Official Title: Suicide Prevention Intervention for Vulnerable Emerging Adult Sexual Minorities

Short Title: Supporting Transitions to Adulthood and Reducing Suicide (STARS)

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INTRODUCTION AND PURPOSE:

We will use the ADAPT-ITT framework to adapt a life skills intervention to increase the desire to live and reduce suicide ideation among at-risk emerging adult sexual minorities (EASM). STARS will embed components of the Safety Plan Intervention as well as modules focused on promoting coping with discrimination, social support, and positive affect. We will pilot test STARS using a Type 1 Effectiveness-Implementation Hybrid Design in a racially/ethnically diverse sample of 64 EASM who report past-month suicidal ideation. We will recruit EASM through social media advertising and invite them to an in-person screening. Eligible participants will provide informed consent and complete a Safety Planning Intervention with a licensed clinician, given the high-risk nature of the sample. They then will be randomized to the control condition (CC, n = 32) or STARS (n = 32). We will follow participants for 6 months, with evaluations at 2, 4, and 6 months. Primary outcomes will be preliminary efficacy outcomes of suicidal ideation and behavior and hypothesized mechanisms of change (improved coping with discrimination, social support, positive affect) to estimate critical parameters for a future trial. Secondary outcomes will be RE-AIM framework indicators (reach, adoption, implementation, maintenance).

OBJECTIVES:

<u>Overall objectives</u>
Our overall objective is to identify the potential clinical utility of STARS for suicide prevention in a vulnerable, often marginalized, population based on key parameters needed to inform a future efficacy trial. Our Specific Aims are:

1. To conduct a systematic suicide prevention adaptation of iREACH (STARS) that incorporates safety planning content and targets coping, social support, and positive affect using the ADAPT-ITT framework;
2. To examine preliminary efficacy (suicidal ideation and behaviors) and mechanisms of action of STARS, relative to our control condition (safety planning protocol alone), using a prospective RCT design, and
3. To examine whether STARS has preliminary evidence for impacting intervention implementation outcomes among EASM compared to the control arm using RE-AIM metrics.

BACKGROUND:

In the US, suicide rates have increased for emerging adults (ages 18-24) in the past decade; suicide is now the second leading cause of death. Youth who identify as sexual minorities are three times as likely to have made a suicide attempt than those identifying as heterosexual. Of all youth who made suicide attempts in 2017, 35.6% identified as a sexual minority, a huge increase from 24.6% in 2009. Recent calls for tailored interventions to reduce suicide risk among youth who identify as sexual and gender minorities highlight the need to consider: 1) multilevel approaches that address family acceptance and social policy; 2) attention to the impact of accumulated stress and developmentally timed interventions; 3) online approaches; and 4) focus on health equity. We propose to adapt an online life-skills intervention (iREACH) to address suicide prevention among EASM Supporting Transitions to Adulthood and Reducing Suicide (STARS). Our life-skills approach acknowledges the developmental transitions

EASM experience and provides a suite of strategies to offset risk for suicidal thoughts and behavior caused by poor social support, discrimination, and low positive affect.

Few interventions address suicide ideation and behaviors for EASM. Interventions that promote protective behaviors and social support may provide a complementary approach to traditional interventions to reduce risk in EASM. Developing youths assets (e.g., coping strategies, activity scheduling to promote positive affect) and linkage to health-promoting resources (e.g., social support, access to safe spaces) may reduce suicidal ideation. EASM who can envision a healthy future in which they achieve their long-term goals have greater psychological well-being, fewer risk behaviors, and improved use of health services. These findings are consistent with the suicide prevention literature, in which goal-action consistency is often targeted to reduce suicide risk and improve mood regulation, and social connection is viewed as a factor that reduces the likelihood of developing or the intensity of suicidal ideation. Researchers have yet to evaluate the extent to which improving coping with discrimination, promoting positive affect, and improving social support is associated with reduced risk for suicide among EASM. We propose to address this gap by examining whether STARS reduces suicidal ideation and exploring possible mechanisms of action.

CHARACTERISTICS OF THE STUDY POPULATION:

1. Target Population and Accrual:

Target population
Emerging adult sexual minorities between the ages of 18 and 24 years of age (inclusive) who report recent suicidal ideation.

