A Pilot Peer Mentor Intervention That Trains Black Men Who Have Sex With Men (BMSM) to Use and Promote Uptake of HIV/STI Self-Testing to Peers and Sex Partners: STAR Study (Self-Testing at Your Residence)

NCT04121962

1/26/2021

JHSPH IRB Research Plan for New Data Collection

Use this template for new data collection and if you also will analyze secondary data. Answer the questions below and for numbered sections that do not pertain to your study, retain the section numbers and bolded questions, and write "N/A". Please start typing in the gray boxes provided.

PI Name: Dr. Karin Tobin

Study Title: A pilot Peer Mentor intervention that trains Black MSM to use and promote uptake of HIV/STI self-testing to peers and sex partners: STAR study (Self testing at your residence)

IRB No.: 9216

PI Version No. / Date: Version 6– 1-26-2021

I. Aims of the Study: Describe the aims/objectives of the research and/or the project's research questions or hypotheses.

The objectives of the study are to assess the feasibility, reach and preliminary efficacy of a brief intervention that trains Black men who have sex with men [referred to as Index] (a) to use home-based testing for HIV and sexually transmitted infections and (b) promote home-based testing to their peers and sexual partners. The study will be conducted in two phases: Component Testing and Pilot Trial. We have completed the phase to test the website components and refine the intervention content. We are now requesting permission to conduct the Pilot Trial.

The overall aims of the study are:

1) To examine feasibility of the Peer Mentor intervention to train BMSM to use and promote to peers and sex partners home-based HIV and STI self-testing kits. Measures include: session attendance, facilitators and barriers to outreach, fidelity to PEER communication tool.

2) To examine the reach of the intervention compared to a control condition (use of the self-testing website only). Measures include: number of peers and sex partners who use the website, characteristics of peers and sex partners (including sexual risk and HIV/STI testing history).

3) To determine preliminary effect sizes of the intervention on self-testing uptake. We expect that a greater proportion of BMSM and their peers and sex partners in the Peer Mentor condition will request test kits, return specimens for STI testing, and receive results compared to those in the control condition.

II. Background and Rationale: Explain why this study is being done. Summarize briefly what is already known about the issue and reference previously published research, if relevant.

Sexually transmitted infections (STIs) increase one's risk of HIV infection, are serious co-infections that affect HIV clinical outcomes, and remain a risk for individuals using PrEP. Black men who have sex with men (BMSM) experience disparities along the HIV care cascade, and there is evidence that STIs are one of the contributing factors. In 2014, rates of chlamydia increased by 2.8% and gonorrhea by 5.1%. Moreover, in the past 10 years in Baltimore, diagnoses of early latent of syphilis in MSM have surged. Yet among BMSM, testing rates for STIs and HIV remain suboptimal.

Self-testing methods address barriers to clinic-based testing by offering convenience and privacy and have been shown to be well accepted by MSM. Therefore, use of self-testing is a potential approach through which to improve HIV and STI testing rates in MSM. Internet-based distribution (herein: web-based) of STI self-test kits enables an individual to request sampling kits via a website, mail biological specimens (e.g. urethral swabs) to a laboratory for testing, and view test results through a web-based account. Web-based self-HIV oral testing enables an individual to request a test kit, collect an oral specimen, and receive results within 20 minutes. Despite these potential benefits and reports of willingness to use free self-testing, uptake has been low due to barriers such as concerns about accuracy of the tests, apprehension to collect specimens, low risk perception, and the desire for counseling.

In the proposed study, we will pilot test a three-session intervention that address these barriers by training BMSM with information about the accuracy of the HIV rapid oral test kit, demonstrating how to properly collect specimens for HIV and STIs (gonorrhea, chlamydia and syphilis) self-testing, and providing resources for linkage to HIV and STI treatment and PrEP services. Study participants will utilize a secure website to request test kits (see details in Section III).

Studies have also shown that BMSM report willingness to distribute self-testing kits to peers, yet barriers to peer referral include fear of peer reactions and anticipated negative effects on peer relationships. This intervention will also train BMSM to be Peer Mentors to address these barriers and promote uptake of HIV and STI self-testing to peers and sex partners. Peers and sex partners will also use a secure website to request test kits and complete surveys about their behavior and satisfaction with home-based testing. Using Peer Mentors is a potentially effective method to increase self-testing uptake as BMSM have rapport and trust with their peers and partners and can communicate in culturally relevant ways.

The self-testing website will be based on the Iwantthekit.org (IWTK), a publicly-funded internet-access self-testing service directed by Dr. Gaydos (Co-investigator) that has been providing self-testing kits to screen for gonorrhea, chlamydia and trichomoniasis since 2010 and more recently HIV test kits. JHSPH Information Technology, Advanced Technology Services (ATS) will develop, administer, and manage the web-based portion of the study. This website will be hosted on a secure server maintained by Information Technology – Johns Hopkins Bloomberg School of Public Health. For the component testing phase of this study, all information entered into the website will be deleted by ATS after the completion of the component testing phase.

III. Study Design:

A. Provide a BRIEF overview of your study design and methods. The study design must relate to your stated aims/objectives. DETAILS WILL BE REQUESTED LATER. *If your study also involves analysis of existing data, please complete Section XI, "Secondary Data Analysis of Existing Data" in the last part of this research plan. If your study ONLY involves analysis of existing data, please use the research plan template for secondary data analysis (JHSPH IRB Research Plan for Secondary Data Analysis of Existing Data/Specimens)*

Component testing Phase: The purpose of this phase is to get feedback on intervention materials and the study website.
A trained facilitator will conduct two sessions with up to two groups of 8-10 participants (Total n=20).

Session 1: Participants will be asked to view the website using their smart phones (if applicable) or via a study computer that will be provided if participants do not have smart phones or choose not to use their smartphone. Participants will navigate the website, establish an account, and request kits. For the component testing phase, no self-test kits will be mailed to the participants. Appendix 1 depicts the flow of the website. Consistent with other web-based survey methods, the self-testing website will be protected with a 128-bit SSL encryption within the firewall of the JHSPH server. An individual will enter a unique code that is provided to them by the researchers. To create their account and set up a password, individuals will be asked to provide their full name, mailing address, cell phone number, and email address. After creating their personal account, individuals will view pictures of the self-testing kits and descriptions of the infections that they are screening for. Individuals will read and acknowledge the MD State Names Based Reporting Law (for STIs) and indicate the clinic(s) that they intend to use to seek treatment for positive results. Participants will also view an example of the STI results page and be asked to comment on the visual appeal as well as whether the results are understandable (e.g. a positive test indicates an active gonorrhea infection that requires treatment with a course of antibiotics.)
At the end of Session 1, the facilitator will explore potential facilitators and barriers of utilizing the self-testing website (such as, "How would you describe your experience with setting up an account, requesting kits, and viewing results? What would you change about the website?"). Participants will also be shown different designs for the coupons to be used to refer peers and sex partners to the website and asked about acceptability of the coupon design. Finally, participants will be asked to spend time over the next week engaging in conversations with their peers and/or sex partners about the referral coupons and website and potential challenges or concerns about being referred to the website. The peers won't be asked to log-onto the website and create an account (because the website will not yet be "live",) but the Peer Mentor will have screen shots of different pages of the site to show their peers. The session will be audio-recorded and observed by the study PI who will take notes with a focus on suggestions for revisions to the intervention materials and website and use these results to refine the materials.

Session 2: Participants will be asked to share the results of their conversations with peers/sex partners, such as challenges to having the conversation, concerns of the peers/sex partners and reactions/suggestions to the referral coupon and screenshots. The session will be audio-recorded and observed by the study PI who will take notes with a focus on suggestions for revisions to the intervention and website. These results will also be used to refine the materials.
Results of the Component Testing: 12 participants completed the component testing phase. Suggestions to change the website included: increase amount of information about STIs and how the testing works, add more visuals such as pictures. Participants were enthusiastic about the concept of being able to self-test at home and share this resources with peers and sex partners.

