ADOLESCENT MEDICINE TRIALS NETWORK FOR HIV/AIDS INTERVENTIONS

PROTOCOL

Enhancing Sexual Safety: Couples' Communication and HIV Testing Among YMSM: ATN 156

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PROTOCOL TITLE:

Enhancing Sexual Safety: Couples' Communication and HIV Testing Among YMSM (WE TEST)

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REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
0	7.8.19	Resubmission into new RAMP template	No
1	7.18.19	Change of randomization procedures, Updated Recruitment, increased age range to 15-24 years	Yes
2	10.10.2019	Updated procedures for Phase 3. Added the STI online portal for Test results, new recruitment images, reporting names to Health Department	Added Phase 3 consent
3	12.2.2019	Deleted 9 month follow-up, Clarified Conditions for Phase 3, Added Long chain referrals,	Yes
4	1.2.2020	Phase 3 Condition revised, Deleted Long Chain Referrals, Changes to CASI questions	Yes
5	3.19.2020	Changed language to allow for remote follow-ups, including HIV and STI at-home testing kits,	Yes
6	9.3.2020	Update Study procedures for COVID, Remote study procedures, remote HIV/ STI Testing options, Information sheet for in office appointments for COVID.	
7	5.10.2021	Updated for national recruitment due to COVID	

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1.0 Study Summary

Study Title	Enhancing Sexual Safety: Couples' Communication and HIV Testing Among YMSM (WE TEST)
Study Design	Comparative Effectiveness Trial (CET), Randomized Control trial (RCT)
Primary Objective	We will conduct a comparative effectiveness trial (CET) of CHTC for adolescent-age (15-24 years) same-sex male couples. This design tests the added benefits of adjunct intervention components delivered prior to receipt of CHTC-Assertive Communication Training (ACT) videos viewed by the couple together and individually delivered Motivational Interviewing-based Communication Skills Training (MI-CST). These target the development of communication skills necessary to participate fully in HIV prevention and sexual safety discussions inherent to CHTC. This project will assess a continuum of intervention packages to address the developmental needs of YMSM (CHTC; ACT videos + CHTC; MI-CST + ACT videos + CHTC) to identify which package optimizes outcomes while minimizing delivery cost.
Secondary Objective(s)	Test a sustainable model of CHTC implementation in real world adolescent HIV clinics. In line with the implementation science focus of SIU U19, we utilize the EPIS to guide our implementation strategy. We will work with SIU Analytic Core's (AC) health-economist, Dr. Kitt Simpson, to conduct cost-effectiveness analyses to inform implementation decision-making. In collaboration with SIU ISC, we will document provider feedback to training and intervention materials to modify materials and create training packages for broad dissemination.
Research Intervention(s)	We are comparing three conditions for HIV testing with adolescents and young adults: Couples HIV Testing and Counseling (CHTC), CHTC-Assertive Communication Training (ACT), and Motivational Interviewing-based Communication Skills Training (MI-CST). These will test the ways in which including communication training improves upon existing HIV testing services.
Study Population	Adolescent-age (15-24 years) same-sex male couples
Sample Size	Phase 2 (n=36 couples → 72 individuals) Phase 3 (n=200 individuals)
Study Duration for individual participants	Phase 2: 3 months; Phase 3: 6 months
Study Specific Abbreviations/ Definitions	Adolescent Medicine Trials Network (ATN) Comparative Effectiveness Trial (CET) Couples HIV Testing and Counseling (CHTC) Individual HIV testing and Counseling (IHTC) CHTC-Assertive Communication Training (ACT) Motivational Interviewing-based Communication Skills Training (MI-CST) Young men who have sex with men (YMSM)

2.0 Objectives*

Aims: We will conduct a comparative effectiveness trial (CET) of Couples HIV Testing and Counseling (CHTC) for adolescent-age (15-24 years) same-sex male couples. This design tests the added benefits of adjunct intervention components delivered prior to receipt of CHTC-Assertive Communication Training (ACT) videos viewed by the couple separately and individually delivered Motivational Interviewing-based Communication Skills Training (MI-CST). These target the development of communication skills necessary to participate fully in HIV prevention and sexual safety discussions inherent to CHTC. This project will assess a continuum of intervention packages to address the developmental needs of YMSM (CHTC; ACT videos + CHTC; MI-CST + ACT videos + CHTC) to identify which package optimizes outcomes while minimizing delivery cost.

Aim 1: Conduct a sequence of randomized control trials (RCTs) to evaluate the acceptability, feasibility, and comparative effectiveness of novel treatment packages.

Aim 1a: In study Phase 2, we will conduct a pilot RCT to evaluate the acceptability and feasibility of adjunct intervention components. This initial trial will recruit n=36 couples who will be randomized to one of 3 conditions: Condition 1: CHTC (only); Condition 2: couples' joint observation of ACT videos + CHTC; Condition 3: each individual within couple receiving MI-CST + joint observation of ACT videos + CHTC. Youth will then complete follow-up assessments at 1 and 3 months post-intervention. YOUTH DO HAVE THE OPTION OF COMPLETING THE INTERVENTION ON THEIR OWN IF THEY CAN NOT GET THEIR PARTNER TO AGREE TO PARTICIPATE. During Phase 3, we will recruit 200 individuals into a CET with two conditions: Condition 1: the optimum adjunct intervention package identified in Phase 2 and Condition 2: Individual HIV Testing (IHTC) as usual. Youth in this CET will complete follow-up assessments at 1, 3, and 6 months. Youth have the choice of attending the baseline visit alone or with their partner and have the option to bring their partner in later after completing the baseline alone.

Aim 1b: Assess self-management model; we posit that assertive communication skills will mediate intervention effects at all follow-ups. In study Phases 2 and 3, we anticipate between-condition differences will be greatest among YMSM with poor baseline assertive communication.

Aim 2: Test a sustainable model of CHTC implementation in real world adolescent HIV clinics. In line with the implementation science focus of SIU U19, we utilize the EPIS to guide our implementation strategy. We will work with SIU Analytic Core's (AC) health-economist, Dr. Kit Simpson, to conduct cost-effectiveness analyses to inform implementation decision-making. In collaboration with SIU ISC, we will document provider feedback to training and intervention materials to modify materials and create training packages for broad dissemination.

We will achieve our aims over two phases of the study.

Phase 2 (n=36 couples): involves a pilot randomized control trial (RCT) to evaluate the acceptability, feasibility, and preliminary efficacy of these adjunct components.

