Medical Monitoring Project

0920-0740

Supporting Statement A

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LIST OF ATTACHMENTS

Attachment Number		**Document Description**
1a		Section 301 of the Public Health Service Act
1b		Authorization to Operate for the Data Coordinating Center
2a		MMP Standard Interview Questionnaire
2b		MMP Short Interview Questionnaire
3a		MMP Medical Record Abstraction Medical History Form
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3c		MMP Medical Record Abstraction Surveillance Period Visit Form
3d		MMP Medical Record Abstraction Surveillance Period Inpatient Form
4		MMP Minimum Dataset
5		Bibliography of MMP Publications
6		Assurance of Confidentiality for HIV/AIDS Surveillance

7		Federal Register Notice (60 day)
8		List of Consultants in the Development of MMP
9		Agreement to Abide by Restrictions on Release of Surveillance Data
10		Model Consent Form
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12		Summary of Changes to Data Collection Instruments
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A. Justification

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention requests a revision and 3 year approval of the currently approved Medical Monitoring Project (MMP) 0920-0740, expiration date May 31, 2012. The patient interview questionnaire was revised. Aside from these changes, the project activities and methods will remain the same as in the previously approved information collection request. The burden has not substantially changed from the burden shown in the current inventory.

The following revisions were made to the OMB-approved project 0920-0740:

- Twenty-one questions were added to the standard interview form and twenty-five were removed. Changes to the previously approved interview instruments are outlined in **Attachment 12**.
- An additional 56 data elements were added to the Minimum Dataset. Because these data are extracted from an existing database using a computer program run by MMP staff, these additions do not change the burden of the project. Changes to the previously approved Minimum Dataset are outlined in **Attachment 12**.
- Estimated annualized burden hours changed from 8,500 to 8,537 because an additional 62 patients will be sampled (total of 9,400 patients from previously approved 9,338 patients, see Exhibit 12.A).

<u>Background</u>
Human Immunodeficiency Virus (HIV) and Acquired Immune Deficiency Syndrome (AIDS) case reporting (OMB Control No. 0920-0573: Adult and Pediatric Confidential HIV/AIDS Case Reports) has been the underpinning of HIV/AIDS surveillance activities since the mid-1980s. All US states have reported AIDS cases using a standard case definition since 1985, and as of 2005, all states conduct surveillance for HIV infection without AIDS. As availability and prescription of highly active antiretroviral therapy (HAART) increased, the interval between HIV infection and opportunistic infection (OI) diagnosis or development of severe immunosuppression became highly variable. Thus, case surveillance data on severe immunosuppression and AIDS-defining OI (AIDS-OI) diagnoses were no longer sufficient for monitoring clinical outcomes of HIV infection.

At the request of Congress, an Institute of Medicine (IOM)

committee in 2003 reviewed the status of HIV/AIDS surveillance data and the extent to which data currently collected by the HIV/AIDS case surveillance and supplemental surveillance systems were adequate for determining allocation of resources for treatment and care of HIV infection. The IOM committee recommended that the Health Resources and Services Administration (HRSA) and the CDC evaluate the cost and utility of redesigning studies to assess the specific needs and circumstances of people living with HIV. One of the approaches proposed by the IOM was to coordinate HRSA and CDC efforts to survey a random sample of HIV-infected persons to develop more accurate measures of need for prevention and care services. The IOM recommendations influenced the development of MMP (0920-0740).

Based on the IOM recommendations, MMP is designed to obtain locally and nationally representative data on behaviors and clinical outcomes of a national probability sample of patients in care for HIV infection.

This request is authorized by Title III – General Powers and Duties of the Public Health Service, Section 301 (241.)a. Research and investigations generally (**Attachment 1a**).

CDC awarded a contract in 2008 to maintain a Data Coordinating Center, which was operational as of January 2009. The contract was renewed in September 2011. The Data Coordinating Center (DCC) is a system with a secure file data server where MMP data are transmitted and stored securely. The DCC uses 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). The DCC has received approval through the Certification and Accreditation process (**Attachment 1b**). In addition to the technical requirements listed above, data management processes are in compliance with *The Guidelines for HIV/AIDS Surveillance – Security and Confidentiality*.

Privacy Impact Assessment

The previously approved data collection was assessed for privacy impact.

Overview of the Data Collection System

MMP is a supplemental surveillance project designed to collect nationally representative data about people living with HIV/AIDS who are receiving medical care in the United States. MMP is sponsored by the U.S. Department of Health and Human Services' Centers for Disease Control and Prevention (CDC), conducted by state and local health departments, and is endorsed by a wide array of national organizations. A total of 23 grantees (16 states, 1 U.S. territory, and 6 separately funded metropolitan statistical areas within funded states) are currently conducting MMP activities: California; Chicago, IL; Delaware; Florida; Georgia; Houston, Texas; Illinois; Indiana; Los Angeles, CA; Michigan; Mississippi; New Jersey; New York; New York City, NY; North Carolina; Oregon; Pennsylvania; Philadelphia, PA; Puerto Rico; San Francisco, CA; Texas; Virginia; and Washington.

MMP has a 3-stage sampling design. During the first stage of sampling, geographic areas were sampled with probability proportional to size based on AIDS prevalence at the end of 2002. During the second stage of sampling, a representative sample of HIV care facilities is chosen from each area with probability proportional to the numbers of HIV-positive patients in their care during a specified 4-month period. Sampling of HIV care facilities occurs every other year. During the third stage of sampling, HIV-infected patients are selected yearly from sampled facilities. All patients with a care visit in the 4-month sampling period have the same probability of selection.

MMP's data collection has two primary components: an interview and medical record abstraction (**Attachments 2a, 2b, and 3a-3d**). Trained health department personnel invite each selected patient to participate in a 45-minute face-to-face or telephone interview. Additional clinical information is abstracted from patient medical records.