Target Accrual: n=64

Accrual
We anticipate reaching our recruitment goal within 9 months of beginning enrollment. In prior trials in Philadelphia with sexual and gender minorities in this age group, we have found that over 40% of individuals who clicked on our online ads through social media screen were eligible. Of those, 80% provided full contact information and about 40% scheduled and attended an in-person enrollment visit. We expect most (~85%) will consent and enroll in the trial. Thus, for the proposed study, we expect to screen about 550 individuals to conduct full eligibility evaluations with approximately 70 EASM inperson over the 9-month period, and consent and randomize 64 for our study. Based on these estimates, we will plan to randomize 5-7 participants per month over the course of 9 months. Recruitment contingency plan: Today, geosocial networking apps and other social media are the primary means through which to recruit EASM, and thus are an ideal environment to engage these populations for research. Our team has worked with the major social media platforms (Facebook, Twitter, Instagram) to enroll participants for more than a decade. Nevertheless, we recognize the ephemeral nature of technology and shifting climate in the popularity of various social media platforms (e.g., emergence of Snapchat, WhatsApp, Telegram, and TikTok as alternate social media avenues). As our team has done for over a decade, we will continually anticipate how platforms have changed to adjust our recruitment and meet our recruitment goals. This will include ongoing conversations with our existing platforms

collaborators, as well as establishing connections with emerging platforms. If necessary, we will also leverage our connections in the Philadelphia community and conduct in-person recruitment and word of mouth referral. Our advertising budget is appropriately robust to account for the true costs for advertising on these platforms and will work with apps/social media to ensure that we are able to meet our recruitment goals within budget.

2. Key Inclusion Criteria:

(1) identify as a sexual minority; (2) live in the Philadelphia Metropolitan Area; (3) report suicide ideation in the prior month; (4) be aged 18-24 years; (5) have daily smartphone access; and (6) not plan to move out of the region for the next 12 months.

3. Key Exclusion Criteria:

(1) Identifies as cisgender heterosexual man or women, (2) Does not live in the Philadelphia Metropolitan Area; (3) Does not meet clinical criteria for suicide ideation in the prior month; (4) Is not between the ages of 18-24 years (inclusive) (5) Does not own a smartphone (6) Plan to move out of the region for the next 6 months (7) Does not consent to study procedures (8) Meets criteria for an unmanaged psychotic disorder

4. Subject Recruitment and Screening:

Social Media Recruitment: With increasing use of the Internet, there exists a great opportunity for reaching traditionally hard-to-reach and vulnerable populations, including EASM and racially diverse groups. We will reach the population living within Philadelphia (given that we are most familiar with emergency service options within the city) using social media ads on sites including Facebook, Tumblr, Instagram, Reddit and Twitter. Ads 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 in our regions based on their age, race/ethnicity and sex) and interests (e.g., TV shows with LGBT themes). Materials will avoid identifying candidates as EASM in the recruitment text to prevent 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 learn about the study. We have recruited through these platforms for over decade with a significant track record of demonstrated success, and plan to use lessons learned from these efforts to guide the implementation of our proposed recruitment strategy. Community Recruitment: In addition to social media outlets, we are extending recruitment to include outreach to LGBTQ+ partners within the Philadelphia community. We will approach local businesses, healthcare and mental health providers, community centers, coffee shops and LGBTQ+ organization by phone, email and in-person in order to share information about the study. With permission, we will provide recruitment materials in the form of paper flyers and palm cards that can be shared with consumers. Study team members will distribute hard copies of flyers and palm cards (or mail USPS as needed). Palm cards (similar to a postcard) will be prioritized for distribution to LBGTQ+ centers and medical/mental health service providers. Flyers

will be posted in community location with permissions of business owners. We will also send recruitment materials via email if requested. The aim of this strategy is to reach a broader demographic of community-based survey respondents, in addition to those recruited via social media outlets.

Recruitment Materials

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 in our regions based on their age, race/ethnicity and sex) and interests (e.g., TV shows with LGBT themes). Materials will avoid identifying candidates as EASM in the recruitment text to prevent 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 learn about the study. We have recruited through these platforms for over decade with a significant track record of demonstrated success, and plan to use lessons learned from these efforts to guide the implementation of our proposed recruitment strategy.

Use of Penn Media & Social Media Services: Ads 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 in our regions based on their age, race/ethnicity and sex) and interests (e.g., TV shows with LGBT themes). Materials will avoid identifying candidates as EASM in the recruitment text to prevent 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 learn about the study. We have recruited through these platforms for over decade with a significant track record of demonstrated success, and plan to use lessons learned from these efforts to guide the implementation of our proposed recruitment strategy.

5. Early Withdrawal of Subjects:

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. PIs may also withdraw participants for reasons including the following:

- Participant safety and/or health
- Participant has not followed the study instructions

6. Vulnerable Populations:

*(HHS regulations 45CFR46 Subparts B, C, & D for, pregnant women, fetuses, neonates, prisoners; and FDA regulations 21CFR50 Subpart B for children) NOTE: Refer to SOP SC 501 for the definition of children.

