SUPPORTING STATEMENT A:

Development and Testing of an HIV Prevention Intervention Targeting Black Bisexually-Active Men

New OMB Application

OMB No. 0920-XXXX

Contact information

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A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention requests approval for a term of 3 years for a new data collection called "Development and Testing of an HIV Prevention Intervention Targeting Black Bisexually-Active Men." The primary purpose of the project is to develop and pilot test three novel interventions to reduce sexual risk for HIV infection and transmission among bisexually-active African-American men who do not inject drugs. The secondary purpose is to study factors associated with sexual risk among bisexually-active African-American men. Three independent sites will develop, implement, and test distinct interventions with the goal of determining effectiveness of the single, site-specific intervention. All sites are described in this OMB application. Where details differ by study site, we have provided site-specific information below the general section.

African Americans continue to be disproportionately affected by HIV/AIDS. Results from the National HIV Behavioral Surveillance Project published in the June 2006 Morbidity and Mortality Weekly Reports showed that during 2001-2004, although blacks accounted for approximately 13 percent of the population, they accounted for the majority (51 percent) of HIV/AIDS diagnoses in 33 states. When compared to men who have sex with men of other racial and ethnic groups, rates of transmitted HIV are substantially higher among Black men who have sex with men (MSM)(Centers for Disease Control and Prevention 2005). Black MSM have been identified as the population segment with the highest rates of HIV infection in the U.S. (Hall, Song et al. 2008) and as a population in need of new HIV prevention interventions(Herbst, Beeker et al. 2007; Millett and Peterson 2007). Previous research indicates that 20% to 40% of Black MSM also have female sex partners (Jimenez 2003; Lauby, Millett et al. 2008; Bingham, Harawa et al. 2003;Montgomery, Mokotoff et al. 2003). Interventions developed for gay men may not be relevant or appropriate for men who have sex with men and women (MSMW), many of whom do not self-identify as gay and who may need different prevention strategies for their male and female partners. Additionally, there is insufficient knowledge regarding bisexually-active African-American men's sexual risk behaviors and the context in which they occur. Although prior research has suggested that the high rates of HIV transmission in African American communities is associated with a myriad of factors including individual-level factors and broader socio-cultural and structural-level factors, the emphasis of most intervention programs has been limited to changing individual-level risk behaviors. Thus, little attention has been paid to examining contextual factors that may confound prevention efforts and contribute to high risk behaviors. Further, no interventions in the scientific literature with demonstrated efficacy in reducing HIV related sexual risk behaviors have been developed and evaluated specifically for bisexually-active African-American men.

The purpose of this study is to develop and pilot test three novel interventions to reduce sexual risk for HIV infection and transmission among bisexually-active African-American men who do not inject drugs. Three independent sites will develop, implement and test distinct interventions. Though the interventions will be unique, they will each provide participants with the information, motivation, and skills necessary to reduce their risk of transmitting or acquiring HIV. In general, the interventions are either individual or group level, are based on behavioral theory, involve multiple-sessions, require a professional facilitator, and include STI screening.

The data to be collected for these pilot studies will be used to establish the preliminary effectiveness of the newly developed interventions and will provide important information about sexual risk behaviors and the context in which they occur. These data are essential for developing effective HIV/AIDS prevention interventions for at-risk bisexually-active African-American men and for informing policies and programs that will more effectively protect them and their partners from infection. The findings from this study will be shared with Division of HIV/AIDS Prevention leadership and the scientific community through publication in peer-review journals and presentations at national conferences. After thorough and appropriate evaluation, if these interventions are found to be effective, those who implement risk-reduction interventions will be able to use the curricula to reach this population successfully. Ultimately, the beneficiary of this data collection will be bisexually active African-American men who are at risk for HIV.

The project supports CDC's Health Protection Goal of Healthy People in Every Stage of Life. It also addresses "Healthy People 2010" priority area(s) of HIV/AIDS. Specifically, the project addresses Objectives 13-5 and -6: Reduce the number of cases of HIV infection among adolescents and adults and increase the proportion of sexually active persons who use condoms. It is in alignment with NCHHSTP performance goal(s) to develop and implement effective HIV prevention interventions. Finally, the study supports several objectives of the Division of HIV/AIDS Prevention Strategic Plan. For Short-Term Milestone 1 (By 2010, decrease by at least 10% the number of persons in the United States at high risk for acquiring or transmitting HIV infection by delivering targeted, sustained and evidence-based HIV prevention interventions.), Objective 2 is *Among men who have sex with men (MSM), increase the proportion who consistently engage in behaviors that reduce risk for transmission of HIV.* Under the same Milestone, Objective 2a is *Increase the number of proven effective behavioral prevention interventions for African Americans and other racial and ethnic groups disproportionately affected by HIV/AIDS,* and Objective 3a is *Increase the number of proven effective behavioral prevention interventions for MSM.*

The following section of the U.S. Federal Code (Attachment 1) is relevant to this data collection: 42 USC 241, Section 301 of the Public Health Service Act authorizes conduct of "research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man."

Privacy Impact Assessment

Overview of the Data Collection System

The study design in each site involves a randomized controlled trial. All data will be collected and maintained by the Grantees. The data collection system involves screening, baseline assessment, acceptability/feasibility survey, immediate post-intervention assessment, and a final 3-month follow-up assessment. Across the three sites, an estimated 1250 men (in total) will be screened for eligibility using the Screening Form (Attachment 3a); this process is estimated to take 5 minutes per Respondent. Data collection will occur either through a brief face-to-face interview or audio-computer assisted self-interview (ACASI). Participants will be recruited through community outreach and chain referral methods.