Full Pilot Trial: This will be a randomized controlled trial with data collection at baseline and 3 month follow-up. There will be two types of participants in the trial: Index and Network. Index will be Black men who have sex with men (BMSM) who will be randomized to the experimental arm or control arm. Index in both arms will be asked to recruit individuals from their personal social networks to enroll in the study via the study web-site (see mock-ups of Star website).
Index will complete study visits (baseline, randomization session, 5 individual sessions (if randomized to experimental condition), 3 month follow-up) at the Lighthouse Studies @ Peer Point community-based research clinic.
Enrolled network members will complete baseline and 3 months follow-up study activities exclusively on-line via the Star website.
Both Index (in both conditions) and Networks will have access to home-based HIV testing and specimen collection for gonorrhea and chlamydia testing via the Star website.
The experimental condition is a five session individual-based intervention that will train Index to be peer mentors and promote home-based testing.
The control condition is one individual-based session that will review information about HIV and STIs, home-based testing methods and how to use the website.

B. Provide a sample size and a justification as to how you arrived at that number. If you use screening procedures to arrive at a final sample a table may be helpful.

Component testing phase: We plan to conduct the component testing with up to 20 participants who will be split into two groups. We will hold one group and make revisions based upon this group's feedback then conduct the second group with the revised materials.

Full Trial: Index participants: We plan to enroll n=140 Index participants.
Network participants: Each Index will be able to recruit up to six Network participants - therefore up to 720 Networks may enroll. Based on estimates from one study of self-testing among MSM with option to refer peers (but were provided no training), we expect the average number of Index coupons distributed to the self-testing website will be to up to 6 peers/partners and that of these 70% of the peers/partners referred will request a self-test kit. For experimental condition this

results in (n=265) kits requested by peers/partners and (n=143) kits requested by control condition peers/partners.

IV. Participants:

Describe the study participants and the population from which they will be drawn. Specify the inclusion and exclusion criteria. If you plan to include children, note their ages and whether you will include children in foster care. Note if the participants are particularly vulnerable in terms of cognitive limitations, education, legal migration status, incarceration, poverty, or some combination of factors.

Component testing phase: The study participants will be Black men who have sex with men.
Full Pilot Trial: Index participants will be Black men who have sex with men.
Network participants will be male and female individuals of any race.

A. Inclusion Criteria:

Component testing phase: self-report (a) male sex, (b) sex with >1 male in the prior 6 months, (c) self-report Black race, (d) aged 18 or older, (e) internet use at least once a week

Full Trial: Index: self-report (a) biological male sex at birth, (b) (c) sex with >1 male in the prior 6 months, (d) self-report Black race, (e) aged 17-54 inclusive, (f) internet use at least once a week

Network: self-report (a) aged 17 or older, (b) given an invitation by the Index

Justification for the age criteria age 17: The HIV home-based test has been approved for use by individuals aged 17 and older. Individuals as young as 14 are allowed to seek sexual and reproductive health services without a parent. The epidemiology of HIV, gonorrhea and chlamydia, indicates that individuals ages 13-30 are the fastest growing groups affected.

B. Exclusion Criteria:

Component testing phase: not meeting inclusion criteria

Full Pilot Trial: Index: (a) self-report age less than 17 or 46 or older, (b) self-report non-Black race, (c) no sex with male in prior 6 months, (d) less than weekly internet use

Network: (a) self-report age less than 17, (b) no invitation

***NOTE**: If you are recruiting participants or receiving, accessing, or using data from a U.S. health care provider, HIPAA review is likely to be required. If you plan to bring identifiable health information from a foreign country to a U.S. covered entity (e.g., lab at the Hopkins SOM), HIPAA may be triggered. Check "yes" to the HIPAA question in the PHIRST application.*

V. Study Procedures:

*In this section, provide details of your procedures, particularly as they relate to human subjects. If this is a multi-center study, make the role of JHSPH clear. If the JHSPH will serve as **data coordinating center**,*

indicate in the sections below which procedures JHSPH will not be performing. Additional information regarding data coordinating centers is requested in a later section. If your study will develop in phases, address each item below by phase.

Due to the COVID-19 pandemic – All study procedures are being conducted fully remotely.

A. **Recruitment Process:**

1. Describe how you will identify, approach, and inform potential participants about your study. Include details about who will perform these activities and what their qualifications are.

   Component testing: Recruitment will be conducted using a variety of methods that focus on venues specific to BMSM. We will post advertisements, both hard-copy and virtual, at venues in the Baltimore-metro area such as cafes, community-based organizations, and health clinics.

   Full Pilot trial: Index: Recruitment will be conducted using a variety of methods that focus on venues specific to BMSM. Participants have expressed a preference to communicate with the study using text messages from the initial point of inquiry about screening including study reminders. The study has a specific cell phone (Hopkins based cellular account) that is in the possession of a trained staff member while at the Lighthouse from 8am -5 pm. The cell phone is kept in a locked filing cabinet when not in use. Inquiries about screening for the study are responded to using a strict protocol which is to indicate that the participant can call either the cell phone or office number to speak to a study staff and have questions answered. We will also post advertisements, both hard-copy and virtual, at venues in the Baltimore-metro area such as cafes, community-based organizations, and health clinics. We will also post virtual flyers on Craigs list and on the Lighthouse Facebook account.

   Networks: Index in both conditions will be e-mailed or mailed invitations to recruit individuals from their social networks (see Network Invitation). Each invitation will have a unique code (herein referred to as StarCode) that will enable investigators to link the recruited networks to the Index.

2. Address any privacy issues associated with recruitment. If recruitment itself may put potential participants at risk (if study topic is sensitive, or study population may be stigmatized), explain how you will minimize these risks.

   Component Testing: This study does involve potentially sensitive or personal information (such as sexual orientation) which could be associated with stigma for participants. Recruitment will therefore be conducted in a discrete manner. Flyers will be posted in areas throughout Baltimore and will allow potentially interested individuals to tear off a phone number slip or write down the Lighthouse contact information in a discreet manner and call from a private location. Trained recruiters will

Full Pilot Trial: Index: This study does involve potentially sensitive or personal information (such as sexual orientation/behavior) which could be associated with stigma for participants. Recruitment will therefore be conducted in a discrete manner. Flyers will be posted in areas throughout Baltimore and will allow potentially interested individuals to tear off a phone number slip or write down the Lighthouse contact information in a discreet manner and call from a private location. Recruiters will be instructed to approach all Black male individuals who appear to be aged 17 or older and to explain, "if this does not apply to you please pass the flyer on to someone who you think may be interested".

Network: The study does involve potentially sensitive or personal information sexual behavior and testing for sexually transmitted diseases. The network invitation indicates that individuals can use the website to order home-based testing kits for HIV and sexually transmitted infections. This content was suggested by participants of the Component testing phase who indicated that a minimal amount of information is desired for their networks to be interested.

B. **Consent Process**:

1. Describe the following details about obtaining informed consent from study participants. If a screening process precedes study enrollment, also describe the consent for screening.

   a. Who will obtain informed consent, and their qualifications:

   Trained research assistants at the Lighthouse, all of whom have completed the CITI training and signed agreements of confidentiality, will obtain the informed consent.

   b. How, where, and when the consent discussion(s) will occur:

   Component Testing: All participants will provide oral informed consent before being screened (see Screening survey). If they are deemed eligible for participation, they will provide written informed consent before completing the discussion sessions. For the screening process, participants will have two options. They can either call the Lighthouse phone number and ask to be screened over the telephone, or they can walk in and be screened on-site. In either case, verbal consent is obtained before screening is conducted. The verbal consent includes a description of the study procedures, an explanation of any risks and benefits of participation, a summary of privacy and the Lighthouse's data protection procedures, and a reminder that participation is entirely voluntary. The consent statement will be read to participants before screening. If they do not provide verbal affirmation of understanding and willingness to proceed, they will not be screened.
   Prior to participation in the discussion sessions, written informed consent will be obtained by a trained research assistant in a private office at the Lighthouse. The signed copy of the written consent will be filed in a locked filing cabinet and a second unsigned copy will be provided to the participant for their records.

