Understanding Barriers and Facilitators to HIV prevention for Men Who Have Sex with Men (MSM) – Pulse Study

OMB# 0920-New

Section A: Supporting Statement

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- **Goal of the study :** The goal of the "Understanding Barriers and Facilitators to HIV prevention for Men Who Have Sex with Men (MSM)" study (Pulse) is to increase understanding of barriers and facilitators of HIV prevention among HIV-negative MSM who reside in Atlanta, GA; Baton Rouge and New Orleans, LA; Miami, FL; and Jackson, MS.
- **Intended use of the resulting data**: Inform ongoing CDC efforts to effectively target HIV prevention activities for black/African American and Latino/Hispanic men who have sex with men (MSM).
- **Methods to be used to collect** : Qualitative in-depth interviews with brief quantitative questions for 105 HIV-negative black/African American and 45 HIV-negative Latino/Hispanic MSM who reside in Atlanta, GA; Baton Rouge and New Orleans, LA; Miami, FL; and Jackson, MS.
- **The subpopulation to be studied :** Among 150 adult participants, we will specifically target 50 YMSM between the ages of 13 and 24. Of these, we expect to include 15-20 minors aged 13-17 that will have the option to complete the interview in English or Spanish.
- **How data will be analyzed :** Qualitative thematic coding of 150 interview transcripts. Statistical analysis of quantitative survey data.

Supporting Statement

A. Justification

1. Circumstances Making the Collection of Information Necessary

The National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP)/Division of HIV/AIDS Prevention (DHAP) is requesting approval for 1 year of a data collection entitled, "Understanding Barriers and Facilitators to HIV prevention for Men Who Have Sex with Men (MSM)."

Every year in the United States, an estimated fifty-thousand individuals are infected with HIV; over 1.1 million individuals aged 13 years and over are currently living with HIV/AIDS.[1,2] The burden of HIV infection in the United States is disproportionately higher among minority groups, such as MSM and racial and ethnic minorities.[3,4] In 2012, black/African-Americans and Hispanic/Latinos had the highest rate of HIV diagnoses (58.3 and 18.5 per 100 000, respectively).[4] Compared with all other races, black/African Americans account for a higher proportion of people living with HIV (PLWH) at every stage from new infection to death.[5] Young adults aged 20-24 years experienced more new HIV infections (7,087) than any other age group.[4] The majority (67%) of those HIV infections among 20 to 24 year olds were due to male-to-male sexual contact.[4]

Young MSM are disproportionately burdened with HIV.[6] Young MSM (13-24 years of age) experienced a 26% increase in new HIV infections between 2008 and 2011.[3] The CDC estimates that 93% of all diagnosed infections among young adults aged 13-19 years were from male-to-male sexual contact. The burden of HIV infection also remains disproportionately high among racial and ethnic minority populations. As of 2011, nearly 60% of all HIV infections in MSM between 13-24 years of age were among Black/African American males, and 20% of HIV infections were among Hispanic/Latino males. [3] HIV diagnoses among Black MSM between

ages 13-24 years have greatly increased in recent years, from 3,762 reported cases in 2008, to 4,619 reported cases in 2011. [3]

In the Southern United States, factors such as poverty, unemployment, inadequate access to healthcare, and sociocultural environmental factors may explain the higher HIV burden among black/African American and Hispanic/Latino MSM. [10] [11] Sociocultural factors that can impact risk behaviors include racial disparities, a lack of access to prevention and education, high levels of poverty and homelessness, suboptimal healthcare, and the inability to obtain adequate health insurance due to low income levels. [12] Issues such as mistrust in the medical system also prevail [11] [13], resulting in greater HIV-related health disparities among minorities. Black/African Americans comprise 19% of the population in the South (19 million persons), making this racial/ethnic group much larger in this geographic setting compared to other regions such as the Midwest (6.5 million). [12] Black/African Americans who engage in high risk behaviors in the South may experience greater stigmatization with HIV prevention or care service utilization. [11] [12]