Specify if the study involves any of the following populations:

- Pregnant women (if the study procedures may affect the condition of the pregnant woman or fetus)

- Fetuses nor neonates
- Prisoners
- Children
- If none of the above populations are to be included into the study, write: “Children, pregnant women, fetuses, neonates, or prisoners are not included in this research study.”

None of the above populations are included in the research study

7. Populations vulnerable to undue influence or coercion:

Using online recruitment methods where the intervention is not pitched by a recruiter minimizes the risk of potential coercion. Instead, EASM will be able to choose and click on the recruitment advertisement and decide if they wish to learn more or not. Similarly, staff will be trained to discuss all elements of the consent process with potential participants. 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:

Design

Although iREACH was developed to reduce HIV risk behavior in sexual minority youth and not intended to address mental health or suicide risk, it includes therapeutic targets for factors that predict suicidal ideation and behavior among EASM. In Aim 1, we will use the ADAPT-ITT framework to develop a complementary approach STARS to reduce suicide ideation among at-risk EASM. STARS will embed components of the Safety Plan Intervention as well as modules focused on promoting coping with discrimination, social support, and positive affect. We will pilot test STARS using a Type 1 Effectiveness-Implementation Hybrid Design in a racially/ethnically diverse sample of 64 EASM who report past-month suicidal ideation. We will recruit EASM through social media and invite them to an in-person screening and consent session. Eligible participants will complete a Safety Planning Intervention with a licensed clinician, given the high-risk nature of the sample. They then will be randomized to the control condition (CC, n = 32) or STARS (n = 32). We will follow participants for 6 months, with evaluations at 2, 4, and 6 months. Primary outcomes will be preliminary efficacy outcomes of suicidal ideation and behavior and hypothesized mechanisms of change (improved coping with discrimination, social support, positive affect). Secondary outcomes will be RE-AIM framework indicators (reach, adoption, implementation, maintenance).*Define the duration of the study and describe how the aims of the study can be met within the specified duration of the study.*

Study duration

The study is funded for approximately 3 years. Once consented, participants will be active in the study for 6 months, as described in the "Design" section.

METHODS:

1. **Measures:**

Primary outcome variable(s): The primary outcomes are cognitive in nature and include: 1) Name: Suicidal Ideation and Behavior a. Type: Primary b. Timeframe: Baseline, 2 months, 4 months, 6 months c. Brief description: The Columbia-Suicide Severity Rating Scale (C-SSRS) is an interview-rated measure that will be completed by a blind independent evaluator. The C-SSRS includes three subscales, namely suicidal ideation, intensity of ideation, and suicidal behavior. The measure has strong psychometric properties, including inter-rater reliability and internal consistency. The suicidal behavior and the suicidal ideation subscales have been shown to predict future suicidal behavior. The following outcomes are treated as mechanisms of intervention action: 2) Name: Social Support a. Type: Secondary b. Timeframe: Baseline, 2 months, 4 months, 6 months c. Brief Description: Support from parents and friends, respectively, will be measured through a five-item emotional support scale developed, with items rated on a 5-point scale. The measure has strong convergent and divergent validity, as well a strong test-retest reliability and internal consistency.

Participants will complete the UCLA Loneliness Scale, a 20 item measure of subjective experiences of loneliness, with items rated on a 4 point scale, reflecting the frequency with which a participant feels a particular way (often, sometimes, rarely, never). The measure has strong convergent and divergent validity, as well a strong test-retest reliability and internal consistency. The Interpersonal Needs Questionnaire-Reduced (INQ) is a 15-item measure of perceived burdensomeness and thwarted belongingness. The measure has strong psychometric properties, including measurement invariance, divergent and convergent validity, and prediction of future suicidal ideation. 3) Name: Positive Affect a. Type: Secondary b. Timeframe: Baseline, 2 months, 4 months, 6 months c. Brief description: The PANAS-Positive Affect subscale is a 10 item measure of positive affect over the past week, including enthusiasm, interest, determination, excitement, inspiration, alertness, activity, strength, pride, and attentiveness. Each item rated on a 1 (very slightly/not at all) to 5 (extremely) point Likert scale. The PANAS has strong internal consistency and convergent and divergent validity. 4) Name: Theory of Planned Behavior Questionnaire for Safety Planning a. Type: Secondary b. Timeframe: Baseline, 2 months, 4 months, 6 months c. Brief description: We will measure attitudes, norms, self-efficacy and intentions regarding adoption of the safety plan using an adapted version of the Theory of Behavior Questionnaire. The measure has strong psychometric properties, including high reliability and validity. 5) Name: Coping with Discrimination a. Type: Secondary b. Timeframe: Baseline, 2 months, 4 months, 6 months c. Brief description: The Coping with Discrimination Scale is a 41 item measure assessing internalization (10 items), disengagement (5 items), drug and alcohol use (5 items), support seeking (5 items), resistance (6 items), resilience (6 items), and education/advocacy (8 items). Participants respond to these items using six response options, ranging from 1 (never like me) to 6 (always like me). Instructions for the measure are: "This is a list of strategies that some people use to deal with their experiences of discrimination. Please respond to the following items as honestly as possible to reflect how much each strategy best describes the ways you cope with discrimination. There are no right or wrong answers. 6) Name: Internalized Homonegativity a. Type: Secondary b. Timeframe: Baseline, 2 months, 4 months, 6 months c. Brief description: We will measure sexuality-related stress using Mayfield's 23-item Internalized

