

Web-Based HIV Behavioral Survey among Men who have Sex with Men

0920-NEW

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Supporting Statement A

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A. Justification

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) requests approval for a new data collection called the "Web-Based HIV Behavioral Survey among Men Who Have Sex with Men (MSM)" (the "web-based survey") for a period of three years.

Background

One of the groups at highest risk for HIV infection in the United States is men who have sex with men (MSM). In 2008, 75% of HIV infections diagnosed were among males, the majority of whom were men who have sex with men (Centers for Disease Control and Prevention 2009). Although MSM are estimated to comprise approximately 4 percent of the U.S. population (Purcell, Johnson et al. 2010), in 2006 they accounted for more than half of all of new infections(53%) (Centers for Disease Control and Prevention 2009) and from 2005-2008, experienced an estimated 17% increase in diagnoses of HIV infections(Centers for Disease Control and Prevention 2010). They are the only risk group for whom infection rates have continued to increase since the 1990's. MSM are more than 44 times as likely to be diagnosed with HIV compared with other men.

Since 2003, CDC has implemented surveillance of HIV-related behaviors among MSM through the National HIV Behavioral Surveillance System (OMB # 0920-0770 exp. 03/31/2011). NHBS has provided critical information to guide HIV prevention efforts, but has some limitations. The geographic scope of NHBS is limited to a maximum of 25 metropolitan areas selected based on HIV/AIDS prevalence. Venue-based sampling with in-person interviewing is used, which is inefficient to implement nationally, and may not reach a broad enough group of MSM in some areas. As interventions to prevent the spread of HIV among MSM are intensified, the value of information like that from NHBS for measuring progress or indicating that the implementation of prevention strategies should be adjusted has increased. Yet data on MSM are collected only every three years through NHBS, which is not optimal for monitoring trends.

The internet holds promise as an alternative way to reach a broad group of MSM to collect information about sexual risk behavior and utilization of HIV prevention services. This

data collection request is for the use of an electronic, self-administered web-based survey that will permit efficient annual data collection nationally. The data are expected to enhance CDC's ability to monitor national HIV risk behavior trends and direct HIV prevention programs and policies for MSM.

The web-based survey will collect annual behavioral data on internet-using MSM within 56 U.S. jurisdictions (all 50 U.S. states, the District of Columbia, Puerto Rico, American Samoa, Guam, the Northern Mariana Islands, and the U.S. Virgin Islands).

A web-based survey approach is expected to have methodological benefits. HIV-related studies among MSM have found that respondents recruited through the internet are demographically different and more likely to report high-risk, sensitive, or potentially stigmatizing behaviors than respondents participating in interviewer-administered surveys(Whittier, Seeley et al. 2004).

Collection of HIV/AIDS case surveillance data is regulated by Title III - General Powers and Duties of Public Health Service, Section 301 (241.)a. Research and investigations generally (Attachment 1a), Section 306 A&B of the Public Health Service Act (Attachment 1b) and Section 308d of the Public Health Service Act (Attachment 1c).

All data collected for this project are protected under a Federal assurance of confidentiality (**see Attachment 6** for details).

CDC awarded a contract in September 2010 to develop and, pending OMB approval, implement the proposed information collection. Survey data will be managed through the secure data transfer algorithm, FIPS 140-2 (Federal Information Processing Standards Publication). The data transfer methodology is compliant with the guidelines set forth in OMB memorandum M-0404 (E-Authentication Guidance for Federal Agencies) as well as with OMB, HHS, and CDC Certification and Accreditation Guidelines outlined in NIST SP 800-37 (Guide for the Security Certification and Accreditation of Federal Information Systems). In addition to the technical requirements listed above, data management processes are in compliance with CDC's Guidelines for HIV/AIDS Surveillance -

Security and Confidentiality (*Centers for Disease Control and Prevention 2006*).

Privacy Impact Assessment

This data collection has been assessed for privacy impact.

Overview of the Data Collection System

Data will be collected annually from internet-using MSM in 56 U.S. jurisdictions, with oversampling in 21 MSAs with high AIDS prevalence. The web-based survey will employ online direct marketing (ODM) through website banner advertisements to recruit MSM to complete a self-administered, web-based behavioral assessment. Formative research was conducted to inform the online direct marketing recruitment strategy. Formative research activities were covered under the Generic Information Collection 0920-0840: Formative Research and Tool Development."

