Attention-Control condition.

4. Administration of Surveys and/or Process:

Surveys: We will collect survey data via online self-completed surveys administered at baseline, and 3, 6, 9, and 12 months, with an additional 15 months survey for control participants. Each survey will last approximately 30 minutes. Participants will enter their own responses to questions directly into the survey on their personal computer, smartphone or tablet. Participants will access the surveys via their profile on their password protected study website account. A total of 6 surveys will be conducted, for a total follow-up period of 15 months. The small time frames between assessments will help us to respond quickly to retention concerns. In addition, we have planned our incentive schedule to reflect the time that participants must spend completing the surveys. Incentives for completing the baseline, the 12-month follow-up survey, and the 15-month follow-up survey (for participants initially randomized into the control condition) will be $30 per assessment, whereas the 3, 6, and 9-month follow-ups will be $25 each since they are shorter in length. These incentives are small enough to avoid coercion, yet sufficiently substantial to promote retention. In order for interventions to be evaluated as potential best evidence-based interventions through CDCs Prevention Synthesis Research activity, data must be available for at least a single follow-up time point for at least 70% of participants. As indicated below, a detailed retention plan for the study will draw on previously successful retention protocols to achieve at least an 80% retention rate for the first follow-up visit. Our experience has shown that successful retention has several key elements. First, it is critical to obtain accurate follow-up contact information. We will use best practices to retain participants (e.g., comprehensive locator information that includes participants' cell phone number, e-mail, Facebook and/ or other social media usernames, and contact information

for 1 peer who could help us contact them), while being sensitive to undue disclosure of AMSM participating in the study. We also have a pre-planned schedule of follow-ups that consists of a variety of follow-up methods. Initially, a respondent who does not respond to an electronic notification that a survey is due will automatically receive additional notifications 36 hours after the initial notification. If the participant has still not completed the assessment 24 hours after the third electronic notification, the retention activities are escalated to a research staff member who will begin escalating contact intensity. Depending on the participants preferences provided upon registration, contacts will be made initially with the preferred mode of re-contact (for example, by SMS text message); if still unresponsive, other available modes (e.g., phone call) will be used. Each contact is logged in an electronic retention system developed by Emory University and used in prior studies to achieve excellent (90%) retention. This system also maintains electronic lists of participants retention status, and automatically creates notification lists for retention staff to ensure that a systematic process is followed and carefully documented for retention.

5. Data Management:

We will implement several strategies to offset risks of loss of confidentiality related to web survey data collection. Participants contact information will be kept in a locked cabinet accessible only to the research staff or on password-protected computer files. We will need to collect a valid e-mail address to reimburse participants for their time (i.e., study incentives) and for internal auditing purposes. To ensure we have sent participants their incentives, we will keep the e-mail addresses in a list to be stored in a password-protected server. In addition, we will use participants' email, IP address, browser/operating system, and time taken to complete survey to flag potential fraudulent/suspicious cases. We will crosscheck email and IP addresses through web applications (e.g., Facebook, IP lookup), yet we will not keep any of this information or link it to any behavioral data. We have taken this approach in prior studies and written on its importance for web survey research. Once identified, we will email suspicious cases and ask for clarification. If verified, we will treat each case as unique; otherwise, we will disqualify the case and not use the entered data. A Certificate of Confidentiality issued by the Department of Health and Human Services has been obtained to cover the research.

Participant contact information will be collected and stored separately from survey and intervention data. Survey and intervention data will be identified using alphanumeric study participant ID numbers, assigned by study staff, which will be unrelated to the participant's name or email address. Survey data will be automated to download onto a secure university server. All web survey data will be secured using an SSL 256-bit encryption. SSL encryption is the standard for all web-based transactions that include any identifiable information, including names, addresses, and credit card numbers. Phone numbers and e-mail addresses to contact the PIs and the IRB will be provided. All web survey data are stored as "packets" or sub-files that, prior to conversion, need to be "accumulated" before they can be used. These data files are protected behind HIPAA-compliant web-servers at the University of Pennsylvania, University of Michigan and Emory University and may not be viewed/ accessed by third-parties (unless there is explicit mal-intent to obtain the data; e.g., hacking). Once downloaded, data exports will be converted into an SPSS working file. Once downloaded from the server, we will expunge data from the servers. We will keep a file containing contact information (i.e., email) and IP addresses separate from study data. This file will be password-protected and stored within a restricted folder on the secure server. The reason for keeping this personal information is solely administrative (i.e., to ensure that we keep a record of incentive payments, and to verify that fraudulent data collection does not occur (e.g., individuals may seek to falsify information on the web survey in hopes of receiving an incentive more than once). Data will be stored in a physically secure environment, and all data files will have encryption and strong password protection. Access to data will be on a role-based standard; only those study staff that require access to identifying data to complete their study-related roles will be allowed access, as described above. All study staff will be trained in security and confidentiality procedures, and will sign a confidentiality agreement before receiving access to any participant data. Contact information used to confirm participation will be held in a password-protected database on a secure university server, accessible only by study staff. This contact information will be held separately from baseline and follow-up survey data, which will contain only the participants study identification number. The database will be backed-up to a hard drive housed in another location, also accessible only by study staff. The contact information (name, email address and phone number) in the database will be destroyed at the end of the study, and will never be associated with the study data collected. Norton Clean-Sweep software will be used to delete the database file from the secure server and the back-up file (s) from the separate hard drive.

Audio/Text Recordings of VSee peer-to-peer sessions: Participants in the intervention arm will have to partake in one introductory session with a peer mentor: they will have the option of face-to-face video chat, video chat in which they can see the peer mentor but the peer mentor cannot see them, audio chat only or text only. All VSee sessions will be recorded, either as audio or text files. No video will be recorded or kept. Access to data collected through surveys and audio-recordings will be limited to the study PIs and relevant staff, all of whom will be trained in the importance of protecting personal health information (PHI). Access to additional researchers may be granted for the purpose of conducting specific secondary analyses but at this juncture the data will be de-identified and only linked to a participants' study ID. These other researchers will be added to the IRB approval as co-investigators and as such are required to have completed human subjects training.

6. Management of Information for Multi-Site Research where a Penn Investigator is the Lead Investigator of a Multi-Site Study, or Penn is the Lead Site or Coordinating Center in a Multi-Site Study.

To ensure effective coordination of responsibilities and manage information continuously, Dr. Bauermeister will communicate weekly with Dr. Stephenson and Dr. Sullivan to discuss the study design, data analysis, and all administrative responsibilities. In the event of any required modifications to the protocol, the research team will discuss any changes and submit a modification to the protocol for review by the IRB. Although there are three sites, intervention recruitment, consent, activities and retention occur online. As a result, we will be able to identify any unanticipated problems and to respond accordingly depending on the potential risk. We also have near real-time access to data which we can use to generate interim reports (as requested by our NIH Program Officer) and our Data Safety Monitoring Board. In the event of an unanticipated problem, we will submit an adverse event report to the IRB.

7. Subject Follow-up:

This study involves follow-ups at month 3, month 6, month 9, and month 12, with an additional follow-up survey at month 15 for control participants.

We will use best practices to retain participants (e.g., comprehensive locator information that includes participants' cell phone number, e-mail, Facebook and/or other social media usernames, and contact information for 1peer who could help us contact them), while being sensitive to undue disclosure of AMSM participating in the study. For example, in a prior study, we allowed AMSM to use our automated messages (e.g., José its time to return to iCON) or design their own reminder messages (e.g., John check-in about your life skills), as well as select how to best be reached (i.e., email, text message, social media private message, voicemail). In addition, based on our qualitative research in preparation for the Checking In online cohort, we allow participants to specify the day of the week and time of day when they would like to receive electronic follow-up surveys. In this way, participants are more likely to receive follow-up assessments at a time when they are able to complete them immediately. We also have a pre-planned schedule of follow-ups that consists of a variety of follow-up methods. Initially, a respondent who does not respond to an electronic notification that a survey is due will automatically receive additional notifications 36 hours after the initial notification. If the participant has still not completed the assessment 24 hours after the third electronic notification, the retention activities are escalated to a research staff member who will begin escalating contact intensity. Depending on the participants preferences provided upon registration, contacts will be made initially with the preferred mode of re-contact (for example, by SMS text message); if still unresponsive, other available modes (e.g., phone call) will be used. Each contact is logged in an electronic retention system developed by Emory University and used in prior studies to achieve excellent (90%) retention. This system also maintains electronic lists of participants retention status, and automatically creates notification lists for retention staff to ensure that a systematic process is followed and carefully documented for retention.