Eligible men will be scheduled for a baseline visit where they will 1) be re-screened to verify eligibility, 2) provide written informed consent (Attachment 4), 3) provide locator information for subsequent visits (Attachment 3b), 4) complete the 45 minute baseline assessment (Attachment 3c) and 5) receive their randomized assignment to the experimental or control condition. Assessments will be conducted either through a combination of face-to-face interview and ACASI or just ACASI. Participants assigned to the experimental condition will then be scheduled to complete the intervention sessions. After completing the intervention sessions, participants will be asked to complete an acceptability/feasibility survey (Attachment 3d) and an immediate follow-up assessment. Control participants will also complete the immediate follow-up assessment after the control activity concludes. Three months after completing the immediate follow-up assessment, all participants will be asked to complete a final three month follow-up assessment. The procedures for the follow-up assessment will mirror those for the baseline.

We will collect information in identifiable form for all participants so that we may track individuals longitudinally. Each study participant will be given a unique identifier, which will appear with the study data (i.e., Responses to assessments, arm assignment and attendance). A linking file will contain the unique identifier, participant name, and month/year of birth. This file will be maintained in a password-protected electronic file and only local study staff engaged in project management will have access to that data. Identifying information will not be included with study data and will not be transmitted to CDC or any other agency. CDC staff will not have access to any identifying information. De-identified data (including the baseline, follow-up assessments, arm assignment, and session attendance) will be transmitted to CDC via a secure data network on a regular basis over the period of data collection. During this time, the unique code will continue to link the data to identifiable information at the study site. The linking file and the locating information will be destroyed once follow-up is complete. Deidentified study data will be maintained at the sites and CDC indefinitely.

Items of Information to be Collected

Participant Screening Data

Screening data to be collected include items related to study eligibility criteria, which are: 1) male, 2) African-American, 3) 18 years of age or older, 4) reside within the geographic boundaries of the catchment area, 5) speak and read English, 6) report male and female partners in the past 12 months, 7) unprotected sex with a man or a woman in the past 3 months, 8) two or more male or female partners in the past 3 months, and 9) no injection drug use in the past 12 months. Screening data will not involve the collection of information in identifiable form.

Methods for collecting screening data and storing data will vary slightly between study sites (as described below). However, all sites will ask 7 items to determine eligibility (in italics below) and 3 "red herring" items (not in italics). The red herring items are included to minimize the potential that the screening criteria become known in the community. The questions are: *Do you consider yourself to be a Black or African-American male? What is your age?* Are you currently involved in a committed relationship with anyone? What County do you live in? How long have you lived in the Chicago area? *When was the last time you had sex with a woman? When was the*

last time you had sex with a man? All together, how many men and women have you had sex with in the last 3 months (by sex we mean either vaginal or anal)? Thinking about the times that you had sex in the past 3 months with both male and female partners, how often did you use condoms? Have you gone to see a doctor for any reason in the past 12 months? *When was the last time you injected drugs?.* In addition to the cross-site eligibility criteria listed above, CSU will also require that men report having been incarcerated within the past 6 months in order to participate. The screening instrument can be found in Appendix 3A

Site Specific Screening Procedures

PHMC: Screening will only be conducted over the phone. Men with a recruitment ticket who are interested in participating will call the project's toll-free phone number. Before asking any questions, the staff member conducting the screening will describe the research project and procedures, explain that participation is voluntary, and describe risks and confidentiality measures. The staff member will then ask if the potential participant is interested in continuing with the screening process. When eligible participants come in for the baseline interview they will be given a written consent form and we will document informed consent at that time.

Nova: Potential participants will be screened for eligibility either in-person or over the phone. Men who call in for screening will be asked the screening questions over the phone by a staff member who will enter Responses on a computer. Men who present for an in-person screening will be seated at an ACASI computer station where they will complete the screening questions themselves. Use of the ACASI allows for potential participants to have more privacy answering the questions rather than having recruiters ask questions and record their answers. Our recruiters will not be able to view or have access to the answers provided by the Respondent. When the potential participant has completed the screening questions, the ACASI will bring up a screen saying "*Thank you for answering the questions."* The software will automatically determine whether or not the Respondent meets the eligibility requirements without staff input or assistance. When the Respondent lets the staff member know that he has completed the screening process, staff will enter a special password to learn whether or not to invite the Respondent to enroll in the study; staff will not know the reason for ineligibility if the potential participant is ineligible. All eligible men will be invited to enroll in the study immediately after completing the screener.

CSU: Potentially eligible inmates that participate in HIV prevention education services in jail will be informed of study eligibility requirements verbally by study staff and asked about their interest in participating. Private screening sessions will be conducted with men who express an interest in the study. Following screening, post-release contact information will be collected from eligible men to allow study staff to follow-up with them once they are released from jail. Re-contacted individuals will undergo eligibility screening again either by phone or in person. Jail-based recruitment will continue for the duration of the study.

Interested potential participants who are not incarcerated at the time of screening will be screened either in-person (at the study office) or over the phone. After briefly describing the study, staff will request permission to conduct an eligibility screening. Men who screen eligible on the telephone will be scheduled to visit the study office for enrollment into the study. When men present for screening in-person, staff will thank the men for their time, explain the purpose

of the study and explain the screening process. If the potential participant does not want to complete the screening questions, the recruiter will thank him for his time.

Participant Locating Information

The locator form (Attachment 3b) will be used by the study staff to collect participant contact information. The form will contain the following categories of information in identifiable form (IIF): name, month/year of birth, mailing address, phone numbers, and email address. In addition, other data, such as names, phone numbers, and addresses of contacts and employer information will be collected. This information will be used to contact participants to remind them of intervention sessions and follow-up visits. The locator information will be kept as a hard copy and not entered into electronic format.