Demographic and HIV-related laboratory information on sampled participants is also extracted from an existing HIV case surveillance database, the national HIV/AIDS Reporting System [HARS]) (OMB Control No. 0920-0573, Exp. 1/31/2013: Adult and Pediatric Confidential HIV/AIDS Case Reports for National HIV/AIDS Surveillance). This minimum dataset (MDS) (**Attachment 4**) is used to adjust for participant nonresponse bias and improve the ability of MMP to monitor ongoing care and treatment of HIV-infected persons.

Interviewers collect the data using a software application loaded onto handheld or laptop computers. All data are encrypted and computers used for data collection are password protected so that unauthorized users will be unable to view, export or modify collected data. Electronic data collected for MMP are maintained indefinitely at CDC.

Items of information to be collected

The MMP interview will collect data from sampled HIV-infected adults on demographic characteristics, access to health care, stigma and discrimination, adherence to antiretroviral therapy, HIV testing, sexual behavior, drug and alcohol use, unmet needs for services, depression and anxiety, access to HIV prevention services, gynecological and reproductive history, health conditions and preventive therapy, and acculturation (**Attachments 2a and 2b**).

The MMP medical record abstraction will collect data from medical records on demographic characteristics, opportunistic illnesses, antiretroviral and other prescribed medications, laboratory test results, receipt of risk reduction counseling and referral, and other clinical diagnoses (**Attachments 3a, 3b, 3c, and 3d**). The medical record abstraction data elements have not changed since the previously approved version.

The MMP Minimum Dataset will consist of data extracted from the HIV/AIDS Reporting System [HARS] (OMB Control No. 0920-0573, Exp. 1/31/2013: Adult and Pediatric Confidential HIV/AIDS Case Reports for National HIV/AIDS Surveillance) including demographics, HIV diagnosis date, and HIV-related laboratory tests (**Attachment 4**).
The only information in identifiable form collected is date of birth, which is collected through interview, medical record abstraction, and minimum dataset. Date of birth is collected by MMP for two reasons. First, it is used to ensure that participants meet the age eligibility criteria for participation in the survey. Second, it is used to identify potential duplicate records or participants who have participated more than once per cycle. Date of birth is sent to CDC, but is not shared beyond the CDC team conducting the data collection (i.e., it is not included in analysis datasets). No other information in identifiable form (IIF) will be collected during the MMP interview. Individuals cannot be indirectly identified through MMP data.

Data collected through MMP are stored and accessed by a survey

identification number, both locally and at CDC. 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

The information collection system will not involve a web-based data collection method, nor will it host a website. There is no website content directed at children under 13 years of age.

2. Purpose and Use of Information Collection

- MMP aims to facilitate understanding of health-related experiences and needs of people living with HIV/AIDS who are receiving HIV care in the U.S. The goals of the project are to 1) provide locally and nationally representative estimates of risk behaviors and clinical outcomes of persons receiving HIV care; 2) describe health-related behaviors; 3) determine accessibility and use of prevention and support services; 4) increase knowledge of the care and treatment provided; and 5) examine variations of factors by patient characteristics.
- The impetus for MMP was an Institute of Medicine report that stated the need for nationally representative estimates of behaviors and clinical outcomes for people living with HIV. Although the HIV/AIDS Reporting System [HARS] (collected under OMB Control No. 0920-0573, Exp. 1/31/2013: Adult and Pediatric Confidential HIV/AIDS Case Reports for National HIV/AIDS Surveillance) provides information on core demographics of HIV-infected persons in the US, MMP provides detailed behavioral and clinical data that is not collected by any other national system. Although MMP shares some data elements with the National HIV Behavioral Surveillance System (NHBS) (OMB 0920-0770, exp. 3/31/2014), which collects information from persons at risk of HIV infection, MMP collects information from persons who have been diagnosed with HIV infection and are receiving HIV medical care.
- One focus of MMP data collection is behavior (such as unprotected sex and drug use) directly related to HIV transmission that is amenable to intervention through prevention programs. The explicit ability to identify gaps in HIV prevention services for persons living with HIV/AIDS who are engaging in behaviors that increase the risk of HIV transmission is a unique aspect of MMP, and one that is critical to monitor the uptake and impact of important national CDC HIV prevention initiatives such as the release of

Prevention with Positives (PWP) guidelines.

- Although other studies monitor clinical factors such as viral load and receipt of medical services for specific cohorts, MMP alone does so for locally representative and nationally representative samples, including persons receiving care in public and private facilities. Because it collects data via linked interview and medical record abstraction, MMP allows description of risk behaviors among HIV-infected persons by clinical characteristics, and assessment of the associations between care-seeking behavior, quality of care received, and clinical characteristics.
- The MMP minimum dataset links the MMP interview and medical record data with the National HIV/AIDS Surveillance System through linkage to the HIV/AIDS Reporting System (HARS). It includes information from HARS on persons sampled for MMP and is a unique feature of MMP previously approved to support quality control (to ensure patients were not sampled for participation in MMP more than once) and for non-response bias analysis. Additions to the minimum dataset proposed in this request will allow monitoring of MMP respondents' care utilization and treatment over time, also described in Supporting Statement B, 2. Procedures for the Collection of Information. This change was made because engagement in medical care and progression of disease are indicators that predict positive health outcomes and costs of care, respectively, for persons living with HIV. The ability to monitor these indicators for persons from whom there is also interview data will add value to the information collected through both MMP and the National HIV/AIDS Surveillance System, and permit assessment (not currently possible) of national progress in meeting National HIV/AIDS Strategy and CDC Division of HIV/AIDS Prevention goals of improving access to and use of high quality medical care.
- Through its unique design and national scope, MMP allows CDC to monitor national progress toward the goals of the National HIV/AIDS Strategy, specifically to decrease HIV transmission and ensure high quality care for all people living with HIV. CDC is responsible for issuing recommendations for various HIV-related services. MMP provides an evidence base for policies and recommendations issued by CDC related to HIV medical care and prevention services for HIV-diagnosed persons. If MMP data were not collected, CDC would be limited in its ability to provide recommendations and guidance regarding HIV treatment, care, and prevention.