STUDY PROCEDURES:

1. Detailed Description:

The research activities involve a two-arm prospective RCT enrolling a sample of 600 AMSM with the aim of maintaining a randomized sample of approximately 500 online-recruited AMSM, assuming 15-20% attrition. After consent and completion of the baseline survey, AMSM are randomized to either the control or experimental condition (Intervention, n=300; Control, n=300). Participants in the control arm will receive access to only the resource locator function of iReach, allowing them to search for local/national resources. Participants in the experimental arm will receive access to all iReach functions, including life skills education, goal setting, a discussion forum related to life skills and goal setting, local/national resource directory, and the ability to link to a peer mentor through the VSee video-chat function. Self-completed study assessments are conducted online every three months across the intervention and attention-control follow-up time points, with a total follow-up period of 12 months. At the end of the trial, we will make the intervention accessible to AMSM in the attention-control condition for a 3 month period, followed by an additional follow-up assessment at month 15. The primary outcomes are cognitive (e.g., HIV prevention attitudes, norms, self-efficacy, behavioral intentions); behavioral outcomes are secondary (e.g., condom use, HIV testing, PrEP use). The proposed study design thus tests the impact of an e-delivered life skills intervention with an embedded video-chat peer motivational interviewing function on cognitive and behavioral HIV-related outcomes on a large (n=600) sample of AMSM.

Central to our intervention is the use of peer mentors who will provide motivational interviewing style counseling to AMSM via VSee video chat. *The first stage we outline in our approach is the selection and training of the peer mentors.* Consistent with a positive youth development framework, we will hire and train young adults to serve as peer mentors and provide MI-based counseling via VSee. Although we discussed recruiting and training AMSM for the intervention, we opted to select a slightly higher age range for our peer mentors in order to promote a mentor-mentee relationship and encourage upward social comparisons (i.e., having someone to look up to in the trial) during their interactions, yet able to relate to adolescent development. Peer mentors will contribute to the proposed activities across the five years: (1) help evaluate tools and programs to ensure age appropriateness and readability, cultural sensitivity and linguistic appropriateness, gender and sexual orientation sensitivity, and minimized burden of intervention strategies, (2) identify sites across each region and populate the resource locator, and (3) serve as peer counselors in the intervention condition.

Recruitment & Eligibility of Peer Mentors: We will recruit and train 15 peer mentors in Philadelphia, PA in order to supervise them in person throughout the trial. As we select peer mentors, we will aim to recruit a diverse team across age, race/ethnicity, and sexual orientation identity. We will apply several recruitment strategies, including study promotion through community partners, ads in online LGBT listservs, flyers in HIV community-based organizations, local coffee shops and bars, college listservs, and advertisements on Facebook. This triangulation of recruitment strategies has yielded success in recruiting a socioeconomically and racially diverse sample of YMSM in our previous projects.

Enhancing Intervention Life Skills Resource Content*:* During the first 6 months of the proposed project we will train the peer mentors to identify existing resources across the four regions included in our study. Following a sequential method, peer mentors will first compile an exhaustive list of HIV/STI testing locations using the AIDSVu directory and supplemental search engine searches. The Emory team has collected a list of PrEP provider registries already and is working with NASTAD, Kaiser Family Foundation and UCSF to launch a national provider registry in summer 2016, which will be available and updated as necessary for this project. We will then verify the information obtained by calling the sites and verifying their hours, services provided, phone numbers, addresses, targeted client age, and cost of services (if applicable). We will also mail a formal letter to these sites asking if they would like to opt out of being listed in a LGBTQ youth directory. In prior studies, we have found this approach to be useful as it helps us identify agencies that are not welcoming to AMSM. A printed letter also enhances legitimacy, as compared to an e-mail communication. Once we have excluded agencies that opt-out from our master list, the peer mentors will enter each site's information into the resources locator console and map them onto specific goals within each life skills domain.

Peer Mentor Training and Intervention Fidelity: After peer mentors have completed populating the resources across the regions, they will be trained to deliver MI-based counseling to AMSM. Existing training and fidelity protocols employed when delivering MI to youth will be used. The mentors will be trained in foundational MI concepts and skills over a 2-day training session, with further skill development through regular skill practice exercises. To provide variability in types of scenarios, we will ask the supervisory team to develop role plays that ensure exposure to diverse populations (e.g., rural areas, questioning gender, and exposure to juvenile justice system). Mentors will only be able to deliver sessions after demonstrating proficiency via audiotaped role-plays using standard coding protocols. Dr. Bonar, a member of the Motivational Interviewing Network of Trainers, and an on-site study coordinator will monitor on-going sessions and be ready to assist peer mentors when necessary. Procedures for monitoring intervention adherence and competence include audio-taping all sessions and coding for Clinical Skill/Competence using *the Motivational Interviewing Treatment Integrity* coding scheme (MITI-4; global ratings empathy, MI spirit; behavioral counts of MI adherent/non adherent behaviors). Biweekly supervision to review audio-recorded sessions will be employed to ensure MI principles are followed; we have found this to be extremely important in prior trials since our peer mentors are not clinicians. Mentors will receive booster trainings every 2-months to reinforce their skills, learn new content emerging from the HIV literature, and address on-going challenges emerging from the intervention sessions. If peer mentors are unable to continue their role during the trial (e.g., move away), these scheduled trainings will ensure that we can bring new peer mentors onboard.

Adaptation of iCON to younger-aged AMSM: We will employ modern Agile software development principles and iterative, incremental development as we adapt the intervention to AMSM. The current iCON interface is built for AMSM as young as 15 years old; consequently, we will adapt the intervention to ensure that there is age-appropriate content for AMSM ages 13-15. The Scientific Team will work closely with the Center for Health Communications Research (CHCR) to make any modifications required, including integrating VSee into our iCON interface and including more images throughout the content as a heuristic to assist in learning. Cyclical developmental processes are key to encourage frequent interactions between our research team, the CHCR programmers, and peer mentors during modification iterations. It also provides opportunities to develop components that are innovative and are not lagging behind the technology (e.g., developing a prototype in Year 1 that would not be implementable if a new operating system emerged by Year 3). Consistent with our prior collaborations, the Scientific Team will have weekly meetings with CHCR to discuss progress and solve arising challenges.

Content Review: To develop, refine, and standardize the intervention's content, we have used an iterative process. First, the original iCON content was reviewed by the TEG member or CI with expertise in that topic area. They provided feedback and edits to help align the content with the new, younger age group of our participants. After this, the TEG members, the CI's, the project managers, and the PI's, came together to discuss, brainstorm, and edit the content together at an all-day retreat. Suggestions and edits to the content were incorporated, and then the content was reviewed for language, relevance, and comprehension. Feedback on content edits was received from LGBTQ-identifying youth aged 13-20 at two different youth centers in SE Michigan. After the youth reviews, suggestions and edits was incorporated, and the content was given to two behavioral scientists at CHCR who focused on making the content heuristic and engaging, and created mock-ups for the WebApp. Once the CHCR team provided the content mock-ups, another round of review was conducted by the appropriate TEG members and CI's to ensure scientific accuracy. These mock-ups were also reviewed by the peer mentoring team at the University of Pennsylvania, and Research Assistants (RAs) at the University of Michigan for youth and LGBTQ-friendliness and contextual relevance. Both the peer mentors and the RAs are LGBTQ-identifying young adults (20-25). After the edits and suggestions to these content mock-ups have been incorporated, a final review of all the content

mock-ups will be reviewed by PI, Rob Stephenson to ensure that all content is developmentally appropriate, scientifically accurate, and that there is an MI consistent tone and flow throughout.

We will also review our existing measures alongside our Adolescent Medicine and Development Working Group, as well as our TEG, to ensure that the measures are developmentally appropriate, contextually relevant, and culturally sensitive to diverse populations of AMSM. Once measures are finalized, we will pilot the HIPAA compliant online survey assessments to ensure that the survey layout works with different mobile devices (e.g., Android, iPhone) and browser platforms (e.g., Safari, Mozilla, Chrome, Explorer), that skip-patterns are correct, and that the server is saving the data appropriately.