The increased risk of HIV transmission and outcomes among racial/ethnic minority adult and minor MSM necessitate targeted interventions towards this group[8] [9]. In order to develop effective programs that decrease risk of transmission and increase preventive behaviors, studies are needed to identify the specific risk factors faced by this vulnerable population. Despite previous studies and efforts, HIV diagnoses are increasing among all MSM, especially for young MSM and MSM of color. Because of this, we continue to need to know more information about how HIV is impacting the lives of MSM. Survey will collect some demographic information to characterize and describe the population of MSM sampled in this information collection request (ICR) and their HIV knowledge. Qualitative methods will be used to explore in-depth the "Whys" and "How's" of HIV transmission and prevention among black/African American and Hispanic/Latino MSM and how these impact increasing prevalence of HIV among communities of MSM of color.

This information collection request will: identify barriers to HIV prevention; explore how MSM[1] integrate HIV prevention into their lives and remain HIV negative (resiliency); explore the role of the wider community in HIV prevention for MSM of color, including the impact of HIV stigma and homophobia; and identify how to integrate biomedical prevention options, such as Pre-Exposure Prophylaxis (PrEP) and non-occupational post-exposure prophylaxis (nPEP), to reduce HIV-related disparities and health inequities among minority MSM. We believe we are among the first to take such a comprehensive approach to examining MSM risk factors, resilience, and potential intervention strategies, such as PrEP and nPEP.

By sampling MSM from five cities in the U.S. South, we will develop a model to help understand the factors associated with specific health risks encountered as well as the protections utilized by MSM in a U.S. region with great HIV burden. By exploring the array of socio-ecological factors across a wide age spectrum and in highly HIV prevalent cities, we will be able to propose meaningful HIV prevention efforts for minority MSM where resources are limited and obstacles such as geographic location, living situation, economics, substance use, poor

[1] For the purposes of this document, MSM includes both minor (13-17 years old, young adult (18-24 years old), and adult (25 and older) men who have sex with men unless otherwise specified.

health, stigma, depression, and lack of health insurance may impact HIV prevention seeking behaviors.
This request is authorized by Title III – General Powers and Duties of the Public Health Service, Section 301 (241.)a. Research and investigations generally (**Attachment 1**). A 60-day Federal Register Notice is provided (**Attachment 2**).

2. Purpose and Use of Information Collection

The purpose of this study is to conduct primarily qualitative research with most at risk HIV-negative MSM based in five cities in the U.S. South. There are four goals to this study: (1) understand issues surrounding HIV risk for MSM; (2) learn more about how gay community or peer norms, and community identification influence risk behaviors; (3) understand individual HIV risk management, such as having a HIV-positive partner with suppressed viral load, barriers and facilitators for use of biomedical interventions (i.e., PrEP, nPEP); and (4) understand factors that promote resiliency among HIV-negative MSM.

The present research will be conducted in the top five Southern metropolitan areas in the United States with the highest HIV diagnoses for MSM– Atlanta, Georgia; Jackson, Mississippi; Miami, Florida; and New Orleans and Baton Rouge, Louisiana. These cities rank among those in the South with the highest prevalence and incidence of HIV and STIs among black/African American and Hispanic/Latino MSM.[16]

Our study population will consist of black/African-American and Hispanic/Latino 1) male adolescents who are attracted to men and report they are HIV negative or have not been tested and 2) adult MSM who are HIV-negative. All study participants will be 13 years of age or older. Participants will be recruited in the selected cities through referrals from Health Departments, clinics and other HIV testing centers. In addition, we will recruit via word-of-mouth referrals or flyers given out by community-based, advocacy, faith-based, and service-providing agencies. For this information collection, MSM includes both minor (13-17 years old, young adult (18-24 years old), and adult (25 and older) men who have sex with men unless otherwise specified. All respondents will respond to the same survey.

For the purposes of this study, we will use a primarily qualitative research design and will include a brief quantitative survey to reduce participant burden where possible (for example, when we do not need to know an in-depth answer for socio-demographics, HIV testing history, housing status, health insurance status). The first portion of the interview instrument consists of brief structured questions to characterize the respondents. The second portion of the instrument consists of open-ended in-depth qualitative questions. This research design was chosen based on the exploratory nature of our study purpose. The data collection instrument is included with this submission (**attachments 3e -f**).