Homonegativity Inventory 277 (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).

Secondary outcome variable(s)

We also include secondary outcomes that apply to the subset of AMSM who are sexually active. These secondary outcomes include: 1) Reach a. Type: Secondary b. Timeframe: Continuous c. Brief description: We will track social media recruitment metrics, including ad impressions (clicks, cost per click (CPC), click-through rate (CTR)); screening (number screened, number eligible, number who provided contact information and cost per eligible contact); and enrollment metrics (number eligible who attend in-person visit, number who enroll). We will document the reasons for refusal among eligible. 2) Adoption a. Type: Secondary b. Timeframe: 2 months, 4 months, 6 months c. Brief Description: Participants will complete the Short Intervention Evaluation Form is a brief 13-item instrument eliciting information about the participants experience with the intervention (i.e., was the intervention interesting, was it relevant to their life, did they learn from the intervention), willingness to use it in the future, and three open-ended items explore what was most and least useful about the intervention. 3) Participant Implementation a. Type: Secondary b. Timeframe: 2 months, 4 months, 6 months c. Brief description: Participants will report the frequency that they felt the need to, as well as used, the Safety Plan. Among STARS participants, we will also measure counts of user log-in sessions to the app, app session length, pages visited, activities completed, and other functions used within the app, which can indicate intervention dosage and which will be reported descriptively. 4) Peer Mentor Implementation a. Type: Secondary b. Timeframe: Baseline, 2 months, 4 months, 6 months c. Brief description: We count the number, frequency and duration of peer mentor sessions requested and attended using our participant logs. We will measure Peer Mentor Clinical Skill/Competence using the Motivational Interviewing Treatment Integrity coding scheme. 5) Maintenance a. Type: Secondary b. Timeframe: Baseline, 2 months, 4 months, 6 months c. Brief Description: We will track the proportion of participants who are retained in the study, as measured by their completion of follow-up surveys.

2. Group Modifications:

No changes will be made to the study instruments. We are using validated scales for our primary outcomes and mechanisms of change.

3. Method for Assigning Subjects to Groups:

Eligible participants will complete a baseline survey and subsequently randomly assigned in a 1:1 ratio into the Intervention or Standard of Care.

4. Administration of Surveys and/or Process:

Surveys: We will collect survey data via online self-completed surveys administered at baseline, and 2, 4, and 6 months. 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. 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 also reflect time to complete the assessments: $50 for the baseline assessment (which will occur in person and is more time-consuming), and $30, $40, and $50 for 2-, 4-, and 6-month assessments, respectively. 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 password protected file. We have used this approach in prior studies to achieve excellent (90%) retention. This list also maintains participants retention status, and facilitates the creation of 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 trial participation and 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. Contact information/personal identifiers will be collected and stored separately from other survey and intervention data. Survey and intervention data will be identified using alphanumeric study participant ID numbers which will be unrelated to the participants name or email address. Data collected through surveys and the web-intervention 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 email 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 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. 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*.

7. Subject Follow-up:

Self-completed study assessments are conducted virtually (REDCap Survey) every two months across the intervention and attention-control follow-up time points, with a total follow-up period of 6 months. Phone follow-up clinical interviews are conducted at 2, 4 and 6 month timepoints.

Retention: Upon study entry, we will make all efforts to retain consented participants. Our study retention plan draws on previously successful retention protocols to achieve at least an 80% retention rate. 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 Twitter username, and contact information for 2 peers who could help us contact them), while being sensitive to undue disclosure of EASM participating in the study. We also have a pre-planned schedule of follow-ups that consists of a variety of follow-up methods.

A study-specific home page allows study staff to monitor participant progress at-a-glance, viewing steps or phases in the dashboard filtered by conditions such as record status, intervention arm, last login to the app, etc. This dashboard facilitates participant retention via prompts to study staff to reach out to participants who have missed a specified number of study activities and by providing a secure platform to communicate with staff and deliver participant incentives. At each follow-up assessment, participants will be able to update their contact information. This allows us to remain connected with participants and facilitates the delivery of reminders regarding upcoming study procedures. 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.