Full Pilot Trial: Assent will be collected remotely via phone appointment.
For Index and Network participants aged 17: The study is requesting a waiver of written informed consent (parental permission) but will obtain informed written assent from participants aged 17. A waiver is requested for multiple reasons. The FDA has approved use of HIV oral rapid self-testing for individuals aged 17 and older. Requiring parental consent could pose the risk of disclosure of sexual attraction, identity, or behavior which could result in harms to the participant such as loss of housing or financial support and experiences of stigma and discrimination. Requiring parental consent "creates a de facto exclusion of youth who are not "out" to their parents about sexual behavior and/or identity." Finally, this behavioral health study poses no more than minimal risk to participants. Possible risks are breach of confidentiality and the chance that answering questions about sensitive topics may be upsetting or embarrassing. As risk for emotional distress from any of the questions is highly unlikely, risks for breaches of confidentiality are minimized by using methods to protect participant privacy and confidentiality.

Index: All participants will provide oral informed consent before being screened (see Screening survey). The verbal consent includes a description of the study procedures, an explanation of any risks and benefits of participation, a summary of privacy and the Lighthouse's data protection procedures, and a reminder that participation is entirely voluntary. The consent statement will be read to participants before screening. If they do not provide verbal affirmation of understanding and willingness to proceed, they will not be screened. Index participants determined to be eligible will provide written informed consent or assent prior to any baseline study activity. Participants will meet with a trained Research Assistant in a private office. The participant will be emailed a copy of the consent to follow as the Research Assistant reads the consent/assent form to them. The participants will be given time at the end to ask questions prior to providing consent/assent.

Networks: Invited network members will be instructed to log-onto the STAR website using the Starcode on their invitation. The network member will be asked to indicate whether they are aged 17 or older and the relationship of the person who gave them the invitation. Then the network will view the written informed consent/assent to read. Contact information to the study personnel is provided so that the interested network can call with questions. Network members will indicate their consent on the website. If a network does not provide consent, no other study activities will take place.

c. The process you will use to determine whether a potential participant meets eligibility criteria:

Component testing: An approved screening survey will be administered to interested participants to determine eligibility for the study. A trained study staff (either over the phone or on-site at the Lighthouse in a private study room) will use an electronic questionnaire

which will include questions about all study eligibility criteria. The research assistant will input the participant's answers into the computer-generated survey. Upon completion of the survey, an algorithm will automatically generate the results indicating whether or not the participant is eligible to continue in the study.

Full Pilot Trial:
Index: An approved screening survey will be administered to interested Index participants to determine eligibility for the study. A trained study staff (either over the phone or on-site at the Lighthouse in a private study room) will use an electronic questionnaire which will include questions about all study eligibility criteria. The research assistant will input the participant's answers into the computer-generated survey. Upon completion of the survey, an algorithm will automatically generate the results indicating whether or not the participant is eligible to continue in the study.
Network: Upon logging into the website - the invited network member is asked to indicate their date of birth which will be calculated by the website. Those who indicate that they are not 17 and older will be provided with information about the IWTK website and resources for sexual and reproductive care and no other study activities will proceed.

d. Whether you will obtain a signature from the participant or will use an oral consent process:

Component testing: An oral consent will be obtained from participants for the screening and a signature will be obtained for the enrollment process.
Full Pilot Trial:
Index: An oral consent will be obtained from participants for the screening. We request a waiver of signature for the enrollment process.
Network: We request a waiver of signature for the enrollment process. Network participants will click on a button to acknowledge that they read the consent but will not need to provide an electronic signature.

e. Whether you will obtain a legally authorized representative's signature for adults lacking capacity:

Adults who lack capacity to provide consent/assent will not be included in this study.

f. If children are included in the study, if and how you will obtain assent from them:

Component testing: Individuals under the age of 18 will not be included.
Full Trial:
Index: We will be including individuals aged 17 and older. An oral assent will be obtained from participants for the screening and a signature will be obtained for the enrollment process.

Network: Individuals will electronically indicate their assent on the website.

g. If children are included in the study, how you will obtain permission for them to participate from their parent, legal guardian, or other legal authority (if child is in foster care or under government supervision):

Component testing: N/A
Full Trial:
Index: We are seeking a waiver of parental informed consent for individuals aged 17.
Network: We are seeking a waiver of parental informed consent for individuals aged 17.

h. If you are seeking a waiver of informed consent or assent, the justification for this request:

A waiver is requested for multiple reasons. The FDA has approved use of HIV oral rapid self-testing for individuals aged 17 and older. Requiring parental consent could pose the risk of disclosure of sexual attraction, identity, or behavior which could result in harms to the participant such as loss of housing or financial support and experiences of stigma and discrimination. Requiring parental consent "creates a de facto exclusion of youth who are not "out" to their parents about sexual behavior and/or identity." Finally, this behavioral health study poses no more than minimal risk to participants. Possible risks are breach of confidentiality and the chance that answering questions about sensitive topics may be upsetting or embarrassing. As risk for emotional distress from any of the questions is highly unlikely, risks for breaches of confidentiality are minimized by using methods to protect participant privacy and confidentiality.

i. Whether you will include a witness to the consent process and why:

Index: The research assistants will serve as witnesses to the consent/assent process to document that consent was obtained. They will provide their signature and date on the written consent/assent.
Networks: The date and time of the consent/assent will be digitally recorded by the website.

j. If the language is unwritten, explain how you will communicate accurate information to potential participants and whether you will use props or audio materials:

N/A

2. Identify the countries where the research will take place, and the languages that will be used for the consent process.

Country	Consent Document(s) (Adult Consent, Parental Permission, Youth Assent, etc.)	Languages
USA	**Adult Consent**	**English**

C. **Study Implementation**:

1. Describe the procedures that participants will undergo. If complex, insert a table below to help the reviewer navigate.

Component Testing will involve participation in two group-based sessions (scheduled one week apart).

Session 1: Participants will be asked to view the home-based testing website using their smart phones (if applicable) or on a provided study computer. They will be asked to navigate the website, establish an account, and go through the steps for requesting kits. These participants will also be asked to give their opinion on the design and content of cards that will be used to refer their peers and sex partners to the study and the website. Then we will ask participants to take time over the following week to talk to their peers and/or sex partners about the website and show them these coupons so that they too can view the materials and provide comments.

Session 2: Participants will be asked to share how the conversations went with peers/sex partners, including any challenges they experienced, acceptability of the coupon design and suggestions to improve the program.

Both sessions will be audio recorded to allow researchers to listen to the discussions. The recordings will be kept on a secure computer with limited access.

Full Trial: See Star Participant Flow for an overview
Index: All Index procedures are being conducted fully remotely via phone calls.
[Baseline Visit] The participant will be contacted by the research assistant via phone at a time that was scheduled based upon the participant's convenience. Informed consent/assent will be obtained and a copy will be emailed to the study participant. The participant will be given the choice of completing the survey self-administered or by the research assistant. If the participant chooses self-administered a link to the Qualtrics survey will be emailed. If the participant chooses research assistant administered the research assistant will directly input responses into the Qualtrics link. No names will appear on the survey data - only a unique code. After the survey, locating information will be collected. This information will be stored in an encrypted and password protected database that is separate from the survey data and the unique code. The participant will be provided with the date and time of the first group session. The participant will receive $50 for completing the baseline visit.

[Randomization] Index Participants will be randomized after the baseline survey and scheduled for their first session with the Health Educator. All Index participants are eligible to be randomized up to 60 days after they complete their baseline visit.

[Experimental condition]: Peer Mentor Training is 5 individual sessions with a 30 day check-in session. This condition is focused on training Index with communication skills to promote HIV and STI testing and treatment and pre-exposure prophalaxis (PrEP) to individuals in their social networks. Peer Mentor training is conducted by a one health educator. The sessions are held once a week and will last approximately 60 minutes. The attached table outlines each session, objectives and main activities. Participants will receive $25 for each session they attend.

[Control condition]: Is one individual-based session which will be conducted by sending a video of a health educator. The session is designed to last up to 60 minutes. The content of the session will include an overview about chlamydia, gonnorhea and HIV, home-based testing and specimen collection procedures and the Star website. At the end of the session participants will be given six invitations labeled with Starcodes and instructed to use them to invite friends, peers or sex partners from their social network to enroll into the study and access free home-based testing kits. Participants will receive $25 for attending this session.