HIV-negative MSM will be purposively sampled from community based HIV prevention organizations, health departments, clinics, and other venues appropriate for the population of interest. Recruiters will schedule in-depth interviews at a time and place convenient to respondents. Interviewers will review study information with the participants and will obtain informed consent and assent (**Attachment 4a-d**) prior to administering the data collection

instrument (**Attachments 3e-f**). We will recruit HIV-negative MSM using recruitment flyers (see **Attachments 6a-d**) which will provide a study phone number for interested persons to call. To determine eligibility of interested respondents, we will administer recruitment screeners (**Attachments 3a-b**). Screeners will provide more information about the study and screen for eligibility. After screening for eligibility and determining eligibility criteria have been met and the individual is interested in participating, recruiters will collect contact information on a separate form (see **Attachments 3c-d**). Using this contact information, interviewers will schedule an in-person interview at a time and place convenient to the participant. Interviewers will obtain consent and assent from the participant (**Attachments 4a-d**) prior to administering the data collection instrument (**Attachments 3e-f**). Participants will have the option of having all procedures (i.e. forms, calls, and in-depth interview) in English or Spanish. Key variables to be explored are described in Exhibit A2.1.

Exhibit A2.1 Items of Information to be Collected

Variables to be explored	**Data collection tool and citation**	**Study Related Procedures**	**Target Population**
Demographics; HIV knowledge; HIV risk behavior; and Resilience; HIV prevention strategies (e.g., negotiated safety); Perceptions of PrEP and nPEP	3e. HIV-negative MSM In-Depth Interview Guide-English	In-Depth Interviews	HIV-negative MSM
Demographics; HIV knowledge; HIV risk behavior; and Resilience; HIV prevention strategies (e.g., negotiated safety); Perceptions of PrEP and nPEP	3f. HIV-negative MSM In-Depth Interview Guide-Spanish	In-Depth Interviews	HIV-negative MSM
Contact information: name, phone number, email	3c. Contact form - English	Contact form	HIV-negative MSM
Contact information: name, phone number, email	3d. Contact form - Spanish	Contact form	HIV-negative MSM

3. Use of Improved Information Technology and Burden Reduction

Due to the sensitive nature of the topics in our interviews, group data collection formats (e.g., focus groups) would not be conducive to obtaining rich information on issues related to HIV prevention such as sexual behavior. For this reason, we will conduct individual interviews. Telephone interviews or visual remote interviews (such as web or Skype interviews) are more difficult for the target population and not a good vehicle for developing the necessary rapport

between interviewer and respondent for a successful qualitative interview on a sensitive topic. Body language and facial cues are critical to understand where additional probing may be needed or should stop, and telephone or web interviews limit the interviewer's ability to read both. Thus, we will conduct individual, in-depth interviews (IDIs) in person. After asking for and receiving permission from the respondent, we will audio-record the interviews and transcribe recordings after the interview. This limits the burden on the respondent (no additional burden after completing the interview) and allows the interviewer to focus on building and maintaining rapport with the respondent.

Following an in-person interview, a project team member will transcribe the recording. We anticipate that Spanish language interviews will be conducted in Miami and Atlanta. They will be transcribed directly into English by an experienced transcriber/translator at the project site (see **Attachment 7** for Spanish Translation Certification).

4. Efforts to Identify Duplication and Use of Similar Information

The interviews will collect key information that the Agency believes is not captured elsewhere. The Agency believes no other survey data collection effort has been conducted or has been planned to collect similar information for these populations. CDC conducted a review of similar studies prior to the issuance of the contract, and determined that this study is collecting unique information from the populations. There is very little research on resiliency among HIV-negative MSM. Also, the biomedical HIV prevention technology is new and rapidly emerging. Knowledge about its uptake or lack thereof, community norms, etc. are not current. Therefore, our evaluation requires the collection of this new primary data. There would be no reason for another Federal Agency to evaluate this.

