Generic

Using Qualitative Methods to Understand Issues in HIV Prevention, Care and Treatment in the United States

Supporting Statement A

OMB No. 0920-New

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Contact Person:

James Carey, PhD, MPH
Division of HIV/AIDS Prevention, Prevention Research Branch
Centers for Disease Control and Prevention
1600 Clifton Road NE, Mailstop E-37
Atlanta, GA 30329
Telephone: 404-639-1903
Fax: 404-639-1950
Email: jfc9@cdc.gov

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EXHIBITS

LIST OF ATTACHMENTS

- The goal of this generic ICR is to conduct qualitative studies to quickly identify barriers and facilitators to HIV prevention, care and treatment in specific regions with high HIV burden in the US.
- Intended use of the resulting data is to identify ways to improve local programmatic activities for specific communities along the continuum of HIV prevention, treatment and care for populations and areas with the greatest HIV burden.
- These qualitative studies will collect data using well established rapid assessment methodologies, including: semi-structured and in-depth qualitative interviews, focus groups; direct observations; document reviews; and structured surveys.
- The populations to be studied include local networks of persons living with HIV and persons at high risk of acquiring HIV, including: persons with different racial and ethnic, age, and socioeconomic characteristics; men who have sex with men; transgender persons; and persons and organizations providing HIV prevention, care, and treatment services to impacted populations.
- Data will be analyzed using well established qualitative analysis methods, such as coding interviews for themes about barriers and successes to HIV prevention, care, and treatment. Structured response surveys will be analyzed using descriptive statistics and other appropriate statistical methods.

A. JUSTIFICATION

The Centers for Disease Control and Prevention (CDC), National Center on HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP), Division of HIV/AIDS Prevention (DHAP) requests 3–year approval for a new generic information collection request (ICR) entitled, Using Qualitative Methods to Understand Issues in HIV Prevention, Care and Treatment in the United States. Qualitative studies conducted under this new generic ICR will be consistent with the National HIV/AIDS Strategy, DHAP Strategic Plan, and DHAP's High-impact HIV Prevention approach.[1,2,3] The data collections supported under this generic ICR will be used to understand barriers and facilitators to local HIV prevention, care and treatment in the United States and territories; specifically to identify ways to improve programmatic activities along the continuum

[1] White House. National HIV/AIDS Strategy. 2010. Available at: http://www.whitehouse.gov/administration/eop/onap/nhas.
[2] Centers for Disease Control and Prevention. DHAP Strategic Plan. 2013. Available at: http://www.cdc.gov/hiv/policies/strategy/
[3] Centers for Disease Control and Prevention. High-Impact HIV Prevention: CDC's Approach to Reducing HIV Infections in the United States. 2013. Available at: http://www.cdc.gov/hiv/policies/hip.html.

of HIV prevention, treatment and care for populations with greatest burden of HIV. The proposed collection is authorized under the U.S. Federal Code 42 USC 241, Section 301 of the Public Health Service Act and Public Health Service Act 308 (**Attachment 1**).

Generic Information Collections submitted under this control number will consist of the following criteria:

- A full SSA and SSB will accompany each of the Gen ICs submitted under this generic clearance.
- Studies will survey specific populations in a particular geographic location/setting.
- Studies will only provide local contextual information about the barriers and facilitators to HIV prevention, care, and treatment experienced by specific communities at risk for HIV infection, by HIV-positive persons across the HIV care continuum, and by organizations providing HIV prevention, care, and treatment services.
- Studies will be qualitative in nature, and include a clear description of the qualitative analytic methods employed.
- Study outcomes will be communicated to local stakeholders and organizations in positions to consider and implement site-specific improvements in HIV prevention, care, and treatment for each of the study sites examined. For stakeholders/organizations/agencies outside the local affected communities, all communications will include clear discussion of the limitations of the region-specific, qualitative methods and the non-generalizability of the study outcomes.
- In presenting our findings, given the study methods, it will be clearly stated that any of the practical antidotes developed are not being recommended as policy recommendations or appropriate for widespread adoptions. The methods are intended to allow researchers

to gather information for a specific geographic area or subpopulation, and are not being done in a way that is generalizable to other areas or the national population.

1. Circumstances Making the Collection of Information Necessary

Background

To identify issues and opportunities related to improving the delivery and provision of HIV prevention, care and treatment services to persons living with HIV, CDC/DHAP has formulated a HIV prevention, care and treatment continuum.[4] The HIV continuum has five main steps: (1) diagnosis of HIV infection through HIV testing, (2) linkage to HIV healthcare for those who test HIV positive, (3) retention in care over time so HIV-infected persons receive regular medical care and treatment, (4) provision of effective ART, and (5) achievement of viral load suppression, or a very low level of HIV in the blood, so HIV-infected persons stay healthy and do not transmit the virus to uninfected persons.