Lastly, we have designed our incentive schedule to encourage completing study assessments, in that after the baseline assessment (which is in person), each of the subsequent assessments pay participant at an increasing rate to encourage them to complete future assessments. Participants will be followed for a total of 6 months post-enrollment. All participants will complete online surveys every two months (2-, 4-, and 6-month follow-up surveys) similar to the baseline survey they completed in person. They will be compensated $30 for completion of the 2-month survey, $40 for the 4-month survey, and $50 for the 6-month survey. This level of incremental compensation has proven highly effective in our prior cohorts. Neither our IRB nor prior advisory boards have found this level of incentive to be coercive. Rather, they have found it commensurate with what would be expected to compensate participants if they were engaged in similar-in-duration face-to-face and online assessments.

STUDY PROCEDURES:

1. Detailed Description:
The research activities involve a two-arm prospective pilot RCT enrolling a sample of 64 EASM. After consent and completion of the baseline survey, EASM are randomized to either the control or experimental condition (Intervention, n=32; Control, n=32). Participants in the control arm will receive safety planning (i.e., standard of care). Participants in the experimental arm will receive safety planning (i.e., standard of care) and access to a webapp that includes life skills education, goal setting, local resource directory and the ability to link to a Peer Mentor through supervised online sessions. Self-completed study assessments are conducted in-person every two months across the intervention and attention-control follow-up time points, with a total follow-up period of 6 months.

2. Data Collection:
n/a

3. Genetic Testing:
n/a

4. Use of Deception:
n/a

5. Statistical Analysis:
Analysis Plan
Prior to conducting our multivariate analyses, we will examine study variables using descriptive statistics and test for differences across demographic characteristics (e.g., race/ethnicity, age, education) using t-tests, ANOVAs, and Chi-squares, as appropriate. As participants will be randomized to the two treatment groups, systematic baseline differences are not expected; however, in the event that some parameters differ across conditions at baseline, they will be included as covariates in subsequent multivariate models. We will calculate descriptive summary statistics corresponding to the study variables at each visit to understand any temporal patterns, as well as compare the two treatment groups in terms of average change from baseline after intervention (averaged across all three FU times). In its simplest form, under the assumption of equivalence between the two randomized groups, we will compare differences from baseline to the 6-month outcomes across our outcome measures using t-tests, ANOVAs, and Chi-squares, as appropriate. For repeated measures analyses, we will use the general

framework of generalized linear mixed models (GLMM) to model the longitudinal outcomes. 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 + visit+ + Trt x visit × , where ij is the mean response corresponding to subject i on visit j (baseline and three follow-ups), g denotes the link function (identity for continuous outcome, logit for binary outcome and natural log for count outcomes); Trti =1 if the i-th subject is in the STARS group and 0 if the i-th subject is in the control arm. The variable Visit can be coded in different ways depending upon how one wants to model the effect of time on the mean response. For example, for characterizing only pre vs. post effect Visit can be coded as a binary indicator with 0 representing baseline and 1 representing post-randomization; Assuming a linear time trend, Visit can be coded as 0,1, 2, 3, or it can be simply coded as a categorical variable representing the distinct effect of each follow-up period (e.g., 2-, 4- and 6-month follow-ups) compared to the baseline. The interaction coefficients Trt X Visit are of interest here, measuring the difference in the rate of change in outcome across the two treatment groups at each visit. If the baseline outcome measure is included as a part of the covariates on the right hand side of the above equation, then we only have three repeated measures on the left hand side of the model (j=1,2,3) and we can look at average treatment effect across visits without including the Trt×Visit interaction term. In this case, the GLMM analysis with continuous outcome will be equivalent to a repeated measures analysis of covariance after adjusting for baseline values. 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 Use of Safety Planning, we will perform an aggregate analysis after collapsing across the repeated measures using simple logistic regression comparing whether the probability of having used the plan at least once over the entire follow-up 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.

RISK/BENEFIT ASSESSMENT:

1. Risks:

The potential risks to participants are detailed as follows: Some participants may be uncomfortable answering questions about their past and/or current suicidal thoughts or behaviors, psychiatric symptoms, or risk behaviors (e.g., sexual behavior, substance use). EASM 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. They will also be informed about the limits of confidentiality as it relates to imminent suicide risk or risk of imminent harm to others and the need to enact emergency procedures to ensure their safety and the safety of others. Psychological distress is a potential risk to EASM during the completion of the interviews or surveys, reading the intervention content, creating a safety plan at the baseline evaluation, and during the peer mentor session. We will provide EASM with information to allow them to contact the study team at any time if they experience psychological distress related to participation in the study. In addition, at the time of study enrollment, we will solicit up to 3 personal contacts of study participants to call in the event that a participant is in a psychiatric crisis but is unreachable for some reason. We will inform participants about why we are collecting information for these emergency contacts, remind them that providing this information is optional, and describe to them the procedure for calling these contacts in the event of an emergency. We will clarify with participants what information will and will not be shared with the emergency contacts. For instance, we will share that we are calling from the Penn Health System and are worried about the participant and want to make sure that he is okay but are unable to reach him. We will then ask the emergency contact whether they have been in touch with the participant and could help us to locate him. We will not reveal the name of the research study or provide any information that has the capacity to unintentionally reveal the sexual or gender orientation of the participant. We will share with participants that they have permission to revoke consent for us to contact these emergency contacts at any time, and to just let us know that preference verbally or in writing. Dr. Brown has used this strategy successfully for working with individuals who are living with HIV and who reported past month suicidal ideation. In the prior studies that used this approach, most participants provided at least one study contact, though we never needed to call any of the emergency contacts because of the strong rapport that we established with participants during the baseline assessment and other research procedures. If psychological distress is apparent during a peer mentor session or other study contact, our licensed clinicians will be available to talk with the participant. Our licensed clinicians are familiar with the emergency management protocols at Penn and throughout the city of Philadelphia. If needed, we will participants in immediate crisis to the Mobile Crisis Response Team which is available 24 hours a day, 7 days a week. This Mobile Crisis Team is a service offered through the city of Philadelphia that can drive to patients/participants home to help transport them to the psychiatric emergency department, or can de-escalate the risk at home. In addition, participants will be provided with the number for the National Suicide Prevention Lifeline and the licensed study clinician at the time of consent. Some participants may opt to include the number for the Mobile Crisis Response Team, the National Suicide Prevention Lifeline, or the number of the licensed study clinician to their Safety Plan, but this will not be required. Research staff will receive training in crisis assessment and management procedures to assist with the management of suicidal and/or homicidal ideation, or child physical/sexual abuse. 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. At the beginning of any phone contact with participants, the researcher will first ask the participant to identify their physical location. This will ensure that if deployment of emergency services is required, we know how to reach the participant in crisis. Unintended disclosure is also a potential risk. Participants will be instructed at different moments during the study (e.g., screening, baseline, follow-up) 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 family members or others, we will suggest that participants create strong passwords (mix of upper/lower case letters, numbers, or symbols) on their STARS and personal e-mail accounts. Further, participants 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 sexuality 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 3 minutes of inactivity as a fail-safe to avoid unintended disclosure; (2) emails with a link to the study web site where participants will enter their results and take the follow-up survey 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, and they will then be asked two security questions; (3) participants will be encouraged to customize their own text messaging reminders and 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.

MI based peer-to-peer sessions are provided using HIPAA compliant virtual platform (BlueJeans, Zoom). Participants will have the option to use the virtual platform in several formats: face-to-face video chat, video chat in which they can see the PM but the PM cannot see them, audio chat only, or a text based conversation. The consent form will include a full description of their options, and will also make it clear that they can opt to have as many or few virtual sessions they wish (after the introductory session).

Participants will request a peer mentors session through the STARS App: when requesting a virtual session participants will be able to indicate the format they would like the session to take (e.g., face to face or audio only). Zoom is compatible on PCs, tablets and smartphones. One potential challenge is the security and confidentiality of virtual platforms. Zooms is HIPAA-compliant as access through https://pennmedicine.zoom.us/ Only the introductory virtual session is mandatory: after this, participants can opt to have as many sessions as they wish.

Each of the PM 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.

Given the nature of the participants in the study, staff will receive training in crisis assessment and