Phase 3 (n=200 individuals): involves a CET comparing the most promising intervention package from Phase 2, consisting of individual MI, ACT video+ a recognition survey, and CHTC, compared to individual HIV testing and counseling (IHTC) delivered as usual. Participants in either condition can come as an individual or with their partner or come first as an individual and then bring their partner. This phase is focused on Implementation and Sustainment phases of the EPIS model informed by outcome analyses, cost analyses, and feedback from youth and ATN staff.

Phase 3 has now been added to this protocol document.

Hypothesis: The primary hypothesis is that because of developing skills in self-management and assertive communication, inclusion of adjunct components will be associated with clinically significant decreases in HIV transmission risk behavior as compared with partnered YMSM who receive individual testing and counseling (only). Secondarily, we propose that these intervention effects will be mediated by assertive communication skills.

3.0 Background*

Partnered young men who have sex with men (YMSM) are a uniquely vulnerable population. Adolescents in relationships continue to be an under-examined subgroup, despite the fact that YMSM (age 15-24) are at among the highest risk of HIV infection. Among men who have sex with men (MSM) age 18 and older, 35–68% of new HIV infections are transmitted between partners in primary (vs. casual) relationships. Of concern, primary partners account for 79% of new infections within the youngest MSM cohort.

Primary partner HIV transmission can result from a higher number of sex acts, more receptive anal intercourse, and lower condom use with primary (vs. casual) partners. Despite this elevated health risk, partnered MSM paradoxically perceive themselves to be at much lower risk of HIV infection, and test for HIV less often. Concomitantly, condom use may be suppressed with primary partners because condomless anal sex (CAS) is often interpreted as an indicator of commitment and emotional closeness. In fact, data reflect a strong, positive association between CAS and relationship seriousness for YMSM. Critical within this cohort, relationship development is still new, and romantic partnerships tend to be of short duration. Thus, frequent brief primary partnerships, low perception of CAS risk, and new negotiation of communicating emotional closeness during this developmental period may all escalate HIV infection among partnered YMSM.

Multilevel Intervention Integrating Couples Interdependence Theory (CIT) and Self-Management Theory as a framework for effective service delivery to partnered YMSM. We conceptualize individual HIV prevention (including HIV testing) in the self-

management framework. Here, problem solving, decision making, and access to care collectively predict health behavior engagement. This in turn develops positive provider relationships that facilitate behavioral skills development and access to care. While useful, the self-management framework does not fully address or incorporate the inherently multilevel and dyadic nature of sexual health decision-making for partnered YMSM. Fortunately, this omission is addressed in Couples Interdependence Theory (CIT). Within CIT, health positive outcomes are proposed to require the coordinated effort of both partners, and partners must accommodate potentially divergent health and safety preferences. Dyads with partners who balance self-interests with relationship-interests are more successful at conflict resolution, including HIV risk management. Work by Protocol Lead (PL) Starks and others, reflects that one strategy by which gay couples accommodate sexual health goals is through negotiating sexual agreements (e.g., rules and boundaries for outside partners).

The process of accommodation generally, and negotiation of sexual agreements specifically, requires advanced and flexible conceptual and communication skills. To be effective, individuals must identify both their own and their partner's preferences and feelings, and then communicate those concepts in constructive ways. Couples HIV Testing and Counseling (CHTC) successfully enhances sexual agreement communication with adult MSM by utilizing CIT. However, CHTC has not been examined with young samples. Yet, this intervention may play a critical role because of their level of cognitive and social development (e.g., still emergent communication skills). Youth may need added support to effectively identify sexual goals and to learn to communicate them carefully and productively, and this support may come in the form of CHTC and additional communication skills training.

Excitingly, our team has expertise across both the use of CHTC among partnered MSM (R34 DA036419 PL Starks) and support of partnered adolescents in communicating sexual and HIV risk reduction goals to their sexual and relationship partners. This is relevant, because data reflect that less than half of partnered adolescents feel comfortable advocating for and discussing condom use before sexual intercourse, contributing to 50% of youth consenting to CAS, despite wanting to use a condom. YMSM show even lower rates of assertive communication relative to heterosexual age-mates. Enhancing communication skills is thus a route to improve sexual safety in this age group.

4.0 Study Endpoints*

The primary goals of this study is to help participants reduce their HIV transmission risk behaviors by increasing their communication skills with their partners, which could lead to fewer number of sex acts, less receptive anal intercourse, and higher condom use with primary (vs. casual) partners.

5.0 Study Intervention

Intervention Design and Procedures: The primary innovation of this multilevel CET lies in the novel packaging of existing interventions in a manner that addresses the

specific developmental needs of YMSM. While MI-CST, video based ACT, and CHTC have individually established efficacy, this study will be the first to evaluate a continuum of prevention packages, which combine these components. In addition, this multilevel intervention seeks to leverage the power of the dyadic processes to enhance motivation for HIV testing and prevention (including biomedical prevention). Our adjunctive components (ACT and MI-CST) are specifically intended to enhance self-management skills (e.g., assertive communication) which are essential to effectively engage relationship partners in collaborative sexual goal development and problem solving. The underlying assumption of this strategy is that improvements in dyadic functioning will lead to reductions in sexual risk for both individuals within the relationship. Finally, we make innovative use of biomarkers to operationalize HIV-transmission risk. Our ability to draw conclusion about intervention effects is enhanced by examining biomedical and behavioral outcomes for both sexual partners regardless of relationship dissolution; this is critical to enhance sexual safety for both individuals of a couple, particularly in light of the short duration and rapid re-partnering of YMSM during this developmental period.

Intervention Training and Supervision: Following Phase 1, to prepare for the roll out of the CET, we will hold a week-long in-depth training on all study procedures. This training will include members of the two ATN sites where CHTC will be implemented in Phase 2. Any staff who cannot attend due to non-resolvable travel restrictions will participate via Skype. This training will include a 2-day training in CHTC (overseen by PL Starks), 2-day training on MI (overseen by PL Feldstein Ewing), and 1 day dedicated to reviewing/practicing protocol delivery, including administration of the ACT videos. Throughout training and fidelity monitoring activities, the implementation team, including the study PLs, will work closely with the SIU ISC to document CHW and supervisor performance and feedback on intervention materials and delivery (reflecting the Exploration and Preparation phases of EPIS). At the conclusion of the CET, the project implementation team will work closely with the ISC to package training and intervention materials in a manner that supports the dissemination of CHTC and adjunct components shown to be effective.

We will build upon the existing ATN infrastructure to complete this in a parallel model to SIU U19. Here, we will use a train-the-trainer model, where CHW supervisors will be brought to OHSU to be trained in implementation and delivery, with the goal that they will serve as local implementation “champions” by instructing and overseeing implementation within their ATN clinics. To maximize accuracy, consistency, and fidelity of intervention delivery, each intervention (CHTC; ACT; MI-CST) will be codified into manuals.