The information collection described in this request is funded through cooperative agreements with state and local health

departments (CDC surveillance activities are routinely funded through cooperative agreements with state and local health departments). The MMP funding announcement was published January 22, 2009 and the project is now in the third year of a 5-year budget period. Up to 23 applicants will be awarded funding each year.

At the national level, MMP data are used for tracking national trends in HIV-related morbidity, and service access and utilization, for focusing and prioritizing national initiatives to improve the provision of treatment and prevention resources, and for benchmarking and evaluating progress toward national prevention and treatment initiatives. Annual or bi-annual national estimates of rates of opportunistic infection (OI) diagnoses will likely be the gold standard for measuring the effectiveness of reducing the severity of HIV-related disease, and for describing the characteristics of persons who have progressive HIV disease and the reasons for progression. This information is used to inform treatment and prevention guidelines for HIV care providers and to guide prevention of clinical outcomes associated with progression of HIV infection. Data from MMP have been used to inform PWP guidelines and will be used to monitor the uptake and impact of the guidelines.

Data are also used at the national level to assess progress toward performance goals of CDC's National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP):

1. Increase the proportion of people who consistently engage in behaviors that reduce the risk of HIV transmission;
2. Develop an integrated monitoring system to measure receipt of appropriate care, treatment, and prevention services for persons living with HIV;
3. Provide locally relevant data for community planning.

Results from the 2005 pilot data collection and from the 2007 data collection cycle have been published as Surveillance Reports. Information from the 2009 MMP cycle on receipt of prevention counseling, use of antiretroviral therapy, and HIV viral load suppression was published in CDC's Morbidity and Mortality Weekly Report. A National MMP Surveillance Report based on results from the 2009 data collection cycle is currently in progress. An analysis of area-specific data on unmet needs for services has been published in a peer-reviewed scientific journal. MMP national and area-specific data have also been disseminated at national meetings. See **Attachment 5** for a bibliography of MMP publications. Experience gained by the grantees from participating in the 2005, 2007, 2009, and

2010 data collection cycles has improved efficiency in completing project activities and increasing data dissemination at both the local and the national level.

At the local level, MMP data are used for local HIV prevention program planning purposes, including the development of local epidemiologic profiles and responding to data requests from the Health Resources and Services Administration (HRSA) and other agencies which manage resources for HIV care and treatment. MMP provides information on the characteristics of persons receiving HIV medical care and the types of care services received, and identifies needs for prevention and care services among a representative sample of HIV-infected persons receiving medical care. Information about access to and use of these services is used in the evaluation of local care and prevention services for people living with HIV.

Deriving state-level estimates of behaviors associated with the transmission of HIV and clinical outcomes using a probability sample improves the quality of information available at the local level in two ways: by 1) providing HIV prevention community planning groups, Ryan White Comprehensive AIDS Resources Emergency (CARE) Act planning consortia and councils (who are charged with prioritizing local resources for HIV prevention and care) with data that is representative of populations living with HIV in their jurisdictions and 2)by allowing estimation of 95% confidence intervals that reflect the precision of point estimates.

Each participating facility or practitioner has authority for the release of their facility-specific data (i.e., they choose whether or not the facility will participate and if patients will be identified to the health department conducting MMP by name or coded identifier). Each participating health department will be responsible for the release of MMP data from its jurisdiction. CDC will have primary responsibility for the release of data aggregated from each geographic area and will provide this information to all collaborating health departments. These data will be distributed to the providers, researchers, policymakers and other interested parties through presentations at local, national and international conferences, publications in peer reviewed journals, and presentations in different forums such as continuing medical education courses and seminars. Furthermore, CDC will regularly publish surveillance reports using data collected annually.

Patients and community members will be informed of MMP findings

through multiple conduits of information. National data will be released in aggregate table form on the CDC's MMP website and through publications and presentations at national conferences. Local data results will be reported back to the community through means such as local publications, Epidemiologic Profile reports, and presentations to local AIDS Service Organizations and community planning bodies and at conferences and workshops.

Without MMP data, the best source of behavioral and clinical data would be the HIV/AIDS Reporting System [HARS] (collected under OMB Control No. 0920-0573, exp. 1/31/2013: Adult and Pediatric Confidential HIV/AIDS Case Reports for National HIV/AIDS Surveillance) (which only collects a limited amount of information from medical records of persons infected with HIV) or smaller-scale cohort studies. These studies do not provide nationally-representative data because they generally collect information on persons receiving care at large HIV specialty care facilities in metropolitan areas. Not collecting MMP data would adversely affect the ability to monitor the HIV/AIDS epidemic both locally and nationally.

Privacy Impact Assessment Information

Information from MMP is being collected to inform care and prevention efforts by 1) providing information about the characteristics, behaviors, and needs of persons living with HIV, 2) providing information on the clinical status and medical care and treatment of persons with HIV, and 3) comparing the characteristics of persons who did and did not participate to facilitate non-response bias analysis and make inference to the population of persons living with HIV in the United States.

The MMP interview will collect data from sampled HIV-infected adults on demographic characteristics, access to health care, stigma and discrimination, adherence to antiretroviral therapy, HIV testing, sexual behavior, drug and alcohol use, unmet needs for services, depression and anxiety, access to HIV prevention services, gynecological and reproductive history, health conditions and preventive therapy, and acculturation (**Attachments 2a and 2b**). Minor changes were made to the previously approved standard interview questionnaire, and these are described in **Attachment 12**).