Strategies to Ensure Sample Diversity: We will reach the population using social media ads on sites including Facebook, Tumblr, Instagram, Reddit and Twitter. Ad targeting within social media sites allows us to specify the age range and other socio-demographic characteristics of individuals who will see the ads based on the information they provide in their online profiles. We will develop ads that promote our target population's interest by including diverse images of youth (i.e., images of different ages, portraying diverse race/ethnicity; see Figure 13), as well as using ad-targeting specific to socio-demographic characteristics (e.g., delivering Facebook/Instagram ads only to youth based on their age, race/ethnicity and sex) and interests (e.g., TV shows with LGBT themes). Materials will avoid identifying candidates as AMSM in the recruitment text to avoid unintended disclosure. Ads will link interested individuals to the study site where they may verify their eligibility, email the team, or locate a toll-free number if they want to talk to a team member about the study.

Data Collection & Retention*:* AMSM will click on viewed social media advertisements and be taken to a homepage containing basic study information including a short description of study activities. ***Screening:*** Interested individuals will be asked to consent to and complete an online screener. We will use this approach as one of our strategies for filtering fraudulent or duplicate entries. Individuals who do not meet the eligibility criteria will be thanked for their interest and automatically routed to the Google page. We will not indicate why they were ineligible to avoid unintentional disclosure and to protect against fraud. ***Consent:*** If they are screened eligible, they will be taken to the study consent form (a waiver of parental consent will be obtained for minor participants). To optimize AMSM's active understanding of the consent process, we will also provide a video of key aspects of the consent form that can be watched by participants. AMSM who do not consent will be taken to a screen thanking them for their interest (which will also include information on HIV testing). AMSM who consent to participate will be directed to a registration process. ***Registration & Randomization:*** After registering, consented participants will complete a 25-minute baseline questionnaire and subsequently be assigned in a 1:1 ratio using a stratified randomization by race and region into the Intervention or Attention-Control condition. Participants recruited nationally will be assigned to a fifth "region" and randomized in a 1:1 ratio to the Intervention or Attention-Control condition. Baseline data will be used by iReach to trigger personalized, tailored content to AMSM assigned to the intervention condition. During the registration process, registrants will provide their contact information including an email address, a cell phone number, a mailing address, and will also be asked to provide a nickname or name of choice. Once a participant submits an email address and a cell phone number as part of the registration process, an email and/or SMS containing a code will be immediately sent to verify the user. Participants must then enter the code as part of the registration process in order to continue.

Measures to protect against fraud and hacking: We will use best practices to reduce the likelihood of online fraud: (1) Keep compensation sufficiently low (i.e., balance incentives with the effort required from respondents) to reduce the chances of respondents participating solely to gain incentive payments. (2) Verify contact information using multiple verification methods, including email, cell phone, and mailing address. The validation, or verification, of participant contact information is the "gold standard" for fraud prevention. This process (see above) is commonly used in online research and will prevent multiple submissions as well as help ensure that the intended participant fills out the responses. We will verify participant information using two forms of personal information, including their mobile phone, to ensure that the participant's mobile phone number is unique in the study database. (3) Run duplicate detection software: we will continually run duplicate detection software (i.e., respondent creates a fake user profile to gain incentives) until recruitment is complete and all subjects are verified.

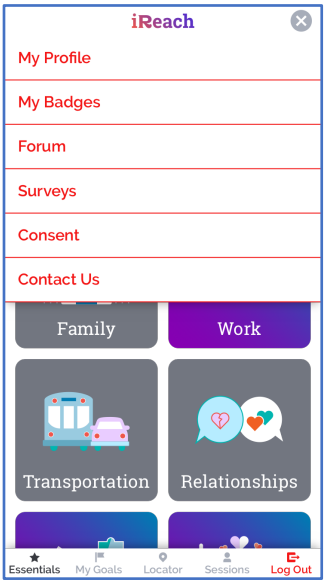
Experimental Group: iReach is a tailored intervention for AMSM. The intervention component of the app aims to facilitate users to lower their vulnerability to HIV infection by (1) providing life skills educational modules tailored on their unique needs and characteristics, (2) setting goals and encouraging participants to use relevant services available locally to help achieve them, (3) accessing LGBTQ-welcoming resources across. The life skills educational content in iReach covers 14 topics and includes resources tied to these topics (e.g. housing, transportation, education, HIV testing and care sites) in their region or national directories to find local resources. The intervention content is written at the 8th grade literacy level. Among newly diagnosed HIV cases, iReach will provide HIV-specific content (e.g., how Ryan White funds can assist with housing and transportation, social support, etc.). Tailored electronic content is based on AMSM's baseline assessment, with opportunities to have new content personalized based on AMSM's answers to the follow-up surveys and as new information/research findings become available. Content is tailored on characteristics collected at baseline (e.g., age,

geographic location, and HIV status). Note that iReach is responsive to the gender development of AMSM; i.e., while we will enroll only male participants who identify with male gender at baseline, participants will have access to information on gender identity and have the ability to edit their profile name and preferred pronouns in their user profile, and will be retained in the study regardless of changes to their gender identity during study participation.

Figure 4. Welcome/Home Page

The iReach *Welcome Page* (Figure 4) displays 14 tiles that contain the life skills educational content. Gray-toned tiles indicate topics that have not yet been viewed and purple/blue-colored tiles indicate topics already seen. There is a fixed menu on the bottom of the screen (Figures 4,5) where the participant can click to navigate to the home pages of the: life skills content ("Essentials"), their list of goals ("My Goals"), the full resource guide ("Locator"), the peer mentor sessions page ("Sessions"), and a button for immediate Log-out. There is also a fixed navigation drop-down menu (Figure 5) in the top-right corner where a participant can choose to look at their user profile ("My Profile"), their earned badges ("My Badges"), the discussion forum ("Forum"), surveys they may need to complete ("Surveys"), the iReach consent form ("Consent"), and an "Contact Us" page that displays the study phone number and email, as well as the National Runaway Safeline and a reminder to call 911 if they are having an emergency.

Figure 5. iReach Navigation Menu Options



Selection of life domain topics and sub-topics: When a participant chooses a topic (e.g., Health) from the Welcome Page, the next page displays several sub-topic options to review. Sub-topics are tailored on HIV status, meaning that there is additional content only seen by participants living with HIV (i.e. Keeping Up with My Treatment Plan, Ryan White Transportation Services), and content only seen by participants without HIV (i.e. PrEP). After selecting subtopics, content is displayed in an interactive format, which includes infographics, Graphics Interchange Format (GIF) images, activities, and accordion headers to improve the ease of navigation, cognitive effort, and maximize the amount of information displayed on small screens.

Goal Setting (see Figure): When AMSM finish reviewing sub-topics on a given topic, the next step is to click on the "*Choose my goals*" button and set goals around that topic. Goal setting has two options: 1) a pre-populated list that reflect the specific life goal modules and skill-sets (e.g. "I will use the Locator to find a place where I can get regular STD and HIV testing"), and 2) a free-text space that allows participants to write-in their own goals. Once goals are chosen and saved, participants are brought to a screen that asks them to set a time-frame for goal completion. Again, participants can choose from a pre-populated list (e.g. "Tomorrow", "Next week", etc.) or choose to write in their own time frame. After they have completed this, they are brought to a screen with options to view or edit their goals, talk to a peer mentor, go to the resource locator, go to the discussion forum, view their badges, or set more goals.

Discussion Forum: From the top drop-down menu participants will be able to access the discussion forum ("Forum"), a function that allows participants to ask questions, process, personalize, and interact with their peers about information from the different life skill content topics. Users will be presented with a set of posting guidelines each time they use the forum, instructing them about what types of content are allowed (e.g. questions or thoughts about goals and life skills content) and not allowed (e.g. identifying information, antagonistic behavior, inappropriately sexual or substance-related posts), and asserting that by using the forum they agree to abide by these rules. This forum will be monitored daily by peer mentors and study staff. New posts will be reviewed on a daily basis to ensure that they do not violate the forum guidelines. Posts that do violate forum guidelines will be immediately removed from the forum and the study team will contact the user who made the post to remind them of forum guidelines, inform them that their post was in violation of the guidelines, and issue a warning. The forum will have a "two strikes and you're out" policy, where after violating forum guidelines twice, the user will lose the ability to post anything to the forum. However, the forum will still be visible to the user, so they can still read and learn about life skills and goals with other users.

Figure 6. iReach Badges

Badges: To encourage engagement with the WebApp, participants will be able to earn various "badges" for completing different activities within the WebApp. Badges can be earned for interaction with the WebApp features including: reading the content, setting and completing goals, scheduling and completing peer mentoring sessions, as well as "liking" posts and making posts to the forum. Badges can also be earned for completing surveys and for the number of hours spent in the WebApp. Some examples of badges are: "Adventurer" (setting goals in 3 areas), "Young Grasshopper" (making 15 forum posts), and "Book Worm" (reading 3 content topics). See Figure 6 for more examples.