The following ongoing HHS/CDC collections are closely related, but have differences that warrant the need for this particular data collection (Pulse) as explained below:

OMB No. 0920-0942: HIV Prevention among Latino MSM: Evaluation of a locally developed intervention: This is a randomized control trial conducted by CDC to identify and fund rigorous evaluations of promising but unevaluated behavioral HIV prevention interventions developed by community based organizations (CBOs) for populations at elevated risk for HIV infection with considerable input from served communities. In 2009, Wake Forest and its CBPR partners (specifically, the Chatham Social Health Council CBO) were funded to enhance, implement, and assess the efficacy of the homegrown HIV prevention intervention targeting adult Latino MSM, *HOLA en Grupos.* This study is different from the current Pulse study in that it is an evaluation of an intervention. The main outcomes are to assess behavior modification in intervention versus control groups and not to answer the qualitative research questions as described in this particular study.

OMB No. 0920-0913: Evaluating Locally-Developed HIV Prevention Interventions for African-American MSM in Los Angeles: This is also a randomized control trial conducted by CDC to identify and fund rigorous evaluations of promising but unevaluated behavioral HIV prevention interventions developed by community based organizations (CBOs) for populations at elevated risk for HIV infection with considerable input from served communities. In 2009, LA County

Department of Public Health partnered with the CBO, In the Meantime, Inc. to evaluate the homegrown intervention MyLife MyStyle for young African American MSM ages 18-29 years old. This study is also different from the current Pulse study in that it is an evaluation of an intervention. The main outcomes are to assess behavior modification in intervention versus control groups and not to answer the qualitative research questions as described in this particular study.

OMB No. 0920-1091: Using Qualitative Methods to Understand Issues in HIV Prevention, Care, and Treatment in the United States: This was a request for 3–year approval for a new generic information collection request (ICR) for the mechanism that funds the task orders from which the Pulse study exists. The data collections supported under this generic ICR will be used to assess barriers and facilitators to HIV prevention, care and treatment in the United States and territories; specifically to identify and test ways CDC can improve programmatic activities along the continuum of HIV prevention, treatment and care. It was approved this year. However, the Pulse study was submitted as a standalone ICR in the interim as the generic ICR package was under review.

5. Impact on Small Businesses or Other Small Entities

Since we will only be recruiting 35-40 participants for each of the 5 cities, we will ask health departments, community based organizations (CBOs), and clinics to aid in recruiting potential respondents by identifying eligible potential participants and providing them with a recruitment flyer. These agencies perform HIV testing. When an individual meeting the recruitment criteria that includes receiving a negative test result, the staff will provide them with the flyer for the study. The agencies that agree to assist in recruitment activities, will distribute study recruitment flyers to potentially eligible men after post-test counseling. There will be no additional impact on small businesses or other small entities.

6. Consequences of Collecting the Information Less Frequently

The present study will provide the primary qualitative data needed to understand barriers and facilitators to HIV prevention among HIV-negative MSM at the greatest risk for HIV infection in the U.S. If this evaluation were not conducted, it would not be possible to identify barriers and facilitators and to use this information to strengthen HIV prevention with these vulnerable populations. The length of data collection is 2-3 months and data will only be collected once.

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

This data collection effort does not involve any special circumstances.

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 in the Federal Register on Wednesday. May 13, 2015, Volume 80, Number 92, Page Number 27316-27318. One public comment was received, as shown below, and no CDC response was sent, (**Attachment 2a**).

> "Members of the CDC: HIV is a major health concern and issue that has and will continue to affect our community. I am a gay man and HIV negative. However, before I comment on this docket, I would like to make it very clear that no matter your sexual orientation or your race, you are not an HIV carrier. Some communities may be more at risk than others but it needs to be clear that the LGBT community is not all HIV positive. An issue that I would like to bring to your attention is that many folks are using Pre-Exposure Prophylaxis (PrEP) and having sex without protection because they think that they will be fine since they are taking this medication. I am afraid that PrEP being frequently prescribed and used will lead to new strains of HIV, as well as folks being too comfortable and careless because of PrEP."

