

SUPPORTING STATEMENT B:

Evaluating Locally-Developed HIV Prevention Interventions for African-American MSM in Los Angeles

New OMB Application

OMB No. 0920-NEW

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B. Statistical Methods

1. Respondent Universe and Sampling Methods

Respondent Universe

The respondents providing the information for the proposed project are young African American MSM (AAMSM) ages 18 to 29 years, residing in Los Angeles County. Estimates of the respondent universe of AAMSM, ages 18 to 29 years, residing in Los Angeles County range between 3,876 and 7,753. The number of eligible participants we expect to enroll (n=528) thus represents 7-14% of all potentially eligible young men making up the respondent universe in Los Angeles County.

Overview of Sampling Method

During the enrollment period, MyLife MyStyle (MLMS) recruiters/study staff will use purposive sampling methods to recruit potential participants for the randomized control trial (RCT) through a variety of community venues, using both active (i.e., venue outreach) and passive (i.e., referral, flyers/handcards) recruitment techniques.

Active recruitment techniques: Active recruitment will consist of outreach at street and physical venue locations, including bars and clubs, and other locations where AAMSM socialize, such as private parties, gay pride events, and public sex environments. In the Meantime Men's Group (ITMT) is familiar with these community settings and social events because ITMT employees reflect the same characteristics as the young men encountered during typical outreach activities. In addition to recruiting from existing physical venues, ITMT may sponsor special events during the enrollment period, such as skate parties and dance competitions, which may serve as another physical venue for the recruitment of MLMS participants.

Passive recruitment techniques: Passive recruitment for the MLMS project will consist of two main types: 1) referrals/word-of-mouth and 2) posting of project information via flyers, placement of handcards, posting via Facebook or other on-line announcements, and print advertisements. Referrals and word-of-mouth techniques, a type of snowball sampling, will occur through local agencies and organizations that provide programs and services for young AAMSM, community advisory board members, and previous study participants.

The second passive recruitment technique will include the posting of flyers and placement of handcards in locations frequented by AAMSM, including local agencies serving young AAMSM, after obtaining permission to do so. We will place advertisements/announcements in print and online media, local gay newspapers, magazines, and banner ads on websites such as BlackGayChat.com. ITMT has also established an Internet presence to appeal to its younger clientele via Facebook and MySpace accounts (e.g., <http://www.facebook.com/pages/In-The-Meantime-Mens-Group-Inc/57067853938>, <http://www.myspace.com/inthetimeantimemen>). ITMT generally uses a more passive recruitment approach to gain new participants with these social networking sites. For example, on a weekly or more frequent basis, ITMT staff post brief

announcements to ITMT's Facebook homepage to alert Facebook "friends" about any number of upcoming social events or HIV prevention groups sponsored by ITMT.

Sample Size Justification

The aim of the study is to determine the preliminary efficacy of the MLMS intervention. The design and sample sizes reflect this consideration. The sample size for each study is based on statistical power calculations. Further detail about statistical power is presented below.

Response Rates

We were able to estimate the participation and eligibility rates among men who are screened using the National HIV Behavioral Surveillance System (NHBS) Los Angeles MSM recruitment data. Of 705 men screened, 88% (n=621) MSM enrolled in the NHBS study. We expect somewhat similar rates in the proposed study due to the similarity of the recruitment methods. We have estimated the eligibility and participation rate of those who are screened for this study to be 75%. Thus, we will screen at least 705 men to achieve a sample size of 528. Recruitment of 528 participants will allow for a ~25% loss-to-follow-up resulting in a total of 400 participants to be included in the RCT's outcome analyses for a six-month follow-up measurement. This sample size of 400 also takes into account the design effect of randomizing individual AAMSM into groups of size 12, a detail that will reduce the effective sample size of the RCT to n=264.