Data collection will begin when a potential respondent completes an eligibility screener (**Attachment 2a**). If the respondent is eligible and consents to participate, the respondent will be directed to the behavioral assessment (**Attachment 2b**). The data collection instruments will also be available in Spanish (**Attachments 3a-b**).

Responses will be collected through a secure website. Data will then be encrypted and stored by the Contractor on a password protected server so that unauthorized persons will be unable to view, export, or modify collected data. Electronic data collected for the survey will be maintained indefinitely at CDC. The survey will not collect names or phone numbers.

Items of information to be collected

Eligibility Screener

Data collected for the eligibility screener will include the respondent's age, race/ethnicity, previous participation in the web-based survey, state, city, zip code and county of residence, gender, and if the respondent ever has had anal or oral sex with a male partner (**Attachment 2a**).

Behavioral Assessment

Information collected for the behavioral assessment will include demographics, access to health care, HIV testing experiences, sexual behavior, substance use, and access to HIV prevention services (**Attachment 2b**). In addition, respondents will be randomized to one of three modules imbedded in the survey that collect information on: 1) health conditions and knowledge of or use of pre-exposure prophylaxis (PrEP), (2) stigma perceived and discrimination experienced related to same-sex attraction, identity, or behavior, and (3) characteristics and sexual behavior of last sexual partner.

The only information in identifiable form that will be collected is Internet Protocol (IP) address. IP address, in combination with several demographic variables, such as race, education and zip code, will be used to determine if duplicate surveys exist. When the Contractor has completed data cleaning procedures, the Contractor will delete IP address from the dataset. At no time will CDC receive IP address information on respondents.

Data collected through the web-based survey will be stored and accessed by a survey identification number. Other data collected through the web-based survey, while sensitive, are not personally identifying; these survey questions are described in **Attachment 2b**. The sensitive information collected will not be linked to any other information in identifiable form and cannot be used to reveal the identity of any one person. There is no link to any name and data will not be collected on paper forms.

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

A secure website will be used for data collection. MSM recruited through banner advertisements will be redirected to the website to complete the on-line, self-administered behavioral assessment. There will be no website content directed at children under 13 years of age.

2. Purpose and Use of Information Collection

The primary objective of the proposed information collection is to elicit HIV-related behavioral information from among MSM at high risk for HIV infection in the United States, to assess prevalence of and trends in: 1) risk behaviors for

HIV infection, 2) HIV testing behaviors, 3) HIV seroprevalence, and 4) exposure to, use of, and impact of HIV prevention services. The focus of the survey is on behaviors directly related to HIV transmission and those that are amenable to intervention through prevention programs. The ability to identify gaps in HIV prevention services for MSM nationally is a unique aspect of this survey.

CDC administers two data collections related to the proposed information collection: the National HIV Behavioral Surveillance System (NHBS, OMB # 0920-0770 exp. 05/31/2014), and the Behavioral Assessment and Rapid HIV Testing (BART) Project (OMB # 0920-0883, exp. 4/30/2014). These projects share some data elements with the proposed information collection, but are focused on different populations or have a different geographic scope and recruitment method. NHBS collects data on MSM every three years in up to 25 metropolitan statistical areas using venue-based sampling. BART samples MSM attending social and cultural events in middle- to small-sized cities.

Data from the proposed information collection will be useful for tracking national trends in risk behaviors, HIV testing, and access to and utilization of HIV prevention service. This information is useful for focusing and prioritizing national initiatives to improve the provision of HIV prevention services, and for evaluating progress towards national prevention objectives.

The proposed information collection will provide a source of data to evaluate progress toward the goals of the National HIV/AIDS Strategy, to: (1) reduce the number of people who become infected with HIV, (2) increase access to care and optimize health outcomes for people living with HIV, and (3) reduce HIV-related health disparities. The proposed information collection also addresses CDC's Goal 5 for monitoring as required by the Government Performance and Results Act: Strengthen the capacity nationwide to monitor the HIV/AIDS epidemic; develop and implement effective HIV prevention interventions; and evaluate prevention programs.