Baseline, Immediate Post-Test and Three Month Follow-up Data

Across sites, the data elements collected in both the baseline and follow-up assessments include the following: demographics, HIV/STI history, social network, social support, and disclosure, identity and community affiliation, sexual behaviors (by main partner and non-main partners; HIV-positive, negative and unknown status partners), partner characteristics, psychological distress, trauma history, intimate partner violence, alcohol and substance use, incarceration, HIV stigma, spirituality, treatment optimism, medical questions for HIV positive participants, HIV status disclosure, and social desirability. The three follow-up assessment will cover the same domains, except the following: network, partner characteristics, trauma history, intimate partner violence, spirituality, and social desirability. The immediate follow-up assessment will cover attitudes, knowledge, and intentions for safer sex behavior.

Acceptability Survey

All participants randomized to the experimental condition will be asked to complete an acceptability/feasibility survey once the intervention is complete (Attachment 3d). The surveys will include an evaluation of each session and overall measures of intervention appropriateness, accessibility, feasibility. This survey will be anonymous.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

Children under the age of 13 are not eligible to participate. At one study site (Nova) data will be collected online. The Acceptability Survey will take place online after the completion of the online intervention. Data will be collected and maintained in a secure manner. None of the study sites will refer Respondents to websites.

2. Purpose and Use of Information Collection

The data to be collected for this study will be used to examine the effectiveness of three newly developed HIV risk reduction interventions for bisexually active African-American men. Each grantee will use a randomized controlled trial design to determine if men who are assigned to the experimental condition report less frequent HIV risk behavior three months following the

intervention compared to men in the control condition. The specific outcomes to be measured are number of unprotected sex acts with male and female partners and number of male and female partners. Secondary objectives of this study are: 1) to test the effectiveness of the intervention for decreasing the number of casual sexual partners, increasing the uptake of STI testing; 2) to examine and describe individual, interpersonal network, and socio-cultural factors that may affect HIV risk behaviors among Black MSMW; and 3) to assess the feasibility of chain-referral sampling methods for recruiting Black MSMW.

Currently, there are no effective interventions for bisexually active African-American men and little information about the correlates of sex risk in this population. Without the proposed data collection, we will continue to lack any effective and appropriate interventions for this at-risk population and current HIV incidence trends will continue. If an intervention demonstrates promising but non-significant results, it may be deemed appropriate for further testing with a larger sample size in multiple settings (in a separate CDC funding announcement or via another source of support). Additionally, published findings from the study can be reviewed by the DHAP Prevention Research Synthesis Project as an intervention to be featured in future Compendium of Evidence Based Prevention Interventions, which community-based HIV prevention programs can use to select appropriate evidence-based interventions to implement in the field. If effective, the intervention could also be replicated via a Replicating Effective Programs project or disseminated through a Diffusion of Effective Behavioral Interventions project (both DHAP activities that aim to translate scientific evidence into program practice). A secondary use of the information collected in this study will be to improve our current understanding of HIV risk behavior and its correlates among bisexually active African-American men. Currently, there are few cross-sectional studies that specifically targeted bisexually active men. Understanding the correlates of sexual risk behavior is important as it informs the appropriate development of risk reduction interventions.

As is typical with RCTs, the study will not include a probability sample because no sampling frame is available. Instead, we will use a modified chain referral sampling strategy, which has demonstrated success in accessing hard-to-reach populations (Ramirez-Valles, Heckathorn et al. 2005; Abdul-Quader, Heckathorn et al. 2006). However, non-probability sampling will limit the *generalizability* of our findings. Promising results from this study would warrant further evaluation with a larger RCT implemented in multiple locations with a larger sample. By establishing baseline risk, effect size estimates, and feasibility about the sampling strategy, the data collected in this study will greatly inform those efforts. CDC funding for these Grantees began in September 2009 and is expected to continue until 2013.

Privacy Impact Assessment Information

The study is being conducted to establish the preliminary effectiveness of the three interventions, which have been developed specifically for bisexually active African-American men. Specifically, the screening instrument will allow determination of eligibility to participate in the study. The participant locator form will facilitate participant retention by allowing study staff to follow-up with participants on a regular basis and to remind them of upcoming appointments. The baseline assessment will capture pre-intervention attitudes, knowledge, psychosocial correlates, sexual risk behaviors, and sexual partner characteristics that will either be targeted by the intervention or may act as moderators or mediators for intervention effectiveness. The

immediate post-intervention assessment will measure key variables related to attitudes, knowledge, and safe sex intentions that may be directly and more proximally influenced by the interventions. Finally, the 3-month follow-up assessment will measure the same items collected in the baseline assessment (minus several domains that are unlikely to change) As a whole, the assessment data will allow us to establish the effectiveness of the intervention in reducing HIV risk behavior and increasing STI screening uptake. The acceptability/feasibility survey will capture participant opinions of and satisfaction about the intervention content and the feasibility of participation. This information will allow intervention developers to refine and enhance the curriculum before further testing.

All data will be collected by the Grantees and will be maintained at the local site. De-identified data (including the baseline, immediate-post, follow-up assessments, arm assignment, and session attendance) will be transmitted to CDC via a secure data network on a regular basis over the period of data collection. During this time, a unique code will link the data to identifiable information at the study site, which CDC will not be able to access. Common items from the baseline datasets from each site will be compiled into an overall dataset and will shared with all three sites once the linking files (containing the unique identifiers, names and month/year of birth) have been destroyed at the local sites. No identifying information will be shared. Results from the study will be shared with the research community via peer-reviewed journals and presentations at national conferences. In order to reach the maximum benefit to existing HIV prevention, CDC will share the study results with the scientific community in the form of publications and presentations.