Sample Size Calculations

We have referenced four data sources to estimate the prevalence of recent UAS reported by AAMSM, ages 18-29 years. The first estimate comes from data collected for the 2008 Los Angeles Men's Survey. Prevalence of UAS behaviors are estimated for the past twelve months in this CDC-funded behavioral surveillance effort. According to the sample of 18- to 29-year-old AAMSM enrolled in this survey, 51% reported at least one episode of UAS in the past twelve months. Our second data point derives from a baseline survey of new participants of In The Meantime's Gay African-American Men's Empowerment (G.A.A.M.E.) Plan. In this health education/risk-reduction program, 38% of Black males, ages 18-29 years, reported UAS in the past six months. Our third data point derives from baseline data collected from participants enrolled in the Men of African American Legacy Empowering Self (MAALES) Project in Los Angeles. According to preliminary data on 37 Black non-gay identified males, ages 20-66 years, 27% reported UAS with a male in the past three months. Finally, baseline data collected for our pilot study of 50 MLMS participants indicated 26% of the young AAMSM reported any UAS in the past three months. Taken together, with varying recall periods across each study, we will assume that baseline UAS prevalence with male partners reported by our young AAMSM participants will fall within the range of 25% and 35% for the past three months.

Table 1 below shows the range of statistical power estimates under various circumstances for the sample size of 400 (approximately 200 retained in each RCT arm) **adjusted for the design effect** of a group-randomized RCT. For example, we expect to have adequate power (>80%) at a 95% confidence level to detect differences across groups if the intervention group achieves at least a 15% absolute reduction in UAS with male partners at six-month follow-up compared with

various levels reported by controls. The calculations are based on an alpha=0.05 using a two-sided test.

Table 1. Statistical power to detect differences in UAS among 264 intervention and 264 control participants, adjusted for design effect of 1.45.

| Estimated prevalence of UAS among intervention group at 6 months | Estimated prevalence of UAS among control group at 6 months | Percent absolute difference in UAS at 6 months | Power |
|------------------------------------------------------------------|-------------------------------------------------------------|------------------------------------------------|------------|
| 15% | 25% | 10% | .55 |
| 10% | 25% | 15% | .91 |
| 20% | 30% | 10% | .48 |
| 15% | 30% | 15% | .85 |
| 10% | 30% | 20% | .99 |
| 25% | 35% | 10% | .44 |
| 20% | 35% | 15% | .80 |
| 15% | 35% | 20% | .97 |

2. Procedures for the Collection of Information

Training for Study Personnel

All study personnel will receive appropriate training to conduct RCT research activities, including instruction in facilitating MLMS group sessions, process-indicator data collection, subject recruitment, informed consent, randomization procedures, and outcome data collection (i.e., baseline and follow-up ACASI administration). MLMS recruiters/study staff who conduct recruitment activities in both physical (community) and virtual (Internet) venues will be specifically trained to screen potential participants for eligibility and to provide information about the purpose, procedures, risks and benefits of the MLMS project. Topics covered in study-related trainings will be included in an Operations Manual to describe details of proper participant recruitment; required elements of informed consent; process monitoring logs; participant tracking for follow-up interview appointments, and scheduling and administering ACASI and qualitative data collection sessions. The Co-PIs will have the responsibility for ensuring all study personnel are trained to implement properly the IRB-approved study protocols.

Recruitment Procedures

During the enrollment period, we anticipate recruiting potential participants for the MLMS RCT through a variety of community venues, using both active (i.e., venue outreach) and passive (i.e., referral, flyers/handcards, internet) recruitment techniques. Each person approached during active recruitment at outreach venues will be given a MLMS project information handcard or flyer that provides a telephone number and basic information regarding the study. MLMS staff

will also provide potential participants with information about the general nature of the study and the time involved (one 1-hour baseline behavioral assessment session, three 2-hour group sessions for half of the men, and two 1-hour follow-up visits). They will also be informed of the token of appreciation: a) \$20 for the baseline assessment, b) \$25 for each group session, and c) \$30 each for completing follow-up assessments approximately four and seven months after the baseline assessment. MLMS staff will then conduct a brief eligibility screener using questions included in the outreach recruitment assessment (**Attachments 3b**). Data collected using these eligibility assessment questions will be recorded on the Outreach Recruitment Assessment Log during all active recruitment activities (in both physical and Internet venues) as part of the process evaluation (**Attachment 3b**).