[Home-based testing and specimen collection kits]: All randomized Index and the networks that they invite and to the study will have access to a secure encrypted website that will enable them to request kits to test for HIV at home and collect specimens that can be mailed to a laboratory for testing for gonorhea and chlamydia. The following are the steps a participant will follow when using the website:

- **You will set up a personal account on the study website that will have a user name and password that you choose. By logging into your account you will be able to view the kits you requested, the dates they were mailed to you, the results to gonorhea and chlamydia testing and to enter the results of your HIV home-based test.**
- **After you set up the account you will be able to view information about the different sexually transmitted infections and treatment and other resources.**
- **The kits will be mailed to you within 3-5 business days in a plain white envelope to the address that you want. The envelope will not indicate anything about the contents or reference the study.**
- **Instructions will be included in the envelope on how to use the different test kits.**
- **For the HIV testing – you will collect an oral swab at your home, place it in a vial of solution and will read your result in 20 minutes.**
- **For gonorrhea and chlamydia testing you will place the specimens in a plastic tube that we provide and mail to the lab for testing. Postage for this will be paid by the study. These specimens will only be labeled with a unique ID number and not your name. The laboratory will**

dispose of the swabs after the testing is complete. The results of these tests will be available to view in your website account within one week of the lab receiving your specimens. Your test results will be communicated to you via your account on the STAR project website

Maryland State names reporting: This is a requirement for gonorrhea and chlamydia tests. Participants who request these kits are required to read and acknowledge the Maryland State names reporting (see website mock up). The HIV test result is not required to be reported to the State.

[3 month follow-up visit]: Three months from the date of the last group session, Index participants will be contacted to schedule their in-person follow-up visit. Networks will be sent an email with a message reminding them that it is time for their 3 month follow-up survey via the STAR website.

2. Describe the number and type of study visits and/or contacts between the study team and the participant, how long they will last, and where/how they will take place.

   Component testing: Participants will take part in two group-based sessions on site at the Lighthouse. These will be scheduled one week apart. Each session could last up to two hours.

   Full trial:
   Index:
   Baseline visit: up to 60 minutes - over phone or self-administered
   Intervention group sessions (five) and check-in session if applicable: up to 90 minutes - private group room at the Lighthouse Studies @ Peer Point
   3 month follow-up visit: up to 60 minutes - private office in the Lighthouse Studies @ Peer Point

   Network:
   Enrollment visit: up to 45 minutes, online www.star.jhsph.edu
   3 month follow-up visits: up to 45 minutes, online www.star.jhsph.edu

3. Describe the expected duration of the study from the perspective of the individual participant and duration overall.

   Component testing: Each session could last up to two hours. Therefore the duration of participation is up to four hours.
   Full trial:
   Index participant: The duration of the study is up to 4-6 months from screening to 3 month survey.
   Network participant: The duration of the study is 3 months from enrollment to 3 month follow-up.

4. Provide a brief data analysis plan and a description of variables to be derived.

Component testing: Audio recordings of the sessions will be transcribed. For each transcript, document variables will be created including the session number, date, and characteristics of the participants (such as number of sessions attended). We will read through each transcript and record situations in which participants described aspects of the website experience and referral coupons that they did and did not like and any suggestions for changes. We will also document experiences participants had talking to their peers about self-testing, HIV, STIs and/or the referral coupon. The study team will evaluate the specific experiences and determine whether each describes a positive (i.e., easy) or negative (i.e., difficult) interaction with a peers or partner on that topic. In addition, we will also identify the specific strategies participants used to overcome these difficulties, such as talking to their peers at a later time, if applicable (as not all participants may articulate a specific strategy). We will create and apply codes about interactions (e.g. positive or negative); response/strategies used by the Peer Mentor, situational characteristics (e.g. planned conversation versus spontaneous) and peer characteristics (e.g. relationship to participant, sex of peer, closeness of the relationship.) We will review and discuss the codes to create a summary about facilitators and barriers experienced by the Peer Mentors to refine the website and the coupons.

Full Trial:

Aim 1: Identify facilitators and barriers to peer outreach and fidelity to the PEER communication tool from the audio-recordings of Sessions 2 and 3. In Session 2 and 3, participants will report their experiences talking to peers about HIV and STI self- testing. Audio recordings of Sessions 2 and 3 will be transcribed and uploaded to MAXQDA, qualitative data management software that allows data organization, categorization, coding, text retrieval, comparison, and analysis. For each transcript, document variables will be created including the session number and date and characteristics of the participants (total attendance, how many described their experiences). We will read through each transcript record situations in which participants described their experiences talking to their peers about self-testing, HIV, STIs and/or PrEP. As a team, we will evaluate each of the specific experiences and determine whether it describes a positive (i.e., easy) or negative (i.e., difficult) interaction with their peers on that topic. In addition, we will also identify the specific strategies participants used to overcome these difficulties, such as talking to their peers at a later time, if applicable (i.e., all participants may not describe a specific strategy). MAXQDA allows for the linking of text passages within a transcript, which will enable us to connect a particular challenge with a specific strategy.

We will create and apply codes about interactions (e.g. positive or negative); response/strategies used by the Peer Mentor, situational characteristics (e.g. planned conversation versus spontaneous) and peer characteristics (e.g. relationship to Index, sex of peer, closeness of the relationship. We will review and discuss the codes to create a summary about facilitators and barriers experienced by the Peer Mentors. Results from this analysis can be used to interpret the preliminary efficacy findings and refine the PEER communication tool. To assess fidelity to

the PEER communication tool, we will code examples of when Peer Mentors use each of the steps of the tool. For example, if a Peer Mentor describes starting a conversation by asking his peer if it is a good time to talk – this will be coded as an example of fidelity.

Quantitative analysis of facilitators and barriers: We will also tabulate the frequencies of facilitators and barriers identified by BMSM in the experimental condition from the 3 month survey.

Aim 2: We will compare the reach of the two conditions in terms of (i) the number of peers recruited to access the self-testing website; and (ii) the characteristics of those recruited including sexual risk behavior, HIV/STI testing behavior, linkage to HIV/STI care, PrEP awareness and self-testing-related perceived norms. For the first part, as the number of peers/sex partners recruited by a mentor is a count, we will fit a model with log link with intervention condition as the only predictor to estimate the treatment-to-control ratio of mean number of peers recruited. For the second part, as the peers are clustered in the mentors who recruited them, we will use general estimating equations (GEE, which allow correlation among clustered units) to estimate treatment-control contrasts in each characteristic. We will include sex as a biologic variable in these analyses.

Aim 3: We will test and estimate differences (i) between intervention and control mentors and (ii) between intervention and control recruited peers in terms of: request of self-testing kits, return of specimens for STI testing, accessing of STI test results, and posting of HIV oral test result (all binary variables). For the mentors, we will use tests of two sample proportions and simple logistic regression with the intervention condition as predictor. For the peers, we will fit GEE logistic models to allow for correlation of outcome among clustered peers and will include sex as a biologic variable.

Secondary Analysis
Changes in knowledge and self-efficacy: We will examine the changes in the continuous measure of Knowledge score using linear regression adjusting for baseline knowledge score and other covariates. We will examine changes in self-efficacy by using a Chi-square test for a difference between two proportions of efficacy score.

Reasons for testing and future preferences: We will tabulate participant responses and compare proportions by condition using Chi-square tests.

5. Answer the following **if they are relevant to your study design**:

   A. If the study has different arms, explain the process for assigning participants (intervention/control, case/control), including the sequence and timing of the assignment.

Component Testing: N/A

Full Trial:
Index: After completing the baseline visit, Index will be informed about the time and date for session 1 of the two different arms (e.g. randomization). Index will be randomized to condition in the order that they arrive on randomization. The study will use a pre-determined randomization sequence that was generated by the Data Manager.
Network: Do not attend randomization. Their assignment to condition is based on the assignment of the Index who invited them to the study.