This study involves the collection of sensitive information. There would likely be an effect on the Respondent's privacy if there were a breach of confidentiality. Therefore, stringent safeguards will be implemented to protect against a breach of security and illegal access to individually identifiable information. Only study staff requiring access to study data for the management of the project will be granted access. All computer files will be password-protected and maintained on secure network drives. All hard copies will be kept in a locked file cabinet in the secure offices of the study manager. Unique codes, maintained in an electronic linking file, will link the study data to individually identifiable information contained in the study locator form.

3. Use of Improved Technology and Burden Reduction

The screening instrument will be will be conducted face-to-face, over the phone or through ACASI and will be limited to items that directly assess study eligibility, plus four additional questions to prevent eligibility criteria from becoming known in the community. Three study assessments will be conducted (baseline, immediate-post, and follow-up) using either a combination of computer-assisted personal interview (CAPI) and ACASI or only ACASI. At sites using both CAPI and ACASI (PHMC and CSU), the majority of the data (including sexual and drug use behavior) will be collected via ACASI. The use of ACASI has been found to reduce Respondent burden and enhance Respondent privacy during data collection. In addition, ACASI has been found in several studies to reduce the effect of social desirability and study demand characteristics on participant self-reports of socially sensitive personal information (Des Jarlais, Paone et al. 1999). In addition to enhancing the validity of self-report data, computerized

assessments can be programmed to customize question wording for individual Respondent and prevent Respondents from having to answer questions that are not applicable to them. The portion of the assessment that involves CAPI was chosen strategically to increase validity. All data collection instruments were designed to be as brief as possible. We will only collect the information necessary to evaluate the effect of the intervention, assess potential interactions, and identify specific predictors of sexual risk and protective behavior.

4. Efforts to Identify Duplication and Use of Similar Information

CDC staff conducted several activities to identify duplication and use of similar information. We reviewed currently-funded programs and did not identify potential areas of duplication. No known department or agency develops and evaluates new behavioral HIV risk reduction interventions for Black MSMW. There are no known sources for HIV-related behavioral data from Black MSMW (with adequate sample sizes to support analysis) available within the department or agency. Hence, this is a unique study.

One significant effort has been a review of the literature, which was done using PubMed. The specifications of the electronic search involved controlled vocabulary and key words in three areas: 1) HIV and AIDS; 2) prevention research; and 3) men who have sex with men and women and 4) African-American and Black. Searches were limited to literature published in English-language journals between 1985 and 2008. We found no published studies evaluating the effectiveness of an intervention designed for bisexually active African-American men.

Several cross-sectional studies have described sexual risk among this population; however, few specifically recruited bisexually active African-American men. Most MSMW studies to date have focused on white men (Lauby, Millett et al. 2008). According to Wheeler et al (Wheeler, Lauby et al. 2008) studies that enroll Black MSMW often pool Black MSMW and MSM together in statistical analysis (Centers for Disease Control and Prevention 2003; Hart and Peterson 2004; Kennamer, Honnold et al. 2000; Peterson, Bakeman et al. 2001), do not recruit enough Black men for race-specific analyses (Kalichman, Roffman et al. 1998) or do not differentiate between Black MSMW and MSMW of other races/ethnicities (Lehner and Chiasson 1998). Another limitation is the classification of Black men based on bisexual identity rather than behavior (Goldbaum, Perdue et al. 1998; Crawford, Allison et al. 2002).

Few cross-sectional studies have identified correlates of sexual risk among Black MSMW. Wohl et al found that among an LA-based sample of MSM who identified as heterosexual, HIV positivity was associated with decreasing age at first sexual experience, a history of injecting drugs, and amphetamine and methamphetamine use (Wohl, Johnson et al. 2002). Two other publications are based on the same sample of men from Philadelphia and New York City. Lauby et al found that HIV-positive MSMW were less likely than HIV-negative men and never-tested men to have engaged in unprotected intercourse with main male and main female partners perceived to be HIV-negative or of unknown serostatus. Additionally, HIV-positive men were equally as likely as HIV-negative men to have unprotected intercourse with non-main male and non-main female partners perceived as HIV-negative or of unknown serostatus (Lauby, Millett et al. 2008). Wheeler et al noted that self-identified sexual orientation, self-reported HIV status, exchange sex for money/food/ drug, and drug use in the past 3 months were significantly

associated with either insertive or receptive UAI in the past 3 months among MSMW. The strongest correlate of insertive UAI was engaging in exchange sex. Differences between MSMW and MSM were found in the areas of forced sexual experiences, disclosure of same sex behavior, and history of being arrested or incarcerated (Wheeler, Lauby et al. 2008).

To summarize the literature review, we identified no effective interventions for bisexually active African-American men. We also found few publications describing correlates of sexual risk behavior among this population. The limited findings do suggest, however, that African-American MSMW are at risk for HIV acquisition and transmission and that tailored interventions are necessary due to unique cultural, social, and economic factors.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this study.

6. Consequences of Collecting the Information Less Frequently

The data collection activities will occur from August 2010 to April 2012. The study involves multiple, but discrete, data collection points, all of which are needed to conduct the study and evaluate the effect of the intervention. Participants are allowed to participate in the study only once.

If data were not collected, we would not be able to describe the feasibility, acceptability, and preliminary effectiveness of these three novel interventions. It would therefore be impossible to develop, test, and distribute a needed intervention for at-risk bisexually active African-American men, a population for whom there are currently no effective risk-reduction interventions.