If eligibility screening is not possible during active recruitment, recruiters will collect limited contact information (e.g., first name, initial of last name, phone number, email address) in order to contact and screen potential participants on the phone at a more convenient time (**Attachment 3c**). For individuals who are screened during active recruitment, study recruiters will also use the limited locator form to collect contact information needed to schedule baseline questionnaire appointments with the persons who are considered eligible for enrollment. If contact information is not collected from a potential participant at the recruitment venue, the MLMS recruiter will encourage the individual to use the MLMS handcard or flyer to contact the ITMT office at a later time for screening by trained study staff. Those who are eligible to participate will be provided with more details about the project. Men made aware of the study through passive recruitment methods, will be screened either in person or on the phone and if eligible, will be asked to provide limited locator information. Men who are interested and eligible in participating will be informed about the a) randomization procedure; b) audio-computer-assisted self-interviews (ACASI) at baseline; c) duration of study participation; d) nature of the group sessions; e) information about wait-list participation; and f) information about the three- and six-month follow-up ACASI assessments. Ineligible men—and eligible men who decline to participate in the project—will be invited to join ongoing ITMT events and discussion groups.

We will maintain all logs of potential participants under strict privacy and locked files and attempt to contact them for screening as soon as possible. Only first names and the initial of the last name will be recorded on these forms to provide increased privacy. Recruitment-source data (i.e., where we encountered potential participants) for all participants who are recruited in either physical and virtual venues will be collected by recruiter staff on Outreach Recruitment Log (**Attachment 3b**). Data on recruitment source will help us to best identify successful recruitment strategies during our process evaluation.

Overview of Data Collection Procedures

Our collaborative team will collect a variety of quantitative variables for both process and outcome evaluations of the MLMS RCT. To reduce interviewer bias in the collection of sensitive sexual behavior data [1], we intend to use audio computer-assisted self interviews (ACASI) for all baseline and follow-up questionnaires. Briefly, the baseline questionnaire will collect information on:

Socio-demographics: age, income, sexual identity, education level, marital status, insurance status, employment status, number of children, housing status, incarceration history

Behavioral and other characteristics: integrated race and sexuality; sexual risk behaviors (condom use, number of partners, sex partner characteristics, exchange sex, sex while on drugs/alcohol); sexual abuse history; internalized homophobia; gender role conflict, social support for safer sex/risk reduction; experiences with homophobia and sexual identity/sexual relationships; knowledge of HIV risk for self and community; HIV knowledge and risk reduction; self-efficacy for condoms and partner communication; anal and penile health knowledge, pre-exposure prophylaxis use, alcohol/drug use; internet and cell phone use for meeting sexual partners; psychological distress; and participation in previous HIV interventions
Clinical variables: date of last HIV test, HIV status, STD history, HIV care and treatment history (for HIV-positive patients)

(Attachment 3d). Three-month and six-month follow-up questionnaires will gather similar variables to the baseline measurement with the exception of immutable demographic characteristics **(Attachment 3g)**.

Once a total of 24 young AAMSM have enrolled and completed baseline questionnaires, they will be randomly assigned into intervention and control groups by the Project Coordinator (12 allocated to each arm via a block-randomization procedure). Given ITMT's experience with the target population, we anticipate that approximately 18 of 24 (~75%) men recruited for each recruitment wave will be retained at six months post-intervention.

Enrollment and Baseline Questionnaire: After completion of each screening/recruitment session, MLMS project staff will use limited contact information (e.g., name, email, telephone number) to set up appointments to complete the informed consent process and up to a 1-hour baseline questionnaire via ACASI at a mutually convenient place and time. ITMT's Project Coordinator or the Data Collection Assistant will be trained to introduce the RCT and to discuss informed consent with the young AAMSM. Study staff will read the consent information to potential participants prior to beginning the baseline ACASI session and thus prior to randomizing participants into the intervention or wait-list control condition. Once enrolled, each study participant will be assigned a unique study identification (ID) number. Signed consent forms will be labeled with a Study ID number. Signed consent forms affixed with the Study ID will be stored in locked filing cabinets initially at ITMT and ultimately at Los Angeles County Department of Public Health HIV Epidemiology Program (HEP). The study ID number will be entered into the ACASI program for all assessments. Once potential participants have enrolled in the project, their limited locator information will be destroyed by project staff and will provide more extensive contact information to be contacted for MLMS sessions and follow-up questionnaires. The study ID number will also be used to link locator information and to identify participants who are due for a follow-up assessment.