The only information in identifiable form (IIF) collected through the MMP interview is date of birth. Date of birth is being collected in order to determine eligibility for MMP data collection, which is limited to persons over age 18. In

addition, date of birth is collected for quality control purposes. Date of birth for sampled participants is compared across MMP interview, abstraction and minimum dataset to ensure that information is collected on the correct person and that duplicate information is not collected.

Although the information collected in the MMP interview on race/ethnicity, sexual behaviors, drug use, incarceration, stigma, and health conditions is sensitive, the purposes of this project cannot be accomplished without their collection. Participants will be told that they may decline to participate without penalty or, if they agree to participate, they may refuse to answer any question. They will also be informed that only aggregated data may be released in published reports.

The MMP medical record abstraction will collect data from medical records on demographic characteristics, opportunistic illnesses, antiretroviral and other prescribed medications, laboratory test results, receipt of risk reduction counseling and referral, and other clinical diagnoses (**Attachments 3a, 3b, 3c, and 3d**). The medical record abstraction data elements have not changed since the previously approved version.

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Although the information collected in the MMP abstraction on race/ethnicity, health conditions, drug use, and services received is sensitive, the purposes of this project cannot be accomplished without their collection. Participants will be told that they may decline to participate without penalty and will also be informed that only aggregated data may be released in published reports.

The MMP Minimum Dataset will consist of data extracted from the HIV/AIDS Reporting System [HARS] (OMB Control No. 0920-0573, exp. 1/31/2013: Adult and Pediatric Confidential HIV/AIDS Case Reports for National HIV/AIDS Surveillance) including demographics, HIV diagnosis date, and HIV-related laboratory tests (**Attachment 4**). In a multi-stage complex sample design

such as that used by MMP, it is important to determine the characteristics of persons who did not participate in order to assess non-response bias and make inference to the national population of HIV-infected persons.

The only information in identifiable form (IIF) collected through the MMP minimum dataset is date of birth. Date of birth is being collected in order to determine eligibility for MMP data collection, which is limited to persons over age 18. In addition, date of birth is collected for quality control purposes. Date of birth for sampled participants is compared across MMP interview, abstraction and minimum dataset to ensure that information is collected on the correct person and that duplicate information is not collected.

Although the information collected in the MMP minimum dataset on race/ethnicity, sexual behaviors, and health status is sensitive, the purposes of this project cannot be accomplished without their collection. Participants will be told that they may decline to participate without penalty and will also be informed that only aggregated data may be released in published reports.

Sensitive information collected through MMP will not be linked to any other personally identifiable information and cannot be used to reveal the identity of any one person. The proposed data collection will have little or no effect on the respondent’s privacy. No information that could directly identify an individual will be collected as part of the interview, medical record abstraction, or minimum dataset. However, data collected for this project are protected under a Federal Assurance of Confidentiality (see **Attachment 6** for details).

Several safety precautions are in place to prevent any information from being connected to a respondent. Security of data on the handheld, desktop, or laptop computers will be maintained through training, password protection, encryption, and controlling access to hardware.

Data collectors will complete state-specific security and confidentiality training and sign a statement designed by each state indicating their understanding of security and confidentiality policies. Interviewers and abstractors will also receive training from CDC staff on how to protect the security and confidentiality of the information collected.

3. Use of Improved Information Technology and Burden Reduction

Interview and medical record abstraction data will be collected on password-protected encrypted handheld and laptop computers using the Questionnaire Development Software (QDS), NOVA Research Company, Bethesda, Maryland for interviews and CDC-developed software for abstractions. It is expected that 100% of interviews and abstractions will be collected using electronic applications. All interviews will be conducted by trained local MMP staff.

CDC will conduct training and site visits to provide instructions and technical assistance on how to use the data collection software, conduct the interviews and abstractions, archive the collected data, and transfer the data. CDC will also provide training to participating state and local health departments and detailed written instructions on methods for conducting the interviews and abstractions. CDC will require local MMP staff providing supervision on the project to monitor interviewers and abstractors regularly. CDC will convene lessons-learned meetings to identify and resolve the problems that can occur with the software and hardware that is used for conducting the interviews and abstractions. Automated edit checks will be built into the computer software programs as a further quality control measure.

Provision of electronic data collection hardware and software, training and technical assistance will help to reduce the burden on grantees conducting MMP. Transfer of data collected electronically will eliminate the need for data entry at the state/local sites. An evaluation of supplemental surveillance data using handheld interview devices such as the ones being used for MMP has shown the following: a reduction in the duration of the interview by up to 20%; a decrease in the average number of interviewer errors per interview such as skip patterns, out of range answers and missing data from an average of 2.5 per interview to .3 per interview; and the elimination of the need for data cleaning associated with data entry and the errors listed above, resulting in a reduction in the time between the last interview and the production of a final analysis dataset from approximately 6 months to only 1 month.

CDC Division of HIV/AIDS Prevention, (DHAP) has implemented the use of handheld and laptop devices for other national surveillance systems. All state and local health departments participating in MMP are licensed to use the software and have extensive experience with implementing interview projects using

electronic data collection in the field.

Computer-assisted personal interviews conducted by an interviewer reduce burden for the respondent because they may improve comprehension (compared with a self-administered questionnaire), and may improve response time. The computer "assists" by customizing the question wording for each respondent, allowing the interviewer to focus on explaining complex terms or definitions, giving instructions, ensuring that answers are relevant and entered accurately, and maintaining the respondent's privacy.

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 locally and nationally representative data on behaviors and clinical outcomes of patients in care for HIV infection.