B. If human biospecimens (blood, urine, saliva, etc.) will be collected, provide details about who will collect the specimen, the volume (ml) and frequency of collection, how the specimen will be used, stored, identified, and disposed of when the study is over. If specimens will be collected for use in future research (beyond this study), complete the "Biospecimen Repository" section below.

Component testing: N/A
Full Trial:
Index: See Biospecimen table
Network: See Biospecimen table

C. If genetic/genomic analyses are planned, address whether the data will be contributed to a GWAS or other large dataset. Address returning unanticipated incidental genetic findings to study participants.

N/A

D. If clinical or laboratory work will be performed at JHU/JHH, provide the JH Biosafety Registration Number.

Component Testing: N/A
Full Trial: The laboratory is CLIA-certified (CLIA # 21D0680509) and undergoes a biennial accreditation inspection administered by the College of American Pathologists (CAP # 1353001). The laboratory is also licensed by the State of Maryland (Permit # 008).

E. If you will perform investigational or standard diagnostic laboratory tests using human samples or data, clarify whether the tests are validated and/or the lab is certified (for example is CLIA certified in the U.S.). Explain the failure rate and under what circumstances you will repeat a test. For all human testing (biomedical, psychological, educational, etc.), clarify your plans for reporting test results to participants and/or to their families or clinicians. Address returning unanticipated incidental findings to study participants.

N/A

F. If your study involves medical, pharmaceutical or other therapeutic intervention, provide the following information:

a. Will the study staff be blind to participant intervention status?

Component testing: N/A
Full Trial:
Index: Group facilitators will not be blind to the condition. Study staff who completed 3 month follow-up procedures will be blind to the intervention status. Group facilitators will not collect follow-up data.
Network: All data collected is self-administered.

b. Will participants receive standard care or have current therapy stopped?

Component testing: N/A
Full Trial:
Index: Participants randomized to the control condition will receive standard care. No participants will have any current therapy that they are on stopped.
Network: No participants will have any current therapy that they are on stopped.

c. Will you use a placebo or non-treatment group, and is that justifiable?

Component testing: N/A
Full Trial:
Index: All Index will receive information and instruction for using the website to request home-based HIV and STI testing. Index in the experimental condition will receive training in communication skills to promote home-based testing to their networks
Networks: who choose to enroll in the study will have access to HIV and STI testing.

d. Explain when you may remove a participant from the study.

Full Trial:
Index: If an Index participant behaves in an aggressive (physically, verbally), abusive (physically, verbally, emotionally), sexually inappropriate, sexual harassment, or engages in theft.
Network: aggressive (electronically via email, verbally), abusive (electronically via email), sexually inappropriate, sexual harassment (electronically via email)

e. What happens to participants on study intervention when the study ends?

Component testing: N/A
Full Trial: All participants will be referred to local HIV and STI testing resources.

f. Describe the process for referring participants to care outside the study, if needed.

Component testing: N/A
Full Trial:
Index: Study staff will provide referrals to HIV and STI care. Information about resources for HIV and STI care will also be listed on the website.

Network: Information about resources for HIV and STI care will be listed on the website. Networks will also be provided with phone and email contact information to reac study staff for referrals.

VI. Data Custody, Management, Security, and Confidentiality Protections:

Note: Principal Investigators are responsible for Data Protection and Use throughout the life of the study. You will need all of the following:

- *a data security plan that addresses each stage: data collection, transfer/analysis, storage, and sharing;*
- *a data management plan overseeing data access, storage, etc.;*
- *a data sharing plan that is consistent with obligations under the funding agreements associated with the study, and with the language in the consent documents.*

A. Personally Identifiable Information (PII):

Please identify the Personally Identifiable Information (PII) that you may be collecting and using at any of the following stages of your study: ***Recruitment***, ***Consent,*** *and* ***Study Implementation (Data Collection)***.

	Recruitment /Consent	Data Collection
Name, signature, initials, or other identifiable code	☐	☒
Geographic identifier: address, GPS location, etc.	☐	☐
Dates: birth, death, clinical service, discharge, etc.	☐	☒
Contact information: phone numbers, email address, etc.	☐	☒
ID: Social Security Number, driver's license number, etc.	☐	☐
Health record identifiers: medical record, insurance plan number, etc.	☐	☐
Account numbers	☐	☐
Device identifiers: e.g., implants	☐	☐
Internet identifiers: IP address, social media accounts	☐	☐
Biometric identifiers, including finger and voice prints	☐	☐
Audio recordings	☐	☐
Video or full face photographic images	☐	☐
Genomic/genetic data	☐	☐
Any other unique identifying number, characteristic, or code (note: this does not mean the unique code assigned by the investigator to code the data)	☐	☐
Other: Click here to enter text.	☐	☐

Recruitment:

Will you collect identifiers for the purpose of contacting potential participants? Yes ☒ No ☐

If **yes**, will you retain the identifiers after the recruitment contact has been made? Yes ☒ No ☐

B. Data Collection:

Collection of data for a research study can take on many forms. It can be as simple as gathering the data with pen and paper or developing an on-line adaptive survey that changes based on the participant's answers. Regardless of the method, PII collection for the purposes of identifying the participants will most likely be collected. Once collected, the raw data should go through a de-identification process to further protect PII.

In what form(s) will you collect and store PII? When you respond, refer back to the table above; think of PII collected during recruitment, consent, data collection, and other study purposes.

1. **Hard Copy/Paper:** Yes ☒ No ☐

   If yes, please answer the following:

   a. How will the data be kept secure during transfer from study collection site to storage site?

      Study collection site and storage site are the same

   b. Will the data be secured in a locked cabinet or room? Yes ☒ No ☐

   c. If study IDs/Codes are used, will they be stored separately from the study data? Yes ☒ No ☐

   d. Will the hard copy/paper be destroyed after data abstraction and cleaning are complete? Yes ☒ No ☐

      If No, when do you plan to destroy the hard copies?

2. **Electronic:** Yes ☒ No ☐

   If yes, please answer the following:

   a. Will the data be collected or stored on a portable device (laptop, mobile phone, tablet, PDA) Yes ☒ No ☐

      If Yes, will the device be protected by encryption? Yes ☒ No ☐

   b. Will the device(s) be study-owned or privately-owned (e.g., personally owned by data collectors or study participants?)
      Personally owned ☒ Study provided ☒
      Note: If personally owned, please address the privacy and data security risks under VII. Risks below.

c. Is the app (application)/website used for data collection being developed in-house (Hopkins) or by a 3rd party vendor? In-house ☒ 3rd party ☐

If 3rd party, provide the name of vendor and URL:

Identify Mobile Ecosystem (check all that apply): Apple ☐ Google ☐ Website ☐

d. Will the data be stored on a secure server (@JHSPH/on-site)? Yes ☒ No ☐

e. Will the data be stored in the Cloud/Web? Yes ☒ No ☐

f. Will it be encrypted? Yes ☒ No ☐

g. Will you be backing up your data? Yes ☒ No ☐

3. **Audio Recording:** Yes ☒ No ☐

If yes, please answer the following:

a. Will you store the audio recording securely in a locked cabinet/room until transcription is complete? Yes ☒ No ☐

b. Will you use a transcription service? Yes ☐* No ☐

**If yes, if the PII comes from JHH/JHHS, you must use an approved vendor; otherwise, be aware of the data security protections that the transcription service provides.*

c. Will the audio recording be destroyed immediately after transcription? Yes ☒ No ☐

If no, why not? How long will it be retained?

4. **Photograph/Video:** Yes ☐ No ☒

If yes, please answer the following:

a. Will the photographs/videos be stored securely in a locked cabinet or room? Yes ☐ No ☐

b. Will the photograph/video be destroyed? Yes ☐ No ☐

If yes, when?

C. PII De-Identification of Data Used for this Study:

1. When will you destroy the PII and/or the code linking the PII with the study ID?

Component testing phase: within 6 months of the completion of this phase. Full Trial: Within 1 year after all study activities are complete.

2. What is the method you will use to de-identify the data?

The Data Manager will remove any variables that are identifiers.

3. Is your research data governed by HIPAA (U.S. clinical data remaining within the covered entity)?
   a. Yes ☐ No ☒

   b. If yes, who is doing the de-identification?

   c. If yes, what level of de-identification will you achieve (Limited data set? De-identified?)