There are no legal obstacles to reduce the burden for Respondents.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the guidelines of 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A 60-day notice to solicit public comments was published on XXX, 2010, page numbers XXXXX. A copy of this publication is attached (Attachment 2). We did not receive public comments.

Several consultations were conducted with various scientists and public health practitioners outside the agency.

In November 2008, CDC held a principal investigator meeting with external researchers, who were funded under the Cooperative Agreement and have experience conducting behavioral

surveys among African-American and MSMW populations. All attendee names, affiliations, and contact information is included in Attachment 6.

The purpose of this meeting was to agree on the 1) the best sampling strategy for recruiting and enrolling men into the study; 2) the key HIV-related behavioral outcomes and other variables that should be included in the survey; and 3) strategies for conducting random assignment to condition. The discussion also focused on the utility of the information for developing HIV prevention programs.

During December 2008 through July 2009 a subcommittee composed of one CDC and three external investigators developed the data collection instrument. All subcommittee members are experienced in conducting behavioral surveys among Black MSM and MSMW. During this time, the larger protocol committee, composed of multiple CDC scientists and representatives from each funded site, met weekly via conference call to develop the sampling strategy, randomization plan, and procedures for screening and data collection. The protocol committee convened in person again in February 2009 to finalize these aspects of the study and refine the domains to be included in the data collection. All attendee names, affiliations, and contact information is included in Attachment 6. Additionally, CDC statisticians developed the power calculations and analysis plans.

In addition to collaboration with external scientists, each study site has collaborated with local Community Advisory Boards (Attachment 7). These are composed of representatives from the target population, staff from partner agencies, and members of AIDS service organizations. These groups have worked with the study sites to ensure that intervention and assessment materials are appropriate for the target population. Though monthly meetings, the CAB members have provided input into all aspects of the study, most notably recruitment methods, data elements to be collected, clarity of instructions and intervention content. In accordance with congressional mandate (Content of AIDS-Related Written Materials, Pictorial, Audiovisuals, Questionnaires, Survey Instruments, and Educational Sessions (June 1992), all intervention materials and research instruments will be reviewed by a local program review panel to ensure that these materials are in accordance with community standards.

9. Explanation of Any Payment or Gift to Respondents

Tokens of appreciation for participation are an important tool used in research and are particularly important for the population in this study. Grantees seek to recruit, enroll, and follow a hard-to-reach and possibly hidden population, while also asking highly sensitive questions about issues such as sexual behavior, HIV status, and substance use. Because of the time commitments necessary to complete the studies, eligible persons will be offered a token of appreciation. These not only indicate to participants that their time is valuable, but offers additional motivation to join and continue participating in the study. The tokens of appreciation will complement the intensive efforts by staff to follow-up with participants and maintain updated contact information during the course of the study. These are likely to boost both enrollment and retention rates (Kamb, Rhodes et al. 1998). With increased response rates, the reliability of the data will be improved as the samples will be more representative of the underlying populations of interest.

Although sites do face the similar challenge of recruiting a significant number of bisexually active men to complete this study, there are important geographic and situational differences between study sites that are important to consider in designing how to best provide tokens of appreciation. Differences clearly exist between sites based on issues such as the local economy, the typical amount offered in similar research projects within the local community, and the prevalence of MSMW willing to participate in an intervention study. In addition, the intervention activities differ by site; time requirements and scheduling issues were also taken into consideration in the local context. In determining the appropriate token amounts for each community, investigators relied on their recent experience conducting similar studies and paid great attention to balancing the importance of sufficient recruitment/retention with the ethical issues of coercion, should the amount be set too high for a given community. Each investigator made considerable effort to determine the most appropriate and fair amount, given the local context. This included consultations with key informants and members of local Community Advisory Boards, composed of men from the focus population. For these reasons, the amounts and structure of the tokens of appreciation vary by geographic location.

Based on these local discussions, site specific plans are as follows:

PHMC: Participants will receive $50 as a token of appreciation for completing the baseline survey. Participants will receive $25 immediately after finishing the baseline survey and $25 when they return for their first session. Participants who decide not to attend their assigned intervention or control group session will be asked to come to the project office to receive the $25. Additionally, as another token of appreciation, participants in waves 1 and 2 will receive $15 for each individual they successfully recruit (i.e., each eligible man who enrolls). Participants will receive $50 for completing the post-intervention interview and $75 for the 3 month follow-up. This is for data collection activities only and will not be tied to attendance at either intervention or control condition sessions. To encourage attendance at intervention sessions, participants will receive a lottery ticket for each session they attend. Drawings for a prize gift valued at around $100 will occur every two months. In addition, participants attending intervention and control sessions will be offered a snack and a beverage.

Nova: Participants will receive a token of appreciation in the amount of $40 in cash for completing the baseline survey. For each intervention session attended, participants will receive $25. Participants will receive $50 for completing the post-intervention interview and $60 for the 3 month follow-up. Additionally, participants in waves 1 and 2 will receive $15 for each individual they successfully recruit (i.e., each eligible man who enrolls).

CSU**:** Participants will receive a token of appreciation of $30 in cash for completing the baseline survey. Participants in waves 1 and 2 will receive $10 for each individual they successfully recruit (i.e., each eligible man who enrolls). Participants will receive $20 for completing the post-intervention interview and $40 for the 3 month follow-up. Those assigned to the intervention condition will also receive $20 for each intervention session attended and $10 for transportation assistance for their roundtrip travel to and from the intervention site.

10. Assurance of Confidentiality Provided to Respondents

The Privacy Act does not apply to this request. Two of the three study sites will not apply for formal confidentiality protections. However, the third site (CSU), which involves men who have recently been released from correctional facilities, will apply for these extra protections.