Peer Mentor Support: Participants will be able to make appointments with a peer mentor to discuss personal goals or concerns related to the iReach topics. AMSM in the intervention condition will be encouraged to complete one introduction session with the peer mentor. In this session, the peer mentor assigned to the user will introduce themselves and walk the user through the features and topics available within iReach. AMSM will be able to request as many sessions as they desire based on their needs. AMSM will be able to schedule a peer mentoring session to discuss the content and/or any additional challenges specific to the user's unique situation. Online peer mentoring sessions will be delivered using VSee. VSee is video-chat application that provides strong security components to ensure protection of sensitive exchanges, while also being sensitive to some users' limited data plans. Telemedicine video conferencing traditionally requires complex hardware, has a difficult user interface, and is costly to maintain. Poor or unworkable video is also an issue for those in rural areas using 3G cellular and satellite broadband networks. Locatis et al.[173] reported that H.323 standard videoconferencing software proved unworkable over a 3G cellular Wi-Fi network when streaming the recommended data rate of 384 Kbps for full motion video as well as lower rates (e.g.,128 Kbps), with unacceptable latency and jitter even when tested on CDMA across different carriers. Vsee, on the other hand, was able to provide video at as low as 50 Kbps. However, VSee's simple low bandwidth telemedicine video platform eliminates the complexities and limitations of traditional telemedicine videoconferencing. With point-to-point 256-bit AES encryption, it is a secure, low cost alternative that requires no server infrastructure to set up or maintain and allows providers to be HIPAA-compliant. VSee is available across PC, Macs, and mobile devices (iPad, iPhone, and Android).

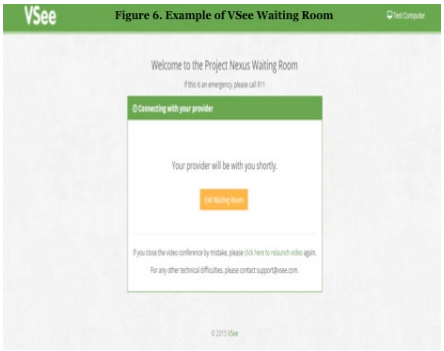
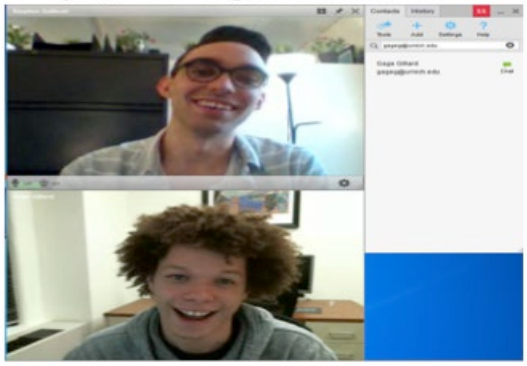


Figure 6. Example of VSee Waiting Room

VSee provides a web-based *Virtual Waiting Room (see Figure 6)* with a familiar walk-in waiting room workflow for secure medical consultations. The Waiting Room allows clients to sign into an online waiting room where they are dropped into a provider-accessible only waiting queue. During the video call, providers and clients can send files and screen-share any application window. Stephenson (Co-PI) is currently using VSee to deliver remote counseling to MSM conducting home-based HIV testing. Similar to Skype, VSee can be used in a number of formats. VSee can we used for face-to-face video chat, where the participant and the peer mentor can see each other. AMSM with concerns about privacy may use VSee in three other ways: video in which they can see the peer mentor but the peer mentor cannot see them, audio only, or using a text-only chat interface.

Peer mentors will be trained to use motivational interviewing (MI) principles in their exchanges with AMSM, and supervised by a licensed clinician (Dr. Bonar) and an on-site manager trained in Motivational Interviewing. In order to identify sets of goals that fit the criteria of being achievable and moderately challenging for participants, goals are discussed with the counselor, and a social problem-solving approach is used to allow the counselor and participant to identify potential solutions to the problems. During the sessions (see Figure 7), peer mentors will interact with the MI Spirit (compassion, acceptance, partnership, and evocation) and follow the three-stage principles framework: *Explore*, *Guide*, *Choose*[91].

Figure 7. Mock Example of VSee Session with YN



In the *Explore* stage, peer mentors use core MI skills (e.g., reflection, open-ended questions) to elicit AMSM's histories and social influences, prior change attempts, and to build rapport (consistent with the engagement phase of MI[174]). During *Explore*, peer mentors will include prompts to enable AMSM to share their goals, values, and strengths. Peer mentors will explore the importance and function of the behavior or area of concern in the AMSM's life and use MI strategies (i.e., OARS skills, such as empathic reflections, providing affirmations of personal strengths) to build engagement and capacity to move through the next stages. In the *Guide* stage, MI principles are applied collaboratively to elicit change talk, focusing on how the participant's behaviors align with their values and goals,

and collaboratively discuss strategies for making changes and/or reducing barriers to change. Mentors will also elicit change talk by building discrepancy between participants' current actions and values/goals using key strategies (i.e., rulers, decisional balance, autonomy support). When addressable barriers to engaging in specific behaviors are mentioned, peer mentors will assist with identifying solutions relevant for the participant (e.g., using Elicit-Provide-Elicit). For example, if participants report transportation difficulties, the peer mentor will help establish a transportation plan. If structural reasons are mentioned (e.g., fear of discrimination), the peer mentor will talk through solutions including locating LGBT-friendly local services in the iReach service locator, as well as provide advice on their rights as a patient, including their right to confidentiality, respect, and privacy. The screen-sharing function in VSee will allow the peer mentor to share online resources with participants and guide them on their use (this can be used without enabling video if the participant does not wish to be see). Further bolstering of self-efficacy can occur in this stage by reviewing past successes with similar problems, or through reflections highlighting how personal strengths have promoted successes in other domains. Readiness rulers will be employed to assess participants' readiness to move to the Choose stage. In the *Choose* stage, peer mentors assist with consolidating commitment and enhancing self-efficacy for desired changes by collaboratively assisting the participant in determining goals, developing an action plan, anticipating barriers, and identifying ways to monitor change. In keeping with the spirit of MI, AMSM who express no ambivalence or desire for change are assisted in exploring hypothetical situations that may lead to desire for change in the future. The peer mentor will place emphasis on providing AMSM with behavioral skills; through role-playing, participants will practice talking about key issues (e.g., discussing sex and HIV with a provider).

Attention Control Condition: Participants randomized to the control condition will receive access only to the Resource Locator embedded within iReach. While the provision of a service locator is a form (albeit weak) of an intervention and may decrease our ability to detect intervention effects, we felt that withholding referrals to services would be unethical given AMSM's vulnerability to HIV and STIs. By providing the existing testing site locator only, we will still be able to test the effect of iReach (i.e., user-tailored content focused on life skills + peer mentor counseling through VSee). Participants initially randomized into the control condition will receive three months of access to the full intervention after they have completed 12 months in the control condition.

Additionally, during months 12 to 15 of participation, we will test whether incentivization of app engagement has any effect on participant utilization of intervention features. Participants initially randomized to the control condition, upon completing 12 months in the attention control condition and receiving three months access to the full intervention, will be informed that they can earn an additional $40 reward for earning badges totaling 25 points in the iReach app (see image of point system below). See page 14 of this document for a description of iReach badges. Participants will be able to choose which badges they want to pursue, and therefore will be able to choose which intervention actions they complete in order to earn the incentive. Badges are set up to reward incremental use of app features (e.g. badge 1 = read one page, badge 2 = read five pages, etc.). We have developed the point system and chosen the target of 25 points so as to reward moderate use of the app, use which requires meaningful but achievable use. Participants who reach the 25 point target during their three months of full intervention access will earn an additional $40 Amazon gift card, paid after the completion of the 15 month survey (or timing out of the survey window).

2. Data Collection:

Data will be collected from participants through web surveys at baseline, month 3, month 6, month 9, and month 12 (and month 15 for participants initially randomized into the control condition). For participants who engage in peer mentoring sessions with peer mentors, information about the session will be documented at the time of the session.