D. Data Storage and Analysis:

One of the keys to protecting PII is the proper use of tools to share and conduct your analysis. JH and JHSPH offers several options for you to consider. Please select the systems that you plan to use to protect your study data by clicking the box. Consult JHSPH IT for assistance if needed.
Check all systems used for data collection, storage and analysis.

☐ **JH Virtual Desktop**: The Hopkins Institute for Clinical and Translational Research (ICTR) provides a virtual Windows desktop (SAFE Desktop). It includes productivity software such as Microsoft Word and Excel, as well as statistical software, including SAS, Stata, R, R Studio, and Python. 100 GB of storage space is provided.

☐ **OneDrive-JHSPH**: Managed by JHSPH IT and available only to people with a JHSPH ID, a file storage and file sharing solution in the Microsoft cloud for faculty, staff, and students. With OneDrive, you can store files and access them anywhere with internet access. (https://my.jhsph.edu/Offices/InformationTechnology/ComputerSupport/SharedFolders/OneDrive-JHSPH/Pages/default.aspx)

☐ **JHU OneDrive**: Managed by IT@JH, personal cloud storage component of the Office 365 produce suite that allows users to store and share documents and files from any device with an internet connection. Share documents with colleagues, inside and outside of JHU (no JHED ID required). (https://it.johnshopkins.edu/services/collaboration_tools/OneDrive/)

☐ **JHSPH RedCAP**: These are departmentally managed applications. RedCAP is an application designed for collaborative research projects.

☐ **JHSPH HPCC:** High Performance Computing Cluster (HPCC: https://jhpce.jhu.edu/) can provide the high capacity computing required for very large data sets.

☒ **JHSPH Sharepoint:** For user-controlled private web sites, secure document storage, navigable directories, contacts and people searches, increased collaboration and sharing opportunities. (https://my.jhsph.edu/Offices/InformationTechnology/CommunicationServices/MyJHSPH/Pages/default.aspx)

☐ **Independent Departmental Servers and Systems**: These servers are typically managed by departmental or research team IT staff. Because these servers are not centrally managed by JHSPH IT, all documentation regarding data security protections will need to be provided by the owner/administrator of the server. This responsibility may fall to the data owners (PI).

☒ **Other**: Please provide details regarding any other systems being utilized, for example Qualtrics, ODK, etc. Examples may include servers and applications located at another university participating in your study or a 3rd party web-based application.

Self-testing web-site: JHSPH Information Technology, Advanced Technology Services (ATS) will develop, administer, and manage the web-based portion of the study. For the Component Testing Phase, the prototype website will not be "live" on the web, and all data entered into the prototype will be deleted by ATS after the group testing sessions are over. This website will be hosted on a secure server maintained by Information Technology – Johns Hopkins Bloomberg School of Public Health. All Information Technology infrastructure and services are maintained by a professional staff certified in the latest technologies, industry standards, and best practices. Information Technology currently supports a mix of physical and virtual servers along with Storage Area Network (SAN) technologies within an enterprise data center. IT also supports an academic and administrative data center as well as a disaster recovery facility. These facilities and systems are protected by a series of security measures, including network-enabled firewalls, intrusion detection devices, and anti-virus and anti-spam systems. Information Technology has taken numerous proactive steps to implement IT security controls to best protect and secure sensitive client data corresponding to a Federal Information Processing Standard (FIPS) 199 system categorization of Moderate that meet the requirements of the Federal Information Security Management Act (FISMA) and improve the security of information systems.

E. Other Data Security Measures:

In addition to the details regarding data collection, please review the following questions. This additional information will be utilized to assist in the development of a comprehensive Data Security plan. This would include the systems used to analyze the data, data security contacts and additional requirements.

1. During the analysis phase, do you plan to use computer systems that are not managed by JHSPH or JH? Yes ☐ No ☒

   If yes, please explain:

2. Do you have a designated person on your research team other than the PI who is the technical contact for a Data Security plan? Yes ☒ No ☐

   If yes, please provide a contact name:

   Joanne Jenkins

3. Does your sponsor have other specific data security requirements for the study data? Yes ☐ No ☒

If possible, please explain:

4. **Please add any other information that you believe is relevant to data security.**
   Data will be housed at Lighthouse Studies, which is located within a secure JHU-monitored facility utilizing access-controlled entry points (i.e., manned security/lobby desks and automated lock/ID systems) to limit passage into the building. Restricted areas throughout the building are further monitored by patrolling security guards and video surveillance. Electronic copies of study data will be stored on a JHSPH sharepoint. AES encryption, in compliance with JHU Information Technology Policies and JHU Institutional Computing Standards, is used to protect data at rest in addition to basic system-level security controls, such as operating system passwords in adherence to JHSPH password complexity requirements, screensaver lock enabled with inactivity limits, regular Operating System (OS) patches, and daily antivirus scans and updates. Backups of the file server are stored on a rotation of hardware encrypted (256-bit AES) external hard drives before being taken offsite to a secure location. Network security is provided by the JHSPH firewall and network security systems. Access to the raw data on the sharepoint will be limited to the Data Manager, who will de-identify the data for relevant analyses. Access controls will be will be administered through shared folders organized using Active Directory groups based on the principle of least privilege. The Data Manager will also serve as the Gatekeeper of data and provide Investigators, Researchers, and Collaborators access to de-identified data.

F. Certificate of Confidentiality:

All NIH studies include Certificate of Confidentiality protections with the grant; the consent form must include the C of C language provided in our template. Other funders may obtain C of C protections through NIH. (https://humansubjects.nih.gov/coc/index)

Does the study have Certificate of Confidentiality protections? Yes ☒ No ☐

G. Data Sharing and Disclosure:

a. Please describe your data sharing plan, including whether you plan to share your data with your sponsors or with other investigators. Explain whether the shared or disclosed data will be individually identifiable. **Your data sharing plan should be consistent with Sponsor requirements, and the consent document should include a description of your data sharing plan.**

b. Are there laws limiting data sharing in the country where the research site(s) is located? If yes, please address those limitations and how you will comply with them.

c. Will you make your data publicly available? If yes, what is your plan for de-identification?

d. Will you deposit it into a repository for broader use? If yes, identify the repository and provide information about the data protections.

H. JHM Clinical Records:

Will you use clinical data of 500 records or more from Johns Hopkins Hospital and its affiliates?
Yes ☐* No ☒

**If yes, please complete the JHM Data Security Checklist available on the JHSPH IRB website: www.jhsph.edu/irb and upload a copy of the checklist to the "Miscellaneous" section.*

VII. Risks of the Study:

A. Describe the risks, discomforts, and inconveniences associated with the study and its procedures, including physical, psychological, emotional, social, legal, or economic risks, and the risk of a breach of confidentiality. These risks should be described in the consent documents.

Participants may face the risk of breaches of confidentiality about their participation or any of the information that they share while involved in this project by project staff or other participants. Participating in the group sessions may present as a burden to the subjects. Subjects will be informed prior to enrolling into the study about the level of time commitment involved. Risks for participants could also involve the potential for adverse psychological reactions from the voluntary disclosure of serostatus and MSM behaviors or in response to the general sensitive nature of the topics being discussed. It is also possible that participants who have conversations with their peers about testing will be the target of negative verbal and physical reactions. Collecting specimens using the swabs may be uncomfortable. Instructions are provided and you can contact the study to ask questions. Participants may also experience stress and anxiety waiting for test results.

B. Describe steps you will take to mitigate or minimize each of the risks described above. Include a description of your efforts to arrange for care or referral for participants who may need it.

Throughout over 20 years of community-based research at the Lighthouse, there have been very few adverse incidents and we do not anticipate the harms we have described. However, we maintain well-rehearsed emergency protocols and ensure that all staff are prepared to address an adverse emotional reaction should it occur for a participant. Participants will be able to request a call from a trained research staff who is certified in pre and post-test counseling.

C. Describe the anticipated frequency and severity of the harms associated with the risks identified above; for example, if you are performing "x" test/assessment, or dispensing "y" drug, how often do you expect an "anticipated" adverse reaction to occur in a study participant, and how severe do you expect that reaction to be?

