National HIV Prevention Program Monitoring and Evaluation Data
0920-0696

Supporting Statement A

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A. Justification

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention requests a revision to approved data collection 0920-0696 (expiration date 08/31/2010) called, "HIV Prevention Program Evaluation and Monitoring System for Health Departments and Community-Based Organizations (PEMS)," which is requested to be renamed the "National HIV Prevention Program Monitoring and Evaluation (NHM&E) Data," for a period of 3 years.

This ICR covers the collection of standardized program monitoring and evaluation data from all organizations funded by CDC, directly or indirectly through health department funding, under all program announcements, to conduct HIV prevention programs. This ICR also covers all data collection for special monitoring and evaluation projects that provide additional funding for expanded data collection using the approved variables. This is to include all types of HIV prevention programs, including but not limited to, Health Education/Risk Reduction (HE/RR) (and associated Health Communication/Public Information and Outreach), Partner Services, HIV Testing (and associated Counseling and Referral), and other CDC-funded HIV prevention programs. This ICR does not cover HIV disease surveillance or research into biomedical interventions or the efficacy of new behavioral HIV prevention programs, which are covered under separate ICRs. A review of the current OMB-approved CDC HIV data collections (see **Attachment 7**) shows that no other approved data collection collects program monitoring and evaluation data on CDC-funded HIV prevention programs currently being conducted by health departments and CBOs.

In an effort to reduce burden, we are requesting to reduce the number of variables that will be required of all grantees, while providing optional variables for local use or collection for any special program evaluation studies covered by this ICR. In the latter case, the project data requirements for these special evaluation studies will be drawn from the NHM&E data variables included in this ICR or a request for change will be submitted. During the past three years we have conducted extensive internal and external discussions about the number and type of variables

required, and this ICR requests that the number of required variables be reduced, though many of those variables are now included in the ICR as optional so they can be used for special monitoring and evaluation studies and by grantees for local monitoring and evaluation.

In addition, the differences between variables required of health departments and community-based organizations (CBOs) have been eliminated, simplifying data collection for health departments that fund CBOs with CDC funding. Some variables have been modified to simplify data collection.

An important goal in reducing the number of new HIV infections is to improve the quality of HIV prevention programs designed to reduce high-risk behaviors in persons most likely to acquire or transmit HIV. The CDC currently funds HIV prevention programs in all state and territorial health jurisdictions (including the Pacific Island territories), 6 city health departments, and approximately 300 CBOs through cooperative agreements. These numbers of CBOs vary over time and may increase, and some grantees may be funded under more than one program announcement. These HIV prevention programs conduct interventions to reduce HIV-related behaviors in targeted populations. Monitoring and evaluation of these HIV prevention programs are essential to helping health department jurisdictions and CBOs develop, deliver, refine, and improve HIV prevention interventions and for strengthening CDC's overall monitoring of HIV/AIDS prevention. Consequently, accurate and reliable program process and outcome monitoring and evaluation data must be collected. The CDC depends on the NHM&E variables for standardized data from all grantees to adequately monitor program performance at both the local and national levels.

In addition, the President's Management Agenda requires all federally funded grantees to report key program performance indicators as a method for demonstrating accountability. The CDC HIV prevention program performance indicators include the grantee's capacity to deliver and monitor prevention services, the implementation of these processes, and outcomes associated with HIV prevention program activity. The grantees and CDC will use performance indicators to show that the programs they implement or support are efficient and effective in achieving their stated HIV prevention program goals and objectives. Most HIV prevention program performance indicators are calculated using data approved in the previous ICR and included in this ICR for NHM&E data.

The NHM&E data make possible national program evaluation; performance indicator calculation; accountability reporting to Congress, the administration, and other HIV prevention program stakeholders; and informed decision-making about funding and HIV prevention. These data will be used for planning and monitoring the delivery of prevention services to clients, implementing and improving HIV prevention programs, and reporting the required program performance indicators. Additionally, NHM&E data will enable CDC to provide valuable feedback to these programs and to better account for the use of HIV prevention resources. All funded health jurisdictions and CBOs, under any and all CDC HIV prevention program funding, will be required to submit the "required" NHM&E data. In addition, some of the "optional" data may be required of grantees that receive additional funding for various special studies or projects, as appropriate. Currently, some of these focused evaluation special studies of CDC-funded interventions are in development. Some special evaluation studies will utilize only variables included in this ICR. Other evaluation studies will use some of the variables included in this ICR and they may also require additional variables that reflect the unique processes and outcomes associated with specific interventions. Therefore, the protocols and data collection variables will be finalized when the interventions to be evaluated have been identified. The additional variables to be collected will include HIV-related attitudes, beliefs, knowledge, and behaviors. As noted above, we will submit to the OMB the requisite change requests to the approved ICR in order to include these new, additional variables in our special studies. However, in no case will client identifying data will be reported to CDC.

Collection of these data is authorized under Section 306 of the Public Health Services Act [42 U.S.C. 242(k)] (**Attachment 1**). Respondents are required to submit NHM&E core (required) data quarterly and are accountable for conducting monitoring and evaluation of major HIV prevention program activities and services, including data collection on interventions provided and clients served. CDC may place conditions or restrictions on the award of funds to respondents that fail to meet these requirements.