ITMT's Project Coordinator will oversee the recruitment, enrollment and data collection activities for the MLMS RCT. He will supervise the Data Collection Assistant who will be the primary person responsible for screening participants, obtaining informed consent, scheduling ACASI baseline appointments, and keeping in contact with project participants during the intervention. The Data Collection Assistant will focus his efforts on scheduling appointments for baseline data collection sessions at ITMT's main office, although he may accommodate ACASI appointments in another mutually agreeable and secure location if requested. The Data Collection Assistant will be responsible for being present during the data collection session and

for providing guidance and technical assistance to participants who may encounter problems during the ACASI session. Data Collection Assistant will also be responsible for documenting issues arising from ACASI sessions (e.g., difficulty understanding questions, etc.) in order to inform the Co-PIs of potential problems with data quality. The computer programming will check for out-of-range and inconsistent answers and will assist with skip patterns. HEP will assess data accuracy and completeness and provide feedback to improve data collection practices for all project staff on a routine basis.

Follow-up Questionnaires: Similar to the procedures described for the baseline data, ITMT's Project Coordinator and Data Collection Assistant will be responsible for keeping in contact with RCT participants for three- and six-month follow-up data collection. The Data Collection Assistant will use participant contact/update logs to track the timing of the participants' two follow-up measurements. He will also use the follow-up interview logs to monitor and schedule these ACASI data collection appointments.

Depending on each participant's preferred method of contact, the Project Assistant will telephone, email, or text each participant on a monthly basis to check in with the men and to confirm that their contact information is current. Logs of these contacts will provide details of the interaction (e.g., participant responded to phone call/email/text message, provided new contact information, etc.). A copy of the six-month contact log is in **Attachment 3i**. To protect participants' privacy, all contact logs containing participant information will be limited to a first name and initial of the last name. All contact logs containing contact information, such as name, phone number, email addresses, will be kept in locked files in the project offices when not in use. Once the contact logs have been completed and entered into a database, the hard copy of the form will be shredded by the Project Assistant. The Project Assistant will attempt to contact each participant up to five times for each of the monthly check-in contacts. If the Project Assistant does not reach the participant after five attempts, he will attempt to contact the participant at the subsequent monthly check-in appointment. If the participant indicates that he is no longer interested in receiving monthly check-in calls/emails/texts, this will be indicated on the contact log by writing "Do not contact" and crossing out future contact entries. If the Project Assistant is not able to contact the participant to schedule either the three- or six-month follow-up questionnaire within the four weeks following their follow-up due dates, the participant will be considered lost to follow-up for that assessment period.

Client Satisfaction Surveys: As a process indicator, MLMS attendees will be asked to complete brief, pen-and-paper surveys immediately following each group. These data will be used to characterize participant satisfaction with specific content areas within the three modules and other aspects of the groups.

Success Case Study Interviews: The research team will also conduct qualitative, in-depth discussions with a subset of participants assigned to intervention group for the "Success Case Study" interviews, which are designed to develop an understanding of the successful and less successful participants' experiences with the intervention and to determine the exact nature and extent of their success.

To identify potential participants for our Success Case Study, the study investigators will analyze the baseline and six-month follow-up data on intervention participants and sort participants into one group who did and one group who did not reduce HIV risk behaviors during the short-term post-intervention period. Thus, “success” will be operationalized as the self-reported presence of UAS at baseline and subsequent report of no UAS behaviors with male partners at six months post-intervention. Conversely, “less success” will be defined as a) any UAS at six months post-intervention or b) attendance at only one of the three scheduled MLMS sessions.