management procedures to handle both suicidal crises, as well as reports of homicidal ideation and risk of child abuse. We will use established protocols from our prior studies conducted with men who have sex with men (MSM) and with individuals at high risk for suicide to guide research staff 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 clinical counselor (Webster) or clinician (Dr. Brown) to manage situations of higher risk. Risk of coercion. Using online recruitment methods where the intervention is not pitched by a recruiter minimizes the risk of potential coercion. Instead, EASM will be able to choose and click on the recruitment advertisement and decide if they wish to learn more or not. Similarly, staff will be trained to discuss all elements of the consent process with potential participants. 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. Informed consent documents will be available in English and have grade 5 reading level. Adequacy of Protection against Risks a. Recruitment and Informed Consent We will recruit subjects through the placement of banner advertisements on Facebook and other social media outlets. For those who click on the ad, they will be taken to a page describing the nature of the study: if they then click on interested in participating they will be asked to complete an interest form which will be used by study staff to schedule an in-person visit. During the in-person visit, eligible participants will be given a written informed consent document. We will employ several strategies to offset risks of loss of confidentiality related to participating in our trial. First, we will petition a Certificate of Confidentiality from the Department of Health and Human Services (an explanation will follow indicating that in studies thus covered the researchers have not been forced to release any research data from participants, even under a court order or subpoena). Participants who experience distress during the survey can access our list of community referrals, which can be viewed on our study's application, or contact the research team directly (toll-free number is embedded into the About Us section of the application). Participants can contact study staff to get referrals to local services, and should participants report or display signs of distress during the teleconference interactions they will be asked to speak with a clinician who is a member of the research team. Any unexpected adverse events will be immediately reported to the IRB, and all study activities will halt pending IRB review and recommendations. It will be made clear to all participants in the consent forms that participation in the pilot RCT will not affect their access to any services in their community. The consent document will make it clear that participants can attend any services in their local area and that they do not have to participate in the trial to access services, nor do they have to reveal their participation in the trial to anyone at these agencies. Participants who chose not to participate in the trial will still be able to access the list of local LGBT resources. Participants addresses and any other identifying information will be kept in a separate, password-protected file to avoid risk of identification. All stored data will be kept in a locked room at the University of Pennsylvania. Electronic data will be maintained in a secure server. Access to the data will be located in a folder with restrictions (i.e., may be accessed only by study team members). 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. We will also develop procedures to minimize indirect disclosure that a participant is enrolled in a study focused on EASMs suicide vulnerability. For each mode of re-contact information,

we will ask specifically whether anyone else potentially has access to that mode of communication, and if it is acceptable to leave a non-specific message about participation in a health study. The contact information and permissions will be updated quarterly. No study-related messages will ever mention the nature of the research study. Additionally, all scripts for email, text message, and telephone contact with participants will be reviewed and approved by the University of Pennsylvania IRB before being used for contact with participants. Participants confidentiality will be breached only to protect the safety and welfare of research participants and only in accordance with state and federal law. The exceptions to confidentiality include if the participant reports imminent suicide risk, homicidality, or the physical or sexual abuse of a child. If necessary, authorities will be notified. Although study assessments will not ask about these issues, in the unlikely event that a participant self-discloses this information to study staff, during virtual tele-conference sessions, or through open fields (e.g., additional comments) in the surveys, we will activate our Adverse Events Reporting protocol (see below). These exceptions to breaking confidentiality the case where a participant reveals child abuse, imminent suicide risk, or homicidality will be explained in detail to participants and prior to completing the consent process. b. Protections against Risk 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 for many of our assessments. Participants will input the answer to the question themselves and will be able to refuse to answer any question that makes them uncomfortable on either the self-report assessments or the clinical interview. Data collected through the web intervention will be automated to download onto a secure server at the University of Pennsylvania. 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. 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 University of Pennsylvania secure 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. We will use Norton Clean-Sweep software to delete the database file from the secure server and the back-up file(s) from the separate hard drive.

2. Benefits:

Participants will be asked about sensitive information, yet adequate protections for internet data collection are in place for this study. EASM in the intervention condition may benefit by receiving life skills and suicide prevention 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 for suicide. 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 and consider strategies to reduce suicide risk. Therefore, these assessments may actually serve as a very minimal intervention (as could any study assessing risky behaviors). Indeed, young MSM in our prior investigations have commented that they have found the questions to be helpful. Second, participants will have access to the test 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 suicide prevention interventions to serve those at highest risk for suicidality.

3. Subject Privacy:

We support the sharing of research data from the perspective of fortifying the principles of scientific inquiry, facilitating alternative examinations of research questions, and avoiding duplicative data collection efforts. We will ensure that data sharing is undertaken with attention to human subjects protections, respect for proprietary data, and maintaining integrity of the source data. To ensure that the data are protected, we use virtualized servers provided by the University of Pennsylvania. Data centers provide protection from lengthy outages, 24/7 staffing, restricted physical access and disaster recovery. Virtual servers are backed up automatically onto encrypted tape for recovery and security. The data centers also reduce the use of physical resources such as electricity and air conditioning. All servers and the back end databases are password protected. The server runs the Ubuntu Linux Server Edition operating system with partitions encrypted with 256-bit AES in cipher-block-chaining mode. Security patches and updates are downloaded and installed automatically. Each server is also protected by firewalls to restrict network access to the server. The study web application software communicates directly with the database on the same server so unencrypted participant data is not transmitted on the Internet.