According to CDC and other sources, there are significant drop-offs at each step or stage of the HIV continuum. HIV-infected persons who drop off in early steps of the continuum are not able to benefit from ART (stage 4) and achieve viral suppression (stage 5). Recent estimates indicate that approximately 18% of the estimated 1.1 million people living with HIV in the United States are undiagnosed and unaware of their infection. Of those diagnosed, only 66% are linked to care, 37% are retained in care, 33% are prescribed ART, and 25% achieve HIV viral suppression.[14] Analyses of the HIV continuum reveals significant health disparities related to race and age. Blacks/African Americans are less likely to be in ongoing care and have their virus

[4] Hall HI et al. Differences in human immunodeficiency virus care and treatment among subpopulations in the United States. JAMA Internal Med. 2013;173:137-44

suppressed than Hispanics or whites.[5] In addition, younger Americans (aged 25 to 34) are least likely to be retained in care or have their virus suppressed than other age groups.

Primary HIV prevention for populations at highest risk of HIV infection continues to be a priority for CDC. Approximately 50,000 Americans are infected with HIV annually, and the overwhelming majority of these new infections occur among minority and vulnerable communities, including racial and ethnic minority persons; gay, bisexual and other men who have sex with men (MSM); transgender persons; injection drug users; and youth aged 13 to 24 years. CDC estimates that of the 1.2 million people living with HIV in the United States, nearly one in seven (more than 168,000 individuals) do not know they are infected.[6] Primary HIV prevention includes the delivery of HIV prevention programs and services to communities and areas at greatest risk of HIV infection.

These statistics indicate that the public health effort to control the HIV epidemic is far from over and there remains a critical need to understand the issues, behaviors, barriers and facilitators experienced by individuals and communities most impacted by HIV, to better focus primary and secondary prevention efforts especially in vulnerable communities, and to increase engagement in HIV treatment and care for all HIV-infected persons. For example, to successfully engage persons living with HIV at every stage of the HIV prevention, care and treatment continuum, it is important to understand why some individuals do not test for HIV or seek medical care when they receive an HIV diagnosis; or drop out of care; or do not adhere to antiretroviral therapy (ART). Both primary and secondary prevention must be successful in order

[5] Whiteside et al. Progress along the continuum of HIV care among blacks with diagnosed HIV- United States, 2010. MMWR Morb Mortal Wkly Rep. 2014 Feb 7;63(5):85-9.

[6] CDC. Monitoring selected national HIV prevention and care objectives by using HIV surveillance data - United States and 6 U.S. dependent areas - 2012. HIV Surveillance Supplemental Report 2014;19(No. 3). Available at: http://www.cdc.gov/hiv/library/reports. Published November 2014. (Accessed November 25, 2014).

to curb the epidemic in the U.S., especially in the most vulnerable populations and geographic areas with the greatest HIV burden.

CDC/DHAP Initiative to Conduct Qualitative Studies

To rapidly explore issues impacting HIV prevention, care and treatment in the United States, the CDC's DHAP created a 5-year indefinite delivery, indefinite quantity (IDIQ) contract mechanism in September 2013. This IDIQ mechanism supports using well established rapid assessment methods to understand critical issues impacting HIV prevention, care and treatment for persons and communities most impacted by the HIV epidemic.

CDC/DHAP intends to use findings from the qualitative studies to strengthen HIV prevention efforts in impacted communities and geographic areas. We anticipate that studies under this generic ICR will explore barriers and facilitators that hinder or promote HIV prevention at a much deeper level than existing quantitative national data collections.[7] [8] [9] Prior studies based on national data collections may suggest reasons for successes and failures in HIV prevention among different populations residing in different parts of the United States. However, only qualitative data collections can explore the "Whys" and "How's" of the successes and failures of HIV prevention efforts, and how the lives of people are directly impacted by specific programs and prevention activities. The following example describes methods that could be used to obtain detailed in-depth assessment of local HIV prevention efforts for high-risk MSM in an urban area of the United States with significant HIV burden. Example data collected would include:

[7] Centers for Disease Control and Prevention (2014, May 16). *HIV Surveillance Supported by the Division of HIV/AIDS Prevention*. Available at: http://www.cdc.gov/hiv/statistics/recommendations/publications.html
[8] Centers for Disease Control and Prevention (2014, April 30). *National HIV Behavioral Surveillance (NHBS)*. Available at: http://www.cdc.gov/hiv/statistics/systems/nhbs/
[9] Centers for Disease Control and Prevention (2014, March 4). *National HIV Behavioral Surveillance (NHBS)*. Available at: http://www.cdc.gov/hiv/statistics/systems/mmp/index.html

- Key participant interviews (KPI) would be conducted with 30 persons who have in-depth knowledge of HIV prevention efforts for MSM in the urban area of interest. Data collection would also include in-depth interviews, 2-3 focus groups, and brief structured surveys.