Thirty-six of the 264 AAMSM assigned to the intervention group will be eligible for the Success Case Study interviews. To protect the privacy of Success Case Study participants’ behavioral risk data, we will create an algorithm using SAS to compare baseline and six-month follow-up data. This statistical algorithm will categorize successful and less-successful participants based on data collected in their ACASI sessions; however, the specific details of the participants’ increased or reduced risk behaviors will not be known by the study team, including the PI. We will randomly select samples of the “successful” and “less successful” young men for participation in the Success Case Study. Qualified men who are randomly selected for the individual interviews will be contacted by the project’s Evaluation Assistant by phone or another preferred method specified during the six-month follow-up data collection session. A separate informed consent procedure, which will describe the study procedures and measures taken to protect participant privacy, will be conducted with the potential participants of these qualitative interviews..

The project’s Evaluation Assistant will conduct a 60- to 90-minute, semi-structured interview with 16 successful program participants (**Attachment 3h**). The Evaluation Assistant will conduct a similar set of interviews with 20 of the less successful program participants. These young AAMSM will have either not attended many group sessions (n=10) or will have reported an instance of UAS at six-month follow up (n=10). These interviews are designed to develop an understanding of the less successful participants’ experiences and impressions of the program. All interviews will be digitally recorded with the consent of the participants and we will produce transcripts of each 90-minute session. Digital interview files and transcripts will be stored on password-protected computers within a password-protected project network file at the HEP project office. We will delete the digital recording once the transcript is accurate and complete.

Quality Control/Assurance

Under the direction of the Principal Investigator, the Project Epidemiologist will be responsible for monitoring all aspects of quantitative data collection for the project. She will work with ITMT’s Project Coordinator to ensure that baseline data, follow-up data, and all process indicator instruments are being collected according to protocol. She will also work with the Project Coordinator to verify that baseline and follow-up data measurements are being scheduled in a timely manner and that all informed consent and data collection sessions are being implemented according to protocol. The Project Epidemiologist will be responsible for developing and disseminating monthly updates to report on subject enrollment, data collection goals, and other study-related indicators.

HEP will develop data entry screens for the ACASI instruments using Questionnaire Development System (QDS) software. These QDS data entry systems will be loaded on password protected laptop computers for the baseline and follow-up data collection sessions. The ACASI program will include checks for out-of-range and logically inconsistent answers, minimizing response and data-entry errors. A codebook of survey variables, response categories, and frequency distributions from survey responses will be developed. Frequency distributions will be examined for outliers and missing data; cross-tabulations will be examined to identify logically inconsistent responses that were not detected by the ACASI/CAPI program. Procedures for handling outliers and logical inconsistencies (e.g., recode, drop) and missing data (e.g., drop cases, impute values) will be developed.

ITMT's Data Collection Assistant will have the primary responsibility for scheduling and monitoring ACASI data collection sessions with the participants. He will also be responsible for moving completed QDS interview files to a password-protected flash drive in preparation for transfer to HEP's main data warehouse. ITMT's Project Coordinator will work with HEP's Project Epidemiologist to establish a regular schedule for transferring electronic files of the completed QDS interviews. HEP's Project Epidemiologist will be responsible for processing interview data and for completing routine reviews of data quality and completion. ITMT's Data Collection Assistant will also be responsible for documenting issues arising from ACASI sessions (e.g., difficulty understanding questions, etc.) in order to inform the Co-PIs of potential problems with data quality.

The Evaluation Consultants will monitor the quality of the Evaluation Assistant's collection of Success Case Study interviews. After providing detailed training on the proper conduct of semi-structured, qualitative interviews to the Evaluation Assistant, the Evaluation Consultant will review the digital recordings of the first three qualitative interviews and provide feedback, if necessary, to improve the Evaluation Assistant's collection of these data.