In addition, Emory University's Rollins School of Public Health, and Research Support Services, Inc. were consulted for development of this study. There were no unresolved issues associated with the consultation process. Aside from the official 60 day public comment period in the Federal Register, there were no other public contacts or opportunities for public comment on this study.

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9. Explanation of any Payment or Gift to Respondents

We will provide HIV-negative MSM who participate with a token of appreciation totaling $40 to encourage their participation, and convey appreciation for contributing to this important study.

Although there has been some debate on the necessity of offering tokens of appreciation, numerous studies have shown that tokens of appreciation can significantly increase response rates and the use of modest tokens of appreciation is expected to enhance survey response rates without biasing responses [2,3]. In addition, HIV has a stigma that other health issues do not have, which makes it difficult to recruit participants for research when compared to other diseases, (e.g. cancer, diabetes, obesity). One study on research participant recruitment in Hispanic communities, researchers noted that the stigma related to HIV/AIDS is a major barrier in subject recruitment for HIV/AIDS behavioral research[4]. Offering tokens of appreciation is considered necessary to recruit minorities and historically underrepresented groups in to research studies. Barriers cited related to recruitment of minorities included (1) lack of trust among minority communities towards the medical research process and research[567] (2) a lack of competence among researchers to use culturally appropriate approaches for recruitment and[8] (3) reluctance to participate due to inconvenience and a lack of time[1516]. In a recent study of recruitment and retention of Black men who have sex with men (BMSM) by a Community Based Organization (CBO), recruiters found it difficult to retain information from the BMSM because many were reluctant to provide their names and contact information because of concerns about being seen giving these personal details to an HIV prevention program[9]. Concern with potential social labeling and HIV-related stigma also may have contributed to their hesitation[16]. Some of those who were screened provided incorrect contact information, making it difficult or impossible to locate them later[16]. In this study, some agreed to participate in the evaluation because of the tokens of appreciation that was offered[16]. Respondents will receive the token of appreciation regardless of whether they complete the interview or skip any questions.

10. Assurance of Confidentiality Provided to Respondents

The CDC NCHHSTP Coordinator has determined that the Privacy Act does not apply to this information collection. Although personally identifiable information (PII) is being collected on the instrument (**Attachment 3a-3f)**, CDC is not receiving any identifiable information. As the

[2] Abreu, D. A., & Winters, F. (1999). Using monetary incentives to reduce attrition in the survey of income and program participation. *Proceedings of the Survey Research Methods Section of the American Statistical Association.*
[3] Shettle, C., & Mooney, G. (1999). Monetary incentives in U.S. government surveys. *Journal of Official Statistics, 15*, 231–250.
[4] Shedlin, M. G., Decena, C. U., Mangadu, T., & Martinez, A. (2011). Research participant recruitment in Hispanic communities: Lessons learned. *Journal of Immigrant and Minority Health, 13* (2), 352-360.
[5] Quinn S. C *(1997). Belief in AIDS as a form of genocide: Implications for HIV prevention programs for African Americans. Journal of Health Education, 28,(Suppl. 6)S6–S11*
[6] Wrobel AJ, Shapiro NEK. Conducting research with urban elders: Issues of recruitment, data collection, and home visits. Alzheimer Dis Assoc Disord. 1999;13(suppl 1):S34–S38
[7] Gauthier, M. A., & Clarke, W. P. (1999). Gaining and sustaining minority participation in longitudinal research projects. *Alzheimer Disease and Associated Disorders,* 13(Suppl. 1), S29-S33
[8] Goodwin, P. Y., Williams, S. W., & Dilworth-Anderson, P. (2006). The role of resources in the emotional health of African American women: Rural and urban comparisons. In R. T. Coward, L.A. Davis, C.H. Gold, H. Smiciklas-Wright, L.E. Thorndyke, & F.W. Vondracek, (Eds.). Rural women's health: Mental, behavioral, and physical issues (pp. 179 — 196). New York: Springer
[9] Painter, T. M., Ngalame, P. M., Lucas, B., Lauby, J. L., & Herbst, J. H. (2010). Strategies used by community-based organizations to evaluate their locally developed HIV prevention interventions: Lessons learned from the CDC's innovative interventions project. *AIDS Education and Prevention*, *22*(5), 387-401.