3. Genetic Testing:
Not applicable.

4. Use of Deception:
Not applicable.

5. Statistical Analysis:
Descriptive statistics of the psychosocial and demographic characteristics of the participants will be described for all and by intervention group. These will be compared between treatment groups using t-tests or Wilcoxon rank sum tests for continuous variables and chi-square tests for categorical variables. In addition, we will use the general framework of generalized linear mixed models (GLMM) to test for intervention effects over time. Note that some of our outcomes are binary, some count and some continuous traits and thus need to be treated differently. The general form of the GLMM will be ()=0 +cov + TimeTime+ InterventionGroup+ Group x Time, where _ij is the mean response corresponding to subject i at Time j (baseline and 4 follow-ups) with the appropriate link function (identity for continuous outcome, logit for binary outcome and natural log for count outcomes); Group =1 if the i-th subject is in the intervention group and 0 if the i-th subject is in the attention-control group. The interaction coefficients _(Group x Time) are of interest here, measuring the difference in the rate of change in outcomes across the two treatment groups over time. The subject-specific random intercepts _0i are assumed to be normally distributed with a common variance and they account for within-person correlation. We will also explore if we need a subject specific random-slope corresponding to visit in the above model. Maximum likelihood estimation will be used for fixed effect parameters. Models will be compared according to information criterion like AIC, BIC. For some binary outcomes like HIV testing, we will perform an aggregate analysis after collapsing across the repeated measures using simple logistic regression comparing whether the probability of having tested at least once over the entire FU period is different across treatment groups, after adjusting for baseline values. To ensure robustness, we will also apply an exchangeable working correlation structure to its corresponding generalized estimating equation (GEE) model. We will also conduct exploratory regression analyses to examine differences based on social determinants of interest: age group, race/ethnicity, and rurality. These regressions will be run with group assignment and the social determinant variables of interest in the models, controlling for region. Interactions between group assignment and these social determinants will be tested to explore potential group-specific moderators of treatment effect. Given our focus on disparities, we also intend to examine mean differences across sub-groups of interest (e.g., race/ ethnicity, developmental age group, urban vs. suburban vs. rural). For example, assuming we used a fixed effects ANOVA model with main effects and interactions by race and intervention condition, we would be able to detect any interaction effect size f of .18 in cross-sectional analyses at 80% power using a two-sided significance level of .05. Similar interaction effect sizes are obtained for developmental age (i.e., early (ages 13-14) vs. middle (ages 15-16) vs. late (ages 17-18) adolescence) and rurality (i.e., urban vs. sub-urban vs. rural). Secondary Analyses: Building on our GLMM framework employed for Aim 2, we will examine whether there are intervention effects in the socioecological factors (e.g., LGBT discrimination; HIV stigma) and life skills components (e.g., personal competence; identity development) associated with our outcomes. The regressions will be run with group assignment only in the model, as well as controlling for participants socio-demographic characteristics, psychological distress, and intervention-related process data (e.g., frequency of use, acceptability). In addition, we will test whether these relationships vary as a function of AMSMs varying engagement with the intervention (e.g., dose analysis; intervention acceptability, frequency of site log-ins; time spent on sites and modules; number and length of VSee sessions used). Interactions between group assignment and these characteristics will be tested to explore potential moderators of treatment effect. Recognizing that social determinants operate beyond the individual-level, we will use HLM to test how regional characteristics influence AMSMs outcomes. HLM allows us to take into account that participants are nested within regions, and examine whether regional characteristics are associated with individual-level outcomes. We will link individual and regional level data using participants residential address at enrollment. Some participants may be residentially unstable and/or would not want to give their exact location. We will estimate a two-level model to account for individual and regional variation.

RISK/BENEFIT ASSESSMENT:

1. Risks:
The potential risks to participants are detailed as follows: 1) Some participants may be uncomfortable answering questions about their past and/or current HIV risk behaviors (e.g., sexual behavior, substance use). AMSM may also feel uncomfortable answering questions about their sexual attractions, or their sexual and gender identity. However, it is important to note that emotional discomfort is an event encountered routinely in daily life and potential discomfort would likely not exceed what is typically encountered in these youths experiences. All information used in enrollment and recruitment describing the research activities will include a detailed description of the content and expected

participation of the respondent, such that the respondent is aware of the nature of the questions to be included in the surveys. The study website will provide these details in full, during the consent process, and once the participant has created their password protected profile they will be able to access full information on the expectations of participation and the types of questions they will be asked. Informed consent documents will inform research participants of the need to keep answers to questions confidential. Participants will have the option to refuse to answer or skip any questions on the surveys that they are uncomfortable answering. 2) Psychological distress is a potential risk to AMSM during the completion of the surveys, reading the intervention content and during the teleconference counseling. We will provide AMSM with information to allow them to contact crisis services at the National Runaway Safeline at any time if they experience psychological distress, and the ability to contact the study team if they experience any adverse effects related to participation in the study. If psychological distress is apparent during a tele-conference, our licensed clinicians will be available to talk with the participant. In addition, we will refer crisis cases to the National Runaway Safeline which is available 24 hours a day, 7 days a week. In consultations with the leadership of the National Runaway Safeline, it was determined that crisis line staff would not need study-specific training in order to provide quality crisis support services to study participants, and actually might complicate the process. National Runaway Safeline staff are trained in providing crisis counseling to this age group, including sexual and gender minority youth. Research staff will receive training in crisis assessment and management procedures in the unlikely event that participants reveal suicidal and/or homicidal ideation, or child physical/sexual abuse. We will use established protocols from our prior studies conducted with youth and MSM for research staff to guide them in responding to crisis or harm situations, including attempting to contact the participant to assess risk level and provide appropriate follow-up (e.g., crisis hotline, safety check, suicide hotline). We will notify participants when we must engage in mandatory reporting during the consent process and when the participant decides to share a reportable event with study staff. 3) Unintended disclosure is also a potential risk. Given parents potential to monitor what apps their children have downloaded on their phones, we opted to keep iReach as a mobile-friendly WebApp. As a result, only individuals who know the URL can access the site. Participants will be instructed at different moments during the study (e.g., screening, baseline, followup) of steps they can take to further protect their privacy (e.g., clear browser history; avoid saving username/password in browser; logging out every time; using the app in private; using a screen lock on their phones, if parents allow). In addition, to limit inadvertent disclosure of their participation in the study to parents or others, we will suggest that youth create strong passwords (mix of upper/lower case letters, numbers, or symbols) on their iReach and personal e-mail accounts. Further, youth will choose how they wish to be contacted by the study staff (e.g., email, text message, private message on Facebook), and none of these exchanges will include sensitive information about HIV/STI, MSM, or anything that may reveal their participation in a study or answers to any of the questions answered in the surveys. Participants will be asked to provide at least two forms of contact information. Because participants are providing these pieces of identifiable information, there is a possibility that their participation in a research study could be disclosed in the following ways: (1) if someone other than the participant sees the intervention content; (2) if someone besides the participant reads the email sent with the link to the follow-up survey in which participants will enter their results; or (3) if someone besides the participant sees the study text messages, or online surveys on participants computer, tablet or phone. The risk of disclosure of participation in a research study through receiving study related emails, receiving text messages, interacting with the online surveys or with the study application on the participants cell phone will be minimized in the following ways: (1) participants must always log-in to re-enter the site after periods of inactivity as a fail-safe to avoid unintended disclosure; (2) emails with a link to the study follow-up surveys will not make any reference to the nature of the survey; for online surveys, participants will be required to login to the study website with the username and password that they created as part of the registration process before beginning the baseline survey; (3) participants will be encouraged to delete any text messages received as part of the study to protect them from an unauthorized individual viewing the messages, and to interact with the study application when in private (e.g., screen lock, complete when alone). Participants will be notified of these risks in the consent process. 4) One potential challenge is the security and confidentiality of VSee. Unlike other video-chat platforms (e.g. Skype), VSee is HIPAA-compliant and will be used for the peer mentoring sessions. Participants will have the option to use VSee in several formats: face-to-face video chat, video chat in which they can see the peer mentor but the peer mentor cannot see them, audio chat only, or a text based conversation. The consent form will include a full description of VSee, their options for using VSee, and will also make it clear that they can opt to have as many or few VSee sessions they wish (after the introductory session). Participants will request a VSee session through the iReach WebApp: when requesting a VSee session participants will be able to indicate the format they would like the session to take (e.g. face to face or audio only). VSee is compatible on PCs, tablets and smartphones. VSee includes the following functions to protect users: - End-to-end encryption without a man-in-the-middle listener. In WebEx, Vidyo, Tandberg, and Polycom architectures, your media is sent to a server (also called a video relay or MCU). Although encryption is applied from the users computer to these servers, the servers still have full access to the users media. In contrast, VSee uses end-to-end encryption where no server, including VSee servers, has the decryption key. VSee uses public/private RSA keys to exchange a 256-bit AES session key with the property that only the endpoints have the AES session key. VSee uses FIPS 140-2 certified 256-bit AES encryption. - One port. H.323 systems not only require many ports, but they require dynamic ports. This means if you want to use H.323 across your firewall, you are essentially opening your network to attackers on many ports. VSee, on the other hand, uses a single port for call signaling and media. The VSee protocol is structured so that only the outgoing port needs to be open because return traffic is always structured as responses to outgoing traffic. This allows administrators to set a policy where if users