All data transferred to HEP will undergo entry (if necessary), data processing, cleaning, and analysis for process-indicator monitoring and evaluation of the stated research hypotheses. HEP will assess data accuracy and completeness and provide feedback to improve data collection practices for all project staff on a routine basis. HEP will prepare monthly or more frequent process-monitoring reports for project meetings

Process monitoring data will be collected throughout the project. The Project Coordinator will abstract necessary data elements from program records and prepare monthly progress reports on the process indicators to be used in quality improvement and monitoring. These reports will be discussed by the project team and necessary retraining or refinement of intervention implementation will be recorded and action will be taken throughout the intervention period, as necessary. For example, we will maintain written documentation of strategies implemented to address lower than anticipated recruitment, screening or enrollment numbers, data entry errors, missing documentation, or missed RCT protocol steps.

Intervention quality assurance activities will begin with the initiation of the MLMS sessions and will continue for up to 30 months. In addition to compiling and analyzing process indicator data, the Evaluation Consultants will plan and implement additional activities to assess intervention

fidelity. The MLMS logic model will guide the intervention quality assurance activities planned for this project. Beginning with the pre-implementation staff orientation and training phase, the project team will explain the purpose and components of the logic model. Explicit examples of session content or activities will be used to illustrate key concepts. For example, discussion in intervention module 1 will address casual sexual encounters. Staff will be trained in responding in a non-judgmental and empowering manner to highly sexualized comments that might be shared during such discussions.

During implementation, quality assurance steps will focus on documenting and analyzing planned and unplanned modifications to the intervention including addition of topics relevant to poverty, stigma, homophobia, and HIV/AIDS education. For planned modifications based on process monitoring, we will assess the impact of modifications on either improved or unaffected recruitment, enrollment or participation during enrollment. For example, if a new outreach venue is identified to bring in new participants, we will compare the monthly program recruitment reports before and after the inclusion of the new venue to assess changes in the number of men who enroll in the RCT. For unplanned modifications, we will instruct the facilitator or other project staff to record reasons for the modifications and the intended effect of the modification in modification debriefing reports.

During the post-implementation phase, we will refer to the curriculum to examine the ability of staff to deliver an empowering intervention appropriate for AAMSM. As needed, additional training or skills-building will be conducted in group facilitation, recruitment techniques, follow-up interview scheduling or other relevant intervention skills. Non-facilitator project staff will use fidelity checklists in their observation of selected MLMS sessions as well as the overall intervention for adherence to session content, adequate facilitation of discussions, accessibility and responsiveness to expressed client needs, and other key process elements (e.g., time allocation, space). Participants' satisfaction with the intervention and their comfort will be assessed after each group session.

3. Methods to Maximize Response Rates and Deal with Nonresponse

Response Rates and Retention

Based on previous experience with the target population, we have learned that a substantial proportion of young ITMT clients lack basic resources such as stable housing and reliable transportation. Contact with these young men can be difficult, especially when social support networks are not well-established and when phone numbers and email accounts change with any frequency. Thus, we recognize it may be challenging to retain all 528 randomized participants for the intervention sessions and follow-up measurements.

Several strategies will be implemented in order to reach the goal of at least 75% retention of both the intervention and control arms for follow-up. Some examples of retention strategies include hiring project staff with extensive knowledge of the target population and the situations in which they live and socialize. These staff members will be trained to provide a range of social support referrals that may help reduce barriers to longer-term participation in ITMT programs.

At the initial enrollment in the study, project staff will elicit a comprehensive list of the names and contact information of clients' friends and family members who may help to locate participants for follow-up appointments. In the months leading up to the three- and six-month follow-up assessments, staff will also attempt to check in with participants (both intervention and control participants) on a monthly basis to keep participants' interest in the project high during this down time. The Project Assistant will attempt to contact each participant up to five times for each of the monthly check-in contacts. The Project Assistant will be trained to convey the following information during the check-in contact: *"Hi, _____, this is _____ from MyLife MyStyle. I'm just checking to see how you are doing and making sure we have your most up-to-date contact information for our follow-up interviews at 3 and 6 months. Is this the best way to contact you? Do you have any new contact information that we should make note of for our future contacts?"* If the Project Assistant does not reach the participant after five attempts, he will attempt to contact the participant at the subsequent monthly check-in appointment. If the participant indicates that he is no longer interested in receiving monthly check-in calls/emails/texts, this will be indicated on the contact log by writing "Do not contact" and crossing out future contact entries. If the Project Assistant is not able to contact the participant to schedule either the three- or six-month follow-up assessment within the four weeks following their follow-up due dates, the participant will be considered lost to follow-up for that assessment period. Also, project contact information will be given to each participant and they can also keep in contact with ITMT through its many social events.