nature of this study is to better understand barriers to HIV prevention, we are sensitive to the need to protect personal health information (PHI). To ensure that respondents' PHI is protected, we will take the following measures to separate personally identifiable information (PII) from study-related data; (1) all respondents will receive unique identification codes, which will be stored separately from PII on a password protected computer and or locked file cabinet. CDC will not have access to the identification codes; (2) contact information collected for the purposes of recruiting (i.e., name and telephone number) will be collected and stored securely and separately from responses to screening and or interview questions. This information will not be transmitted to CDC and (3) we will train researchers who play a role in data collection and analysis in proper procedures for securing project data.

We will inform respondents that their responses will be kept private to the extent permitted by the law. All respondents interviewed will be informed that the information collected will not be attributable directly to the respondent and will only be discussed among members of the evaluation team. Terms of the CDC contract authorizing data collection require the contractor to maintain the privacy of all information collected.

In addition, the study plans to utilize a Certificate of Confidentiality to protect the privacy of respondents enrolled in the study. The certificate protects respondents by withholding from all persons not connected with the conduct of such research, the names or other identifying characteristics of respondents without their consent (**Attachment 9**).

Access to all data that identify respondents (or such keys that link de-identified codes to personal information) will be limited to research staff with a data collection or analysis role in the project. Such data will be needed only for scheduling interviews with respondents, and will not be used for analyses. Transcripts will be completed on password protected standalone (non-networked) computers. Access to the transcript files on these computers will require a password, and will only be allowed for staff working on this project and with a need to access. No PII will be included in the transcription. If the respondent divulges PII during the interview, the transcriber will convert the PII to bracketed non-PII descriptor information (i.e., [Daughter's Name]). Although transcripts will *not* contain PII, all transcripts will also be encrypted. No names or identifiers will be used when transcribing the data. Any data sent to CDC will not contain personal identifiers or any other identifier that would allow individual identification of study respondents.

In conjunction with the data policy, members of contractor project staff are required to:

- Ensure project data are secured against improper disclosure or unauthorized use of information by relying the password protected computers and locked file cabinets.
- Access information only on a need-to-know basis when necessary in the performance of assigned duties.
- Notify their supervisor, the Project Director, and the organizational Security Officer if information has either been disclosed to an unauthorized individual, used in an improper manner, or altered in an improper manner.

- Report immediately to both the Project Directors and the organizational Security Officer all contacts and inquiries concerning information from unauthorized staff and non-research team personnel.

The security procedures implemented by the project staff cover all aspects of data handling for hard copy and electronic data. Transcriptions (stripped of PII) will be stored on encrypted flash drives. Additional information about the security protocols for all materials and transcripts can be found in the Data Security Plan (**Attachment 8**) submitted with this document. We will investigate immediately if any item is delayed or lost. When not in use, all completed hardcopy documents will be stored in locked file cabinets or locked storage rooms. All project related documents and audio recordings will be destroyed when no longer needed for the project.

11. Justification for Sensitive Questions

This study is an initiative aimed to assess barriers and facilitators of HIV prevention. As such, our study entails measurement of sensitive HIV-related information. We plan to ask the following questions that may be sensitive to participants:

Potentially Sensitive Questions	**Justification**
Do you think of yourself as Gay, Straight, that is, not gay, Bisexual, Something else, or Don't know/Questioning?	Sexual identity serves to identify affiliation and identification with sexual minority communities (aka "outness")
Of the people you know or see day-to-day, how many know that you are sexually attracted to other males?	Serves to identify avenues of potential instrumental and emotional social support and sense of connectedness to community and/or others.
Now thinking about sex, with how many guys have you had oral sex, that is, penis in mouth or anal sex, that is, penis in butt, within the past 6 months?	Measuring number of sexual partners and sexual acts serves to identify risk factors for HIV/STD acquisition.
In the last 6 months, have you met a new sex partner at the following places: School, Party, Work, Friends, Gay bar/club, Straight bar/club, Internet, Bathhouse, Porn theater/arcade, Other public place, No new sex partner, Refuse to answer	Measuring sex seeking behaviors serves to identify HIV/STD risk.
How frequently have you used the internet to meet sexual partners in the past 6 months?	Measuring internet sex seeking serves to identify HIV/STD risk.
What do you think might put you at risk for getting HIV? How? Why?	Sexual risk perception serves to identify HIV/STD risk and the concordance of the perceptions with actual sexual behaviors.
Who do you personally know that is HIV-positive? Tell me about them without mentioning their names.	This assesses HIV awareness, knowledge regarding the day to day life of HIV positive persons, how the participant feels about their relationships as it relates to their friend/family/associate's HIV status and any