- Persons sampled for the KPI would be purposively selected to include varied perspectives on the local HIV epidemic among MSM living in the urban area. For this example genIC, persons recruited would include: HIV and STD control program staff from the local health department; Ryan White program personnel involved with HIV clinical care; non-governmental HIV healthcare providers (including mental health and drug treatment providers); staff from other governmental agencies that provide other HIV support services to MSM (e.g., non-HIV healthcare facilities, social services); staff from community-based organizations who work with MSM; local researchers who may study MSM in the urban area; members of community planning groups with an interest in public health issues; MSM advocacy groups; men from the local gay community, and other persons with a relevant perspective on the local HIV epidemic among MSM, including persons with different racial and ethnic, age, socioeconomic, and HIV status characteristics.

- Data collection would occur over a 3-4 week period depending on participant schedules.

- Transcripts of audio-recordings would be entered into qualitative data analysis software. The interviews would be systematically coded for themes using well established qualitative analytic methods. Codebooks would be created inductively or deductively depending on the study purpose. Structured-response data would be entered into

statistical software and analyzed using descriptive statistics and bivariate or multivariate statistical procedures as appropriate.

The findings from studies conducted under this generic IC umbrella would identify barriers, successes, and other issues in local HIV prevention resources for individuals with HIV. Analysis would provide a detailed description of the contextual factors of HIV prevention and care efforts, activities, successes, and challenges in the urban area. Results from each data collection under this umbrella generic ICR will be communicated to relevant public health officials and community stakeholders in the study locations. The findings would not be generalizable to other urban areas or subpopulations and the data will not be combined to infer national representativeness.

We expect each study under this generic ICR to focus on specific study populations, geographic locations, and settings that have been identified as having the most acute HIV prevention, care and treatment needs (e.g., areas that have high HIV incidence, prevalence, or previously documented challenges in the successful delivery of HIV prevention, care, or treatment services). Identification of these specific study populations, geographic locations, and settings will be determined by CDC DHAP as a result of other existing research and public health surveillance data collected by CDC or other Federal, state, and local agencies. Different jurisdictions throughout the United States have widely divergent HIV prevention, care, and treatment needs. Although there are commonalities across jurisdictions, there is no single set of specific public health solutions that optimally fit the needs of all groups in all areas of the country. For example, HIV-related public health needs in Broward County, Florida are very different from the challenges faced in New York City.

Studies covered under this generic ICR will provide local contextual information about barriers and facilitators to HIV prevention, care, and treatment experienced by communities at risk for HIV infection, by HIV-positive persons across the HIV care continuum, and by organizations providing HIV prevention, care, and treatment services. Examples of HIV prevention, care, and treatment activities and programs that might benefit from a better understanding of local barriers and facilitators include:

- Delivery of primary prevention programs, including PrEP (pre-exposure prophylaxis) and nPEP (post-exposure prophylaxis) with HIV-negative populations engaged in high-risk sexual or drug use behaviors
- HIV testing programs and providers
- Successful delivery of HIV test results
- Successful linkage of persons diagnosed with HIV to qualified medical care providers and services
- Sustained retention of HIV-positive persons in medical care
- Delivery of HIV treatments prescribed to HIV-positive patients in accord with current Department of Health and Human Services (DHHS) HIV treatment guidelines[10]
- Patient engagement in HIV treatment and care plans
- Patient adherence to their HIV anti-retroviral treatment medications

[10] Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Department of Health and Human Services. Available at http://aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf. Section accessed September 11, 2014

- On-going medical supervision of patients taking HIV anti-retroviral treatment medications (e.g., monitoring unwanted drug side effects, or effectiveness of the specific treatment regimen in suppressing the patient's HIV viral load in their body)
- Linking HIV-positive persons to other medical or social services that may affect the success or failure of their HIV treatment (e.g., mental health, substance abuse, homelessness, language or cultural issues, transportation, other sexually transmitted diseases, other major health conditions, poverty, health insurance, etc.).

Collections conducted under this generic evaluating the aforementioned programs will be qualitative in nature and region-specific, and thus not intended to evaluate program efficacy, outcomes, impact—or influence determinations of future funding for such programs. Generic studies in this clearance may be utilized to inform the design of broader impact evaluations or provide suggestions that will facilitate process improvement in programs within specific communities.

Each specific sub-study will consist of 30 (minimum) to 200 (maximum) persons selected from a variety of potential sources that will be appropriate for the study, such as: (1) potential respondent lists generated by partner organizations (e.g., National Medical Associations), (2) advertisements placed on the Internet (e.g., banner ads, electronic bulletin boards, Listservs), (3) individuals who respond to advertisements placed by external partner organizations (e.g., community-based organizations, health departments, community health centers, STD and HIV care clinics, VA hospitals and clinics, non-governmental organizations), (4) individuals recruited from venues populated by those at high risk for acquisition or transmission of HIV (e.g., bars,

clubs, events), or (5) individuals who receive HIV prevention, treatment and care services from external partner organizations.