Privacy Impact Assessment

Overview of the data collection system

Each respondent will determine how data are to be collected. There are no required forms or other data collection instruments. For HIV Testing data only, respondents have the option of using a CDC supplied scannable form (see Attachment 3, B and C) and scanning data tool that works with commercially available scanning hardware and software. However, while the number changes over time, about half the health department respondents collect testing data using their own forms and non-CDC scanning tools or they key-enter data using their own data entry system. A few key-enter HIV testing data into the optional, CDC-provided HIV Prevention Program Evaluation and Monitoring System (PEMS) software. The rest use the CDC supplied forms and scanning tool for HIV testing data entry.

For non-HIV testing data, about half the health department jurisdictions maintain their own electronic data collection systems. The other health departments and almost all community-based organization (CBO) grantees use the CDC-supplied HIV Prevention Program Evaluation and Monitoring System (PEMS), an optional, electronic, secure, browser-based software application designed to provide the necessary mechanism for collecting and reporting standardized, sensitive HIV prevention data. (CBOs in New York State use the New York State data collection software.) CDC grantees can gain access to the PEMS application through a secure internet connection, which requires electronic authentication of the users and maintains data confidentiality and security.

All data, from all systems, are submitted electronically, using approved encryption, through a Secure Data Network (SDN) maintained by CDC. This submission must be done in a CDC-defined format or using the PEMS software.

Program data accessible by CDC through either submission mechanism will not contain client names, but will include “sensitive” information such as client demographics (age, gender, race, pregnancy status, HIV status, risk behaviors, etc.) and exposure characteristics. Information in Identifiable Form (IIF), such as name, address, birthday, etc., may be collected by the health department or CBO working with the individual for purposes of local program activity such as case management. All NHM&E data is covered

by a CDC Assurance of Confidentiality specific to NHM&E data under the Public Health Services Act 308(d), as well as state confidentiality laws. In cases where health departments and CBOs utilize the CDC-developed PEMS, data will then be transmitted over the Internet using the Secure Data Network (SDN) to an intermediate database (DB1) at CDC. CDC will not access data on this database. A subset of those data, excluding IIF, will then be submitted regularly to the PEMS database (DB2) from DB1. The data on the PEMS database (DB2) will not contain any Information in Identifiable Form.

Since the design and intent of the data collection is not to develop or contribute to generalizable knowledge (i.e., it is not possible to induce or derive a general conclusion or principle about all HIV prevention from the particulars of the evaluation of a particular grantee's activities), but to improve individual HIV prevention programs and services provided by CDC-funded health departments and CBOs, CDC has determined that NHM&E is not research and IRB review is not required.

Items of Information to be collected

See **Attachment 5** for a complete list of all data elements (variables and values, with definitions, and information as to which variables are "required" of all respondents or "optional" for local use or inclusion in the requirements for special evaluation studies or projects). The information to be collected includes data about the agency, the CDC funding received, the programs planned to be conducted, the clients served and their associated HIV risk factors, and the interventions conducted (including, but not limited to, HIV testing; health education and risk reduction and associated health communication, public information, and outreach; partner services; and community planning). This information is reported by the grantees from their usual and customary data collection, using the standardized NHM&E variables.

No Information in Identifiable Form (IIF) is reported to CDC. However, for those grantees that elect to use the PEMS software, the software, as noted above, will accept IIF and store it on a CDC server for grantee use only. This IIF is filtered out when the data is copied to a second server for CDC use. The PEMS software will accommodate the entry on the local level of IIF such as name, date of birth, local

client ID number (which may be based on the Social Security Number), mailing address, phone numbers, limited medical information and notes, other local use numbers and fields (which may include medical record numbers), certificates, web URLs, email addresses, education records, and employment status. See section A-10 for a detailed explanation of how identifying data is removed before being reported to CDC.

Identification of Websites and Website Content Directed at Children Under 13 Years of Age.

There is no content directed at children under 13 years of age. For grantees that choose not to use the optional PEMS software, no website is involved. For grantees that choose to use PEMS, data are entered into an electronic, secure, browser-based software application designed to provide the necessary mechanism for collecting and reporting standardized, sensitive HIV prevention data. Access to this website is tightly controlled using the CDC Secure Data Network digital certificate process as well as separate access rights to the PEMS software. Access is limited to appropriate grantee and CDC staff. Cookies are not used. Rules of conduct are enforced as part of memoranda of understanding with all grantees (see **Attachment 6**).