MMP data collection replaces CDC's Adult/Adolescent Spectrum of HIV Disease Project (ASD) (clinically exempt from OMB) and the Supplement to HIV/AIDS Surveillance Project (SHAS) (OMB 0920-0262, exp. 06/30/2004). A few data elements are shared with CDC's National HIV Behavioral Surveillance (NHBS) (OMB 0920-0770, exp. 3/31/2014), HIV Outpatient Study (HOPS) (clinically exempt from OMB), Study to Understand the Natural History of HIV/AIDS in the Era of Effective Therapy (SUN) (clinically exempt from OMB), and the HIV/AIDS Reporting System [HARS] (collected under OMB Control No. 0920-0573, exp. 1/31/2013: Adult and Pediatric Confidential HIV/AIDS Case Reports for National HIV/AIDS Surveillance).

These existing information collections listed above cannot be modified, used partially, nor in aggregate format to satisfy the needs of the proposed project. CDC discontinued the ASD and SHAS projects in anticipation of MMP and to avoid duplication of data collection efforts. NHBS collects data on specific populations at increased risk for HIV infection (men who have sex with men, drug users and high risk heterosexuals), not on a population-based sample of HIV-infected patients in care. HOPS and SUN collect information from HIV-infected patients in a limited number of HIV specialty care facilities, so the data collected are limited for monitoring national or local care and prevention efforts. Although HIV case surveillance through the National HIV/AIDS Surveillance System collects information on

all persons diagnosed with HIV, it provides information on a more limited set of demographic and HIV-related laboratory variables than are collected through the proposed data collection.

CDC established relationships with other Federal stakeholders and consultants during the conception and development of MMP. Beginning in September 2003, consultations have been held with state and local health departments, the RAND Corporation, ICF Macro, National Institutes of Health (NIH), HRSA, and other agencies. To promote collection of data that can be used by multiple agencies, ongoing communications with these federal and non-governmental partners have continued for the duration of this project. Meetings with these Federal stakeholders and consultants (who are aware of data collection focused on persons with HIV infection) ensure that duplicate or similar data collection efforts would have been identified if they existed. Other surveys may have obtained data related to topics covered in MMP, but most have been more limited in the questions they asked, the populations they represented, the geographic areas they covered, or all of these factors.

5. Impact on Small Businesses or Other Small Entities

Small medical facilities that provide HIV care have a chance of being selected for participation in MMP. Facility participation is voluntary. Data collected for MMP is the same for small and large medical facilities. For MMP, an estimated patient load for each HIV care facility (for facility sampling purposes) and a list of patients seen during a 4 month time period (for patient sampling purposes)are necessary. These activities are estimated to take an average of 2 hours and 30 minutes, respectively. If permitted, MMP staff will recruit sampled patients. However, in cases in which the facility prefers to introduce the project to patients before recruitment by MMP staff, it is estimated this will take an average of 5 minutes per patient. If permitted, MMP staff will pull the medical records of sampled patients. However, in cases in which facility staff prefer to do this, it is estimated to take an average of 5 minutes to pull each medical record for data abstraction.

6. Consequences of Collecting the Information Less Frequently

MMP data collection activities occur annually during each data collection cycle, for 3 years from the approval date. Every other year, a sample of facilities will be drawn. Sampled

facilities will participate for two data collection cycles. From each selected facility, patients will be sampled for participation in the MMP. It is possible that a patient receiving HIV care will be selected for participation in MMP in more than one year, as patients in care will have some probability of being selected each project year. Patients selected during a data collection cycle are only eligible to participate once during that cycle. There are no legal obstacles to reduce the burden.

Data for prevention and resource planning must be collected on an annual basis to meet reporting requirements of CDC and HRSA. Collecting data less than annually would not be advantageous, nor would it meet the needs of the grantees collecting the data and planning groups that rely on the data for resource allocation.

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

None of the special circumstances in the guidelines of 5 CFR 1320.5 applies.

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

8A. A 60-day notice to solicit public comments was published in the Federal Register on January 13, 2012, Vol 77, No. 9, pages 2066-20667. No substantive comments have been received (See **Attachment 7** for a copy of the Federal Register notice).

8B. Several consultations were conducted with various scientists and public health practitioners outside the agency. All names, affiliations, and contact information are included in (**Attachment 8**).

Consultations to discuss sampling methods and lessons learned from previous projects; to commence planning, identify sampling approaches and design for clinical outcomes surveillance; to discuss Medical Monitoring Project domains; to discuss second and third stage sampling, review project progress and discuss sampling issues, stratification parameters, and review scientific quality issues; and to discuss patient sampling methods and tasks were held with the RAND Corporation in September 2003 March 2004, October 2004, and September 2005. They also participated in bi-weekly conference calls with CDC

on these matters from 2004 to the July 2010.
A consultation to discuss how to use MMP data to meet HRSA data needs, how to avoid redundancy in data collections by CDC and HRSA grantees, and discuss research questions of interest to HRSA, and future collaborations between CDC and HRSA on MMP were held with HRSA and NIH in November 2004. Dr. Victoria Cargill from HRSA has been consulted as needed since 2004.

Biweekly consultation calls to discuss design, sampling methods and analytic considerations for clinical outcomes surveillance were held with ICF Macro from June 2010 to July 2011.

In the spring of 2009, the Division of HIV/AIDS Prevention (DHAP), National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC), solicited feedback on its programs through an External Peer Review (EPR). Based on a recommendation from the peer review panel, a formal evaluation of MMP was conducted by Dr. Stephanie Broyles from Pennington Biomedical Research Center and staff from ICF Macro. A final report was completed in December 2010. CDC staff are currently exploring several key recommendations from the evaluation—including adjustments to the medical record abstraction, focusing staff on data dissemination, and refinement of sampling processes.

No major problems arose that could not be resolved during the consultations. MMP does not affect the work of other federal agencies.

9. Explanation of any Payment or Gift to Respondents

MMP involves conducting surveys with hard-to-reach and highly selective populations; sensitive questions are asked, including questions about sexual behavior and drug use. Because the interview takes approximately 45 minutes to complete, eligible persons are offered remuneration to participate in order to increase response rates. We anticipate that increased response rates will lead to improved representativeness of the underlying population of interest (Kulka, 1995).