In-person interviews will be conducted by project staff at agreed-upon times and in convenient locations, and informed consent will be obtained from all respondents prior to data collection. For example, in a study of HIV providers, participants will be sampled and selected from a pre-determined list of known HIV care providers in a given area, and recruiters will schedule interviews at a time and place convenient to the participant and obtain informed consent prior to conducting the interview. In studies that include at-risk populations, for example, participants will be recruited using flyers which provide a telephone number for interested persons to call for more information. Information about the study will be provided and eligibility will be determined over the phone or in person by a trained recruitment specialist using a brief screener. Recruiters will collect basic contact information from eligible and interested participants for the purposes of scheduling an interview. The interviewer will contact the participant to schedule an in-person interview at a time and place convenient to the participant. Interviewers will obtain informed consent prior to administering the interview.

Over a 3 year period, an estimated maximum of 9 data collections (i.e., an average of 3 data collections per year) will be conducted, each involving 30 to 200 respondents. If 3 data collections occur per year, then between 90 to 600 respondents will be recruited each year, resulting in 270 to 1,800 total study respondents over a 3-year period. The data collection instruments will be submitted with each GenIC under this generic ICR.

2. Purpose and Use of Information Collection

The overall purpose of the qualitative studies supported under this generic ICR is to conduct qualitative studies to identify issues and answer questions necessary to improve local programmatic activities along the continuum of HIV prevention, treatment and care for populations and communities with greatest HIV risk and disease burden. Populations for this generic ICR include: persons living with HIV who are in treatment; persons living with HIV who are out of treatment and who may or may not be seeking treatment at healthcare facilities; persons at high risk for HIV acquisition (HIV negative) and HIV transmission (HIV positive); persons from groups at high risk for HIV including gay, bisexual and other MSM, transgender persons, and injection and non-injection drug users; persons from racial and ethnic minorities; and healthcare providers or other professionals who provide HIV prevention, care and treatment services. Other populations may include individuals who provide non-HIV services or otherwise interact with persons living with HIV or persons at risk for HIV acquisition.

Results from each data collection under this umbrella generic ICR will be communicated to relevant public health officials and community stakeholders in the study locations. The relevant stakeholders to receive study results will be specified in each GenIC submitted under this generic ICR. For example, relevant public health officials might include local health department personnel involved with HIV prevention, care, treatment. Relevant community stakeholders might include non-governmental healthcare service providers or staff of community based organizations involved with HIV prevention, care, treatment. These local public health officials and community stakeholders will use the study results to guide strategies to further strengthen their local HIV prevention, care and treatment efforts within their regions.

3. Use of Improved Information Technology and Burden Reduction

This generic ICR involves the use of qualitative methods to quickly collect timely data to understand issues impacting effective HIV prevention, care and treatment among groups with the greatest HIV burden in specific communities within the United States. These methods also may include descriptive statistical reporting of quantitative structured response surveys to describe participant socio-demographics, HIV prevention knowledge, attitudes, behaviors, and intentions, and other descriptive information of the study sample collected using Computer Assisted Survey Instrument (CASI) technology. CASI data collection will involve the use of a laptop or tablet to facilitate ease of response. Respondents move through the computerized instrument privately and responses are stored in a database. This assists with respondent privacy and can be quicker to administer than face to face or paper and pencil survey instruments, thereby reducing some of the burden on the respondent.

4. Efforts to Identify Duplication and Use of Similar Information

In designing the qualitative data collection activities, we have taken several steps to ensure that this information is not captured elsewhere. Further, we believe that no existing data sets would address the proposed study questions. To identify the need for a qualitative study, CDC conducts a review of the literature and findings from surveillance and other datasets prior to the issuance of the IDIQ contract. For example, CDC reviews existing data to determine whether information on local barriers and facilitators of HIV prevention, treatment and care exist Available data include data collected by the Behavioral Risk Factor Surveillance System[11] the

[11] Centers for Disease Control and Prevention (CDC). (2005). *Behavioral Risk Factor Surveillance System Survey Data*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention.

National Health Interview Survey[12], the National Survey on Family Growth[13], National HIV Behavioral Surveillance Survey[14] and the Medical Monitoring Project (MMP).[15] Once CDC determines that relevant information does not exist in these available data, the call for a qualitative study is issued.

5. Impact on Small Businesses or Other Small Entities

No small entities will be included in this data collection.

6. Consequences of Collecting the Information Less Frequently

The present qualitative study generic ICR will provide timely and relevant contextual data needed to understand and respond to barriers and facilitators to HIV prevention, care, and treatment in selected cities and jurisdictions with greatest HIV burden in specific communities within the United States. If these collections were not conducted, it would not be possible to assess the impact of contextual issues on effective HIV prevention, care, and treatment for populations at greatest risk for HIV infection and transmission, or the immediate needs of frontline HIV care and service providers for these populations. Although the period of performance for the task order contracts may be longer, the length of each data collection will be 2 to 12 months, and data will only be collected once for each task order.