2. Purpose of Use of the Information Collection

The NHM&E data variables provide a comprehensive, yet parsimonious, standardized set of program data variables essential to monitoring and evaluating HIV prevention programs. As program evaluation, the results of analyses of NHM&E data are not generalizable (i.e., it is not possible to induce or derive a general conclusion or principle about all HIV prevention from the particulars of the evaluation of a particular grantee's activities). Moreover, given the variety in implementation of HIV prevention interventions among health departments and CBOs, when utilized for assessing outcomes associated with CDC-funded HIV prevention program activities, the results of analyses of NHM&E data will not be generalizable. However, the NHM&E data will enable CDC to track program activity, identify best practices, and assist grantees in redesigning interventions that do not accomplish stated goals, such as the reduction of high-risk behaviors in targeted populations. CDC will use the NHM&E data, in combination with surveillance and research data, for the following purposes:

- Assess CDC HIV budget allocations with respect to prioritized risk populations
- Identify gaps in HIV prevention service provisions
- Assess the extent to which HIV prevention programs have reached their target population
- Determine if the interventions are being delivered as intended
- Highlight opportunities to strengthen collaboration among CDC, its prevention partners, and other federal agencies
- Assess the annual performance of CDC and its grantees in meeting priority goals and objectives
- Produce standardized and specialized reports that will inform grantees, CDC project officers, and other stakeholders of the status and trends of a host of process, outcome, impact, and accountability measures. Reports could include reports for quality assurance, comparison of planned activities or expenditures to actual activities or expenditures, data for calculating required performance indicators, and data on specific interventions. These types of reports will be available on the grantee, jurisdiction, and national level.

The NHM&E data variables have been developed with extensive input from respondents (representatives of health jurisdictions and community-based organizations), other HIV prevention partners, and the leadership of the Division of HIV/AIDS Prevention (NCHHSTP/CDC). See **Attachment 4** for a list of organizations and persons who provided input to the development or modification of the MHM&E variables during the past three years. The data variables are based on HIV prevention business processes and sound scientific approaches to HIV prevention. Specifically, the NHM&E data variables cover a range of HIV prevention activities such as agency information, program planning, community planning, HIV testing, partner services, a range of health education and risk reduction interventions, and other interventions such as Comprehensive Risk Counseling and Services.

Collection of the NHM&E data will supply program managers with service-level information regarding intervention processes (e.g., who delivered what to whom, how many, where, and when) and client-level information (e.g., client demographics, behavioral risk factors, exposure to services, verified referrals into other services, and changes in risk-behaviors for selected interventions) for monitoring and

enhancing local HIV prevention programs. See **Attachment 5** for the NHM&E data variables and values. See **Attachment 3A** for a sample of the PEMS Home Page.

Without these data, CDC would be unable to determine what is being done with the funding it provides, what populations are being served, what services are being provided, or which programs are having the most effect in preventing HIV. It would be unable to account to the administration, Congress, or other stakeholders for the proper use of public money or provide transparency for the programs it funds.

3. **Use of Improved Information Technology and Burden Reduction**

All NHM&E data are to be submitted to CDC electronically. While grantees may collect the data by whatever means they choose, data must be submitted to CDC electronically using the SDN. Grantees are given the option of using their own software system to collect and report NHM&E data or using the CDC-provided PEMS software. Grantees who use their own software must collect the standardized NHM&E data and then convert those data into a CDC-specified format for transmission through the SDN to CDC. Grantees who choose to use PEMS are provided a free, browser-based, secure electronic mechanism for collecting and reporting the standardized NHM&E HIV prevention program data. Consequently, agencies that were relying on paper-based data collection and submission systems have been able to transition to electronic reporting using PEMS.

The optional PEMS software application was designed with input from representatives of health jurisdictions, community-based organizations, and other HIV prevention partners. The PEMS software application and supporting database were designed to combine agency, program, intervention, and client data into one system. This integrated system reduces the burden of entering client data separately by intervention and allows for enhanced flexibility in monitoring and analyzing data across a range of HIV prevention activities.

In addition, for HIV testing data collection, grantees have the option to use a CDC-supplied data collection form (see **Attachment 3B**), which was developed for use with an optical scanner and CDC-supplied supplemental software. Since the

use of the CDC form and scanning data tool is optional, some grantees use the form but not the scanning function, instead key-entering data into PEMS or their own software system. Others may use the form with their own scanning software. Some grantees have developed and use their own forms. However the data are collected, they must be submitted to CDC via the SDN in the prescribed format.

Note that the HIV testing data collection form (Attachment 3B) includes optional fields requested by health jurisdictions. Not all the data on the form are required by or reported to CDC, and IIF data are not reported to CDC. Optional fields are noted on the form. A separate but similar form has been developed for use by the Pacific Island jurisdictions at their request (See **Attachment 3C**).

The PEMS software also generates pre-specified reports and includes an export data transfer process. The export function enables users to extract data to analytical software packages, such as SAS and SPSS.

Finally, data variable business rules have been built into the PEMS software application to enhance the reliability and integrity of the data. These business rules establish the interrelationships among variables and serve as system performance checks for accurate data entry. CDC grantees gain access to the PEMS application through a secure internet connection, which requires electronic authentication of the users and maintains data confidentiality and security.

4. Efforts to Identify Duplication and Use of Similar Information

Efforts to identify duplication of NHM&E data include the assessment of existing or previously used HIV prevention data collection systems used by CDC, other federal agencies, as well as health department jurisdictions and community-based organizations. It should be noted that because the NHM&E data reporting requirements are specific to CDC-funded HIV prevention activities, the only possible duplication is if other federal or state organizations or entities are also funding the same HIV prevention activities to be performed by the same grantees.