	stigma that may be underlying, and how that relationship and knowledge has impacted the participants own beliefs. This question is important because this population and youth, in particular, could be naïve about living with HIV or overwhelmed and fatalistic with knowing many friends/associates who have HIV and the program wants to assess either of those possibilities and its impact on risk or resilience

Understanding the slight possibility of emotional response or anxiety on the part of the respondent, all staff will be trained to provide respondents with city-specific hotlines for HIV and mental health care organizations as needed. We will inform all respondents that they may skip any question or stop participation at any time for any reason. This study has been reviewed and approve for Human Subjects Protections (**Attachments 5a-e).**

12. Estimates of Annualized Burden Hours and Costs

12A. Estimated Annualized Burden Hours

Recruitment will consist of health departments and CBOs who conduct testing to give HIV negative males who meet the recruiting eligibility criteria the study flyer following post-result counseling. We estimate 1 minute for the flyer distribution (**Attachments 6a -6d)**. We anticipate screening a total of 300 respondents, at various locations, and anticipate the screening process to take 5 minutes per respondent for a total of 26 burden hours (**Attachments 3a-b)**. Of the 300 respondents screened, we anticipate a 50% response rate. We anticipate that recording a participant's contact information to take 1 minute per respondent for a total of 3 burden hours for the 150 participants (**Attachments 3c-d**). We will conduct a 1 hour in depth interview for HIV-negative MSM (minors and adults)**.** We anticipate that the in depth interviews will take a total of 150 burden hours for all 150 study participants (**Attachments 3e-f**). Atlanta, GA is targeted for 40 participants; Jackson, MS is targeted for 35 participants; New Orleans and Baton Rouge, LA are targeted for 35 participants; and Miami, FL is targeted for 40 participants. The total number of burden hours is 179.

Exhibit A12.1: Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses Per Respondent	Average Burden Per Response (in Hours)	Total Burden Hours
General Public- Adults and Minors	3a. HIV-negative MSM Screener-English	210	1	5/60	18
General Public- Adults and Minors	3b. HIV-negative MSM Screener-Spanish	90	1	5/60	8
General Public- Adults and Minors	3c. HIV-negative MSM Contact Information Form-English	105	1	1/60	2
General Public- Adults and Minors	3d. HIV-negative MSM Contact Information Form-Spanish	45	1	1/60	1
General Public- Adults	3e. HIV-negative MSM In-Depth Interview Guide-English	95	1	1	95
General Public- Minors	3e. HIV-negative MSM In-Depth Interview Guide-English	10	1	1	10
General Public- Adults	3f. HIV-negative In-Depth Interview Guide-Spanish	35	1	1	35
General Public- Minors	3f. HIV-negative In-Depth Interview Guide-Spanish	10	1	1	10
Total					**179**

12B. Estimated Annualized Burden Costs

The annualized costs to the respondents are described in Exhibit A12.B. The United States Department of Labor Statistics May, 2014 http://www.bls.gov/oes/current/oes_nat.htm was used to estimate the hourly wage rate for the general public and health diagnosing and treating practitioners for the purpose of this request. This cost represents the total burden hours to respondents multiplied by the average hourly wage rate for adults ($22.71) and the minimum hourly wage rate for minors ($7.25).