This training sequence will be offered again prior to Phase 3 in order to bring new ATN sites online and update staff at existing sites.

Ongoing supervisor’s conference call. PL Feldstein Ewing has a demonstrated track-record of training and supervising clinical interventions in real-world practice sites, including MI, from a distance. Using the same model proposed here with rural school-based health providers (NHLBI R01; PL Kong, Co-Lead Feldstein Ewing), PL Feldstein

Ewing has shown a high degree of clinical impact, fidelity, and integrity for execution of MI for the 5 year roll-out of the project. And active interventionist will work directly with the CHW supervisors during weekly clinical supervision calls. PLs Feldstein Ewing and Starks will be on the phone during these calls, but not actively participate. PLs Feldstein Ewing and Starks will then work directly with clinical supervisor to debrief any issues that arose during the calls. Clinical Supervisor will follow up with the CHW supervisors to address outstanding clinical issues. Similarly, as with Dr. Feldstein Ewing's prior work in implementation science, in addition to weekly supervision meetings, clinical supervisor will visit each site annually, and greater frequency in situations where there is therapist drift, to practice the intervention approaches with study providers to get them back to parity with other CHWs. As with Dr. Feldstein Ewing's successful work with rural adolescent medicine, this procedure has been supported with a high degree of clinical success and integrity in prior multi-site implementation science work with underserved adolescents.

Assurance of Intervention Fidelity: All sessions will be audio recorded for the purposes of systematic supervision so PLs can assess fidelity and prevent therapist drift. The PRIDE Research Consortium (formerly Center for HIV Educational Studies and Training (CHEST)) at Hunter College maintains a team of Motivational Interviewing Treatment Integrity (MITI) coders trained in the assessment of MI and Dr. Starks maintains a group of research assistants trained in the assessment of CHTC fidelity. These coders will review the first 10 sessions completed by each CHW and a random 20% of sessions for the remainder of the trial (approximately 25% of sessions completed by each CHW over the entire trial). Coding of all initial sessions will ensure fidelity across therapists at the start of the trial and subsequent coding will identify any therapist drift that occurs for the remainder of the trial. Tapes will be coded to ensure the presence of essential elements of the intervention. Consistent with procedures in our previous effectiveness trials, when therapists exhibit low levels of intervention integrity or significant drift, this feedback will be relayed to the on-site supervisor. The training team (PLs Starks and Feldstein Ewing) will then work with the local supervisor to develop a remediation plan to bring the CHW back up to parity with other interventionists. This process will be facilitated by regular contact with on-sight supervisors as detailed in our training and implementation plan below.

6.0 Procedures Involved*

Enrollment and Consent: Utilizing enrollment procedures established within ATN, clinic staff will invite YMSM who present for HIV testing services the opportunity to screen. These interested index partners will complete a brief iPad eligibility screener.

For Phase 2, IF ELIGIBLE, THE SCREENER WILL RANDOMIZE THEM TO COMPLETE THE BASELINE AS A COUPLE OR AN INDIVIDUAL.

If randomized to individual, staff will schedule a baseline assessment for the invited youth. If randomized to couple, staff will schedule a baseline assessment for the invited youth at a time both they and their relationship/romantic partner are available. Partners

will independently complete informed consent at the beginning of the baseline visit, prior to assessment following ATN-wide established protocols.

FOR PHASE 2, IF THE YOUTH IS RANDOMIZED TO COMPLETE THE BASELINE AS A COUPLE, AND THEY INDICATE THAT THEY WILL BE UNABLE TO HAVE THEIR PARTNER COME FOR THE APPOINTMENT, THEY WILL BE ALLOWED TO COME TO THE BASELINE AS AN INDIVIDUAL.

For Phase 3, study sites are given the options to deliver the intervention in-person as usual, or entirely remote delivery. This is to allow sites more flexibility surrounding COVID-19 closures and restrictions, which vary by site.

For Phase 3, index partners will be able to choose to attend their baseline appointment on their own or with their partner. While scheduling the baseline, staff will ascertain whether the participant is planning to come in alone or with their partner so they can reserve adequate time, space and resources for the appointment. Regardless of whether the index partner attends alone or with their partner, after the participant(s) complete the survey at the beginning of the baseline appointment, the index partner will be randomized to the We Test intervention or individual HIV testing (IHTC) as usual. If alone and randomized to the We Test intervention, the index partner will participate in the intervention as an individual. If both members of the couple attend and are randomized to We Test, they will participate in the intervention as a couple. If both members of the couple attend and are randomized to IHTC, they will each receive IHTC as usual. The index partner who participates as an individual (in either condition) will be offered the opportunity to bring their partner to participate in the WeTest. The partner will be enrolled into the same condition as the index partner.

Baseline Visit – PHASE 2 (up to $50)
1. Informed Consent process
2. STI testing ($20)
3. CASI survey ($10)
4. Randomization to one of three conditions (phase 2)
5. Session 1 (phase 2): will occur at this time in accordance with the randomized condition.
a. Condition 1: CHTC
b. Condition 2: ACT videos + CHTC
c. Condition 3: MI-CST + ACT videos + CHTC

FOR COUPLES WHO ARE ASSIGNED TO A CONDITION THAT INCLUDES VIDEOS, PARTICIPATING COUPLES WILL WATCH THE VIDEOS SEPARATELY. AFTER VIEWING THE VIDEOS SEPARATELY, A VIDEO RECOGNITION SURVEY (ATTACHED) IS COMPLETED BY THE COUPLE TOGETHER.

Baseline Visit – PHASE 3 (up to $50)
1. Informed Consent process
2. CASI survey ($30)

3. Randomization
4. HIV testing ($10)
5. STI testing ($10)
6. Session 1: will occur at this time in accordance with the randomized condition.
a. Condition 1: individual HIV testing (IHTC) as usual condition
b. Condition 2: We Test intervention

Randomization Stratification: Randomization will be stratified by stratified by Site, Age (either partner under 18 vs both 18 & older), Race/Ethnicity (Both White vs not both White) and whether the index partner attended individual vs couple.

After completing the baseline assessment for both Phases 2 and 3, YMSM will complete follow-up assessments a month after baseline, and 3 months after baseline. In Phase 3, participants will also complete assessments at 6-months post-baseline. Online CASIs will be completed at each follow-up either at home or in-office. In addition, STI and HIV testing will occur at the 3-month and 6-month follow-ups. All follow-ups will be conducted individually to facilitate retention, even if the couples dissolve.