Privacy of subjects is also considered. Participant contact information will only be kept for administrative purposes. We will need to collect valid contact information to remind participants to schedule follow-up visits and ensure we have contact information for any emergency. Identifiers will be retained for record keeping purposes until five years after the completion of the study and then destroyed. Identifiers will be retained in a separate password-protected file located within a University server with restricted access. Email addresses and survey completion data will not be linked to survey

data. Because this is a WebApp, participants are able to access the content and resource guide at a location of their choice on a computer, phone, or tablet. When a participant accesses the study website, content is transmitted securely using the Transport Layer Security (TLS) protocol, the same protocol used to protect financial and other personal information when transmitted from a web site to a user's browser. This prevents anyone else on the network from intercepting and viewing the content that is being provided by or to the participant. Additionally, if a participant opts-in to receiving text message reminders, they will need to log in to the survey with their username and password. That way, if someone picks up the participant's phone, they will not be able to access the participant's survey account. Data are provided to researchers in de-identified form, with all personally identifying information removed. Data that are provided to researchers is encrypted if it is transmitted across the Internet. At the end of the research study, all data are permanently de-identified for archive and distribution to other researchers.

4. Subject Confidentiality:

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.

Subject Confidentiality

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 for many of our assessments. Participants will input the answer to the question themselves and will be

able to refuse to answer any question that makes them uncomfortable on either the self-report assessments or the clinical interview. Data collected through the web-intervention will be automated to download onto a secure server at the University of Pennsylvania. 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 email 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. 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 University of Pennsylvania secure 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. We will use Norton Clean-Sweep software to delete the database file from the secure server and the back-up file(s) from the separate hard drive. During informed consent, participants will be made aware about the information that would necessitate a breach of confidentiality, for instance, if a participant indicated acute suicide risk necessitating a higher level of care. This breach of confidentiality will only occur unless absolutely necessary to ensure the safety and welfare of participants.

5. Protected Health Information

For this Study we will collect the following identifiers:

X Name

X Street address, city, county, precinct, zip code, and equivalent geocodes

X All elements of dates (except year) for dates directly related to an individual and all ages over 89

X Telephone numbers

X Electronic mail addresses

X Web addresses (URLs)

X Internet IP addresses

X Biometric identifiers, including finger and voice prints

6. Compensation:

Our incentive schedule will encourage assessment completion, increasing the rates to encourage completion of future surveys. Incentives also reflect time to complete the assessments: $50 for the baseline assessment (which will occur in person and is more time-consuming), and $30, $40, and $50 for 2-, 4-, and 6-month assessments, respectively.

7. Data and Safety Monitoring:

In accordance with the National Institutes of Health (NIH) requirements, we will adopt a Data and Safety Monitoring Plan. We will use the centralized Data Safety Monitoring Board (DSMB) that was developed for the Center. The DSMB will meet regularly to review the study progress, review modifications, and monitor compliance with IRB rules, human subjects procedures and OHRP regulations. 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 in a locked metal file cabinet housed in the Department of Psychiatry. Electronic files and records will be stored in a firewalled, encrypted server at the University of Pennsylvania; only research staff will have access to this directory. To ensure participants safety as well as the datas validity and integrity, only staff with extensive experience with SGM youth and suicide 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 web-sites (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. Penn 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 University of Pennsylvania's secure and dedicated firewalls. Mandated breach of 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. In addition, in compliance with the NIH policy, 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 of Pennsylvania 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. 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 suicidal ideation and behaviors among sexual minorities. 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 suicide risks. Thus, the unlikely risks entailed by participation in this study are offset by its potential benefits.

INFORMED CONSENT:

1. Consent Process:

Overview

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 asked to complete a study consent form. Consistent with prior studies with youth, we have designed our consent form so that participants have to consent to the different elements of the consent process. This strategy reduces the likelihood that prospective participants will scroll down and not take a moment to examine their rights as participants and the study procedures. 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.

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 Mentor session and made sure that they want to have their scheduled session. If a participant wishes to dis-enroll from the study, they can do so by deactivating their account in the WebApp's Profile menu or reaching the MPIs via phone or email

2. Waiver of Informed Consent:

No Waiver Requested

RESOURCES NECESSARY FOR HUMAN RESEARCH PROTECTION:

As noted in the protocol, our team is comprised by an interdisciplinary team of psychologists and public health professionals with expertise in conducting research with youth, sexual and gender minorities, and racial/ethnic minorities through technology-assisted interventions. All staff will complete human subjects research 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 be expected to complete a training in Mental Health First Aid. Youth Navigators 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 on-going supervision, we have also scheduled weekly supervision meetings to reinforce protocol guidelines and strengthen their skills. In-person data collection will occur at the Market 3535 Psychiatry offices. Participants will complete the surveys in one of our private therapy offices on the 6th floor. We have locked filing cabinets to keep any paper records, but the default will be to use RedCap for data entry.