In addition, data on key indicators of MSM behavioral risks for acquiring HIV infection, utilization of prevention services, access to care can help to identify needs for improved interventions, or unmet needs for services.

The information collection described in this request will be funded through a contract. The Contractor will be responsible for developing and implementing the web-based data collection system. CDC will be responsible for monitoring the Contractor's performance and conducting analysis of key data for use in prevention planning.

Without the proposed information collection, the best source of behavioral data is the National HIV Behavioral Surveillance System (NHBS) which monitors HIV-related behaviors among MSM in up to 25 metropolitan cities once every three years. The NHBS survey is administered by an interviewer in venues attended by MSM, which is not feasible on a national scale. Therefore, the collection of data on MSM at risk for HIV infection in a more frequent and geographically comprehensive manner through the proposed information collection will enhance CDC's ability to identify trends in MSM risk and service utilization behavior.

The proposed information collection will complement and extend the current triennial HIV behavioral surveillance through an annual HIV behavioral survey among MSM that is geographically inclusive of 56 U.S. jurisdictions. In addition, the collection of three consecutive years of data allows for critically important trend analysis of risk behaviors, utilization of prevention services, and access to medical care. Data will be disseminated at the national level via CDC-related publications (MMWR and Surveillance Summaries), journal articles, and conference abstracts.

Men recruited for the proposed information collection will constitute a convenience sample that may not be generalizable to the greater population of MSM. However, because recruitment will be conducted via the internet, the proposed information collection will reach larger numbers and a geographically broader group of MSM than would otherwise be possible, which may help compensate for some limitations imposed by convenience sampling.

To meet the primary purpose of the survey to characterize trends, it is important both to describe biases when possible and to address whether there are changes in population surveyed over time. The latter will be of primary importance in evaluating trends in relevant outcomes over time. Also, demographic and behavioral characteristics

of MSM recruited for the proposed information collection will be compared to MSM recruited through the National HIV Behavioral Surveillance system, which collects triennial MSM data from up to 25 priority MSAs using venue-based sampling, an offline recruitment methodology for hidden or hard-to-reach populations.

Privacy Impact Assessment Information

The proposed information collection will be conducted in 56 U.S. jurisdictions to 1) determine eligibility and 2) inform prevention efforts by providing information about the characteristics and HIV risk behaviors of MSM.

The eligibility screener is necessary to ensure that respondents meet minimum criteria for participation in the survey. To be eligible, a person must be at least 18 years old; male; must have had anal or oral sex with another man; must be a resident of the United States of America or territory thereof; must be able to complete the behavioral assessment in English or Spanish; and must not have participated in the survey during the same survey cycle year. The inclusion of these criteria to the eligibility screener reduces the burden on respondents who would otherwise be determined eligible but would not be included in analyses of the survey data.

Whether the respondent consents or refuses to participate in the survey is collected during the consent process. No other information is collected as part of this process. Respondents are informed that they may refuse to answer any question. Respondents will also be informed that the data is used to improve HIV prevention services for persons at increased risk of HIV and that all data will be aggregated prior to public release.

The behavioral assessment is self-administered, and involves collecting information on the respondents' sexual or drug use behaviors that increase the risk for acquisition or transmission of HIV, and patterns of HIV testing and medical care access. The purposes of this project cannot be accomplished without the collection of sensitive information. Respondents can decline to participate at any time by closing the browser window displaying the website. Likewise, a respondent can refuse to answer any question.

Internet protocol (IP) address will be collected for each respondent for de-duplication purposes only. Records that have exactly the same IP address will be compared on date of survey and demographic information such as race, education and zip code; whether a record is a duplicate or a participant has previously taken the survey will be determined based on how closely this information matches. Encrypted IP address will be removed from the database two months after data collection ends, when data cleaning processes have been completed. At no time will CDC receive information on IP address.

The Contractor will ensure that all employees with access to the survey system's data will undergo confidentiality training.