Immediate Post-Test Assessment (1 month after BL)
1. CASI ($30)

Three Month Follow-Up (up to $50)
1. CASI ($30)
2. HIV testing ($10)
3. STI testing ($10)

Six Month Follow-Up ($50)
1. CASI ($30)
2. HIV testing ($10)
3. STI testing ($10)

All ATN clinics in this project are currently performing HIV testing as part of the services they offer to the local community. Therefore each clinic has a protocol in place to deliver HIV positive results and link patient who test HIV positive to timely access to health care, including antiretroviral therapy. Participating clinics will be performing HIV testing as part of their routine services and will follow their local protocol for delivering HIV positive results for those testing positive for HIV. Meaning of the test results will be discussed with all youth who test for HIV prior to screenings.

Participants who test positive for HIV while enrolled will be referred for a confirmatory HIV test when needed. Research staff trained in HIV testing and counseling will discuss the meaning of the HIV test results and explain the importance of timely access to health care, including antiretroviral therapy.

Participants WHO RELOCATE OR ARE UNABLE TO ATTEND AN ATN SITE AFTER BASELINE WILL HAVE THE OPTION for at home HIV and STI testing or TESTING THROUGH a central lab such as Quest. SUCH PARTICIPANTS WHO TEST

HIV positive at a follow up assessment will receive the result from a member of PRIDE team who are key personnel on the project and are trained in HIV testing and counseling. See the attached PRIDE Response Management Plan which includes the protocol for delivering HIV positive results. Due to COVID, there are now at home and central lab testing options for Baseline and intervention testing.
Participants who test positive for an STI at baseline or follow up assessments will be referred using the ATN clinics' local protocol for positive STI results if STI testing occurs at one of ATN clinics. Participants who test positive for an STI through at home or central lab testing such as Quest will follow the attached protocol for delivery of positive STI results. STI RESULTS WILL BE SENT TO THE PARTICIPANT VIA A SECURED WEBPAGE AND PARTICIPANTS WILL RECEIVE A UNIQUE PASSWORD TO VIEW THEIR RESULTS.

For at home HIV/STI testing, kits may be mailed to a home address. Research staff will allow kits to be shipped to an alternate location deemed as a safe space, such as a youth center, and will require youth to speak with a trained staff member to ensure these arrangements are both safe and allowable. The at-home testing kit will come either from Molecular Labs or as a OraQuick HIV test.

If a couple comes in together they will view an assertive communication training video separately and complete a video recognition survey together after. If a participant comes in without their partner, they will view the ACT video and complete the video recognition survey after.

All compensation is payable as cash or gift card based upon site restrictions.

Specimen Collection: HIV data will be collected via a blood draw or oral swab using a HIV rapid test and biomarkers STI will be collected via urine and rectal screen. The only purpose of the collected data is research. Participants who test positive for STI's will be reported to the local health department in accordance with state laws for surveillance purposes. Participants who test positive while enrolled in We Test will be referred for a confirmatory HIV test and care following standard procedures at the clinic. Following standard ATN procedures, data will be coded with a unique study ID number at the time of enrollment, unrelated to their name or other personal identifying information; all specimens and survey data will be labeled with this unique identifier to provide anonymization of the data. The people who will have access to the data include members of the research team. Test results will not be shared with individuals outside of the research team. For at home testing procedures, we will share name and address with Molecular Labs for shipping the test kit only. Anonymized data will be coordinated with the broader ATN using established multi-site data sharing avenues.

7.0 Data and Specimen Banking*

Data for Future Use
Participants consent to these procedures as part of the consent/assent process.

The research team, authorized staff, and government agencies that run this type of research may have access to research data and records in order to check on the research. Research records given to approved researchers will be de-identified. If a researcher requests the data, they will be special permission from the Research Compliance Administrator. Data collected during this research study may be used for future research purposes. The data stored will be de-identified.

Data that cannot be linked to participants (i.e., de-identified data) will be kept indefinitely; this data will be saved for future use and may be shared with other researchers.

Biological samples collected for the purposes of this study will not be used to conduct any future research. They will be destroyed after analysis is completed

At the end of the study data collected will be made available, in accordance with the NIH Data Sharing Policy (http://grants.nih.gov/grants/policy/data_sharing). These data will be saved for future use and may be shared with other researchers. By participating in this study, you are agreeing to allow us to save and share your data anonymously.

8.0 Sharing of Results with Subjects*

Phase 2 and Phase 3: HIV and STI Testing Results

Rapid HIV tests are performed, and results shared with the participants at both the baseline and 3-month, and 6-month (Phase 3 only) assessments. HIV test results are delivered in-person with referrals for PrEP/PEP and linkage to care (in the event of a positive test result). STI test results are sent individually to the participant via email. Results are entered into an online Qualtrics portal and sent to participant's email address where they can view and save their results. The participant can confidentially view their STI results through the Qualtrics portal.

For at-home Testing- Rapid HIV testing is performed with the person over ZOOM during the intervention. STI testing samples are collected and returned to the central lab for processing. Results are provided to the study team via a secure website. Those results are entered into an online Qualtrics portal and sent to participant's email address where they can view and save their results. The participant can confidentially view their STI results through the Qualtrics portal.

In Phase 3, we will be reporting positive STI results to departments of health in New York, Michigan, and California for surveillance purposes. Reporting of names for this purpose is state law and not exempted by research studies. We will inform the participants in the consent form that this will occur. Name, Date of Birth, and phone number will be reported.

All results are not shared with any other individuals.

9.0 Study Timelines*

Phase 2: Individual participants are in the study for three months (Baseline, 1-month at-home survey, 3-month follow-up).
Phase 3: Individual participants are in the study for nine months (Baseline, 1-month, 3-month, 6-month follow-ups).

All study subjects will be enrolled over the course of 60 months.

10.0 Subject Population*

Inclusion Criteria:
YMSM couples who express interest in We Test must demonstrate the following inclusion criteria to be enrolled in the study:
•At least one partner must be HIV-negative or status unknown
•THE INDEX PARTNER must be 15-24 years old
•YMSM under age 18 MUST HAVE AN AGE CONCORDANT PARTNER TO PARTICIPATE IN THIS STUDY, I.E., MINORS may only participate in the study with a partner within 2 years of age OF THE MINOR SUBJECT'S AGE. THE AGE CONCORDANT PARTNER MUST BE AT LEAST FIFTEEN YEARS OLD.
•INDEX PARTNER MUST BE SEXUALLY ACTIVE (ANY ACTIVITY THAT COULD LEAD TO ORGASM)
•CURRENTLY SEEING SOMEONE, DATING, EXPERIMENTING WITH RELATIONSHIPS OR IN A RELATIONSHIP
•HAVE HAD SEX, HOOKED UP WITH OR MADE OUT WITH THAT PERSON
•Both relationship partners must agree to attend an assessment together at an ATN affiliated clinic
•Both partners must be able to communicate in English.
• GENDER IDENTITY AS MALE OR nonbinary, GENDERQUEER, agender OR GENDER NONCOMFORMING •MALE SEX AT BIRTH REMOVED ON 8.21.18
•"HAVE THAT PERSON'S AGE BE OVER 14 BUT WITHIN 2 YEARS OF INDEX PARTNER"; ALL PREVIOUS APPROVED CRITERIA STILL APPLY EXCEPT FOR THE AFORMENTIONED DELETED CRITERIA
•To participate in the intervention remotely, youth must be at least 17 and over the age of sexual consent in their state of residence. If participating as a couple, both must be over the age of sexual consent in their state. If a participant lives in the following states and want to participate remotely, they will need to be 18 years old: Arizona, California, Delaware, Florida, Idaho, North Dakota, Oregon, Tennessee, Utah, Virginia, and Wisconsin.