Participants are given approximately $25 in cash for participation; the specific amount is determined by grantees based on local standards. If local regulations prohibit cash tokens of appreciation, equivalent tokens of appreciation may be offered in the form of gift certificates, cash cards, or bus or subway tokens.

The need for and amount of the remuneration is based, in part, on the fact that other, similar research projects that ask HIV risk behavior questions in many of the participating areas offer similar incentives. Thus, MMP would be competing with local researchers who do offer remuneration. Persons at risk for HIV infection have frequently been the focus of health-related data collections, in which remuneration is the norm (Thiede 2009; MacKellar 2005). Research has shown that financial incentives are effective at increasing response rates among female residents in minority zip codes (Whiteman 2003). A meta-analysis of 95 studies published between January 1999 and April 2005 describing methods of increasing minority enrollment and retention in research studies found that incentives enhanced retention among this group (Yancy 2006). Data from MMP's 2007 cycle indicate that 65% of respondents reported a race or ethnicity other than non-Hispanic white. Providing remuneration to MMP respondents is critical to achieve acceptable response rates.

Remuneration has been used in other HIV-related CDC data collection efforts such as for National HIV Behavioral Surveillance (OMB 0920-0770, exp. 5/31/2014) and the Transgender HIV Behavioral Survey (OMB 0920-0794 exp. 12/31/2010), both of which ask questions similar to those in MMP and have a similar length of time for completing the patient interview. In both of these other projects incentives were used to help increase participation rates; participants were offered approximately $25 as compensation for their time. Other studies have also found that incentives modestly improve response rates (Shaw et al. 2001).

10. Assurance of Confidentiality Provided to Respondents

A. This section has been reviewed by CDC's Information Collection Review Office, which has determined that the Privacy Act does not apply because the survey does not collect name, social security number, or other personally identifying information.

MMP is anonymous (neither names nor social security numbers are collected). Full date of birth is collected by MMP for two reasons: to ensure that participants meet the age eligibility criteria for participation in the survey, and for identifying potential duplicate records or participants who have participated more than once per cycle. Records that have exactly the same date of birth are compared on date of survey and other demographic information such as race/ethnicity, and

education; determinations of whether a record is a duplicate or a participant has already participated during the cycle (due to being sampled from another participating facility) are made based on how closely this information matches. Data collected through MMP, both locally and at CDC, are stored and accessed by a survey identification number. Other data collected through MMP, while sensitive, are not personally identifying; these data elements are described in **Attachments 2a, 2b, 3a-3d, and 4**.

B. The amount of personally identifying information collected for MMP is limited. Additionally, MMP is covered by an Assurance of Confidentiality for HIV/AIDS surveillance data (**Attachment 6**). The Assurance provides the highest level of legal confidentiality protection to the individual persons who are the subjects 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

The MMP interview will be conducted by trained MMP staff in a private location where the questions and responses cannot be overhead by others. MMP interview and abstraction data will be transmitted to CDC via the secure system described above on page 5, the Data Coordinating Center (DCC). Encryption security for all MMP data must meet the current National Institute of Standards and Technology (NIST) Federal Information Processing Standards (FIPS), which meet or exceed Advanced Encryption Standards (AES). 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).

A number of required protections ensure the security of the data on the data collection computers. The handheld computers

and laptop computers are solely used for MMP data collection activities. MMP data are encrypted when stored on a handheld device or laptop. Computers are protected by using a coded password only known by authorized MMP project staff. MMP data are deleted from the handheld and laptop computers after they are uploaded to the main secured database. The handheld and laptop computers must be kept with the staff at all times in the field; the computers are collected and secured by the field supervisor after return to the local MMP office. When not in use in the field, the computers are to be locked in a drawer or an office.

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. State and local health department personnel who conduct HIV/AIDS surveillance are subject to the confidentiality obligations described in the CDC guidelines for the security and confidentiality of National HIV Surveillance System data (http://www.cdc.gov/hiv/topics/surveillance/index.htm) and are required to undergo security and confidentiality training.

MMP data collectors and data managers undergo annual security and confidentiality training consistent with the guidelines set forth in the document “Technical Guidance for HIV/AIDS surveillance Programs, Volume III: Security and Confidentiality Guidelines” (www.cdc.gov/hiv/surveillance.htm). CDC’s Procurement and Grants Office will require the inclusion of 308(d) clauses 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 (**Attachment 9**), 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.” CDC-funded cooperative agreements with state and local health departments reference the Assurance of Confidentiality as a condition of award. Any MMP data maintained at CDC that are released to persons other than project staff will not include full date of birth.

C. Informed consent will be obtained from all respondents prior

to the interview. The informed consent process for respondents will be fulfilled by obtaining a consent document signed by the respondent, or by having the interviewer sign a consent document attesting to the respondent's verbal consent. All sites must obtain consent from respondents and store the consent forms in a secure location. An example model consent document is included as **Attachment 10**. Respondents will be informed that data collected from them for MMP will be kept private and secure and that the data will be reported in aggregate format.

The approved Project Determination Form (**Attachment 11**) indicates that because MMP is not considered research, and therefore that the protocol will not be reviewed by CDC's IRB. Each participating health department may obtain local IRB approval before data collection according to the needs of the jurisdiction.

11. Justification for Sensitive Questions

HIV can be transmitted from person to person through sexual contact and the sharing of HIV contaminated needles and syringes. In addition, HIV-infected persons with higher HIV viral loads may be at increased risk of transmitting the virus to others. These modes of transmission necessitate the collection of sensitive data regarding HIV/AIDS status, medical history, sexual orientation, sexual practices, and alcohol and drug use. The MMP data collection will also request sensitive information relating to race/ethnicity, alcohol and drug use, mental health conditions such as depression and psychosis, history of suicide attempt, and history of arrest. Although the information requested is highly sensitive, the purposes of MMP cannot be accomplished without their collection. Collection of these data will be used to understand barriers to HIV care and treatment and the impact of behaviors and health conditions on the clinical course of HIV disease, for example how depression might affect adherence to antiretroviral medication and lead to higher HIV viral load. These data will also be used to enhance HIV prevention programs designed to reduce high risk behaviors in persons most likely to transmit HIV.