inside their network are using VSee then their firewall lets VSee traffic securely cross the firewall, however, if users inside their firewall stop using VSee then the firewall will block external port scans. – Automatic HTTP/SSL tunneling. VSee prefers to use UDP since it allows higher performance video. However, if the firewall does not allow UDP, VSee will automatically switch to HTTP/SSL tunneling. – Cloud Control. A number of VSee customers have specific security policies for their users: the U.S. Congress does not allow recording and Kaiser Permanente does not allow unscreened external calls into its users. VSee's cloud solution allows enterprises to maintain central control of their security policies to a large number of end points even though the service is hosted by VSee. It does this by having VSee clients always connect first to VSee servers in the cloud, where the policies are controlled. The cloud servers determine whether any of these security policies should be applied and enforces them at the VSee client. This allows us to set our own security settings and to record the sessions. - No-install client. Video conferencing software clients tend to be large and to leave a big foot print on the users' system. Almost all of them require administrator permissions to install. Once the client software gains administrator permissions, they can severely compromise computer security. VSee is a lightweight client that does not require administrator permissions or installation. VSee offers the HIPAA-required Business Associate Agreement (BAA) where VSee agrees to be responsible for keeping all patient information secure and to immediately report any breach of personal health information. In his current studies, Stephenson has entered into a BAA with VSee, and this will be extended to cover the proposed activities. The VSee sessions will include identifying information (e.g. voice recordings). All identifying information will be stripped from the recorded VSee sessions before they are sent to the team for content analysis. It is not necessary that the recorded VSee sessions be linked to respective participants: in terms of intervention efficacy we are only measuring how many VSee sessions each participant took part in. The de-identified transcripts of the VSee sessions will undergo content analysis only for training purposes of the MI skills for the peer mentors. For participants, instructions on how to download VSee will be available via a short instructional video embedded into the iReach WebApp. The video includes a demonstration of VSee functions. A Your VSee Session page on the iReach WebApp will provide advice and instruction on planning their VSee session, including: the need for audio and visual privacy, a reminder of their options for the format of the session, the ability to cease the session at any point, and a brief description of what to expect during a VSee session (an outline of the general flow of the session). 5) For those in the intervention group, some participants may be uncomfortable talking with a peer mentor about sensitive information (e.g., sexual behavior, coming out). Only the introductory VSee session is mandatory: after this, participants can opt to have as many VSee sessions as they wish. Each of the peer mentors will be trained in Motivational Interviewing (MI) and supervised by a trained counselor during these sessions. Motivational interventions are collaborative and non-confrontational and engagement strategies combined with employing the MI spirit eschew any form of coercion or threat, as one of the key principles of MI is autonomy support. The use of brief motivational interventions greatly reduces risks to participants from interventions; however, unexpected events can always occur in intervention research. Thus, staff will receive training in crisis assessment and management procedures in the unlikely event that participants reveal suicidal and/or homicidal ideation, or child physical/sexual abuse. We will use established protocols from our prior studies conducted with MSM for research staff to guide them in responding to crisis or harm situations, including attempting to contact the participant to assess risk level and provide appropriate follow-up (e.g., crisis hotline, safety check, suicide hotline). Staff will be required to contact our full-time counselor (James Wolfe), and on-call risk assessment supervisors (Dr. Bonar) to manage situations of higher risk. 6) Risk of coercion. Using online recruitment methods and consent processes where the intervention is not pitched by a recruiter minimizes the risk of potential coercion. Instead, AMSM will be able to choose and click on the recruitment advertisement and decide if they wish to learn more or not. Consent documents will fully explain the study procedures, potential risks, and potential benefits. Participants will also be reminded that the study participation is voluntary and that refusing to participate in the study or withdrawing from the study is an option at any time.

2. Benefits:

Participants will be asked about sensitive information, yet adequate protections for internet data collection are in place for this study. AMSM in the intervention condition may benefit by receiving life skills content and having a peer trained in MI discussing these topics with them, with the potential to reflect on changing behaviors or taking steps to reduce risk. Furthermore, participation in the proposed study could potentially benefit participants in a few important ways. First, it is possible that the screening, baseline, and follow-up assessments may be beneficial to all participants by asking them to review their risk behaviors. Therefore, these assessments may actually serve as a very minimal intervention (as could any study assessing risky behaviors). Indeed, YMSM in our prior investigations have commented that they have found the questions to be helpful. Second, participants will have access to the resource locator if they desire to reach community organizations providing LGBT-welcoming services in their area. In sum, potential benefits for the research far outweigh the risks for the participants. Others will benefit because the study will result in increased knowledge about HIV prevention interventions to serve those at highest risk for HIV infection.

3. Subject Privacy:

All study interactions occur either over the internet or by phone, with specific precautions taken to support participants' privacy. To minimize the risk of participants feeling uncomfortable about answering personal questions, we will use self-completed online surveys. Participants will input the answer to the question themselves and will be able to refuse to answer any question that makes them uncomfortable. This format also allows participants to choose where and when they are

comfortable completing study questionnaires. We also allow participants to indicate their preferred method of contact (email, text, social media private message, voicemail), and their preferred timing of contacts.

Privacy in the intervention: MI based peer-to-peer sessions are provided using VSee. Participants will have the option to use VSee in several formats: face-to-face video chat, video chat in which they can see the peer mentor but the peer mentor cannot see them, audio chat only, or a text based conversation. The consent form will include a full description of VSee, their options for using VSee, and will also make it clear that they can opt to have as many or few VSee sessions they wish (after the introductory session). Participants will request a VSee session through the iReach WebApp: when requesting a VSee session participants will be able to indicate the format they would like the session to take (e.g. face to face or audio only). VSee is compatible on PCs, tablets and smartphones.

4. Subject Confidentiality:

Confidentiality refers to the subject's understanding of, and agreement to, the ways identifiable information will be stored and shared.

How will confidentiality of data be maintained? Check all that apply.

☒ Paper-based records will be kept in a secure location and only be accessible to personnel involved in the study.

☒ Computer-based files will only be made available to personnel involved in the study through the use of access privileges and passwords.

☒ Prior to access to any study-related information, personnel will be required to sign statements agreeing to protect the security and confidentiality of identifiable information.

☒ Whenever feasible, identifiers will be removed from study-related information.

☒ A Certificate of Confidentiality will be obtained, because the research could place the subject at risk of criminal or civil liability or cause damage to the subject's financial standing, employability, or liability.

☒ A waiver of documentation of consent is being requested, because the only link between the subject and the study would be the consent document and the primary risk is a breach of confidentiality. (This is not an option for FDA-regulated research.)

☒ Precautions are in place to ensure the data is secure by using passwords and encryption, because the research involves web-based surveys.

☒ Audio and/or video recordings will be transcribed and then destroyed to eliminate audible identification of subjects.