In situations in which sensitive information may be collected, as for this project, loss of confidentiality could potentially result in harm to respondents. Safety precautions are in place to protect these data based on security practices reflecting the latest industry standards, utilizing networking monitoring software and incorporating penetration testing and vulnerability scanning. Data will be located on password-protected servers in a secure facility with 24-hour surveillance and multiple authorization mechanisms to gain access to the facility. Staff with access to the facility must successfully pass a multi-factor authentication procedure to gain access to the data.

3. Use of Improved Information Technology and Burden Reduction

All data for the proposed information collection will be collected via a web-based behavioral assessment that is self-administered and accessible to respondents in 56 U.S. jurisdictions. Burden is minimized as this allows respondents to participate in the study at their convenience (location and time), forgo having to answer sensitive questions through a face-to-face interview, and move through the behavioral assessment at their pace.

Data will be collected through a self-administered web-based behavioral assessment. Men will be recruited for the survey through an on-line direct marketing approach (ODM) that involves banner advertisements placed on a variety of

websites, such as general social networking sites, as well as gay-focused or MSM-focused websites. Men who click on the banner advertisement will be redirected to the Contractor's website to complete the eligibility screener first, then the behavioral assessment if they are eligible and consent.

To keep the survey to no more than 15 minutes, respondents will also be randomly assigned to complete one of three supplemental questionnaire modules imbedded within the survey (**Attachment 2b**). Each module takes approximately 3 minutes. These modules inquire about: (1) health conditions and knowledge of or use of Pre-exposure prophylaxis (PrEP), (2) stigma felt and discrimination experienced related to MSM-related attraction, identity, or behavior, and (3) characteristics and sexual behavior of last sexual partner.

CDC will require the Contractor to monitor data collection daily to ensure that any problems with the website or questionnaire software is immediately identified and remedied. CDC and the Contractor will maintain regular meetings to discuss problems and lessons learned as well as to help reduce the burden to respondents participating in the proposed information collection.

Use of electronic data collection also reduces the burden on the Contractor. Electronic data collection results in a reduction in the time to prepare the final analysis dataset as the need for entry of behavioral assessment response data has been eliminated, and automated edit checks and skip patterns are built into the interview program for real-time quality control.

An evaluation of health-related surveys and research using web-based data collection methods has shown the following: 1) an improvement of data quality has been found with the addition of definitions (e.g., through pop-up windows) to increase respondents' understanding of questions, pre-programmed skip patterns to ensure respondents are not asked irrelevant questions, and automated validation checks incorporated into the behavioral assessment to assist the respondent when incomplete or implausible responses are provided; 2) the need for data cleaning associated with data entry and the errors listed above is eliminated, resulting in a reduction in the time between the last interview and the production of a final analysis dataset; and 3) web-based systems greatly reduce financial costs of surveys compared to interviewer administered surveys,

despite the increased start-up costs associated with website design, testing, and implementation(van Gelder, Bretveld et al. 2010).

4. Efforts to Identify Duplication and Use of Similar Information

We reviewed currently funded programs and did not identify potential areas of duplication. We are not aware of any department or agency that collects or maintains national-level HIV risk behavior data among MSM.

Within CDC, there are some complementary systems already in place or under development that contain similar data elements to the web-based survey:

- National HIV Behavioral Surveillance System (NHBS) (OMB 0920-0770 exp. 05/31/2014)
- Behavioral Assessment and Rapid HIV Testing (BART) Project (OMB 0920-0883 exp. 4/30/2014)
- Medical Monitoring Project (OMB 0920-0740, exp. 5/31/2012).

These existing surveys cannot be modified, used partially, nor in aggregate format to satisfy the needs of the proposed project: BART collects risk behavior information from respondents at gay pride and other events, but only in small and middle size cities; MMP collects data on a population-based sample of HIV-infected patients in care, not specific populations at increased risk for HIV; and NHBS is a triennial surveillance system that collects HIV risk behavior among three higher-risk populations in up to 25 metropolitan areas with the most HIV/AIDS cases. One higher-risk population is surveyed each year, heterosexuals at increased risk, injection drug users, or men who have sex with men, resulting in data collection once every three years for each population. Additionally, the NHBS methodology is not feasible to conduct annually on a national scale.