ITMT's long history of providing HIV prevention programs to members of the target population indicate that modest tokens of appreciation for participation in group discussions are critical to involve and retain a broad range of AAMSM ages 18 to 29 years. Likewise, local research projects (e.g., MAALES Project, Brothers Project, LA Men's Survey) involving AAMSM cite numerous examples of improved recruitment and retention of study participants with modest tokens of appreciation ranging from \$20 to \$50.

The token of appreciation amounts are based on ITMT's and HEP's previous experience with research participants in similar community-based research studies. All RCT participants will be given a token of appreciation of \$20 for completing the baseline ACASI questionnaire. Intervention participants will be given \$25 for each of three MLMS sessions they complete over a three-week period. Wait-list control participants will also be given \$25 for each of these same three sessions but the sessions will occur seven or more months later. All RCT participants will be given \$30 for the three- and six-month follow-up ACASI sessions. Finally, a subset of 36 intervention participants will be given a \$50 token of appreciation for completing a 90-minute qualitative Success Case Study interview.

We will use statistical methods (e.g., multiple imputation) to address missing variables within the self-reported, quantitative survey data, if necessary. For participants who did not complete their 3-month follow-up assessment, we will use the last value-carried-forward approach to impute data for this time point. Although this approach has the potential to underestimate the variance, it will conservatively assume that men who did not complete the 3-month assessment remained at their baseline levels.

Assessing Non-Response Bias

The use of an eligibility screener will allow comparison of the demographic and eligibility-related behavioral data on those who are eligible and ineligible and those who accepted participation and those who did not. Additionally, we will assess differential attrition by comparing the characteristics of participants retained in the study through all follow-up data collection with those who were lost to follow-up. These characteristics will include demographics as well as behavioral risk. Chi-square and t-tests will be used as appropriate to the measure used.

Accuracy and Reliability of Information Collected

To reduce interviewer bias in the collection of sensitive sexual behavior data [5], we intend to use audio computer-assisted self interviews (ACASI) for all baseline and follow-up measurements. Previous studies have demonstrated that respondents are more likely to reveal engaging in sensitive behaviors in a computer-assisted self interview than in a face-to-face format [1,2]. The assessment includes multiple instruments that have been previously tested with this or similar populations and have acceptable reliability as determined through statistical evaluation. **See Table B4.** below for a summary of the measures used that have been applied with similar populations and the reliability statistics as reported in the literature.

Generalizability

The aim of this study is to establish the preliminary efficacy of the homegrown intervention MLMS and will provide important information about sexual risk behaviors and the context in which they occur. These data are essential for identifying effective homegrown HIV/AIDS prevention interventions for young at-risk African American MSM and for improving the quality of HIV prevention services the CBO delivers in their community.

True generalizability from a single randomized controlled trial testing an intervention targeted to young African American MSM would be very difficult to achieve due to the hard-to-reach nature of the population, the strict eligibility criteria, and the geographical limits involving in testing individual-level interventions.

The study site will attempt to recruit a diverse sample of young African American MSM. MLMS recruiters/study staff will conduct recruitment activities in a variety of physical (community) and virtual (Internet) venues. During recruitment, sites will perform monthly assessments of these participant characteristics and adjust recruitment strategies as needed.

4. Test of Procedures or Methods to be Undertaken

The measures to be used in the questionnaire were chosen with input from community collaborators and the Community Advisory Boards (CABs). This process helped to insure that the questions are culturally-appropriate and use language that can be easily understood. We presented the final data collection instruments to the CAB, have received feedback, and

addressed all concerns. We also piloted the data collection instrument in a previous study and also with staff from the implementing agencies.