☐ Other (specify):

DATA COLLECTION We will implement several strategies to offset risks of loss of confidentiality related to web survey data collection. Participants contact information will be kept in a locked cabinet accessible only to the research staff or on password-protected computer files. A Certificate of Confidentiality issued by the Department of Health and Human Services will cover the research. To minimize the risk of participants feeling uncomfortable about answering personal questions, we will use self-completed online surveys. Participants will input the answer to the question themselves and will be able to refuse to answer any question that makes them uncomfortable. Data collected through the web intervention will be automated to download onto a secure university server. This procedure increases the security of the data, as commercial survey providers (e.g., SurveyMonkey, Alchemer, etc.) store the data in their own servers, increasing the risk of outside parties seeing the data. Furthermore, all web survey data will be secured using an SSL 256-bit encryption. SSL encryption is the standard for all web-based transactions that include any identifiable information, including names, addresses, and credit card numbers. Phone numbers and e-mail addresses to contact the PIs and the IRB will be provided. We will need to collect a valid e-mail address to reimburse participants for their time (i.e., study incentives) and for internal auditing purposes. To ensure we have sent participants their incentives, we will keep the e-mail addresses in a list to be stored in a password-protected server. In addition, we will use participants' email, IP address, browser/operating system, and time taken to complete survey to flag potential fraudulent/suspicious cases. We will crosscheck email and IP addresses through web applications (e.g., Facebook, IP lookup), yet we will not keep any of this information or link it to any behavioral data. We have taken this approach in prior studies and written on its importance for web survey research. Once identified, we will email suspicious cases and ask for clarification. If verified, we will treat each case as unique; otherwise, we will disqualify the case and not use the entered data. Once downloaded from the server, we will expunge data from the server. Survey and intervention data files will be identified using alphanumeric study participant ID numbers, assigned by study staff, which will be unrelated to the participant's name or email address. We will keep a file containing contact information (i.e., email) and IP addresses separate from study data. This file will be password-protected and stored within a restricted folder on a server. The reason for keeping this personal information is solely administrative (i.e., to ensure that we keep a record of

incentive payments, and to verify that fraudulent data collection does not occur (e.g., individuals may seek to falsify information on the web survey in hopes of receiving an incentive more than once). All web survey data will be collected using Alchemer (formerly Survey Gizmo), a secure, encrypted electronic platform with whom the Emory site team has established a business associate agreement to ensure HIPAA-compliance. Study data stored by Alchemer are maintained on a dedicated secure server, with no co-mingling of study data with other Alchemer customer data, or between Emory projects administered by Alchemer. Access to data will be on a role-based standard; only those study staff who require access to identifying data to complete their study-related roles will be allowed access. All study staff will be trained in security and confidentiality procedures, and will sign a confidentiality agreement before receiving access to any participant data.
Data exports will be converted into an SPSS working file. Data will be stored in a physically secure environment, and all data files will have encryption and strong password protection. Access to data will be on a role-based standard; only those study staff that require access to identifying data to complete their study-related roles will be allowed access, as described above. All study staff will be trained in security and confidentiality procedures, and will sign a confidentiality agreement before receiving access to any participant data. Contact information used to confirm participation will be held in a password-protected database on a secure university server, accessible only by study staff. This contact information will be held separately from baseline and follow-up survey data, which will contain only the participant's study identification number. The database will be backed up to a hard drive housed in another location, also accessible only by study staff. The contact information (name, email address and phone number) in the database will be destroyed at the end of the study, and will never be associated with the study data collected. PRIVACY IN INTERVENTION MI based peer-to-peer sessions are provided using VSee. Participants will have the option to use VSee in several formats: face-to-face video chat, video chat in which they can see the peer mentor but the peer mentor cannot see them, audio chat only, or a text based conversation. The consent form will include a full description of VSee, their options for using VSee, and will also make it clear that they can opt to have as many or few VSee sessions they wish (after the introductory session). Participants will request a VSee session through the iReach WebApp: when requesting a VSee session participants will be able to indicate the format they would like the session to take (e.g. face to face or audio only). VSee is compatible on PCs, tablets and smartphones. One potential challenge is the security and confidentiality of VSee. Unlike other video-chat platforms (e.g. Skype), VSee is HIPAA-compliant. VSee includes the following functions to protect users End-to-end encryption without a man-in-the-middle listener. In WebEx, Vidyo, Tandberg, and Polycom architectures, your media is sent to a server (also called a video relay or MCU). Although encryption is applied from the users computer to these servers, the servers still have full access to the users media. In contrast, VSee uses end-to-end encryption where no server, including VSee servers, has the decryption key. VSee uses public/private RSA keys to exchange a 256-bit AES session key with the property that only the endpoints have the AES session key. VSee uses FIPS 140-2 certified 256-bit AES encryption. One port. H.323 systems not only require many ports, but they require dynamic ports. This means if you want to use H.323 across your firewall, you are essentially opening your network to attackers on many ports. VSee, on the other hand, uses a single port for call signaling and media. The VSee protocol is structured so that only the outgoing port needs to be open because return traffic is always structured as responses to outgoing traffic. This allows administrators to set a policy where if users inside their network are using VSee then their firewall lets VSee traffic securely cross the firewall, however, if users inside their firewall stop using VSee then the firewall will block external port scans. Automatic HTTP/SSL tunneling. VSee prefers to use UDP since it allows higher performance video. However, if the firewall does not allow UDP, VSee will automatically switch to HTTP/SSL tunneling. Cloud Control. A number of VSee customers have specific security policies for their users: the U.S. Congress does not allow recording and Kaiser Permanente does not allow unscreened external calls into its users. VSee's cloud solution allows enterprises to maintain central control of their security policies to a large number of end points even though the service is hosted by VSee. It does this by having VSee clients always connect first to VSee servers in the cloud, where the policies are controlled. The cloud servers determine whether any of these security policies should be applied and enforces them at the VSee client. This allows us to set our own security settings and to record the sessions. No-install client. Video conferencing software clients tend to be large and to leave a big foot print on the users system. Almost all of them require administrator permissions to install. Once the client software gains administrator permissions, they can severely compromise computer security. VSee is a lightweight client that does not require administrator permissions or installation. VSee offers the HIPAA-required Business Associate Agreement (BAA) where VSee agrees to be responsible for keeping all patient information secure and to immediately report any breach of personal health information. In his current studies, Stephenson has entered into a BAA with VSee, and this will be extended to cover the proposed activities. The VSee sessions will include identifying information (e.g. images of the participant, voice recordings), but recordings will only include audio. Audio recordings will only be kept until they have been transcribed. All identifying information will be stripped from the recorded VSee sessions before they are sent to the team for content analysis. It is not necessary that the recorded VSee sessions be linked to respective participants: in terms of intervention efficacy we are only measuring how many VSee sessions each participant took part in. The de-identified transcripts of the VSee sessions will undergo content analysis only for training purposes of the MI skills for the peer mentor. For participants, instructions on how to download VSee will be available via a short instructional video embedded into the iReach WebApp. The video includes a demonstration of VSee functions. A Your VSee Session page on the iReach WebApp will provide advice and instruction on planning their VSee session, including: the need for audio and visual privacy, a reminder of their options for the format of the session, the ability to cease the session at any point, and a brief description of what to expect during a VSee session (an outline of the general flow of the session).

5. Protected Health Information

The following PHI identifiers will be collected in this study:

- Name
- Street address, city, county, precinct, zip code, and equivalent geocodes
- All elements of dates (except year) for dates directly related to an individual and all ages over 89
- Telephone numbers
- Electronic mail addresses
- Web addresses (URLs)
- Internet IP addresses
- Biometric identifiers, including finger and voice prints
- Full face photographic images and any comparable images
- Any other unique identifying number, characteristic, or code

6. Compensation and Incentivization:

Compensation for completing the baseline, the 12-month follow-up survey, and the 15-month follow-up survey (for participants initially randomized into the control condition) will be $30 per assessment, whereas the 3, 6, and 9-month follow-ups will be $25 each since they are shorter in length.. This compensation is small enough to avoid undue influence, yet sufficiently substantial to compensate for time and effort, and promote retention. Participants will be eligible to receive $135 - $165 compensation for completing surveys, depending on which group they are randomly assigned to, if they complete all assessments.

Additionally, participants randomized into the control condition will be eligible to earn a $40 incentive for intervention use during their three month period of full intervention access from months 12 to 15. Participants earn this incentive for collecting iReach badges totaling 25 points, markers of completing the various actions described in the Experimental Group description above. Given the minimal risks associated with intervention use, this incentive does not constitute an undue influence. Participants randomized into the intervention group will not be eligible for this incentive.

All compensation and incentives will be paid as Amazon gift cards. Payment for the baseline survey will be sent once participants have completed the survey and have responded to the email containing their iReach WebApp login credentials. All subsequent compensation Amazon cards will be sent after the participant completes the associated survey. The incentive will be sent to participants who earn it after the 15 month survey. Participants who earn the incentive but do not complete the 15 month survey will receive the incentive after they time out of the 15 month survey window.