The Computer Retrieval of Information on Scientific Projects (CRISP) database was searched for federally funded projects involving national behavioral survey systems among men who have sex with men. This search was conducted using the RePORT Expenditures and Results (RePORTER) query tool. Four federally-funded research projects were identified: one project accesses MSM's internet dating behaviors and condom use intentions; one project investigates HIV risk behaviors

of African American young MSM; one project investigates structural factors and alcohol-related HIV risk among MSM; and the final project investigates relationship dynamics and sexual risk behaviors in gay and bisexual male couples in the San Francisco Bay area. None of these projects are able to provide national-level data on MSM HIV-related behaviors.

CDC has established relationships with other federal stakeholders and consultants during the conception and development of the proposed web-based data collection. Meetings with these federal stakeholders and consultants who are aware of data collections from persons at risk for HIV infection ensured that duplicate or similar data collection efforts do not exist. Other questionnaires may have obtained data related to topics covered in the proposed information collection, but most were more limited in the questions they asked, the populations they surveyed, the geographic areas covered, or all of these factors.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this data collection.

6. Consequences of Collecting the Information Less Frequently

This data collection request is for annual data collection. Less frequent data collection would not allow assessment of year-to-year trends in risk behavior and access to prevention programs at a time when the delivery of interventions to reduce HIV risk behaviors among the targeted population is being intensified. Collecting the data less frequently would not allow mid-course changes in the types of interventions or strategies for delivering interventions in the event that such changes might be needed to minimize the spread of HIV.

This is a one-time data collection request. Data collection activities will occur in three 12-month cycles, one cycle during each calendar year from 2012-2014. Participation in the proposed information collection is permitted once per cycle and respondents are asked prior to the start of the questionnaire if they have already completed the survey during the current survey year. Those who indicate that they have participated will not be allowed to participate again. However, respondents may choose to participate in the

survey more than once in different survey years.

There are no legal obstacles to reduce the burden.

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

This request fully complies with the regulation 5 CFR 1320.5.

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

8A. The 60-day notice to solicit public comments was published in the Federal Register on June 29, 2011 (Volume 76, Number 125, pages 38181- 38182). See **Attachment 4** for a copy of the Federal Register notice. One comment was received (**Attachment 5a**). A response was sent to this comment (Attachment 5b).

8B. Several consultations were conducted with various scientists and public health practitioners outside CDC. All names, affiliations, and contact information are included in **Table 8-A-1**.

A consultation on best practices for recruiting MSM using web-based methods was held in February 2011 with European researchers involved in large-scale HIV behavioral surveys. Key participants included Mr. Peter Weatherburn, Dr. Ford Hickson, and Dr. Jonathan Elford.

A consultation with researchers working with young minority MSM was held in February 2011. That consultation included discussions on the use of web-based methods for reaching this population. Key participants included Dr. Perry Halkitis and Mr. Donovan Jones.

A consultation was held in March 2011 with U.S.-based researchers with expertise in web-based methods to solicit input on the methodology for this data collection. Key participants included: Drs. Mary Ann Chiasson, Sabina Hirschfield, Simon Rosser, Sheana Bull, Deb Levine, Scott Rhodes, Anne Bowen and Joshua Rosenberger.

Table A-8-1: Consultants in the Development of the Web-Based HIV Behavioral Survey among MSM

<p>Mary Ann Chiasson, DrPH Vice President, Public Health Solutions Associate Professor of Clinical Epidemiology, Columbia University 40 Worth Street, 5th floor New York, NY 10013 Phone: 646-619-6411 Email: machiasson@healthsolutions.org</p>	<p>Simon Rosser, PhD Professor, Division of Epidemiology and Community Health (University of Minnesota School of Public Health) Division of Epidemiology and Community Health 1300 South Second Street, Suite 300 Minneapolis, MN 55454 Phone: 624-0358 Email: rosser@umn.edu</p>
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<p>Joshua Rosenberger, MPH Indiana University Center for Sexual Health Promotion 1025 East Seventh Street Bloomington, IN 47405 Phone: 812-855-3627</p>	<p>Ford Hickson, PhD Senior Research Fellow, Sigma Research London School of Hygiene and Tropical Medicine 15-17 Tavistock Place</p>

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This data collection is not expected to affect the work of other federal agencies.