In addition, whenever possible, the investigators have selected measures that have been developed for and tested with populations of African American gay and bisexual men. Since there are few measures specifically for African American MSM, we included measures developed for MSM and Black heterosexual populations and adapted the language as needed. In addition, when appropriate measures were not available for adaptation, we developed measures, with input from our Community Advisory Board.

Table B4. Table of Measures

| Instrument Name | Population Previously Used With | Publication | OMB Approved? |
|-------------------------------|----------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| Integrated Race and Sexuality | African-American gay and bisexual men | Soto, T. et al. The Influence of dual-identity development on the psychosocial functioning of African-American gay and bisexual men. <i>Journal of Sex Research</i> . 2002; 39(3):179-89 | No |
| Internalized homophobia | Minority gay men | Meyer IH. Minority stress and mental health in gay men. <i>Journal of Health and Social Behavior</i> . Mar 1995;36(1):38-56. | No |
| Gender role conflict | Undergraduate men; African American MSM | O'Neil JM, Helms BJ, Gable RK, David L, Wrightsman LS. Gender role conflict scale: college men's fear of femininity. <i>Sex Roles</i> . 1986;14:335-350. Bingham TA, Williams JK, Harawa NT. Gender role conflict among African American men who have sex with men and women (MSMW): Associations with mental health and HIV risk-related knowledge, perceptions, and behaviors. Submitted to <i>AJPH</i> , March 2011. | No |
| HIV Knowledge | Heterosexual men and women of various races/ethnicities; African American Men who have sex with men and women (MSMW) | Catania JA, Coates TJ, Golden E, Dolcini M, et al. Correlates of condom use among Black, Hispanic, and White heterosexuals in San Francisco: The AMEN longitudinal study. <i>AIDS Education and Prevention</i> . Feb 1994;6(1):12-26. Loue S, Cooper M, Fiedler J. HIV risk among a sample of Mexican and Puerto Rican men and women. <i>Journal of Health Care for the Poor and Underserved</i> . Nov 2003;14(4):550-565. | No |

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|---------------------------|-------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----|
| | | <p>Sikkema KJ, Heckman TG, Kelly JA, Anderson ES, et al. HIV risk behaviors among women living in low-income, inner-city housing developments. <i>American Journal of Public Health</i>. Aug 1996;86(8, Pt 1):1123-1128.</p> <p>Williams JK, Ramamurthi HC, Manago C, Harawa NT. Learning from successful interventions: A culturally congruent HIV risk-reduction intervention for African American men who have sex with men and women. <i>Am J Public Health</i>. Jun 2009;99(6):1008-1012.</p> | |
| Self-efficacy for Condoms | African American Men who have sex with men and women (MSMW) | Williams JK, Ramamurthi HC, Manago C, Harawa NT. Learning from successful interventions: A culturally congruent HIV risk-reduction intervention for African American men who have sex with men and women. <i>Am J Public Health</i> . Jun 2009;99(6):1008-1012. | No |
| Partner Communication | African American Men who have sex with men and women (MSMW) | Williams JK, Ramamurthi HC, Manago C, Harawa NT. Learning from successful interventions: A culturally congruent HIV risk-reduction intervention for African American men who have sex with men and women. <i>Am J Public Health</i> . Jun 2009;99(6):1008-1012. | No |
| Disclosure | MSM of various races/ethnicities | McFarland W, Chen YH, Raymond HF, Nguyen B, Colfax G, Mehrtens J, Robertson T, Stall R, Levine D, Truong HH. HIV seroadaptation among individuals, within sexual dyads, and by sexual episodes, men who have sex with men, San Francisco, 2008. <i>AIDS Care</i> . 2011 Mar;23(3):261-8. | No |

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The primary person involved with statistical aspects of this project and data analysis for this study is Dr. Trista Bingham of the Los Angeles County Department of Public Health's HIV Epidemiology Program (HEP). The study design and development of data collection instruments were a collaborative effort between CDC, Los Angeles County Department of Public Health's HIV Epidemiology Program (HEP), University of California Los Angeles (UCLA), and In the Meantime Men's Group (ITMT). The site will be collecting the data for this study and analyzing data generated by the study. The federal staff members who are involved with the various aspects of designing and implementing the study are listed below.

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