Exhibit A12.B. Estimated Annualized Burden Hours

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
State Health Departments and CBOs	6a-6d Recruitment Flyers	5	22.71	113.55
General Public-Adults	3a. HIV-negative MSM Screener-English	16	$22.71	$363.36
General Public - Minors	3a. HIV-negative MSM Screener-English	2	$7.25	$14.50
General Public-Adults	3b. HIV-negative MSM Screener-Spanish	6	$22.71	$136.26
General Public - Minors	3b. HIV-negative MSM Screener-Spanish	2	$7.25	$14.50
General Public-Adults	3c. HIV-negative MSM Contact Information Form-English	2	$22.71	$45.42
General Public – Minors	3c. HIV-negative MSM Contact Information Form- English	1	$7.25	$7.25
General Public-Adults	3d. HIV-negative MSM Contact Information Form-Spanish	1	$22.71	$22.71

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
General Public-Minors	3d. HIV-negative MSM Contact Information Form-Spanish	1	$7.25	$7.25
General Public-Adults	3e. HIV-negative In-Depth Interview Guide-English	95	$22.71	$2,157.45
General Public-Minors	3e. HIV-negative In-depth Interview Guide-English	10	$7.25	$72.50
General Public-Adults	3f. HIV-negative In-Depth Interview Guide-Spanish	35	$22.71	$794.85
General Public – Minors	3f. HIV-negative In-depth Interview Guide-Spanish	10	$7.25	$72.50
Total 0				**$3,822.10**

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

There are no costs to respondents for participating in this survey. All data collection costs for contacting the respondents or record keepers are borne by the federal government through the data collection contractors.

14. Annualized Cost to the Government

The estimated cost to the government is $548,166. This estimate includes the cost of recruitment, screening, conducting the interviews, analysis and reporting, as well as the total cost of the tokens of appreciation ($40 per completed interview, for a total of $6,000).

Exhibit A14.1: Annualized Cost to the Government

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to	CDC, COR (GS-14 0.20 FTE)	$23,362

the Federal Government		
	CDC, Contracting Officer (GS-14, 0.20 FTE)	$23,362
	CDC, Contracting Officer (GS-13, 0.20 FTE)	$29,654
	CDC, Contracting Officer (GS-12, 0.30 FTE)	$23,471
	Subtotal, Direct Costs	**$99,849**
Cooperative Agreement or Contract Costs	Contract Cost: Research Support Services (RSS)	$448,317
	Subtotal, Cooperative Agreement or Contract Costs	**$448,317**
	TOTAL COST TO THE GOVERNMENT	**$ 548,166**

15. Explanation for Program Changes or Adjustments

This is a new information collection request (ICR).

16. Plans for Tabulation and Publication and Project Time Schedule

A final meeting to present the findings from the study will be held in person at CDC in Atlanta at least two weeks before the end of the contract. Tabulation will include descriptive characteristics of study respondents collected in the first part of the interview (e.g., demographics, city, age, race/ethnicity). The project timeline is detailed in exhibit A16.1.

Exhibit A16.1: Project Time Schedule

Activity	**Time Schedule**
Data collection tools, sampling and data pans, study protocol development	2-3 months before OMB approval
Recruitment	1 month after OMB approval
Data Collection	2-3 months after OMB approval
Data analysis finalized and report drafted	4 months after OMB approval
Final data set and final report submitted to CDC	5 months after OMB approval

Rather than providing a traditional final report, CDC has requested that the final report consists of multiple manuscript documents that will be ready or near-ready for submission for publication. The final manuscripts will be submitted March 2, 2016. In addition, a PowerPoint presentation describing results and manuscript production would be produced to describe the findings. A final data set will also be provided. At the same time, in addressing a new and

untested method of presenting findings it is expected that members of contractor project staff will need to work closely together to develop expectations for the number and draft-to-final quality of each manuscript and presentation material achieved by the end of the contract period.

We anticipate that multiple manuscripts will be published in peer reviewed journals, presented at national conferences, and provided on conference websites. Links to these publications will be available through the CDC website.

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

We do not seek approval to eliminate the expiration date.

18. Exemptions to Certifications for Paperwork Reduction Act Submissions

There are no exemptions to the certification.