Exclusion Criteria:
YMSM couples will be excluded from the study if they indicate any of the following:
•Unstable, serious psychiatric symptoms
•Current suicidal/homicidal ideation
•Current or prior Intimate Partner Violence (IPV) on the part of either relationship partner
•IF EITHER PARTICIPATING PARTNER FELT PRESSURED OR COERCED TO PARTICIPATE IN THE STUDY OR FELT ANYONE MADE THEM FEEL THEY HAD TO PARTICIPATE IN THEY STUDY WHEN THEY DID NOT WANT TO.

We will include individuals who are not yet adults:
Study procedures involve no more than minimal risk. The nature and scope of the proposed research study, communication skills training and the CHTC intervention do not pose more than "minimal risk" to participants as defined in 45 CFR Part 46.102, "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves that those

ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests".

We will not include individuals who are adults unable to consent, pregnant women, and prisoners.

11.0 Vulnerable Populations*

We will enroll research participants 15-24 years of age. The nature and scope of the proposed research study and We Test intervention do not pose more than “minimal risk” to participants, as defined in 45CFR Part 46, 102. “the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.” Given that some participants will be under the age of 18, adequate provisions will be made for soliciting informed consent.
We will not require parental consent for study enrollment. Parental consent may decrease participation rates because some youth will fear that they may be "outed" as a result of participation. Disclosure of sexual orientation may place participating youth at risk for parental harassment, abuse or expulsion from the home.
The intervention and measures utilized in this study are standard in this population, as are waivers of parental permission for survey and interview studies. Additionally, consistent with national policy recommendations from the Society for Adolescent Medicine, requiring parental permission for the proposed study would have a number of possible negative effects, including: (1) reducing the validity of the findings by effectively eliminating potential participants unwilling to share permission forms with their parents/guardians; (2) increasing risk to some youth whose parents have a negative response to the material in the permission forms that would suggest their child has a minority or alternative sexual orientation; and (3) adding little in the way of actual subject protection, given the minimal risk of study participation. Our procedures for the waiver of parental consent are consistent with the guidelines provided by the Department of Health and Human Services: http://www.hhs.gov/ohrp/humansubjects/ guidance/45cfr46.html#subpartd.

We will obtain assent from participants who are under 18 years of age.

We are protecting this vulnerable by limiting at home testing option to those who meet criteria for FDA approval for Oraquick home testing (17 years of age) and age of sexual consent in their respective state (17 in New York and Michigan, 18 in California).

12.0 Local Number of Subjects

Phase 2: 36 Couples or 72 individuals
Phase 3: 200 individuals

13.0 Recruitment Methods

Recruitment and Screening: Leveraging existing ATN infrastructure, participants will be recruited and screened for eligibility via 2 different ATN sites in Phase 2 and 3 ATN sites in Phase 3 that provide HIV testing and prevention services to YMSM. All ATN clinics, as well as PRIDE, have extensive relations with the gay, lesbian, bisexual, and transgender communities, community service organizations, health service organizations, and providers for MSM. This may be supplemented by online advertising conducted through SIU’s Recruitment and Enrollment Core (REC). Potential Participants may be identified at these local sites through testing services, outreach activities, and online social media and dating apps (e.g., Facebook, Instagram, Reddit, Tumbler, Grindr, Scruff, Adam4Adam, Jack’d). While advertising will be distributed through SIU’s REC, they will be targeted to the geographic areas surrounding the ATN sites for this project and

will contain information about participation at the ATN clinic. Given the shift to remote testing, intervention delivery, and study visits in Phase 3 due to COVID-19, recruitment via online advertisements will be expanded nationwide. Couples will be screened through an indexcase approach. One partner in the couple will be asked to provide screening information about themselves and their partner. If the couple is preliminarily eligible based upon the report of the index partner being screened, that index partner will be asked to schedule a baseline appointment SCHEDULING WILL TAKE PLACE VIA EMAIL, TEXT MESSAGE, AND PHONE at a time both they and their partner can attend. Contact information for the index partner will be collected at this point and added in REDCap for tracking purposes.

Additionally, PRIDE (formerly CHEST) at Hunter College will assist in referring potentially eligible participants to the We Test study through existing online recruitment efforts. PRIDE utilizes the Hunter College IRB-approved Online Master Screener (OMS) to preliminarily screen individuals who are interested in participating in studies being conducted through PRIDE. If an individual is preliminarily eligible for a study, the individual is asked to provide contact information to PRIDE for follow up. For the purposes of this study, the OMS will only be used to refer potentially eligible YMSM to HIV testing sites by sending them an email referral informing them about the We Test study and where to go to determine eligibility after completing the OMS. The contact information collected through the OMS will not be provided to the HIV testing clinic sites. However, We Test clinic sites will be made aware that a potentially eligible YMSM has been referred to their testing services for the study. The OMS, in this instance, will primarily be used as a referral mechanism for the study, directing participants to which study they may be eligible for, including We Test. YMSM who complete the OMS and screen preliminarily eligible, WILL BE CALLED FOR PHONE SCREENING TO DETERMINE STUDY ELIGIBILITY OR SENT A LINK VIA TEXT AND EMAIL. IF THEY ARE ELIGIBILE, THEY WILL BE REFERRED TO THE ATN CLINIC STAFF FOR THE BASELINE APPT.