9. Explanation of any Payment or Gift to Respondents

No payments, gifts, or tokens of appreciation will be provided to respondents for their participation in the study

10. Assurance of Confidentiality Provided to Respondents

A. This section has been reviewed by ICRO, which determined that the Privacy Act does not apply because the survey does not collect name, social security number or other information in identifiable form.

IP address will be collected. IP address will be encrypted using cryptographic hashing, to produce a 256 bit hash value. Encrypted IP address will be removed from the database two months after data collection ends, when data cleaning processes have been completed. At no time will IP address be transmitted to CDC or linked to respondent data at CDC.

Data collected through the proposed information collection, will be stored and accessed (by both the Contractor and by CDC staff) by a survey identification number. Other data

collected through this survey, while sensitive, are not information in identifiable form; these questions are described in Section 11.

B. In addition to limiting the amount of identifying information collected, the proposed information collection is covered by an Assurance of Confidentiality for HIV/AIDS surveillance data (**Attachment 6**). The Assurance provides the highest level of legal confidentiality protections to the individual persons who are the subject of this data collection, and to the individuals and organizations responsible for data collection. The terms of the Assurance of Confidentiality reflect the collective experience of CDC, health departments, and the Council of State and Territorial Epidemiologists with respect to the collection, electronic transmission, and dissemination of HIV/AIDS surveillance data. The Assurance includes established policies and procedures governing all aspects of data collection and de-identification, physical security for paper forms and records, electronic data storage and transmission, and the release of aggregate data in forms that cannot be linked back to individual respondents. The protections afforded by the Assurance of Confidentiality last forever, and endure even after the respondent's death.

Privacy Impact Assessment

Responses to screen for eligibility, document informed consent, and assess behavior will be collected by the Contractor via a secured (secured socket layer, or SSL) internet connection similar to that used for banking and other secured transactions. Data will be stored on a secure server. Study data will be backed up on a separate, secure server nightly. Access to the backup files will be subject to the same restrictions as access to the primary database. Data transmittals will be safeguarded by encryption security that meets all security and confidentiality guidelines for HIV/AIDS Surveillance programs. See the document "Technical Guidance for HIV/AIDS surveillance Programs, Volume III: Security and Confidentiality Guidelines" for further information (www.cdc.gov/hiv/surveillance.htm)(Centers for Disease Control and Prevention 2006).

The Contractor's computer systems are password protected to ensure that unauthorized users are not able to view, export, or modify collected data.

The Contractor will transmit the web-based survey data to CDC via the Secure Data Network (SDN). Encryption security for all survey data meet the current National Institute of Standards and Technology (NIST) Federal Information Processing Standards (FIPS), which meet or exceed Advanced Encryption Standards (AES).

The proposed information collection is covered by an Assurance of Confidentiality under Section 308(d) of the Public Health Act granted for HIV/AIDS surveillance data (**Attachment 6**). The Assurance of Confidentiality is enforced with appropriate training and contractual agreements which clarify the responsibilities of all participants in HIV/AIDS surveillance activities who have access to directly identifiable data or to data that are potentially identifiable through indirect means. The Contractor personnel will undergo security and confidentiality training. CDC's Procurement and Grants Office will require the inclusion of 308(d) clauses of the Public Health Act in any HIV/AIDS support services work done by contractors (e.g., data analysis, computer programming, LAN support). All CDC permanent employees and their contractors will be required to attend annual confidentiality training, to sign a Nondisclosure Agreement and to update their confidentiality agreements on an annual basis. Contractors must sign a "Contractor's Pledge of Confidentiality." Access to HIV/AIDS surveillance data maintained at CDC is restricted to authorized personnel who have signed the "Agreement to Abide by Restrictions on Release of Data."

C. The informed consent process will be fulfilled by obtaining consent from each respondent through the internet connection before the behavioral assessment is administered. An example model consent document is included (**Attachment 7**).