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

This data collection effort does not involve any special circumstances.

[12] Lethbridge-Çejku, M., Rose, D., & Vickerie, J. (2006). *Summary health statistics for U.S. adults: National Health Interview Survey, 2004.* Hyattsville, MD: National Center for Health Statistics.
[13] Abma, J. C., Martinez, G. M., Mosher, W. D., & Dawson, B. S. (2004). *Teenagers in the United States: Sexual activity, contraceptive use, and childbearing, 2002.* Hyattsville, MD: National Center for Health Statistics.
[14] Gallagher, K. M., Sullivan, P. S., Lansky, A., & Onorato, I. M. (2007). Behavioral surveillance among people at risk for HIV infection in the U.S.: The national HIV Behavioral Surveillance System. *Public Health Report, 122*(Suppl 1), 32–38.
[15] Valverde E, Beer L, Johnson C, Blair JM, Mattson CL, Sanders C, Weiser J, Skarbinski J. Prevention counseling practices of HIV care providers with patients new to HIV medical care: medical monitoring project provider survey, 2009. J Int Assoc Provid AIDS Care. 2014 Mar-Apr;13(2):127-34.

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 2/24/2014, Vol. 80, No. 36, pages 9727-9728 (**Attachment 2**). Public comments were received and are included in **Attachment 2a**. The standard CDC courtesy response was sent in reply to each comment. No comments were received in response to the 30 day notice, which was published in the *Federal Register* on 5/28/2015, Vol. 80, No. 102, pages 30462-30463 (**Attachment 2b**).

Atlas Research and Research Support Services may consult with public health scientists on the study design, and data collection instruments, and with several survey specialists to estimate the interview burden for each respondent. When needed, specific consultants will be identified in each GenIC.

9. Explanation of any Payment or Gift to Respondents

For most ICRs submitted under this generic ICR, we anticipate tokens of appreciation. Small tokens of appreciation may be used, and would include but are not limited to gift certificates to grocery stores or retail pharmacies and cash. The type and amount of the token of appreciation will depend on the burden imposed by different activities. Amounts will be consistent with government-wide practices, including, a $40 incentive for a one-hour cognitive interview (designed to include needs associated with traveling to a facility (e.g., gas, parking, taxi, day care needs)), up to $75 for a 90 – 120 min. focus group (includes travel associated needs. We will include a written justification in the specific genIC request for any 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.[16,17] 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 noted that the stigma related to HIV/AIDS is a major barrier in subject recruitment for HIV/AIDS behavioral research.[18] Offering tokens of appreciation is sometimes necessary to recruit minorities and historically underrepresented groups in to research. In a recent study of recruitment and retention of black men who have sex with men by a Community Based Organization, recruiters found it difficult to collect information from the men as 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.[19] Concern with potential social labeling and HIV-related stigma also may have contributed to their hesitation.[16] In this cited study, some agreed to participate in the evaluation because of the tokens of appreciation offered[16]. Respondents who show up at a testing facility for a focus group, test, or interview may receive the token of appreciation regardless of whether they complete the interview or skip any questions.

10. Assurance of Confidentiality Provided to Respondents

In each qualitative study, respondents will be informed 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

[16] 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.*
[17] Shettle, C., & Mooney, G. (1999). Monetary incentives in U.S. government surveys. *Journal of Official Statistics, 15*, 231–250.
[18] 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.
[19] 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.

discussed among members of the research team (**Attachment 4**). Terms of the CDC contracts (Contract # 200-2013-57341 for Research Support Services, and Contract # 200-2013-57339 for Atlas Research LLC) authorizing data collection require the Contractors to maintain the privacy of all information collected. Accordingly, data will be kept private and protected to the extent permitted by law and in accordance with current federal information security standards and other applicable regulations.

IRB Approval

Each qualitative study will be required to obtain local IRB review and approval, which will be included as supplementary documentation with each Gen IC submission. Each study will also be reviewed to determine the need for CDC IRB approval based on the access by CDC staff to personally identifying information or information in an identifiable form provided by study respondents. Should CDC staff have access to respondent information in an identifiable form, CDC IRB oversight is required in addition to local IRB oversight. When the study has been approved by the IRB, a copy of the approval letter will be submitted as an attachment to the genIC under this generic ICR.