CHWs who conduct standard of care HIV testing services for the We Test clinic sites will be trained to provide information about the We Test study after HIV-negative results are delivered at their clinic or in the field at mobile testing events. The CHW will be trained in appropriate and ethical methods of recruiting participants in clinical settings and in the field. To minimize the risk for coercion, the staff member and the study information will emphasize the optional nature of participation and that it will not affect, in any way, their access to healthcare services. If the potential participant is interested in finding out if they are eligible for We Test after learning about the study, the CHW will provide an iPad with a secure online REDCap We Test Study Screener (IRB approved). The confidential We Test Study Screener will be completed on the iPad by the potential participant and no one will be able to see the responses; the iPad will only indicate whether the potential participant is eligible. THE WE TEST SCREENER WILL ALSO BE AVAILABLE FOR DELIVERY OVER THE PHONE WITH POTENTIAL PARTICIPANTS BY PRIDE STAFF OR CAN BE COMPLETED AT HOME VIA AN ONLINE LINK.

YMSM who screen ineligible for the study do not need to provide contact information and may screen again after 30 or more days provided they get tested HIV-negative at the clinic site in the past 90 days or they again test HIV-negative at the clinic site. Participants are also able to re-screen should they test HIV-negative at the clinic site or through mobile testing efforts associated with the clinic site.

14.0 Withdrawal of Subjects*

Criteria for Premature Discontinuation

On the next page, there are the categories of "dropping" participants along with their definitions. These categories should be accurately used in the site's tracking materials if one of the conditions below occurs.

Category: Definition	Procedure	Notes
Refused baseline (BL) (Prior to Consent): **Screened eligible, but never shows up for assessment and/or no longer wishes to be contacted.**	Remove from rescheduling call lists and mark as "Do Not Contact" in REDCap.	Counted towards screened number only.
Withdrew during BL (After Consent): **Provided consent but refused to finish BL assessment.**	Mark as "Baseline concluded" but not "Baseline completed"	Counted up to and including magic number; these participants get marked as "Withdrew from Study" for IRB purposes.
Withdrew during BL (After Consent): **Provided consent but their partner refused to participate.**	Mark as "Baseline concluded" but not "Baseline completed"	Counted up to and including magic number; these participants get marked as "Withdrew from Study" for IRB purposes.
Withdrew after BL (After Consent): **Participant completed the BL but asked to be removed from the study thereafter.**	Remove from Follow-Up Call Lists; should be Tracked as enrolled and have a condition assigned.	Counted up to and including randomized/enrolled and stays in all denominators for Follow-Up retention; these participants get marked as "Withdrew from Study" for IRB purposes.
Ineligible during BL (After Consent): **Provided consent but was found to be Ineligible during the BL assessment.**	Mark as "Baseline concluded" but not "Baseline completed"	Counted up to and including magic number; these participants get marked as "Withdrew from Study" for IRB purposes.
Ineligible after BL (After Consent): **Participant either completed the BL, both BL and sessions, OR all BL, sessions and follow-ups but was found ineligible for enrollment at a later date (e.g., found to have psychiatric conditions while collecting BL data◊)**	Remove from Follow-Up Call Lists; should be Tracked as enrolled and have a condition assigned	Counted up to and including randomized/enrolled and stays in all denominators for Follow-Up retention; these participants get marked as "Withdrew from Study" for IRB purposes.
Refused intervention (if applicable), Still Enrolled: **Participants who are no longer interested in the**	Remain in Database to be called for Follow-Up visits	Treated as other enrolled participants except they wouldn't show up on session-specific call lists.

intervention sessions, but have indicated a willingness to continue to be followed for Follow-Up Visits		
Passed away: **Participant was enrolled but later passed away**	Notify Clinical Site Management Center (CSMC) immediately with details regarding the situation (i.e. Date of Death, Date Notified, Cause of Death, Participant Age and Sex); Remove from Follow-Up Call Lists	Counted up to and including randomized/enrolled and stays in all denominators for Follow-Up retention; these participants get marked as "Withdrew from Study" for IRB purposes.
Other	If a participant withdraws for any other reason not listed here, please contact the CSMC immediately to discuss how to proceed.	

15.0 Risks to Subjects*

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The study has the following risks: The risks and discomfort associated with participation in this study are no greater than those ordinarily encountered in daily life, standard medical care or physical/psychological tests. However, there is some risk of emotional discomfort or distress due to the personal nature of the topics discussed in the training and counseling sessions.

Other risks: There is a risk of pain at the site of the finger prick for the HIV test.

16.0 Potential Benefits to Subjects*

The benefits to study participation are:
This study can benefit you and other adolescents and young adults like you by helping develop a counseling intervention that is better suited for younger same-sex male couples. Of course, because everyone responds differently, no one can know ahead of time if it will help you.

17.0 Data Management* and Confidentiality

We have strict guidelines to protect privacy of participants during recruitment, consent process, and research procedures.

For recruitment, the HIV tester or phone screener discusses the study with the participant in a private setting. The screening survey is done through an online survey to make the screening process private. If the participant is eligible, contact information is collected

electronically and not with paper and pencil. That contact information is password protected and kept separate from the screening questions.

For the Consent process, being consented into the study will take place in a private setting. The signed consent will be kept separate from all other participant information, survey data, and other materials in a locked cabinet.

For the research process, authorized research staff who are trained on the ethical conduct of research will contact participants by telephone, email, or mail, depending on the participants' preferred method of contact, to schedule appointments for study visits. Staff are trained to be discrete when contacting participants. Furthermore, to offset the risk of violation of data confidentiality, strict confidentiality will be maintained; records that have personal identifiers (i.e., contact information) will be stored in files that have password protection and are kept separate from research records. All research forms are stripped of personal identifiers, with the participant number being used to identify specific research forms. No presentation or publication of the study results will refer to participants individually. Manuscripts published regarding this work will be based on the accumulated database. A federal Certificate of Confidentiality, which protects subjects' records against subpoena, will be obtained prior to study start. Exceptions to confidentiality for participants are those required by law (information that would lead to suspicion of child abuse, elder abuse, or threat of imminent action on suicidal or homicidal ideation). Participants will be informed of these exceptions in the informed consent process.

No identifying information about participants will be recorded on audio files. Participants will be instructed not to identify themselves or third parties during their study visit. Audio record of the interviews conducted will be stored electronically; to which only research staff and those authorized will have access to transcribe the material. Audio recordings will only be identified with alphanumeric IDs. No identifying information about participants will be recorded in the Internet based survey. The structured questionnaires will be computerized and self-administered. We are using a software program called Qualtrics to program the online survey for this study. Developed by a social psychologist, the Qualtrics software program is a sophisticated electronic survey creation and management tool. It is recognized as a valuable assessment program and is currently used in a vast array of research and academic settings across the US. The survey will be SSL encrypted and accessible using an HTTPS URL. Data are encrypted, downloaded, and stored on a secure server, which is password protected and routinely backed up. Participants will be identified in the questionnaire only by an assigned numeric study ID. No identifiers (e.g., name, address, date of birth, social security number) will be collected using the questionnaire itself. The programmed questionnaire and any data resulting from it will reside on a server that is protected by an internal firewall.