All data will be treated in a secure manner. Each study site is Responsible for carrying out the following procedures:

The Screening Form will be used to collect information to ascertain participant eligibility and will not involve the collection of information in identifiable form. The participant locator form will facilitate participant retention by allowing study staff to follow-up with participants on a regular basis and to remind them of upcoming appointments. The baseline assessment will capture pre-intervention attitudes, knowledge, psychosocial correlates, sexual risk behaviors, and sexual partner characteristics that will either be targeted by the intervention or may act as moderators or mediators for intervention effectiveness. The immediate post-intervention assessment will measure key variables related to attitudes, knowledge, and safe sex intentions that may be directly and more proximally influenced by the interventions. Finally, the 3-month follow-up assessment will measure the same items collected in the baseline assessment (minus several domains that are unlikely to change) As a whole, the assessment data will allow us to establish the effectiveness of the intervention in reducing HIV risk behavior and increasing STI screening uptake. The acceptability/feasibility survey will capture participant opinions of and satisfaction about the intervention content and the feasibility of participation. This information will allow intervention developers to refine and enhance the curriculum before further testing.

The three behavioral assessments will contain the participant's unique identification number. A linking file will contain this code and the participants' names and month/year of birth. Data will not be retrieved using name, social security number, or other personal information. No personal identifiers will be transmitted to the CDC. At each site, the data manager will be Responsible for assigning the participant ID number. These data will be linked for the duration of the follow-up period. After the follow-up period, the locator form will be destroyed. Only the data manager, project director, and principal investigator at each site will have access to the identifiable information contained on the hard copy locator form. No identifiable information will be sent to CDC under any circumstances. Screening forms for eligible persons will be destroyed immediately after the trial is completed.

Local IRB approval was granted at each site.

<u>Privacy Impact Assessment Information</u>

A.
This request does not need compliance with the Privacy Act.

B.
This project is covered by an Assurance of Confidentiality under Section 308(d) of the Public Health Act granted for HIV/AIDS surveillance data (Attachment 8). The Assurance provides the highest level of legal confidentiality protections to the individual persons who are the subject of

this data collection, and to the individuals and organizations Responsible for data collection. The terms of the Assurance of Confidentiality reflect the collective experience of CDC, health departments, and the Council of State and Territorial Epidemiologists with Respect to the collection, electronic transmission, and dissemination of HIV/AIDS surveillance data. The Assurance includes established policies and procedures governing all aspects of data collection and de-identification, physical security for paper forms and records, electronic data storage and transmission, and the release of aggregate data in forms that cannot be linked back to individual Respondent. The protections afforded by the Assurance of Confidentiality last forever, and endure even after the Respondent's death. The Assurance of Confidentiality is enforced with appropriate training and contractual agreements which clarify the Responsibilities of all participants in HIV/AIDS surveillance activities who have access to directly identifiable data or to data that are potentially identifiable through indirect means.

Screening forms will be stored in locked file cabinets in the research office at each study site. Paper copies of the screener form will be destroyed immediately after the information is entered into a computer file which will be stored in an encrypted and password protected computer in the principal investigator's research office with access only to research team members with work-related needs. The computer file will be destroyed within 6 months after the end of the intervention trial. Data collected from the screener form will not be sent to CDC.

Participants will fill out the locator form (Attachment 3b) in which they will be asked to provide their names, addresses, email addresses, telephone numbers, and the names and contact information for other people who regularly know their whereabouts. This information will be entered into a computer file which will be stored in an encrypted and password protected computer in the research office with access only to the Principal Investigator, Project Manager and Data Manager. The paper copies of the Locator Form will be destroyed immediately after the information is entered (on a daily basis) into the computer file on an encrypted and password protected computer in the research office with access only to the Principal Investigator, Project Manager and Data Manager. The computer file will be destroyed within 6 months after the end of the intervention trial. Data collected from the Locator Form will not be sent to the CDC.

Signed consent Forms (Attachment 4) will also be stored in a separate locked file cabinet in the Principal Investigator's research office at each study site and will be destroyed 5 years after the final reports are completed. Only the Principal Investigator, Project Manager and Data Manager will have access to the Consent Forms.

The baseline and follow-up data will be stored on a computer in the research office at the study sites with only an ID number and not with a direct personal identifier such as name or social security number. Each day, Data Collectors will transfer and back up the completed assessments on each of the data collection computers. Only the Principal Investigator, Project Manager and Data Manager will have access to back-up disks following their transfer. Data will be deleted from the data collection computers and from the disks as soon as the data is successfully transferred to the Data Manager's computer – through which the data will be stored on a secure network. Weekly, baseline and follow-up data will be encrypted and uploaded to CDC via a secure data network based at CDC. Data files that are submitted through the SDN will be encrypted before being sent to CDC. No personally identifiable information will be sent to CDC

Physical access to the study site research offices is limited to research personnel only. All project staff will be trained on and adhere to strict ethical guidelines regarding professional conduct and will sign a pledge of confidentiality.

The following safeguards will be applied to the data on laptop computers used for interviews: 1) the laptop computers are solely used for the current project activities; 2) all data files are encrypted when stored on a laptop computer; 3) laptop computers are protected by using a coded password only known by authorized project staff; 4) Computers are secured by the data collectors after the last interview each day; and 5) when not in use, the laptop computer is to be locked in a drawer or office.

C.