We have a highly trained staff who has experience with handling sensitive and personal data, ensuring confidentiality, conducting testing and counseling for HIV and STIs, and managing emergency procedures. We have developed numerous protocols to ensure that risks are minimized during recruitment, assessment, and retention activities. Staff are monitored by the Data Manager

and the PI. In addition, monthly supervision meetings are held with assessment and intervention staff to discuss quality assurance and human subjects' protections.

Audiorecordings of survey visits and intervention sessions are also stored on a password protected computer. All data files/recordings are backed up daily on hard drives of IBM compatible computers and burned on a CD at the Lighthouse and protected by the use of a password and encryption security system and firewall protection from the Internet. All systems will be virus-protected with software updates weekly.

D. Describe the research burden for participants, including time, inconvenience, out of pocket costs, etc.

Component testing: Participation will entail attendance at two sessions scheduled one week apart that will last up to 2 hours each. Participants will be informed during the screening and consent process about the level of time commitment involved to ensure that they have the capacity to take part in the group sessions.

Full Trial:
Index: Participation will entail time for a brief screening call to determine eligibility, a baseline and 3 month in-person visit which will last up to 90 minutes, and up to five group sessions which will last approximately 60 minutes. Participants will also have the option to spend time on the study website to request home-based testing kits - this process entails creating an account (less than 5 minutes), reading about the kits and requesting the kits.

Network: Participation will entail time to create an account on the study website (less than 5 minutes), a baseline survey (approximately 20 minutes) and the option to spend time on the study website to request home-based testing kits - this process entails, reading about the kits and requesting the kits. Networks will also be asked to complete a 3 month follow-up survey (approximately 20 minutes).

E. Describe how participant privacy, and if relevant – family privacy - will be protected during data collection if sensitive questions are included in interviews, or if study visits occur in the home setting.

Component testing: In the group sessions, participants will be asked to respect each other's opinions and to not discuss personal information about other participants outside of the group. Participants will be requested to only use their first name in the intervention sessions.

Full trial:
Index: Participants in both randomization conditions will be asked to not share personal information with others outside of the group. Participants will be asked to only use their first name.

VIII. Direct Personal and Social Benefits:

A. Describe any potential direct benefits the study offers to participants ("payment" for participation is not a direct personal benefit).

There may be no benefit to individuals from participating in this study. The facilitator will provide resources to local service and medical providers during the session which may benefit participants.

B. Describe potential societal benefits likely to derive from the research, including value of knowledge learned.

Disparities in HIV and STI rates persist among BMSM. Lack awareness of serostatus and delayed treatment are factors that contribute to this public health problem. Culturally-tailored, sustainable interventions are urgently needed to engage BMSM and their peers/sex partners in uptake of testing and subsequent linkage to clinical and prevention services. The combination of Peer Mentors and self-testing technology in a behavioral intervention will facilitate testing for hard-to-reach, at-risk individuals who are disproportionately affected by HIV and sexually transmitted infections.

IX. Payment or Token of Appreciation:

A. Do you plan to provide a non-monetary token of appreciation (food, soap, tea, chlorine tablets, etc.) to study participants? If yes, please describe below.

B. If you plan to provide a monetary payment, describe the form, amount, and schedule of payment to participants. Reimbursement for travel or other expenses is not "payment," and if the study will reimburse, explain.

Component testing: Participants will receive $40 in the form of a check at the end of each session they attend.

Full Trial:
Index: Baseline visit $50, group sessions $25 each, 3 month follow-up $50.
Network: Baseline visit: $25, 3 month follow-up $35

C. Include the possible total remuneration and any consequences for not completing all phases of the research.

Component testing: Total possible remuneration is $80. If a participant does not attend a session they will not receive remuneration.
Full trial: Index Total possible: $250
Network: Total possible $60

X. Study Management:

A. Oversight Plan:

1. Describe how the study will be managed.

Dr. Tobin will be responsible for implementation and management of the study.

2. What are the qualifications of study personnel managing the project?

Dr. Tobin is an Associate Professor and has been managing research studies with MSM and other vulnerable populations for nearly 18 years.

3. How will non-professional personnel (data collectors) involved with the data collection and analysis be trained in human subjects research protections? (Use the JHSPH Ethics Field Training Guide available on the JHSPH IRB website: www.jhsph.edu/irb)

   All personnel will have completed the CITI Human Subjects training course and the HIPPA training course. In addition all personnel sign a Pledge of Confidentiality.

4. If the PI will not personally be on-site throughout the data collection process, provide details about PI site visits, the supervision over consent and data collection, and the communication plan between the PI and study team.

   The PI has an office on site and will be present throughout data collection. In the event that the PI is not physically on-site, a Clinic Coordinator is available and staff is able to reach Dr. Tobin via cell phone or email.

B. **Recordkeeping:**

Describe how you plan to ensure that the study team follows the protocol and properly records and stores study data collection forms, IRB regulatory correspondence, and other study documentation. For assistance, contact: housecall@jhu.edu

C. **Safety Monitoring:**

1. Describe how participant safety will be monitored as the study progresses, by whom, and how often. Will there be a medical monitor on site? If yes, who will serve in that role?

Our quality assurance program provides monitoring and oversight to all aspects of data collection and adherence to the study protocol. This QA program consists of the following components:

- **Audio-recordings of discussion groups. 10% of these are randomly audited by Study Investigators to assess adherence to standards and protocols.**
- **Data entry checks conducted monthly by the Data Manager. Monthly reports are provided to study investigators.**
- **Monthly checks of consent form storage by the Data Manager**
- **Monthly supervision meetings to review protocols. The study PI meets with the entire research staff to discuss study progress and protocol.**
- **IRB correspondence database is an internal tool used to centralize all communication with the IRB.**
- **Locked filing system that houses all hard copies of study data collection forms, IRB regulatory correspondence, and other study documentation.**

2. If a Data Safety Monitoring Board (DSMB), or equivalent will be established, describe the following:

   There will be no DSMB for this pilot trial.

   a. The DSMB membership, affiliation and expertise.

b. The charge or charter to the DSMB.

c. Plans for providing DSMB reports to the IRB.

3. Describe plans for interim analysis and stopping rules, if any.

D. **Reporting Unanticipated Problems/Adverse Events (AEs) to the IRB (*all studies must complete this section*)**:

Describe your plan for reporting to the IRB and (if applicable) to the sponsor. Include your plan for government-mandated reporting of abuse or illegal activity.

During the consent process, study staff will remind participants to report any physical or social harm related to study participation to the study staff immediately so that participants may receive counseling or other assistance. When an unanticipated problem or adverse event is reported to the study staff, the staff documents the details of the event and refers the participant to medical, psychological or social services as deemed appropriate. If deemed necessary by the investigators, action may be taken to terminate the participant from the study. The IRB and NIMH will be notified of all study-related unanticipated problems or adverse events.

NOTE: The IRB does not require PROMPT reporting of all AEs, only those that are **unanticipated, pose risk of harm to participants or others, and are related to the study**. Anticipated AEs may be reported with the Progress Report.

E. **Other IRBs/Ethics Review Boards:**

If other IRBs will review the research, provide the name and contact information for each IRB/ethics review board and its Federal Wide Assurance, if it has one (available on OHRP's website at http://www.hhs.gov/ohrp/assurances). **For federally funded studies, subrecipient AND subrecipient's IRB MUST have a Federal Wide Assurance (FWA) number.**

N/A

Non-JHSPH IRB/REC	FWA Number

F. **"Engaged" in Human Subjects Research:**

For studies that involve collaboration with non-JHSPH institutions, complete the chart below by describing the collaboration and the roles and responsibilities of each partner, including the JHSPH investigator. This information helps us determine what IRB oversight is required for each party. Complete the chart for all multi-collaborator studies.