The information obtained during this research will be kept confidential to the extent permitted by law and will be stored at our research offices for 3 years after the study is completed. Data that cannot be matched to you may be saved for future use and may be

shared with other researchers. As part of the consent process, participants will be agreeing to allow us to save and share their data anonymously.

In Phase 3, we will be reporting positive STI results to departments of health in New York, Michigan, and California for surveillance purposes. Reporting of names for this purpose is state law and not exempted by research studies. We will inform the participants in the consent form that this will occur. Name, Date of Birth, and phone number will be reported.

How will you store participant data?:
With codes Participants are assigned a unique ID number that is 10 digits. Links to codes are stored in our REDCap databases in our password-protected computers.

PRIDE staff and other site staff will have access to links, including the Protocol Leads, research assistants and project managers; will have access to the links to be able to contact participants for follow-up assessments during the period of time prior to anonymizing the data. Links will not be released to external researchers.

List the identifiers that will be stored:
For Interviews with site staff members only, audio files are stored on our secured server and may contain names of site staff members implementing the projects. After three years, we delete all audio files for this study, including any link between information on a site staff person and the information in the Qualitative interview. ATN We Test intervention sessions with the study participant will also be audio recorded, these audio files are stored on our secured server will not contain names and only be labeled with the participant ID number.

Will codes be deleted (and data anonymized) at a later date? Yes

When will codes be deleted?
NIH, our funding agency, mandates that we keep records for a period of at least 3 years for auditing purposes and therefore, data will be retained for a minimum of 3 years after study completion. At the end of this time, all identified information (e.g., contact information) will be deleted, effectively destroying the link between the data, unique codes, and participants' identities and de-identifying/anonymizing the data. The codes themselves will be retained indefinitely to allow for identifying each participant across datasets, but the codes will no longer be linked to any identified information and thus the data will be anonymous.

What will you do with the data once the research has been completed?: Save data for future use / create data bank

Purpose of the data bank:
To allow external researchers to access the data bank for future analyses and meet requirements for submitting data to repositories as required for publication in some journals. This data is also collected as part of a larger NIH priority to study the

epidemiology of HIV; thus, researchers will likely conduct future analyses with pooled data across studies.

Data points that will be included in the data bank: All de-identified data (i.e., survey data and test results, but not the specimens themselves) will be included in the data bank.

18.0 Provisions to Monitor the Data to Ensure the Safety of Subjects*

This research involves no more than Minimal Risk to subjects.

The protocol has a Data Safety Monitoring Plan and is reviewed semiannually by a Study Monitoring Committee.

The Scale-It-Up (SIU) U19 Data Safety and Monitoring Plan will utilize a single monitoring system for all SIU protocols (including We Test) in order to harmonize review standards across protocols. The review process of the most vulnerable protocol will be applied to all SIU protocols thereby ensuring adequate oversight. We propose utilizing an independent study monitoring committee (SMC). A SMC was selected as the Clinical Research Management (CRM) as it is the highest level CRM needed for the most vulnerable SIU protocol. The proposed SMC will be composed of three independent experts who possess the relevant expertise (e.g., HIV-related research and prevention, adolescent medicine, and sexual health) to evaluate each SIU protocol and whom do not have a conflict of interest. Mary Velasquez, Jim (Xinguang) Chen, and Dushyantha Jayaweera have formally agreed to serve on the SIU SMC. Together, they represent an academically diverse and highly experienced team capable of providing the necessary foresight and oversight to ensure data safety monitoring plans are diligently designed and implemented. SIU has the appropriate funding available to financially support the activities of the SMC. The SMC will review each research protocol and plan for data and safety monitoring every 6 months, with additional ad-hoc reviews as necessary. All SMC meetings and reviews will be held via telephone conference.

Adverse Events Reporting

The Site Protocol Lead (PL) is responsible for the detection and documentation of events meeting the criteria and definition of an adverse event (AE) or serious adverse event (SAE). Data for monitoring participants' safety will be captured within the REDCap database as part of the required study data. Site study staff may ask questions concerning adverse events via the SIU query system, but must formally report them via email and REDCap. Information on unexpected events including SAE will be reported as per the policy of SIU's single IRB (sIRB).

Information to be collected includes the nature, date of onset, stop date, intensity, duration, treatment, causality, and outcome of the event. Site PLs should follow usual clinical practices at their institutions for reporting serious, unexpected events related to standard of care. SAEs that occur after 30 days after completion of the study will be

collected only if they are considered by the PL to be related to study participation. In addition, any AE resulting in potential participant withdrawal must been reported to the SIU REC prior to participant withdrawal when possible.

Site PL s must report any AE to the REC within one business day of learning of it. The REC will then report all SAEs to the IRB within 3 business days and all AEs within 5 business days, upon learning of them from site study staff.

19.0 Compensation for Research-Related Injury

NA: The research does not involve more than Minimal Risk to subjects.

20.0 Economic Burden to Subjects

Research subjects are responsible for their transportation to and from the research facility/office.

21.0 Consent Process

Site PLs must ensure that participants are fully informed about the purpose, responsibilities of participating and potential risks or other critical issues related to participation in SIU studies. Written informed consent or assent must be obtained from every participant or, in those situations where consent cannot be given by participants, their legally acceptable representative, prior to clinical study participation.

A waiver of parental permission has been obtained for minors choosing to participate with parental permission.

The rights, safety, and well-being of SIU study participants are the most important considerations and should prevail over interests of science and society. If there is any question that the prospective participant will not reliably comply with study procedures and/or follow-up, they should not be enrolled in a SIU study.

Consent will be discussed and documentation obtained in person at subjects' baseline visits prior to any data collection or other study procedures. Informed consent procedures will be conducted privately with each participant in order to minimize the potential that youth feel pressured by a partner to participate in the study. For Phase 3, we are changing these procedures so informed consent occurs over the phone before sending any At-home testing kits.

The Research Assistants (RAs) from Detroit, Hunter College, and San Diego (Phase 3 only) will be the individuals who will obtain consent from participants. The RAs will be trained on the protocol and the consent process, RAs will obtain CITI training which will be submitted to the IRB. The RAs will not engage in any research activity until they are registered as Research Staff with the FSU IRB and IRB approval is granted for their role on the research project.

Subjects are asked to: (1) name things they will be expected to do during the study, (2) explain what they would do if they no longer wished to participate in the study, (3) explain what they would do if they experienced distress during the study and (4) identify potential risks for participating in the study.

Non-English Speaking Subjects
Eligibility includes criteria that participants must speak English. No separate plan for obtaining consent is needed for non-English speakers.

Waiver or Alteration of Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception).