All eligible participants interested in participating in the study will be asked to provide written consent (Attachment 4) before enrolling in the study. The consent form provides details of the study procedures, risks, benefits, site contact information, and the nature of confidentiality and voluntary participation. The consent process also provides information about the trial and that the participant will receive a token of appreciation for their time and travel expenses. Participants will be informed that their data will be kept in a secure manner, the data will be reported in aggregate format, and names will not be in any report about this study. Participants will also be informed that no identifying information will be attached to the assessments, just an ID number. Participants will be told that personal information will not be disclosed, unless otherwise compelled by law. Before a participant signs the consent form, staff will thoroughly review each of these points, ask if the participant understands the content, and answer any questions. Participants will be given a copy of the consent form for their records. The signed copy will be kept in a locked file in the main office of the study site, which can be accessed only by the Principal Investigator, Project Manager and Data Manager.

The consent process will be conducted by trained staff in a private location where the questions and Responses cannot be overheard by others. This project was approved by the local IRBs (Attachment 5).

D.
All participants will be informed of the voluntary nature of their participation during the consent process. All the questions in the eligibility screener and the assessments allow the Respondent the option of refusing to provide a Response. Respondents will be advised that summary (aggregate) and no individually identifying information will be shared with CDC.

Site Specific Information

PHMC: Local IRB approval was granted on 10/23/2009. See Attachment 5.

Nova: Local IRB approval was granted on 11/3/2009. See Attachment 5.

CSU: Local IRB approval was reviewed on 12/3/2009. Approval is pending. Because this site will be recruiting MSMW who have recently been released from correctional facilities, the site will apply for a Certificate of Confidentiality through CDC.

11. Justification for Sensitive Questions

This intervention seeks to decrease risk for HIV and involves sensitive questions about HIV-related sexual risk behaviors with male, female, and transgender partners, alcohol and drug use, religious beliefs, intimate partner violence, childhood sexual abuse, mental health, incarceration history, HIV status, and history of STI diagnosis. All of these domains will be assessed in the baseline assessment, and a portion will be collected in the follow-up assessments
Sensitive questions in the baseline assessment are as follows:

Section Name	**Question Numbers**
STD History and Testing	1-2
HIV Testing and Status	1-6
Sexual Risk	Parts A-F
Partner Characteristics	Parts A-B
Mental Health	1-25
Trauma History	1-18
Intimate Partner Violence	1-7
Substance Use	1-18
Incarceration	1-8
Spirituality	1-6
HIV Medical Care	1-7

Without this information the study would not be able to answer the primary research question of whether the proposed risk reduction intervention is effective. These data will increase our understanding of the HIV prevention needs among African-American MSMW. During the consent process, participants will be informed that this study involves collecting sensitive information. Participants will also be informed at the beginning of each assessment (Attachment 4) of their right to skip questions that they do not wish to answer. The screening instrument involves several sensitive questions; however, this information is critical to determine eligibility for the study. Participants will be consented before answering the screening questions.

12. Estimates of Annualized Burden Hours and Costs

12A.
Based on our time tests of the study instruments, the estimated time needed to complete screening 1350 potential participants for eligibility is 5 minutes per participant (Attachment 3a). Across all three sites, it is expected that a total of 750 men will be eligible to participate in this study. The locator form will take 10 minutes, the baseline assessment 60 minutes, the acceptability/feasibility form 10 minutes, the immediate post assessment 30 minutes, and the 3 month follow-up assessment 60 minutes.

Table 12.A presents participant burden hours for completion of the study. The total participant burden for this data collection is estimated at 2250 hours.

Exhibit A12.A. Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. Responses Per Respondent	Average Burden Per Respondent (in hours)	Total Annual Burden in Hours
Prospective Participant	Screener	1250	1	5/60	104
Enrolled Participant	Locator Form	750	1	10/60	125
Enrolled Participant-PHMC	Baseline Assessment	250	1	1	250
Enrolled Participant-Nova	Baseline Assessment	240	1	1	240
Enrolled Participant-CSU	Baseline Assessment	260	1	1	260
Enrolled Participant-PHMC	Acceptability/ Feasibility Survey	250	6	10/60	250
Enrolled Participant-Nova	Acceptability/ Feasibility Survey	240	1	10/60	40
Enrolled Participant-CSU	Acceptability/ Feasibility Survey	260	1	10/60	43
Enrolled Participant-PHMC	Immediate Post Assessment	225	1	30/60	113
Enrolled Participant-Nova	Immediate Post Assessment	216	1	30/60	108
Enrolled Participant-CSU	Immediate Post Assessment	234	1	30/60	117
Enrolled Participant-PHMC	3 month Follow-Up Assessment	200	1	1	200
Enrolled Participant-Nova	3 month Follow-Up Assessment	192	1	1	192
Enrolled Participant-CSU	3 month Follow-Up Assessment	208	1	1	208
Total					2250

Table A12.B displays the annualized cost to Respondents for burden hours shown in Table 12.A. In order to estimate the cost to the Respondents, we used the seasonally adjusted average hourly

wage earnings of total production and non-supervisory workers on private nonfarm payrolls proposed for January 2008 by the US Department of Labor.

Exhibit A12.B. Estimated Annualized Burden Costs

Type of Respondent	Total Annual Burden in Hours	Average Hourly Wage Rate	Total Annual Respondent Cost
Prospective Participant-Screener	104	$17.75	$1,842
Enrolled Participant-Locator Form	125	$17.75	$2,218
Enrolled Participant-PHMC-Baseline	250	$17.75	$4,438
Enrolled Participant-Nova-Baseline	240	$17.75	$4,260
Enrolled Participant-CSU-Baseline	260	$17.75	$4,615
Enrolled Participant-PHMC-Acceptability	250	$17.75	$4,438
Enrolled Participant-Nova-Acceptability	40	$17.75	$710
Enrolled Participant-CSU-Acceptability	43	$17.75	$769
Enrolled Participant-PHMC-Immediate Post	113	$17.75	$1,997
Enrolled Participant-Nova-Immediate Post	108	$17.75	$1,917
Enrolled Participant-CSU-Immediate Post	117	$17.75	$2,077
Enrolled Participant-PHMC-3 month	200	$17.75	$3,550
Enrolled Participant-Nova-3 month	192	$17.75	$3,408
Enrolled Participant-CSU-3 month	208	$17.75	$3,692
Total	2250		$39,930

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no other costs to Respondents or record keepers associated with this study.