The context in which questions are asked helps to overcome their potential sensitivity. There are several steps taken in MMP to minimize sensitivity and reiterate to the respondent the legitimate need for the information:

- Nearly all questions allow for responses of "don't know"

or “refuse to answer.”

- Consent scripts make it clear that the survey is sponsored by CDC and the local health department and that the information will be put to important uses.
- Toll-free phone numbers are provided if the respondent has questions about the survey.
- The questionnaire is carefully organized to lead smoothly from one topic to another. Transitions are made clear to respondents and the need for the information explained. Assurances about the privacy and confidentiality of the data are reiterated.
- The use of encrypted, password-protected computers for data collection addresses concerns the respondent might have about privacy (that others can see their answers).
- The token of appreciation indicates clearly to the respondent that the information is important to the survey sponsors.

All in-person interviews will be conducted by trained MMP staff in a private location, either as part of a routine visit to a medical facility or by an interview in the patient’s home, in a hospital or clinic, or other mutually agreed-upon location. Telephone interviews will be administered in a private location that ensures the confidentiality of responses. Interviewers will be trained to administer the consent script and all interview questions by reading each item verbatim, thus ensuring that all respondents receive the same information from the consent process and are asked the same questions. No interviews will be conducted without the consent of the respondent.

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

The estimate of annualized burden hours has not been substantially changed from the current inventory. The annual burden increased by 37 annual burden hours because an additional 62 patients will be sampled, for a total of 9,400 patients from the previously approved 9,338 patients. Although revisions were made to the previously approved data collection instruments (see **Attachment 12**), these revisions did not result in a change in the average time required to complete the data collection, and therefore did not result in any change in

burden hours. The number of questions added to the patient interview questionnaire is offset by an approximately equal number of questions that were deleted. There were no changes to the previously approved medical record abstraction forms. The burden of medical record abstraction will not change because there is no change in the number of medical records to be pulled. Likewise, there are no changes in the amount of time required for providing estimated patient loads or patient lists, or approaching patients for enrollment compared with the previously approved information collection request. The collection of the minimum dataset does not affect project burden hours because the data are collected via an automated computer program run by MMP staff that extracts the data from an existing database (HARS). Although changes have been made to the minimum dataset, this does not affect the burden of the project.

Health department staff in most project areas will recruit sampled patients to participate in MMP. In some facilities, providers may inform the patients that they have been selected to participate in the MMP and refer them to the health department MMP staff. Model patient recruitment scripts are included (**Attachments 13a and 13b**).

CDC’s current goal is to interview 80% of 9400 patients or 7520, 96% of whom (a total of 7219 patients) will complete the standard interview which will take approximately 45 minutes, and 4% of whom (a total of 301 patients) will complete the short interview which will take approximately 20 minutes. Thus, the total annual burden (in hours) is 8,537. Interviews of patients who engage in few risk behaviors or have no risk behaviors (sexual behavior, drug and alcohol use) or who take few HIV-related medications or no medications will take slightly less time. Interviews of patients who engage in many risk behaviors or are taking many HIV-related medications may take slightly longer.

MMP medical record abstractors and project coordinators at state and local health departments provided estimates of time required to pull patient medical records, estimate patient loads, provide patient lists and approach patients for enrollment. Medical records are only pulled once for each abstraction, the estimate to abstract 7,520 medical records is 3 minutes per record. The burden for this activity remains the same as in the previous data collection cycle. It is estimated that approximately 936 patient loads will be completed with an average burden of 2 hours each. Providing 1,030 patient lists

is estimated to take 30 minutes each. It is estimated that 3,120 patients will be approached by facility staff to participate in the project; this process is estimated to take 5 minutes per patient.

Exhibit 12.A: Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Burden (in hours)
Sampled, Eligible HIV-Infected Patients	Standard interview	7219	1	45/60	5,414
Sampled, Eligible HIV-Infected Patients Unable to Complete the Standard Interview	Short interview	301	1	20/60	100
Facility office staff pulling medical records		7,520	1	3/60	376
Facility office staff providing Estimated Patient Loads		936	1	2	1,872
Facility office staff providing patient lists		1,030	1	30/60	515
Facility office staff approaching participants for enrollment		3,120	1	5/60	260
Total					8,537

B. Estimated Annualized Cost to Respondents

Table 12.B: Estimated Annualized Burden Costs

Note: The hourly rate was determined by using information obtained from the US Department of Labor, Bureau of Labor Statistics:
ftp://ftp.bls.gov/pub/suppl/empsit.ceseeb2.txt

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Patients Interviewed with standard form	5,414	$19.07	$103,245
Patients Interviewed with short form	100	$19.07	$1,907
Facility staff pulling medical records	376	$20.12	$7,565
Facility staff providing estimated patient loads	1,872	$20.12	$37,665
Facility staff providing patient lists	515	$20.12	$10,362
Patients approached by facility staff for enrollment	260	$20.12	$5,231
Total	8,537		$165,975

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 $44,100,384. The annualized cost is summarized in Exhibit 14.A.