10.1 Privacy Impact Assessment Information

Overview of the Data Collection System - CDC's Contractors, Atlas Research or Research Support Services, will implement all qualitative studies. In some cases, Atlas Research or Research Support Services may arrange for project staffing assistance from other subcontracting organizations. Data collection methods used in these qualitative studies include well established qualitative methods, including in-depth open-ended individual interviews, semi-structured open-ended individual interviews, focus groups, direct observations (for example, of neighborhoods),

and document reviews (for example, of testing venue procedures for linking recently diagnosed persons to medical care). Quantitative methods include the use of brief structured surveys, using interview administered, pen and paper, web-based, or computer assisted survey techniques in ways that minimize respondent time burden. All respondents will provide informed consent and will be told that participation is voluntary. Interviews will be conducted after consent is obtained at a time and in a location convenient to the participant. Interviews will be available in Spanish as necessary.

Description of the Information to be collected – Qualitative studies will collect qualitative and quantitative data relevant to the research purpose of each assessment. Examples of research purposes include: "How to increase access to and utilization of care, improve health outcomes, and reduce HIV-related health disparities and inequities among black/African American men living with HIV in Jackson, MS? "What are the perceived barriers and facilitators among HIV providers to provision of HIV care and treatment, with a specific emphasis on engagement in care and retention in care for MSM of color in Washington, DC?" "How receptive are gay, bisexual and other men who have sex with men in 5 cities in the U.S. South at greatest risk for HIV infection, to antiretroviral use for Pre-Exposure Prophylaxis (PrEP)?" and "What strategies do male partners of MSM living with HIV in Miami use to manage their HIV risk (e.g., frequency of HIV testing, partner selection, condom use, antiretroviral use for pre-exposure prophylaxis or PrEP)?"

In-depth or semi-structured individual interview guides will include questions and probes designed to collect information pertinent to the research purposes of the specific study. Question topic areas for interviews with high risk HIV negative persons and for HIV positive persons will include, but are not limited to, HIV risk behavior, sexual risk behavior, challenges to condom

use, perceptions of Pre-Exposure Prophylaxis (PrEP), exploration of participants' understanding of treatment adherence, barriers to attending medical appointments, or the impact of HIV stigma on treatment seeking decisions. In addition to open-ended qualitative questions, we may collect quantitative information on the following: socio-demographics; other respondent characteristics; sexual identity, sexual attraction and gender identity; behaviors, attitudes, and intentions; HIV testing; substance use; if HIV-infected, information regarding date of diagnosis, current HIV-1 viral load and CD-4 count, use of ART, and length of time in HIV care.

In studies that sample HIV providers or others who provide prevention, care, and treatment services to persons with HIV or at risk for HIV infection, we will include qualitative questions about professional experiences engaging HIV patients in care, issues related to referring patients to other services, following patients and maintaining engagement, providing treatment, and medication adherence. Quantitative data will include: socio-demographics, or other respondent characteristics, such as roles in the organization, medical specialty, or years in practice. Qualitative studies included under this generic ICR will collect contextual information, such as characteristics of respondents' communities, workplaces, affiliated organizations, or locations. The collected socio-demographic and contextual information will be used to describe the characteristics of the population and to discuss limitations of generalizability to other populations.

It is expected that the majority of research studies will include participants 18 years of age or older. Depending on the focus of the qualitative study, information may be collected from respondents under the age of 18 years. Information will not be collected from respondents under the age of 13 years. Protocols for participants under the age of 18 will comply with 45 CFR 46.408 regulations. Prior to data collection, all protocols for studies conducted under this generic

ICR will undergo human subject's protection review and receive documented approvals by the Institutional Review Boards (IRB) relevant to the needs of each specific study.

As the nature of each qualitative study under this generic ICR is to understand issues related to HIV prevention, care and treatment, we are sensitive to the need to protect personal health information (PHI) or other individually identifying information. The Contractors (Atlas Research and Research Support Services and their subcontractors) take several measures to separate personal identifiable information from study-related data and maintain restricted access to all information collected. All respondents will receive unique identification codes which will be stored separately from identifiable information. Contact information is collected for the purposes of scheduling interviews only (i.e., name, telephone number) and will be stored securely and separately from responses to screening or interview questions. We will train researchers who play a role in data collection and analysis in proper procedures for data handling. Only authorized Contractor staff will have limited need-to-know access to personal identifiers, and this information will be destroyed as quickly as possible after it no longer is required for study purposes. The Contractors will use systems to protect PHI and IIF that comply with the current federal information security standards and other applicable regulations, and overseen by the CDC Office of the Chief Information Security Officer. It is the intent of each qualitative study to never allow CDC access to any personally identifying information. The Contractor staff will be prepared to describe these procedures in full detail and to answer any related questions raised by participants.