14. Annualized Cost to the Government

The cost of the studies for the three years is estimated to be $796,613. The annual cost to the government is in Exhibit A.14.

Exhibit A14. Annualized Cost to Government

Expense Type	Government Related Expenses	Annual Costs (dollars)
Direct cost to the Federal Government		
	CDC Project Officer (GS-14, .20 FTE)	$19,784
	CDC Co-Project Officer (GS-13, .25 FTE)	$20, 928
	CDC Behavioral Scientist (GS-14, .05 FTE)	$4,946
	CDC Behavioral Scientist (GS-13, .05 FTE)	$4,185
	CDC Statistician (GS-14 .05 FTE)	$4946
	Travel	$8000
	Subtotal, direct costs to the government	$41,861
Contractor and other expenses		
	Cooperative Agreement: Nova Southeastern University	$264,537
	Cooperative Agreement: California State University – Dominguez Hills	$243,467
	Cooperative Agreement: Public Health Management Corporation	$246,748
	TOTAL COST TO THE GOVERNMENT	**$796,613**

Salary estimates were obtained from OPM salary scale at the following web address: http://www.opm.gov/oca/09tables/html/atl.asp.

15. Explanation for Program Changes or Adjustments

There is no change in burden requested as this is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Analysis Plan

The proposed studies will be nested cohort group-randomized trials (GRTs) with social networks randomly assigned to study conditions, and observations taken on individual participants.

These studies present a number of challenges that must be addressed in the primary and secondary analyses. First, the analytic approach must take into account the correlation among patients within networks and two measurements on each participant (baseline and 3 months post-intervention). Second, as with any longitudinal cohort study, there is potential for attrition over the course of the study and differential attrition between treatment conditions. Third, the three primary outcome variables used to assess the impact of the intervention will be non-normally distributed.

Prior to beginning analyses to evaluate treatment effects, preliminary analyses for all three studies will be conducted to determine whether randomization was successful in creating equivalent groups of participants across study conditions at baseline. Methods appropriate to the distribution of the variable of interest will be used, including Pearson Chi-square tests, Fisher's Exact Chi-square tests, nonparametric methods and models for zero-inflated data. Any differences between treatment and control conditions at baseline will be controlled for in subsequent evaluations of the treatment effect. Variables examined in this analysis will include age, sexual identity, income, insurance status, reported HIV status, reported MSMW network size, sexuality disclosure, and substance use. Analysis will also be conducted for the purpose of describing the baseline sample and examining the distributions of each of the outcome variables prior to fitting more complex models.

For the main outcome analyses, numerous options are available for tests of the effectiveness of the interventions. Mixed-model regression methods are often used for the analysis of GRTs and easily accommodate the over-time correlation at the group and member level, as well as the correlation of observations within groups. However, in the current studies, we may have a number of participants who do not refer others to the study and thus have a social network size of one. Under these circumstances, mixed models may encounter difficulty with convergence. Generalized Estimating Equations (GEE) offers an alternative that avoids specifying the joint distribution of the data and instead adjusts the variance to account for intraclass correlation. GEE models can be fit for binary outcomes and those with a negative binomial distribution (among others) in PROC GLIMMIX in SAS 9.2. We propose to use a GEE approach to test for a difference between study conditions at 3 months, incorporating the baseline measurement as a covariate.

All models will include fixed effects for the baseline value of the outcome variable and study condition. The baseline measurement will be included as a covariate because this approach is often more powerful than including the baseline measurement in a repeated-measures analysis of variance. Initial models will also include a random effect for group to control for correlation within groups (social networks).

The main outcome analysis for all three studies will use an intent-to-treat approach (i.e. each participant will be analyzed in the study condition to which his social network was randomly assigned). Secondary analyses will explore the impact of actual treatment received, which will vary across participants.

Following the analysis of the observed data, we will repeat the primary outcome analysis using multiple imputation to address the potential for bias due to missing data. Multiple imputation

'fills in' the missing data using the association between variables in the dataset, and reflects the uncertainty in the imputed values by basing variance estimates on between- and within-imputation variability. This study is likely to have a moderate amount of missing data due to the nested cohort design, and ignoring this missingness may lead to bias in the estimates of the treatment effect.

Combined analyses across the three studies at baseline will be done to describe the participants. Variables of interest for these analyses will include number of reported male or female sex partners, frequency of unprotected sex with male or female partners, % of participants engaging in any unprotected sex with male or female partners, and % of participants engaging in serodiscordant sex with male or female partners. Combined analyses will also describe the degree to which partner characteristics (age, race/ethnicity, sex) are associated with sex risk. Additionally, we will describe associations between psychological variables (depression, trauma, social support, perceived risk) and participants' sexual risk behavior.

Timeline

Exhibit A16. Project Time Schedule

Activities	**Time Schedule**
Begin recruitment	2 months post OMB approval
Complete recruitment, intervention implementation, and data collection	19 months post OMB approval
Data management and validation	20-22 months post OMB approval
Analysis of key outcomes	23-24 months post OMB approval
Dissemination of results	25-36 months post OMB approval

17. Reason(s) Display of OMB Expiration Date is Inappropriate

We do not seek approval to eliminate the expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification statement.

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