Men eligible to participate in the behavioral assessment will be redirected to a screen with the informed consent form. The form explains that their responses are confidential and all data will be reported in aggregate format. Respondents will also be informed that the intended use of the web-based survey data is to monitor behavioral trends of MSM on an annual basis and that data will be reported via CDC-related publications (*Morbidity and Mortality Weekly Report* and *Morbidity and Mortality Surveillance Summary*), journal articles, and conference

abstracts. Consent or lack thereof will be documented in the electronic database by the stored variable indicating consent or lack of consent. Respondents who choose not to consent to the behavioral assessment will be thanked for their interest in the survey.

The approved Project Determination Form is provided in **Attachment 8**. This form indicates that the project is considered to be public health surveillance, not research.

D. Respondent participation is voluntary

The consent form informs the respondent that participation in the behavioral assessment is voluntary. Also, all questions in the eligibility screener and behavioral assessment allow the respondent the option of refusing to provide a response and moving to the next question.

11. Justification for Sensitive Questions

The collection of HIV/AIDS status is sensitive because of stigma associated with HIV infection. In addition, the modes of transmission of HIV (through sexual contact and the sharing of HIV-contaminated needles and syringes) necessitate the collection of sensitive data regarding sexual practices and drug use. In keeping with the purpose of this data collection, other sensitive data will be collected about specific behaviors, experiences or conditions that have been shown to be associated with HIV infection. Specifically, the sensitive data to be collected for the proposed information collection include sexually transmitted disease and HIV diagnosis and testing, hepatitis diagnosis and vaccinations, history of incarceration in the past 12 months, alcohol use, and income. Geographic information, such as the respondent's state and county of residence, will be collected to characterize the geographic distribution of disease and risk. Questions about race and ethnicity will be asked using OMB's two-question format. These questions will be used to report on racial and ethnic disparities that have been well documented in other research on HIV risk and risk behaviors.

Although the information to be requested from respondents is highly sensitive, the purpose of the proposed information collection cannot be accomplished without their collection. Collection of these data will be used to understand barriers

to engaging in protective behaviors and to using HIV prevention services. These data will also be used to enhance HIV prevention programs designed to reduce high-risk behaviors among persons most likely to acquire or transmit HIV.

The context in which questions are asked will help to overcome their potential sensitivity. Steps to minimize the sensitivity of the questions and ensure communication of the legitimate need for such information include:

- All questions allow for the response of 'don't know' and respondents can refuse to answer any question and continue onto the next question.
- The consent script makes it clear that the behavioral assessment is sponsored by the CDC.
- The behavioral assessment is carefully organized to lead smoothly from one topic to another. Transitions are made clear to respondents and definitions are provided to the respondent, when necessary.

Social security numbers will not be collected from respondents.

No data will be collected from agencies regarding their policies, performance data, or other practices.

12. Estimates of Annualized Burden Hours and Costs

Estimates of respondent burden for each data collection form are provided below. For the proposed information collection, approximately 309,090 individuals will be screened to participate during each 12-month period. An eligibility screener will be used to determine eligibility by assessing the respondent's gender, age, race/ethnicity, and county of residence, and whether the respondent ever had anal or oral sex with a man. We estimate that it will take one minute to complete the eligibility screener, totaling 5,152 hours per year. We anticipate that 45% of respondents will either not be interested in completing the behavioral assessment or will be ineligible after completing the screener; and that 170,000 persons will be eligible and will complete the behavioral assessment. We estimate that it will take 14 minutes for each respondent to complete the behavioral assessment. The average annual burden for the behavioral assessment is therefore estimated to be 39,667 hours. The total average annual burden, including both the eligibility

screener and the behavioral assessment, is estimated to be 44,819 hours.

Table A-12-1: Estimate of Annualized Burden Hours

Respondents	Form name	Number of Respondents	Number of Responses per Respondent	Average burden per Response (in hours)	Total burden (in hours)
Persons screened for eligibility	Eligibility Screener	309,090	1	1/60	5,152
Eligible persons	Behavioral Assessment	170,000	1	14/60	39,667
TOTAL					44,819

B. Estimated Annualized Cost to Respondents

Table A-12-2: Annualized Cost to Respondents

Note: The hourly rate was determined by using information obtained from the US Department of Labor, Bureau of Labor Statistics.