Within CDC, data elements from several previously used HIV prevention data collection systems were identified and assessed. These include the following systems:

- The Evaluation Reporting and Analysis System (ERAS), an electronic system used by health jurisdictions to submit health education and risk reduction data at the aggregate level. Evaluating CDC Funded Health Department HIV Prevention Programs (OMB No. 0920-0497, expired March 2006)
- Community-based Organizations System (CBOS), an electronic system used by selected CBOs to submit health education and risk reduction intervention data at both the client and aggregate levels. Assessing the Effectiveness of CBOs for the Delivery of HIV Prevention Programs (OMB No. 0920-0525, discontinued February 2005)
- HIV Counseling and Testing System (CTS), implemented in 1989 and used to collect client-level HIV counseling and testing (CT) data from health jurisdictions. As the volume of CT data increased, scan forms were created by CDC to facilitate data entry. HIV/AIDS Prevention and Surveillance Project Reports (OMB No. 0920-0208 expired October 2005)
- STD Management Information System (MIS) developed by CDC/NCHSTP/DSTDP and used by some state health jurisdictions in collaboration with HIV prevention programs to collect Partner Services (PS) data. The data collected on STD/MIS have been recently modified to match NHM&E data for those items related to HIV PS so that funded state or city health departments have the option of using PEMS, STD/MIS, or their own system to collect PS data. Other STD/MIS data are not reported to CDC, except for morbidity data, which are reported through the NETSS system). (Refer to OMB No. 0920-0497, Evaluating CDC Funded Health Department HIV Prevention Programs, Partner Counseling and Referral Services).

To reduce duplication, the NHM&E dataset combines these four datasets into one. With the exception of the STD/MIS system, the other systems (ERAS, CBOS, and CTS) are replaced by the standardized, routinely reported NHM&E data and optional PEMS software. The STD/MIS collects additional information, not reported to CDC, outside the purview of HIV prevention. Only NHM&E PS data collected in STD/MIS are reported to CDC as part of the NHM&E data collection.

In addition to systems at CDC, other federal systems were reviewed. Specifically, consultations were held with the

Health Resources and Services Administration (HRSA) and the Substance Abuse and Mental Health Services Administration (SAMHSA) to identify and match similar data elements to avoid duplication. Given that HRSA and SAMHSA do not collect detailed HIV prevention program data, very few similarities were identified. The only overlap detected was in the collection of HIV testing data, and SAMHSA determined that they would use the NHM&E HIV testing data variables and HIV testing data collection form to collect data from their grantees. SAMHSA submitted a separate ICR for this data collection. The burden for the SAMHSA data collection is not included in the burden calculations for this ICR.

Finally, an appraisal was conducted to obtain a comprehensive understanding of existing health department jurisdiction and CBO systems and their HIV prevention processes. Beginning in October 2002, reviews were conducted via consultations, workshops, and site visits. Several large health jurisdictions have developed data collection systems that have electronic and/or paper submission processes to meet jurisdiction-specific needs. Examination of these systems revealed that the information collected varied widely from state to state and program to program, providing only a limited and fragmented view of HIV prevention services. Several of the existing systems were not designed to collect client-level data. With these systems, clients could not be linked across programs and their referrals could not be tracked. Furthermore, the data collected for these systems were not of sufficient detail to cover the range of data needed for a national perspective.

If the number of new HIV infections is to be reduced, the quality of HIV prevention programs designed to reduce high-risk behaviors in persons most likely to acquire or transmit HIV must be improved. The NHM&E data significantly advances the monitoring and evaluation of HIV prevention programs by providing national, standardized information. Using standardized data will allow CDC to evaluate programs on national and regional scales and to compare programs providing similar services or targeting similar populations. On the local level, use of the standardized NHM&E variables will enhance the capacity of HIV prevention programs to thoroughly assess and refine their HIV prevention interventions and to identify unmet needs and redundancies while providing accountability to their stakeholders.

5. Impact on Small Business or Other Small Entities

State health department jurisdictions and community-based organizations that receive CDC funding for HIV prevention vary greatly in size and in their capacity to collect and report the NHM&E data. Some of them would qualify as small businesses or other small entities. The NHM&E variables represent a parsimonious set of data with sufficient detail to monitor and improve client outcomes, service delivery, and program design and implementation. In addition, collection of the data will enable agencies to meet their program indicator reporting mandates. Required NHM&E data variables have been kept to a minimum (and reduced from the previous ICR), and thus all respondents will be expected to complete the required data. Moreover, the cost of collecting and reporting this data are included in the CDC funding to all grantees. For small organizations, collection and use of these data are essential to maintaining and improving their HIV prevention activities. When faced with limited resources, these agencies will have the data needed to defend and make the case for expanding existing programs, thereby ensuring continued service delivery to populations in need.