Insert collaborator names and FWA numbers, if available. Note who will be "engaged" in human subjects research by filling in the following table:

	JHSPH		
For federally funded studies, collaborators' FWA	00000287		
Primary Grant/Contract Recipient			
Grant/Contract Subrecipient			
Hiring Data Collectors			
Training Data Collectors			
Obtaining Informed Consent and/or Identifiable Data			
Accessing/Analyzing Identifiable Data			
Overseeing storage, access and use of biospecimens			

COMPLETE THE FOLLOWING SECTIONS WHEN RELEVANT TO YOUR STUDY:

XI. Secondary Data Analysis of Existing Data:

A. **Study Design:**

1. Describe your study design and methods. The study design must relate to your stated aims/objectives.

2. Provide an estimated sample size and an explanation for that number.

3. Provide a brief data analysis plan and a description of variables to be derived.

B. **Participants:**

1. Describe the subjects who provided the original data and the population from which they were drawn.

Note: If you are receiving, accessing, or using data from a U.S. health care provider, the need for HIPAA review is likely. If you plan to bring identifiable health information from a foreign country to a

U.S. covered entity (e.g., lab at the Hopkins SOM), HIPAA may be triggered. If either of these conditions is met, check "yes" to the HIPAA question in the PHIRST application.

2. If you plan to analyze human specimens or genetic/genomic data, provide details about the source of those specimens and whether they were collected using an informed consent document. If yes, explain whether your proposed use is "consistent with" the scope of the original consent, if it potentially introduces new analyses beyond the scope of the original consent, and/or if it introduces new sensitive topics (HIV/STDs, mental health, addiction) or cultural/community issues that may be controversial.

3. Explain whether (and how) you plan to return results to the participants either individually or as a group.

XII. Oversight Plan for Student-Initiated Studies:

A. For student-initiated studies, explain how the PI will monitor the student's adherence to the IRB-approved research plan, such as communication frequency and form, training, reporting requirements, and anticipated time frame for the research. Describe who will have direct oversight of the student for international studies if the PI will not personally be located at the study site, and their qualifications.

B. What is the data custody plan for student-initiated research? *(Note: Students may not take identifiable information with them when they leave the institution.)*

XIII. Creation of a Biospecimen Repository:

Explain the source of the biospecimens, if not described above, what kinds of specimens will be retained over time. Clarify whether the specimens will be obtained specifically for repository purposes, or will be obtained as part of the core study and then retained in a repository.

A. Describe where the biospecimens will be stored and who will be responsible for them.

B. Describe how long the biospecimens will be stored, and what will happen at the end of that period.

C. Explain whether the biospecimens will be shared with other investigators, inside and outside of JHU, how the decision to share will be made, and by whom. Include your plans, if any, for commercial use. Also explain how downstream use of the specimen will be managed, and what will happen to left-over specimens.

D. Describe whether future research using the biospecimens will include specimen derivation and processing (cell lines, DNA/RNA, etc.), genomic analyses, or any other work which could increase risk to participants. Explain what additional protections will be provided to participants.

E. If future research could yield unanticipated incidental findings (e.g., an unexpected finding with potential health importance that is not one of the aims of the study) for a participant, do you intend to disclose those findings to the study participant? Please explain your position.

F. Explain whether the specimens will be identifiable, and if so, how they will be coded, who will have access to the code, and whether the biospecimens will be shared in linked (identifiable) form.

G. Explain whether the repository will have Certificate of Confidentiality protections.

H. Explain whether a participant will be able to withdraw consent to use a biospecimen, and how the repository will handle a consent withdrawal request.

I. Describe data and/or specimen use agreements that will be required of users. Provide a copy of any usage agreement that you plan to execute with investigators who obtain biospecimens from you.

XIV. Data Coordinating Center:

Complete if JHSPH serves as the Data Coordinating Center.

A. How will the study procedures be developed?

B. How will the study documents that require IRB approval at each local site be developed? Will there be some sort of steering or equivalent committee that will provide central review and approval of study documents, or will template consent forms, recruitment materials, data collection forms, etc. be developed by and provided to the local sites by the coordinating center without external review?

C. Will each local clinical site be overseen by its own IRB with an FWA, or will a Single IRB review the study? State whether the coordinating center will collect IRB approvals and renewals from the clinical centers; if not, explain why.

D. How will the coordinating center provide each local site with the most recent version of the protocol and other study documents? What will be the process for requesting that these updates be approved by local clinical center IRBs?

E. What is the plan for collecting data, managing the data, and protecting the data at the coordinating center?

F. What is the process for reporting and evaluating protocol events and deviations from the local sites? Who has overall responsibility for overseeing subject safety: the investigators at the recruitment site, the Coordinating Center, the Steering Committee, or a Data and Safety Monitoring Board (DSMB)? Is there a DSMB that will evaluate these reports and provide summaries of safety information to all the reviewing IRBs, including the coordinating center IRB? Please note that if there is a DSMB for the overall study, then the coordinating center PI does not have to report to the coordinating center IRB each individual adverse event/problem event that is submitted by the local site PIs.

G. Some FDA regulated studies have different AE reporting criteria than that required by the IRB (IRB Policy No. 103.06). How will you reconcile the different requirements, and who is responsible for this reconciliation?

H. Who is responsible for compliance with the study protocol and procedures and how will the compliance of the local sites be monitored and reviewed? How will issues with compliance be remedied?

XV. Drug Products, Vitamins, Food and Dietary Supplements:

Complete this section if your study involves a drug, botanical, food, dietary supplement or other product that will be applied, inhaled, ingested or otherwise absorbed by the study participants. If you will be administering drugs, please upload the product information.

A. List the name(s) of the study product(s), and the manufacturer/source of each product.

Name of Study Product	Manufacturer/Source

B. List each study product by name and indicate its approved/not approved status.

Approved by the FDA and Commercially Available	Approved by Another Gov't Entity (provide name)	Cleared for Use at Local Study Site

C. If your study product has an Investigational New Drug (IND) application through the U.S. Food and Drug Administration, provide the IND number, and the Investigators Brochure.

D. If your study product is a marketed drug, provide the package inserts or other product information. If the study product WILL NOT be used for its approved indication, dose, population, and route of administration, provide a detailed rationale justifying the off-label use of the study product.

E. If the study product does not require FDA approval (e.g., dietary supplements, botanicals, products not subject to the U.S. FDA, etc.), provide safety information (as applicable) and a certificate of analysis.

F. Explain who will be responsible for drug management and supply, labeling, dispensing, documentation and recordkeeping. Complete and upload into PHIRST the Drug Data Sheet available on the JHSPH IRB website at www.jhsph.edu/irb.

G. What drug monitoring and/or regulatory oversight will be provided as part of the study?

XVI. Medical Devices:

Complete this section if your study will involve an approved or investigational medical device (**diagnostic**, non-significant risk, significant risk).

A. List the name(s) of the study product(s), the manufacturer/source of each product, and whether or not it is powered (electric, battery). Provide product information. If it is electric, upload documentation of clinical engineering approval or its equivalent from a local authority, to ensure that the device is in good working order.

Name of Study Product	Manufacturer/Source	Powered?
Oraquick Advance HIV rapid test	**Orasure Technologies**	**No**
FLOQ Swabs	**Copan flock technologies**	**No**

B. List each study product by name and indicate its status as approved by a government authority or not approved.

Approved by the FDA and Commercially Available	Approved by Another Gov't Entity (provide name and approval information)	Not Approved
Oraquick Advance HIV rapid		

test		
FLOQ Swabs		

C. If your investigational device is Exempt from the FDA IDE regulations, explain which section of the code applies to your device and why it meets the criteria provided. If it is a **diagnostic device**, provide pre-clinical information about the sensitivity and specificity of the test and the anticipated failure rate. If you plan to provide the results to participants or their physicians, justify doing so, and explain how those results will validated (or not) against the current "gold standard".

N/A

D. If you believe the investigational device is not IDE exempt under 21CFR 812.2(c), but is a "Non-Significant Risk" device considered to have an approved IDE application, provide information from the manufacturer supporting that position.

N/A

E. If you are using an investigational device that is a Significant Risk Device, provide the IDE number given by the FDA, or if not under FDA jurisdiction, explain why it is appropriate to use this device in this study. Provide a description of the device, and upload a picture or manufacturing schematics into PHIRST. Provide any other information relevant to a determination of its safety to be used for the purposes outlined in this research plan.

N/A