Access to all data that identify respondents (or such keys that link de-identified codes to personal information) will be limited to Contractor 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 in the analysis. Transcripts will be completed on password protected standalone (non-networked) computers. Access to the transcript files on these computers will require password, and will only be allowed for staff working on this project and with a need to access the data. No personal identifying information will be included in the transcriptions of the interviews. If the respondent divulges personal identifying information during the interview, the transcriber will convert the personal identifying information to bracketed descriptor information (i.e., [Daughter's Name]). Although transcripts will *not* contain personal identifying information, all transcripts will also be encrypted to further enhance data security. 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 identification of study respondents. In conjunction with the data policy, members of Contractor project staff are required to:

- Comply with a Privacy Pledge and Security Manual procedures to prevent improper disclosure, use, or alteration of private information. Staff may be subjected to disciplinary and/or civil or criminal actions for knowingly and willfully allowing the improper disclosure or unauthorized use of information.
- 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 project staff cover all aspects of data handling for hard copy and electronic data. Transcriptions (stripped of personal identifying information) will be stored on encrypted flash drives or password-protected study laptops. We will investigate immediately if any item is delayed or lost. Completed hardcopy documents will be stored in locked file cabinets and in locked storage rooms or offices. These documents will be destroyed at the completion of the project. While sensitive information will be collected, the complete separation of IIF and survey data as described will safeguard and secure respondent privacy and minimize the chances of a breach of privacy. See Section A.11 for additional details related to the collection of sensitive information for data collection activities.

CDC will receive data for analysis in aggregate form. The randomly generated numbers assigned as participant ID numbers will not link data to individuals. CDC will never have access to any type of personally identifying information. Information in identifiable form (IIF) will not be shared with CDC. This information will be stored separately from the survey and interview data and will not be linked in any way to participant responses. After it is no longer needed for study purposes, the Contractors will destroy IIF. Procedures for collecting, managing, and safeguarding IIF will be thoroughly described in each written protocol for each qualitative study conducted under this generic ICR. Before any data is collected, each study protocol will be reviewed for human subjects' protection issues by the relevant Institutional Review Boards (IRB).

11. Justification for Sensitive Questions

Due to the nature of the proposed qualitative study topics, we anticipate that some of the information we collect (i.e. sexual behavior and practices, HIV status, etc.) will be sensitive in nature. However collecting this information is essential to our understanding experiences of discrimination and stigma, and other HIV-related social determinants of health; and how these experiences are related to health outcomes such as delayed entry into HIV care and treatment, lower retention levels once in care, poor adherence to antiretroviral therapy (ART), and excessive HIV-related morbidity and mortality. Understanding the possibility of emotional response or anxiety on the part of the respondent (e.g., PLWH, HIV-discordant partner, etc.), all staff will be trained to provide respondents with local resources for HIV and mental health care organizations. We will inform all respondents that they may skip any question or stop participation at any time for any reason or if a question makes them uncomfortable.

12. Estimates of Annualized Burden Hours and Costs

12A. Estimated Annualized Burden Hours

Exhibits A12.1 and A12.2 provide details about how this estimate of burden hours and costs were calculated. We calculated the overall burden per respondent by multiplying the frequency of response by the time to complete each data collection item. We anticipate that screener forms (**attachment 3a**) will take 5 minutes to complete each, contact information forms (**attachment 3b**) will take 1 minute to complete each, and consent forms (**attachment 4**) will take 5 minutes to complete each. We anticipate 50 percent of the targeted populations screened will be eligible for the study. Of eligible persons, 75% will agree to participate. Brief structured surveys (**attachment 3c and 3e**) will take 15 minutes to complete. In-depth interviews or focus groups with respondents (**attachment 3d**) are expected to take 60 minutes (1 hour) to complete.

In-depth interviews or focus groups with healthcare providers are expected to take 45 minutes to complete (**attachment 3f**). An estimated 9 data collections will be conducted over a 3 year period.

For a given year, each separate data collection will range from 30 (minimum) to 200 (maximum) respondents based on the nature and scope of the research purposes. If there are 3 data collections, the maximum number of expected respondents is 600. In a given year, we anticipate that we will need to screen 1600 persons to identify 800 eligible persons, of which 600 persons will agree to participate. The total annual response burden based on an average of 600 study respondents per year (assuming 3 large data collections involving 200 participants each) is estimated at 918 hours (see Exhibit A12.1). Assuming an average of 3 data collections occur per year, there will be an estimated range of 270 (minimum) to 1800 (maximum) total study respondents summed over a 3-year period. For this 3 year generic ICR, the number of burden hours is estimated at 2,754.

Exhibit A12.1: Estimated Annualized Burden Hours

	Form Name	No. of Respondents*	No. of Responses Per Respondent	Average Burden Per Response (in Hours)	Total Burden Hours
General Public-Adults	Study Screener (att 3a)	1600	1	5/60	133
General Public-Adults	Contact Information Form (att 3b)	600	1	1/60	10
General Public-Adults	Consent Form (att 4)	600	1	5/60	50
General Public-Adults	Demographic Survey (att 3c)	500	1	15/60	125
General Public-Adults	Interview Guide (att 3d)	500	1	1	500
General Public-Adults	Provider Demographic Survey (att 3e)	100	1	15/60	25
General Public-Adults	Provider Interview Guide (att 3f)	100	1	45/60	75
				Total	**918**

12B. Estimated Annualized Burden Costs

The annualized costs to the respondents are described in Exhibit A12.2. The United States Department of Labor Statistics May, 2013 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 generic ICR. The total estimated cost of the burden to respondents is approximately $21,858.94 per year (assuming 3 large data collections that include 200 participants each). For a 3-year period, the estimated cost of the burden is $65,576.82.