6. Consequences of Collecting the Information Less Frequently

Respondents are required to submit data to the CDC on a quarterly basis. Less frequent data submission would result in a lag time between the occurrence of program problems and their identification. This delay could result in costly program inefficiencies, defects, and failures to continue or worsen without a timely opportunity for CDC to provide valuable assistance and corrective measures to agencies funded to prevent the spread of HIV. There are no legal obstacles to reducing the burden.

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

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

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

A 60-day notice to solicit public comments was published in the *Federal Register*, April 12, 2010, Volume 75, Number 69, page 18502. See **Attachment 2** for a copy of the *Federal Register* notice. No public comments were received.

CDC developed the NHM&E data variables with feedback from state, territorial, and local health jurisdictions and CBOs. Developing the NHM&E data variables has been a long and collaborative process. A detailed listing of agencies and persons consulted during consultations, site visits, workshops, etc. is found in **Attachment 4**. Representatives from funded agencies continue to be informed through monthly phone calls and e-mail correspondence. Additional consultations, workshops, and site visits will occur as needed.

9. Explanation of Any Payment or Gift to Respondents

No payments or gifts will be provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

Much of the information to be collected as part of the NHM&E data relates to program activities and characteristics of respondent organizations. However, the health jurisdictions may also collect identifiers (name, address, etc.) on clients who receive HIV prevention services, including HIV testing. The Privacy Act is not applicable to the client-level data because the information will become a part of the health department jurisdictions' already established record systems; moreover, its availability and use will be limited to the provision of services at the local level.

Privacy Impact Assessment Information

A. For grantees that choose to use their own data collection software, no IIF is submitted to CDC, and, as explained in more detail below, the data that is submitted is submitted in encrypted form using the CDC Secure Data Network. For grantees that choose to use the optional PEMS software, each individual client record will be identified by a randomly generated

unique key that is linked to a particular agency and state. This key is maintained in PEMS, but only at the local level can the client key be re-linked to identifiers. The client-level data accessible by CDC will not contain IIF such as client names, but will include client demographics (age, gender, race, pregnancy status, HIV status, risk behaviors, etc.) and exposure characteristics (see **Attachment** 5 for more information on the client key and demographic variables). Because of the highly sensitive information and the potential for indirect identification of individuals, as is true with CDC HIV/AIDS surveillance systems, the program has determined that an Assurance of Confidentiality for prevention program clients (and the organizations furnishing the information) under section 308(d) of the Public Health Service (PHS) Act is necessary. This Assurance of Confidentiality for the NHM&E data (formerly known as PEMS data) has been granted by the CDC Associate Director for Science (see **Attachment 10** for AOC Letter of Approval). Safeguards for client data during data analysis, such as deleting small cell sizes, requiring confidentiality agreements, and other safeguards similar to those used for HIV/AIDS surveillance data have been imposed.

CDC grantees gain access to the PEMS application through a secure internet connection, which requires electronic authentication of the users and maintains data confidentiality and security. All system users are provided information on privacy, confidentiality, and security policies; and a memorandum of understanding between CDC and each PEMS agency is established. All system users will be required to sign appropriate 308d pledges. Written rules of behavior have been developed for PEMS Agency System Administrators (**Attachment 6A**) and Users (**Attachment 6B**) to clarify rules, roles, and responsibilities associated with the system.

While sensitive data will be submitted to CDC, IIF will not be submitted to CDC. In cases where health jurisdictions and CBOs utilize the CDC-developed PEMS software, the data will then be sent to an intermediate database (DB1) at CDC. A subset of those data, excluding IFF, will then be submitted to the PEMS

database (DB2) from DB1. The data on the PEMS database (DB2) will not contain any IIF information. In cases where health department jurisdictions choose not to use the CDC-developed PEMS software, but enter data into their own software, only the de-identified data will be submitted to CDC. These data are encrypted using an encryption software and submitted via the SDN. Public use data sets derived from the de-identified data will be further protected by eliminating cells with small numbers and other steps to prevent the identification of individuals. The PEMS system has passed the full Certification and Accreditation Process and has an authority to operate (ATO) until November 2012. (See **Attachment 8**.) This means that our security measures meet the requirements of the NIST 800-53, HHS, and CDC.

The PEMS application uses Secure Sockets Layer (SSL) between web-browser clients and the web server that accepts data from users. Additional SSL sessions secure data between the web server and the application server and between the application server and the database server. Each of these SSL sessions employs the same type of encryption used by all major financial services and electronic commerce sites today. Thus, from a user’s perspective, sensitive information is encrypted from the time it leaves the PC to the time it is stored in the central database.

PEMS also supports persistent encryption of specific data variables (identified as sensitive by the CDC) using the 3DES algorithm. This algorithm is also known as Triple DES, employs a 168-bit encryption key, and is FIPS 140-2 compliant. Thus, in addition to being encrypted with SSL during transit, some information remains encrypted within the database, visible only to the agency that entered it. The process for handling security incidents is defined in the system's Security Plan. Event monitoring and incident response is a shared responsibility between the system's team and the Office of the Chief Information Security Officer (OCISO). Reports of suspicious security or adverse privacy-related events should be directed to the component's Information Systems Security Officer, CDC helpdesk, or to the CDC Incident Response Team. The CDC OCISO reports to the HHS Secure One Communications Center, which reports incidents to US-CERT as appropriate.