7. Data and Safety Monitoring:

The project RFA initially requested that a Data Safety and Monitoring Board (DSMB) oversee the trial, but after review of the project, the NIMHD rescinded this request and instead request that the project follow the following data safety plan (see attached email correspondence from the Program Officer, Jennifer Alvidrez, PhD). The Principal Investigators will provide oversight of all study procedures and quality assurance checks. The data safely and monitoring plan includes the following protocols: All printed records pertaining to the study containing collected data will be securely stored by the Principal Investigators. Electronic files and records will be stored in a firewalled, encrypted server at the University; only research staff will have access to this directory. To insure participants safety as well as the data's validity and integrity, only staff with extensive experience in studies with LGBT youth and/or HIV prevention will be hired. All staff will have signed a confidentiality agreement. We have several mechanisms to ensure the security and integrity of the data. The intervention content, questionnaires, and personal information will be secured with role-based security that will provide different types of users with different access privileges. Further, we will have separate modules as well as separate websites (questionnaire and intervention program) to collect personal identifying information, questionnaire data, and to run the actual program. At a high level, the three user types and the associated privileges are: a. Participants will be the actual study participants and, once consented, they will be able to go through the assessments and intervention screens. b. Research Project staff will view/access personal data related to individuals. They will also be able to send e-mails, process subject incentive fees, and email/call participants to remind them of follow-up assessments. c. Research Investigators will be the master users with access to all modules and will be required to use a valid user ID and password to log into/access the system. U of M research staff will be able to maintain users (view/add/modify users), and generate export files for analysis. We will use a unique registration ID for participants and have the rest of their details maintained securely outside of the computer database. Code numbers and contact information will be accessible only to the Research Investigators and Research Project staff. All data will be secured during transmission by using a 256-Bit SSL encryption or higher. The SSL certificate will be from VeriSign or other certificate providers of repute. Critical data fields will be encrypted and stored in the database. The database server itself will be located within the security of the secure and dedicated firewalls at the University of

Pennsylvania, Emory University, and the University of Michigan. Breaks in confidentiality will occur in the event that a participant is a danger to him or herself or to others, or is in danger from others. We will report this in accordance with rules for mandatory reporting. There is a statement in the consent form and assent form notifying participants of this possibility. All study personnel will have either completed the Human Subject Training established by the CITI program, or the comparable training required by their home institution. In addition, in compliance with the NIH policy, University graduate students and staff will participate in at least 8 hours of mandatory case study and discussions regarding scientific integrity and human subjects. Any additional personnel who may join the project will complete this training before they handle any subject data. Further, issues regarding confidentiality will be reinforced prior to each intervention and data collection with project personnel. Reporting Adverse Events Additionally, all staff will be trained on recognition and documentation of any unusual events or circumstances that occur during data collection. Staff will be trained to report any adverse events that concern them immediately to the Principal Investigators and the University IRB. If an adverse event appears to be research-related, it will be reported to the OHRP and the funding institution project officer, along with summaries of discussions concerning the event. The funding institution project officer will be informed of any IRB action taken concerning any adverse event. The Principal Investigators and Project Director will monitor staff closely. Staff deficient in any aspect of performance will be re-trained, closely monitored for proficiency, and if not adhering to established protocols and procedures, will be terminated. When data are collected via Alchemer, they are automatically encrypted, with the coded access only available to the Project Director and the PIs. No names or other identifying information appear on data documents or in data files as the re-contact information will be stored separately. Only designated staff will have access to the data. The Principal Investigators and Co-Investigators will be responsible for dissemination of study findings through presentations and publications. The Principal Investigators will also be solely responsible for handling any requests from other investigators to examine the data collected during this study.

8. Investigator's Risk/Benefit Assessment:

No more than minimal risk: The risks to research participants enumerated above are reasonable in relation to the anticipated increase in knowledge about HIV risk behaviors and barriers among young men who have sex with men. Each new case of HIV infection constitutes a burden to the individual, the health care system of our country, and to society. Our study is expected to result in benefit to society since it will provide a basis of knowledge on which barriers participants face when trying to access services to help them lower their risk of acquiring or transmitting HIV. Thus, the unlikely risks entailed by participation in this study are offset by its potential benefits.

INFORMED CONSENT:

1. Consent Process:

Potential participants will be directed to a website that will include a brief description of the study and a link to a short, online eligibility screener. Participants will be asked to consent to an eligibility screener. This will allow us to retain all data from these screeners and compare/contrast who sought to enroll in the trial. For the purpose of this study, "eligible" participants will have access to the intervention modules. Ineligible participants will be thanked for their time and redirected to the Google homepage. Eligible participants will then be shown a video highlighting key elements of study participation and consent, a method that previous studies have shown increase engagement and comprehension of consent. After the video, eligible participants will then be asked to review the complete study consent form and either consent to or decline participation in the study. The consent outlines the voluntary nature of the study, participant's freedom to discontinue the survey at any time, approval to retain data for future research, approval to retain email addresses to send incentives, and the procedures to guarantee their confidentiality. Currently, our consent has a literacy level of 8th grade (tested with the Coleman Liau index), which we believe makes it accessible for all ages, including 13-17 year-olds. As we adapt our intervention, we will re-examine whether we need to reduce its reading level to the 5th grade. If so, we would request a modification to the approved protocol prior to study enrollment. The emails of the participants who agree to the content of the consent will be stored in a file on an university server with strict technical access controls (e.g. only study staff will have access). The file where emails are stored will also be password protected. Recruitment will continue until the target number of participants is achieved. Informed consent will consist of an electronic document displayed to participants and made available for download. A waiver of written documentation of consent has been provided by the IRB. Finally, we recognize that consent is an ongoing process. Participants will have access to the consent form at all times, as a copy is programmed to be available in the menu of the application. Participants in the Intervention arm will be assented at each peer mentoring session and made sure that they want to have their scheduled session. If a participant wishes to dis-enroll from the study, they are given instructions on the "Contact Us" page to contact the study staff via phone or email.

Children and Adolescents

We are recruiting AMSM ages 13-18 who may not have disclosed their same-sex attractions to their parents/caregivers. Under 45 CFR 46.408 (c), an IRB has the authority to waive parental permission if it determines that a research protocol is designed for conditions or a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects and an appropriate mechanism for protecting the children who will participate as research subjects is substituted and that the waiver is not inconsistent with Federal, State, or local law. A waiver of parental permission for studies with lesbian, gay, bisexual, transgender and questioning (LGBT) youth that do not involve greater than minimal risk

is a common practice among researchers working in the area of gay and lesbian health/mental health. This is done to avoid the selection biases operating in only recruiting youth whose parents are both aware of and comfortable with their sexual orientation. Commonly these youth have explored their sexual orientation without their parents knowledge as the youth struggle with issues of disclosure and its consequences within the social, religious, and economic context of their families. A requirement for parental permission in this type of study could not only affect a persons willingness to participate, but could also potentially impact the ability of researchers to engage in this type of research with sexual minority youth. If the purpose of requiring parental permission as stated in CFR is to protect the minor subject, then requiring parental permission for youth in these circumstances is not a reasonable requirement. Additional privacy protections are provided in that all assessments, notes, reports, and other records will be identified by only a coded number to maintain participant confidentiality. These records and any forms that do contain identifying information (e.g., consent forms, contact information) will be kept in a locked, limited access area (such as a locked file cabinet) at the participating site. Youth will be able to provide written e-consent (consent provided electronically). The rationale for the parental waiver is based on: (1) determination of mature minors (i.e., capacity to understand the risks and consequences), with decisional capacity to promote healthseeking behaviors including HIV prevention services; (2) disclosure of high risk behaviors may increase the risk of adverse events on their well-being due to potential reactions from parents or other family members (i.e., rejection, verbal and physical abuse), and (3) that the research could not be practicably be carried out with such a waiver as many youth who might benefit from such an intervention would potentially avoid participation if required to obtain parental consent.

2. Waiver of Informed Consent:

Youth will be able to provide e-consent (consent provided electronically) via a web consent form. Thus we have requested and been granted a waiver of written documentation of consent. The research involves no more than minimal risk, and this waiver of written consent will not adversely affect the rights or welfare of participants. Rather, allowing participants to give e-consent allows for greater privacy for the study population, as it allows them to participate in the research when and where they choose, and reduces the likelihood of inadvertent disclosure of their participation. Also, given that the research is being implemented via a mobile WebApp across large geographical regions, the research could not practicably be carried out without the waiver or alteration.

RESOURCES NECESSARY FOR HUMAN RESEARCH PROTECTION:

As noted in the protocol, our team is comprised by an interdisciplinary team of physicians, psychologists, and public health professionals with expertise in conducting research with youth, MSM, and racial/ethnic minorities through technology-assisted interventions. All staff will complete CITI training and data safety training as part of their project on-boarding. We have both the physical and virtual infrastructure necessary to carry out this project and ensure the protection of human subjects. All study staff who are expected to interact with study participants will complete a training in Mental Health First Aid. Peer mentors will also be trained in motivational interviewing skills and crisis identification. They will be required to demonstrate proficiency in these techniques before they can interact with participants. Along with ongoing supervision, we have also scheduled booster sessions every 2-months to reinforce these skills.