Exhibit 14.A. MMP Annualized Cost to the Federal Government*

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to	MMP – Personnel Epidemiologist-14 6 100% $646,620	$1,739,628

the Federal Government	Epidemiologist-13 3 100% $273,600 Behavioral Scientist-13 1 75% $68,400 Statistician-14 1 50% $53,885 Nurse Coordinator-12 1 100% $71,901 Public Health Analyst-12 1 75% $57,520 Public Health Analyst-9 1 75% $37,185 IT Specialist-14 1 50% $50,517 Support Staff Data Managers 5 100% $400,000 Project Coordinator 1 100% $80,000	
	Cooperative agreement funds to project areas	$11,600,000
Contractor and Other Expenses	Data Coordinating Center (CDC Contractor for data collection)	$1,100,000
	Contracted Project Coordinators (1)	$80,000
	Contracted Questionnaire Programming (2) 0.5 FTE	$60,000
	Travel	$30,000
	Meetings and Trainings	$85,000
	Spanish language translation	$2,500
	Printing	$3,000
	TOTAL COST TO THE GOVERNMENT	$14,700,128

*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 MMP data collection include project officers (epidemiologists and behavioral scientists) at the GS-13 and 14 levels, a GS-14 level statistician, GS-12 and 9 level public health analysts, a nurse coordinator, a project coordinators, an Information Technology Specialist, and data managers/analysts. Travel is related to providing technical assistance and conducting site visits. Examples of meetings that will be held include medical record abstraction training and the local principal investigators' meeting.

The information collection described in this request will be funded through cooperative agreements with state and local health departments (CDC surveillance activities are routinely funded through cooperative agreements with state and local health departments).

Data for MMP are compiled by staff in local health departments and sent via a secure network to a central processing location, called the Data Coordinating Center (DCC). The DCC will be funded through a separate contract. The purpose of the DCC is

to receive data from data managers at the local health departments, track the progress of the data, and distribute monthly monitoring reports to health department staff. The DCC will process all data sent from local health departments and produce a clean, final data set for use by CDC and each health department at the completion of each data collection cycle.

MMP data analysts will have responsibility for analyzing the final data set. They will work with MMP epidemiologists and behavioral scientists to create data tables to be displayed in surveillance reports and other products.

15. Explanation for Program Changes or Adjustments

The burden has not substantially changed from the burden shown in the current inventory.

The following revisions were made to the OMB approved project 0920-0740.

- Twenty-one questions were added to the standard interview form and twenty-five were removed. Changes to the previously approved interview instrument are outlined in **Attachment 12**.
- An additional 56 data elements were added to the Minimum Dataset. Because these data are extracted from an existing database using a computer program run by MMP staff, these additions do not change the burden of the project. Changes to the previously approved Minimum Dataset are outlined in **Attachment 12**.
- Estimated annualized burden hours changed from 8,500 to 8,537 because an additional 62 patients will be sampled (total of 9,400 patients, from previously approved 9,338 patients). see Exhibit 12.A).

16. Plans for Tabulation and Publication and Project Time Schedule

Data will be collected in 12-month cycles; clearance is requested for 3 years. The following is a brief overview of the MMP Timeline.

Activities	**Time Schedule**
Facility recruitment (2012 cycle)	1 month after OMB approval
Patient lists obtained	2-3 months after OMB approval
Interview patients	3-6 months after OMB approval
Abstract medical records of	3-6 months after OMB approval

interviewed patients	
Data management	3-6 months after OMB approval
Evaluation	7-8 months after OMB approval
Analysis	9-12 months after OMB approval
Publication	12 months after OMB approval
Facility recruitment (2013 cycle)	13 months after OMB approval
Patient lists obtained	14-15 months after OMB approval
Interview patients	15-18 months after OMB approval
Abstract medical records of interviewed patients	15-18 months after OMB approval
Evaluation	19-20 months after OMB approval
Analysis	21-24 months after OMB approval
Publication	24 months after OMB approval
Facility recruitment (2014 cycle)	25 months after OMB approval
Patient lists obtained	26-27 months after OMB approval
Interview patients	27-30 months after OMB approval
Abstract medical records of interviewed patients	27-30 months after OMB approval
Evaluation	31-32 months after OMB approval
Analysis	33-36 months after OMB approval
Publication	36 months after OMB approval

Data from MMP will continue to inform prevention and care services and increase existing knowledge in the area of treatment on HIV and prevention of onward transmission. National surveillance reports will be published annually for MMP (for an example, see http://www.cdc.gov/mmwr/preview/mmwrhtml/ss6011a1.htm?s_cid=ss6011a1_e). A 12-month period is required for data collection, and data collection will occur annually. Therefore, a 3-year clearance is requested. Data collection must begin following the Population Definition Period – the first four months of the calendar year.

Most of the results are expected to be useful at the local

level, while other results will be more meaningful aggregated across sites. Each participating health department has responsibility for the release of local data. CDC has primary responsibility for the release of cycle-specific data aggregated from all geographic areas. These data are distributed to the participating agencies, researchers, policy makers and other interested parties through presentations at local, national and international conferences, publications in peer reviewed journals, and presentations at different forums such as continuing medical education courses and seminars. Furthermore, CDC regularly publishes surveillance reports using data collected annually. For instance, the 2007 data collection cycle results (end of data collection September 2008) were published in September 2011. The time required from the end of data collection to the dissemination of results is expected to improve as CDC now has an established contracting arrangement to procure a clean, final MMP data set more rapidly; for example, the 2009 data collection cycle reports are expected to be available 24 months from completion of data collection in May 2010.

Community members will continue to be informed of MMP findings through multiple conduits of information. National data results will be released through national publications and presentations at conferences. Local data results will be reported back to the community through means such as local publications, Epidemiologic Profile reports, presentations to local AIDS Service Organizations and community planning bodies and at local conferences and workshops.

CDC analyses will focus on the following key behavioral and clinical outcomes:

- Prevalence of unprotected discordant vaginal and anal sex in the past 12 months;
- Prevalence of multiple (opposite sex) partners;
- Prevalence of non-injection drug use in past 12 months;
- Prevalence of use of antiretroviral therapy;
- Prevalence of detectable HIV viral load.

Data for MMP will be weighted to account for the complex sampling design.

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.