Because the primary purpose of this data collection is to improve HIV prevention programs and services, CDC has determined that the data collection activity does not require IRB review and approval.

C. Information about agencies and programs is required as part of the Program Announcement. Information about clients is collected by the agencies as part of their routine data collection, and clients are informed of any consent required by the agency or state regulations.

D. As described above, no IIF is being reported to CDC. IIF in CDC secure servers (DB1), accessible only by the agency that entered the data, has been granted an Assurance of Confidentiality (Section 308[d]).

11. Justification for Sensitive Questions

Some of the client-level data to be collected are highly sensitive. HIV can be transmitted from person to person through sexual contact and the sharing of HIV contaminated needles and syringes. These modes of transmission necessitate the collection of sensitive data regarding sexual practices as well as alcohol and drug use. Because collection of these data will be used to provide improved HIV prevention services to high-risk populations and enhance HIV prevention programs at the local level, and to reduce high-risk behaviors in persons most likely to acquire or transmit HIV, specific information about client demographics and client risk profiles is essential to designing appropriate interventions and programs and to monitoring and evaluating these programs.

This data collection also includes race and ethnicity questions, which may also be viewed as sensitive by some respondents, for use in data analysis (e.g., designing and evaluating programs, as discussed above) and to support compliance with the HHS Policy Statement on Inclusion of Race and Ethnicity in DHHS Data Collection Activities of October 24, 1997.

12. Estimates of Annualized Burden Hours and Costs

Annualized Burden Hours

The estimates for the number of annualized burden hours are provided in simplified form in the table below. There are two types of organizations that are required to provide data. The first is State, Territorial, and directly funded local health departments, whose burdens are described in the first 4 lines of the burden table. There are 65 health jurisdictions and the data required by respondents for this ICR include variables for the following NHM&E data sets:

- Agency and Program Plan Data
- Health Education and Risk Reduction (HE/RR) Data
- HIV Testing Data
- Partner Services (PS) Data (formerly PCRS)

Some jurisdictions will provide scanned testing data and others will provide non-scanned testing data. The numbers on the burden table (Table A.12-A) are estimates since the use of the CDC-provided scanning system is optional and jurisdictions may opt in or out of the scanning system at any time. In addition, new program announcements may alter the number and types of services provided at any time. All health departments will also receive training on NHM&E, as noted in the burden table.

The second type of organization providing information is community-based organizations (CBOs). They will be providing the same data sets as shown in the bullets above and their burdens are summarized on lines 5-7 of the table. The estimate is that there will be a maximum of 300 CBOs, of which about 100 will provide HIV testing data. Again, all of these numbers are subject to change with new program announcements, funding changes, and closing or defunding of grantees. All CBOs will be receiving training on NHM&E, as noted in the burden table.

The calculations for annualized burden are derived from the time needed to search the PEMS database for existing records, gather and maintain the data, complete the collection of records, and review the information prior to submission to CDC.

The annual NHNM&E data reporting burden is summarized in the following table. For simplicity, the burdens for Agency and Program Plan Data and for HE/RR data (and for PS data for health departments) have been combined since all agencies report these data. For explanation of how these numbers were derived, see **Attachment 9**.

Table A.12-A. Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per response (in hours)	Total Burden Hours
Health jurisdictions	NHM&E Data Variables and Values	65	***4***	***138***	***35,880***
Health jurisdictions (HV Testing-scan)	HIV Testing Form	30	***4***	***616***	***73,920***
Health jurisdictions (HIV Testing non-scan)	NHM&E Data Variables and Values	35	***4***	***439***	***61,460***
Health jurisdictions (Training)	NHM&E Data Variables and Values	65	***4***	***10***	***2,600***
Community-Based Organizations	NHM&E Data Variables and Values	300	***4***	***84***	***100,800***
Community-Based Organizations (HIV Testing)	HIV Testing Form	100	***4***	***30***	***12,000***
Community-Based Organizations (Training)	NHM&E Data Variables and Values	300	***4***	***10***	***12,000***
Total					***298,660***

The total estimated annualized hourly burden anticipated for all data collections would be approximately 298,660 hours. A total 181,512 burden hours per year were approved under the existing ICR covering August 22, 2007 – August 31, 2010. During this period, as requested by OMB in the last approval, there have been numerous efforts in collaboration with grantees to reduce the burden on grantees. This is shown by the reduction in the number of required variables indicated in this ICR, and the simplification of the requirements so that health departments and CBOs report the same data. The increase in estimated burden is based on additional funding for HIV testing, special outcome

evaluation studies that require collection of the same data at multiple times, and additional grantees reporting NHM&E data. There are more grantees providing more prevention services to more clients. We anticipate additional funding in the future to support even more grantees to conduct even more prevention activities, especially HIV testing. We have offset some of this increase in burden by reducing the number of required variables and are continuing to work with the grantees to keep the burden to a minimum while still obtaining the data necessary for national reporting and program management. The increase in prevention activities, not an increase in the reporting requirements, causes the increase in burden.