We are obtaining a waiver of parental consent. Our research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects.

Parental or guardian permission is not a reasonable requirement for our research with the 15-17 year old participants. Youth will be completing surveys and discussing sensitive topics such as their sexual behavior and substance use. Parental permission would put those youth whose parents do not already know about their sexual orientation at risk of their parents learning about this by the nature of requesting their permission to participate in a study of this kind. This may then place these youth at risk for parental harassment, abuse or expulsion from the parental home. Parental permission could not only place these youth at increased risk, but it would also substantially limit the generalizability of our research.

Our justification for this waiver is informed by prior research with the target population, which has demonstrated risks of parental victimization during coming out or discussions of sexual orientation. Most YMSM are unwilling to ask their parents' permission to be in an HIV-focused study and those who are willing are significantly different on key variables. In addition, research suggests that young YMSM have the capacity to make an informed decision regarding participation (e.g., appreciation of risks/benefits to themselves, understanding research components such as randomization) despite this not meeting the legal definition of consent. As shown in prior research—including that of our consultant, Dr. Brian Mustanski, parents with LGBT-identified children appreciate the rationale for waivers of their permission when the study and its purpose are explained. This evidence supports the fact that YMSM are a population for whom parental or guardian permission is not a reasonable requirement to protect the participants and a waiver of parental permission is appropriate under 45 CFR 46.408(c). This determination was further supported by the fact that this study poses minimal risk (i.e., does not expose participants to greater risk than encountered in everyday life) and therefore the waiver could also be approved under 45 CFR 46.116(d) based on the evidence described above that the research is not possible if parental permission is required. Additionally, consistent with national policy recommendations from the Society for Adolescent Medicine, requiring parental permission for the proposed study would have a number of

possible negative effects, including: (1) reducing the validity of the findings by effectively eliminating potential participants unwilling to share permission forms with their parents/guardians; (2) increasing risk to some youth whose parents have a negative response to the material in the permission forms that would suggest their child has a minority or alternative sexual orientation; and (3) adding little in the way of actual subject protection, given the minimal risk of study participation.

Cognitively Impaired Adults

- *NA*

Adults Unable to Consent

- *NA*

22.0 Process to Document Consent in Writing

Consent can be obtained in writing using a consent or assent form which details all study procedures and expectations for participation or via an online consent/Assent in QualtricsFor in person consent, the RAs and the participant will both sign two copies of the consent/assent forms. The RA will retain one for filing and the participant will be able to take a copy with them. For remote Baselines, the RA will call the participant to conduct the informed consent process. The link will be emailed to the participant that they will complete during the consent process.
The consent and assent forms was written using the Template consent document (HRP-502)

23.0 Setting

This research is being conducted at the PRIDE Health Research consortium at Hunter College, New York, NY and Wayne State University Prevention (W'SUP) at Wayne State University, Detroit, MI. In Phase 3, appointments will also occur at the LGBT Community Center of San Diego.

Please see submitted Local context forms for additional information about each site.

Potential Participants are identified at these local sites through testing services, outreach activities, and online social media and dating apps. Please see recruitment sections for more information.

At both locations, the research will be conducted in private assessment rooms equipped with either a computer or iPad for the participant to complete the online CASI. All research procedures will be performed in the offices of the research facility or remotely via a HIPAA compliant Zoom. Rapid HIV tests will be performed in the facilities' phlebotomy room and STI sample collection will take place in a private restroom. For At-home testing, the Rapid HIV test will occur via zoom with the participant and the Community Health Worker as part of the intervention. The STI samples will be collected privately at the participant's home and returned to the central lab for processing.

The Community Advisory Board for this protocol is a part of the national Youth Community Advisory Board for the Scale IT Up program of research. They meet on a quarterly basis via skype to discuss study progress, recruitment strategies, and recommendations for youth engagement.

24.0 Resources Available

Since this study is currently in phase 2 of 3 phases, the goal is obtain enough information on feasibility and acceptability of the intervention. The information obtained will inform the RCT of the selected intervention versus the standard Couples HIV testing and Counseling. We plan to enroll for Phase 2 through until we have an N= 40 participants. We hope to obtain the desired number of anticipated participants. As of Decemeber 2019, we have all participants enrolled for Phase 2. We have made substantial changes to the overall design (see previous amendments) and hope these changes will increase our recruitment.

As we commence Phase 3, we will utilize the resources at Hunter College at CUNY to assist with this project. Hunter College's Promoting Resilience, Intersectionality, Diversity, and Equity in Health Research Consortium was created to serve as a hub for Hunter's expanding work in sexual and gender minority health and broader focus on sexuality, gender, and health. The PRIDE Consortium supports research at the nexus of psychology, public health, and the health and helping professions that is relevant to understanding and addressing the health needs of diverse SGM individuals.

PRIDE Serves as the Management core (MC) to track project procedures and assist with study recruitment across the different sites. The MC, maintain responsibility for the overall conduct and implementation of the study; the MC is also responsible for management of recruitment and retention including enrollment and retention. The REC will also be responsible for Data Management while the AC will be responsible for analysis and reporting. The Protocol Leads are responsible for scientific leadership and dissemination. Protocol meetings are held bi-weekly to keep all assisting personnel informed about the protocol and its procedures. Moreover, Dropbox is utilized to facilitate the storage and sharing of study-related documents, which further informs protocol personnel about any updates to research procedures.

25.0 Multi-Site Research*

This research is being conducted at the PRIDE Health Research consortium at Hunter College, New York, NY and Wayne State University Prevention (W'SUP) at Wayne State University, Detroit, MI. In Phase 3, this research will also be conducted at the LGBT Community Center of San Diego.

Recruitment: Both sites will recruit individually for participants as outlined in the recruitment section above. This also applies to San Diego in Phase 3. Each site will have site specific recruitment materials for potential participants. See attached materials.

Enrollment: All Sites have site specific consent and assent forms for participants to sign. All data is collected with Qualtrics, which means that the sites will not have local copies of the data at their offices. All data will be stored on the cloud through program servers.

Site oversight: The Scale It UP management core have daily contact with the sites regarding participant procedures. The Protocol Leads meet monthly with the site PIs. The Site PI for the PRIDE site is also the Protocol Lead for this protocol. So there is constant communication between sites. In addition there is an online support request form through the Scale It UP Site Communication System for sites to submit queries and questions regarding this protocol. Additionally, the Management Core sends quarterly reports to each site outlining whether the site meets the established expectations for site enrollment and progress.

Reporting of serious adverse events and unintended events: Both sites have procedures set in place to report any unintended events to the Scale It UP management core. The sites can submit an online support request of any events through the Scale It UP Site Communication System.