This cost represents the total burden hours to respondents multiplied by the average hourly wage rate ($22.33 for general public) and ($35.93 for healthcare providers). We assume this estimate is higher than what it may actually be based on data from the Bureau of Labor Statistics' Current Population Survey in which respondents who identified as Black or African American and respondents who identified as Hispanic or Latino Ethnicity reported lower median weekly earnings than respondents who identified as White.[20]

Exhibit A12.2. Estimated Annualized Burden Costs

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
General Public-Adults	Study Screener (att 3a)	133	$22.33	$2,969.89
General Public-Adults	Contact Information Form (att 3b)	10	$22.33	$223.30
General Public-Adults	Consent Form (att 4)	50	$22.33	$1116.50
General Public-Adults	Demographic Survey (att 3c)	125	$22.33	$2,791.25
General Public-Adults	Interview Guide (att 3d)	500	$22.33	$11,165.00
General Public-Adults	Provider Demographic Survey (att 3e)	25	$35.93	$898.25
General Public-Adults	Provider Interview Guide (att 3f)	75	$35.93	$2,694.75
			Total	**$21,858.94**

***Assumption:** 3 large qualitative studies that include 200 participants per year; 600 participants total.

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

[20] BLS, "Usual Weekly Earnings of Wage and Salary Workers: Third Quarter 2013," http://www.bls.gov/news.release/wkyeng.toc.htm.

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 carry out the data collection activities each year of the project is $515,374 (See Exhibit A14.1). 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 $4,000).

Exhibit A14.1: Annualized Cost to the Government

Expense Type	**Expense Explanation**	**Annual Costs (dollars)**
Direct Costs to the Federal Government	CDC, COR (GS-14 0.20 FTE)	$22,901
CDC oversight of contractor and project	CDC, Contracting Officer (GS-13, 0.20 FTE)	$19,950
	CDC, Contracting Officer (GS-12, 0.30 FTE)	$21,570
	CDC, Contracting Officer (GS-12, 0.30 FTE)	$21,570
	Subtotal, Direct Costs	**$85,991**
Cooperative Agreement or Contract Costs	Contract Cost (ATLAS)	$139,526
	Contract Cost (RSS)	$289,857
	Subtotal, Cooperative Agreement	**$429,383**

	or Contract Costs	
	TOTAL COST TO THE GOVERNMENT	**$ 515,374**

15. Explanation for Program Changes or Adjustments

This is a new generic information collection request (ICR).

16. Plans for Tabulation and Publication and Project Time Schedule

A final meeting to present the findings from the qualitative studies will be held in person at CDC in Atlanta at least two weeks before the end of the contract. The project timeline detailing key events and reports is shown 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; Range 2-12 months maximum
Data analysis finalized and manuscript(s) drafted	4-14 months after OMB approval
Final data set and final manuscript(s) submitted to CDC	5-15 months after OMB approval

16.1 Tabulation

Tabulation will include descriptive characteristics of study respondents collected in the first part of the interview (e.g., demographics, geographic area).

16.2 Publication

After a study is completed and we have developed a series of pragmatic action steps on how to use and disseminate our findings and recommendations to local stakeholders and organizations in positions to consider and implement improvements in HIV prevention, care, and treatment for each of the study sites examined. Specific dissemination methods might include but not be limited to face-to-face meetings; group or conference presentations at the local, state, or national level; Internet websites or webinars; conference calls; scientific journal articles; or other written reports. In presenting our findings, given the study methods, we will be clear that any of the practical antidotes developed are not being recommended as policy recommendations or appropriate for widespread adoptions. Our methods will allow us to gather information for a specific geographic area or subpopulation, and are not being done in a way that is generalizable to other populations, areas or the national population. We forecast that the people and organizations reached through these dissemination efforts may include but not be limited to:

- Community residents, stakeholder groups, organizations, or public health researchers in the area where the study took place
- State and local health department personnel, especially including individuals involved with HIV/AIDS programs
- Branches within CDC/DHAP that are involved with direct programmatic support, communication, and capacity building assistance for jurisdictions and community based organizations throughout the nation.

- Personnel and offices involved with HIV issues in other Federal agencies (e.g., Ryan White HIV care and treatment programs supported by HRSA, etc.); we will emphasize the qualitative nature of our study approach when sharing results in this space.

- Individual providers, networks, and professional associations involved with promoting HIV prevention, care and treatment, as well as related public health and social services, at the local, state, and national level; we will emphasize the qualitative nature of our study approach when sharing results in this space.

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.