B. Annualized Cost to Respondent

The collection and reporting of NHM&E data are part of the activities specified in the HIV prevention program announcements as part of the funded activities. Any expense incurred collecting and submitting the NHM&E data, above the routine collection of data required to conduct business, is supported by CDC funding. There is no actual cost to the respondent.

The estimated cost to be supported by CDC funding is as follows. It is estimated that health jurisdiction staff who collect PEMS information will be paid $40,000 annually. Comparable annual salary for Federal General Schedule (GS) employees is that of a GS-9 step 1 ($39,795 annually or $19.07/hour).

To derive an estimated pay for CBO staff, the salaries of four (4) mid-level staff were obtained from a CBO in Texas and a CBO in New York City. The average salary is $29,899 annually. Comparable annual salary for Federal General Schedule (GS) employees is that of a GS-6, step 2 ($30,252 annually or $14.50/hour). The average annual salary of four mid-level staff working in CBOs located in New York City and Texas: $33,798 + $26,000 = $59,798 divided by 2 locations = $29,899.

Table A.12-B. Annualized Cost to Respondents

Type of Respondents	Number of Respon	Form Name	Number of Respon	Average Burden per	Hourly Wage Rate	Total Respondent Cost

	-dents		ses per respon dent	Response (in hours)		
Health jurisdic-tion Staff	65	NHM&E Data Variables and Values (HD)	4	138	***$19.81***	***$699,848***
Health jurisdic-tion Staff HIV Testing -Scan	30	HIV Testing Form	4	616	***$19.81***	***$1,464,355***
Health jurisdic-tion Staff HIV Testing - non-scan	35	NHM&E Data Variables and Values (HD)	4	439	***$19.81***	***$1,217,523***
Health jurisdictio ns Training	65		4	10	***$19.81***	***$51,506***
CBO Staff	300	NHM&E Data Variables and Values (CBO)	4	84	***$14.57***	***$1,468,656***
CBO Staff HIV Testing	100	HIV Testing Form	4	30	***$14.57***	***$174,840***
CBO Training	300		4	10	***$14.57***	***$174,840***
					TOTAL	***$5,251,568***

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

There are no costs to respondents that are not supported by CDC funding under the program announcement beyond usual and customary business practices that would be carried out even if NHM&E data collection were not required. The conditions

of the cooperative agreements that CDC awards for HIV prevention programs require recipients to conduct evaluation of major program activities, interventions, and services, including data collection on interventions and clients served. Program announcements specify that a portion of the funding is to be used for evaluation activities, including data collection. Although the data previously collected by health jurisdictions and CBOs varied widely from state to state and program to program, it is the usual and customary business practice of the grantees to gather and maintain HIV prevention program data, complete the collection of records, and review the information prior to submission to CDC. Since the collection of data is a routine and customary practice, grantees that collect NHM&E data should incur little or no net additional costs to respond to this data collection.

Overall, respondents may choose one of the following options in which to enter and submit the required NHM&E data variables:

1) Use the PEMS software provided by CDC at no cost to the respondent (PEMS)
2) Revise their existing HIV prevention information technology system and submit data in the prescribed format via the SDN(External PEMS, “XPEMS”)

In addition, respondents may choose to enter the required NHM&E HIV testing data variables using the CDC-developed scan form and the associated scanning technology, or use one of the methods mentioned above.

Services offered to the grantees by CDC to support NHM&E data collection include training, technical assistance, and continued support to grantees through a help desk, website, and various forms of correspondence. Implementing the PEMS software will require no start-up costs for the respondents electing to use the PEMS option. Similarly, grantees who choose to use their existing systems should experience no start-up costs.

For those health jurisdictions and directly funded CBOs who chose to use the optional HIV testing scan form, the capital costs associated with this technology option are estimated to be approximately $1,000.00 per scanner. This would affect the approximately 30 health jurisdictions currently using the CDC-supplied scanning system. This cost can be

annualized over the useful lifespan of the scanner, estimated to be 7 years (based on the timeframe that health jurisdictions presently replace their scanners). This would result in an annualized cost of $143/year over 7 years for each organization that purchases a scanner.

There will also be the additional cost of the scanning software for the 30 health jurisdictions that will scan the new CT form. The cost of this software is estimated to range from $16,000 - $30,000, with an average of $20,000. The lifespan of this software is estimated to be 13 years; based on the life of the present CTS software. The annualized estimated average cost for the software is $1,538/year over 13 years for each of the 30 health jurisdictions that decide to purchase this software ($20,000/13 years = $1,538/year).

Release of various PEMS software versions will be necessary over time, but it is anticipated that PEMS and the NHM&E data variables will be essential tools for monitoring and evaluating HIV prevention programs for many years and there will be no cost to the grantees for these updates.

14. Annualized Cost to the Federal Government

The NHM&E data collection and PEMS software are multi-year projects expected to be in use for many years. For the purposes of this submission, a three year life expectancy has been used to estimate the annualized cost to the government.