Type of Respondent	No. of Respondents	No. of Responses per Respondent	Average burden per Response (in hours)	Total Burden Hours	Hourly wage rate	Total Respondent Cost
Persons screened for eligibility	309,090	1	1/60	5,152	\$19.07	\$ 98,249
Eligible persons	170,000	1	14/60	39,667	\$19.07	\$756,450
TOTAL						854,699

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

There are no other costs to respondents associated with this proposed collection of information.

14. Annualized Cost to the Federal Government

The cost of this project for the three years is estimated to be \$1,055,487 per year. The annual cost is summarized in Exhibit 14.A.

Exhibit 14.A. Annualized Cost to the Federal Government

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government	Web-based survey - Personnel	\$127,151
	Epidemiologist- 13 100% \$91,200 Epidemiologist- 12 50% \$35,951	
Contractor and Other Expenses		
	Contract Deliverables	\$928,336
	Task 1 - Kick-off meeting	\$3,194
	Task 2- Web-based platform report	\$35,736
	Task 2a - Data security report	\$19,542
	Task 3- Program survey instrument	\$27,248
	Task 4- Market research report	\$25,078
	Task 5- Develop progress plan	\$38,354
	Task 5a- Programming routines	\$14,333
	Task 6- Recruitment materials	\$23,368
	Task 7 - Test of recruitment strategy	\$31,394
	Task 8 - Implement survey system	\$114,660
	Task 9 - Monitoring reports	\$430,502
	Task 10 - Trend analysis report	\$80,806
	Task 11 - Final data sets	\$84,121
	Spanish language translation	\$1,380
	TOTAL COST TO THE GOVERNMENT	\$1,055,487

Salary estimates were obtained from the US Office of Personnel Management salary scale at <http://www.opm.gov/oca/11TABLES>.

The personnel related to the data collection include epidemiologists at the GS 13 and GS 12 levels.

The information collection described in this request will be funded through a contract.

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Activities	Time Schedule
Implement Data Collection System	2 months after OMB approval
Implement Year 2 Data Collection System	12 months after OMB approval
Implement Year 3 Data Collection System	24 months after OMB approval
Conduct Trend Analysis	28 months after OMB approval
Analysis and Publication of Data	32 months after OMB approval

An analysis will be conducted at the end of three years of data collection to assess trends in key indicators of behavioral risk. Results will inform prevention programs and services as well as increase existing knowledge of the behaviors that lead to acquisition of HIV infection. Results will also be used to guide national behavioral surveillance efforts.

Data from the survey will be distributed to jurisdiction health departments, researchers, policymakers and other interested parties through presentations at local, national and international conferences, publications in peer reviewed journals, and presentations such as continuing medical education courses and seminars. Furthermore, CDC will regularly publish surveillance reports using data collected annually.

Stakeholders may be informed of the findings in local jurisdictions through multiple information conduits. National results will be released through national publications and presentations at conferences.

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

The OMB expiration date will be displayed.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

References

- Centers for Disease Control and Prevention (2006).
"Technical Guidance for HIV/AIDS Surveillance Programs,
Volume III: Security and Confidentiality Guidelines."
Centers for Disease Control and Prevention (2009). HIV
Surveillance Report 2008. **20**.
- Centers for Disease Control and Prevention (2010). HIV
among Gay, Bisexual and Other Men Who Have Sex with Men
(MSM).
- Purcell, D. W., C. H. Johnson, et al. (2010). Estimating the
National Population Size of Men Who Have Sex with Men
to Develop HIV/AIDS and Syphilis Rates. Atlanta, GA,
CDC.
- Raymond, H. F., G. Rebchook, et al. (2010). "Comparing
internet-based and venue-based methods to sample MSM in
the San Francisco Bay Area." AIDS Behav **14**(1): 218-224.
- van Gelder, M. M. H. J., R. W. Bretveld, et al. (2010).
"Web-based Questionnaires: The Future in Epidemiology?"
American Journal of Epidemiology **172**(11): 1292-1298.
- Whittier, D. K., S. Seeley, et al. (2004). "A comparison of
web- with paper-based surveys of gay and bisexual men
who vacationed in a gay resort community " AIDS
Education & Prevention **16**(5): 476-485.