CDC supports costs for HIV prevention program cooperative agreements using funds budgeted for these purposes. Additional expenses will be incurred by CDC for training grantees, providing technical assistance, monitoring and analyzing the submitted NHM&E data, and generating assorted reports. Total costs for these activities are estimated at $439,660 annually (see table below).

Training for grantees is currently being developed. Instruction will include topics such as confidentiality and computer security, use of PEMS, evaluation principles, and use of data for program improvement. The base Federal General Schedule (GS) salary for full-time employees (FTEs) with experience in these areas is estimated to be a GS-13 step 5. It is expected that the equivalent of two FTEs paid $46.43/hour will each expend approximately twenty-five

percent (25%) of their time or 1040 hours/FTE annually to oversee these trainings.

Technical assistance will be provided through an e-mail service center overseen by a CDC FTE. It is expected that the equivalent of two GS-13 step 7 ($49.16/hour) FTEs will expend approximately twenty-five percent (25%) of working hours (1040 hours) to oversee this service center.

Monitoring, analyzing, and reporting the NHYM&E data are projected to require the expertise of the equivalent of one data manager and three data analysts. The data manager would be at the pay scale of GS-13 step 5 ($46.43/hour) and the data analysts would be at the pay scale of GS-12 step 5 ($39.05/hour). Prior to NHM&E, a data manager and two analysts reviewed, analyzed, and interpreted HIV prevention program data submitted by 65 health jurisdictions and 90 CBOs. It is estimated that one additional analyst is needed for NHM&E data due to the increase in data anticipated from grantees and the submission of data from 70 additional CBOs.

Employee Function	**Annual Burden (in hours)**	**Hourly Wage Rate**	**Annual Cost**
Training	1040	$46.43	$ 48,287.20
Technical Assistance	1040	$49.16	$ 51,126.40
Monitoring, Analyzing and Reporting	2080 6240	$46.43 $39.05	$ 96,574.40 $243,672.00
TOTAL ANNUAL FEDERAL GOVERNMENT COSTS: $439,666.00			

15. Explanation for Program Changes or Adjustments

This is a program change of a currently approved data collection. While there have been some modifications to the

variables themselves, such as changing some from required to optional, adding or changing some value choices under the variables, editing the wording of the variable or value definitions, and other minor changes to variables, the major change is in the burden. The previously approved burden was 181,512 hours, not counting the changes to include additional respondents and variables for special evaluation projects during the period of approval. Total approved hours are not known because some modification requests are still in process. We currently request approval for 298,660 burden hours.

This significant increase in burden, despite the reductions in the number of required variables, has several causes. First, the Pacific Island jurisdictions, which were not included previously, are now included. Second, we have already received more funding for HIV testing than included in the previous burden calculations and anticipate further expansion of this activity during the period of approval of this ICR. Third, we are in the process of competing several program announcements open to state and local health departments, CBOs, and other organizations capable of providing HIV prevention services. This may result in an increase in the number of organizations provided funding and in the number of HIV prevention programs conducted by each funded organization. Fourth, we anticipate an expansion in the number and scope of the special studies or projects that will use the NHM&E data as the basis for evaluation studies of program outcome or effectiveness. The Substance Abuse and Mental Health Services Administration, as noted above, also uses the CDC HIV Testing scan form, but this data collection is not included in the burden calculations for this ICR.

The burden hours changed because of each of these causes is difficult or impossible to estimate at this time. However, the costs above the normal cost of doing business are covered by the CDC funding rather than imposing a financial cost on the grantee. All of these data collections will be part of HIV prevention programs funded by CDC so that even the hours spent collecting the data are part of the CDC funded activities, so, in effect, there is no burden. Therefore, we request a large enough total burden to cover any contingencies. These activities should be made visible to OMB through the normal program announcement approval

process, so that OMB is aware of the programs that are covered under this ICR.

16. Plans for Tabulation and Publication and Project Time Schedule

Data are being collected under the existing approved ICR, and is anticipated to continue quarterly without interruption if this ICR is approved.

Analysis is focused on improving program monitoring, conducting national analysis of HIV prevention programs, identifying needs for prevention research and evaluation studies, and responding to data requests from Congress and the Executive Branch. All of these activities are currently in process. Annual reports on the data, starting with reports on the 2009 data, are scheduled to be produced beginning in the summer of 2010. NHM&E data will also be analyzed in conjunction with data from other Division of HIV/AIDS Prevention (DHAP) collection systems for enhanced monitoring of the HIV epidemic.

In addition, NHM&E data will be used to improve knowledge of local prevention practices, implementation of effective HIV prevention interventions, implementation of the Advancing HIV Prevention Initiative (AHP) interventions, and adherence to program reporting requirements. Reports generated by the system include reports for quality assurance, comparison of planned activities or expenditures to actual activities or expenditures, data for calculating required performance indicators, data on specific interventions, data for contract monitoring, and data for assessing needs. These types of reports are available on the grantee, jurisdiction, or national level.

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

Not applicable.

18. Exceptions to Certification for Paperwork Reduction Act (PRA) Submissions 5CFR 1320.3(h)(1)-(10)

No exception is requested.