Medical Monitoring Project

OMB #0920-0740
(EXP. 5/31/2015)

Supporting Statement A

May 28, 2015

Project Officer:
Dr. Joseph Prejean
Branch Chief, Behavioral and Clinical Surveillance Branch
National Center for HIV, Hepatitis, STD and TB Prevention
Coordinating Center for Infectious Diseases
Centers for Disease Control and Prevention
1600 Clifton Rd, NE, MS E-46
Atlanta, Georgia 30333
Phone: (404) 639-5273
Fax: (404) 639-8640
E-mail: nzp1@cdc.gov

TABLE OF CONTENTS

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

EXHIBITS

Exhibit 12.A Estimated Annualized Burden Hours
Exhibit 12.B Estimated Annualized Burden Costs
Exhibit 14.A Estimated Annualized Costs to the Government

LIST OF ATTACHMENTS

Attachment Number		**Document Description**
1		Section 301 of the Public Health Service Act
2		Federal Register Notice (60 day)
3a		Overall Summary of Changes
3b		Summary of Changes to Data Collection Instruments
4a		Model Patient Recruitment Letter
4b		Model Patient Recruitment Script-Project Area
4c		Model Patient Recruitment Script-Facility
4d		Model Patient Recruitment Script-Text and E-mail
5		References
6		Agreement for Cross-Jurisdictional Data Collection
7		Contact Attempt Tracking Data Elements
8a		MMP 2015 Interview Questionnaire-English
8b		MMP 2015 Interview Questionnaire-Spanish
8c		MMP 2014 Interview Questionnaire-English
9		MMP Medical Record Abstraction Data Elements
10		MMP Minimum Dataset Data Elements
11		Bibliography of MMP Publications and Presentations
12		Authorization to Operate for the Data Coordinating Center
13		Assurance of Confidentiality for HIV/AIDS Surveillance
14		Consultations Conducted Before 2010
15		CDC Project Determination Form
16		Agreement to Abide by Restrictions on Release of Surveillance Data
17		Model Consent Form
18		MMP Patient Sample by Project Area

- Goal: The Medical Monitoring Project (MMP) is a supplemental surveillance project designed to describe the health-related behaviors, experiences and needs of adults diagnosed with HIV in the United States.
- Intended use: To guide national and local HIV-related service organization and delivery, and monitor receipt of HIV treatment and prevention services and clinical outcomes.
- Methods: Interviewer-administered survey and abstraction of medical records of an annual probability-based sample of adults from the National HIV Surveillance System.
- Subpopulation: Adults with an HIV diagnosis reported from the 26 participating project areas (19 states, including 6 separately funded cities, and 1 territory).
- Analysis: Descriptive statistics and multivariable analyses to assess the prevalence of and trends in: 1) risk behaviors for HIV transmission, 2) HIV care and treatment, and 3) exposure to, use of, and impact of HIV

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) requests a revision and 3 year approval of the currently approved Medical Monitoring Project (MMP) (0920-0740, expiration date May 31, 2015). The sampling methods, the number of proposed data collection sites (project areas), the patient interview questionnaire, and the information elements for medical record abstraction (MRA) have been revised. The changes proposed in this request update the data collection system to meet prevailing information needs, and enhance the value of MMP data, while remaining concordant with the project's purpose. The burden is less than the burden shown in the current inventory.

The following revisions were made to the OMB-approved project 0920-0740 (for details, **please see Attachment 3a**):

- Three project areas that initially participated in MMP--and were subsequently dropped in 2009 because funding was restricted—have been restored as primary sampling units. This change, conditional on the availability of funding, would increase the total number of project areas from 23 to 26.
- Sample size will be increased in three areas that were previously allocated comparatively small samples to improve national representativeness and the ability to collect enough data to produce representative local estimates in these

areas.

- The sampling method was changed from health care facility-based sampling to sampling from the existing HIV case surveillance database, the National HIV Surveillance System (NHSS, OMB Control No. 0920-0573, Exp. 2/29/2016). This change expands the population of inference from HIV-infected persons receiving medical care to all HIV-infected persons who have been diagnosed and reported to the NHSS. The reduced role of health care facilities associated with this change more than offsets the increase from the three added project areas and the increased sampled size, resulting in a substantial reduction in burden hours.
- Sampled persons may be interviewed wherever they currently reside (no longer limited to MMP project areas), conditional on local law and policy, and in a manner specified by a written, project-specific agreement with the HIV surveillance unit at the health department in the jurisdiction of current residence.
  - The interview instrument, which has had only minor modifications since 2009, was revised to enable the collection of critical information from HIV-infected persons not receiving medical care. In addition, changes were made to existing questions to improve their coherence, boost the efficiency of the data collection, and increase the relevance and value of the information. Based on a pilot of the questions directed toward persons not receiving care (Formative Research and Tool Development for the Medical Monitoring Project: Testing Solutions for Challenges of Sampling, OMB Control No. 0920-0840, expiration 2/29/2016) and an evaluation of the currently approved MMP interview instrument involving stakeholders, 170 questions were added to the interview form and 220 questions were removed. However, the average amount of time to complete the interview did not change. Changes to the previously approved interview instrument are outlined in **Attachment 3b**.
- Because new sampling methods may result in more recruitment by project areas as opposed to recruitment by HIV care facility staff, model recruitment letters and telephone, text, and E-mail scripts were added (**Attachments 4a, 4b, 4c, and 4d**).
- Videoconferencing was added as an optional mode of interview administration.
- Six data elements were removed from and two data elements were added to the MRA form. Because the medical records are abstracted by MMP staff, these changes do not affect the burden of the project. The changes to the previously approved

MRA form are outlined in **Attachment 3b**.

- Seventy-four data elements were removed from and forty-four data elements were added to the Minimum Dataset (MDS) data elements. Because these data elements are extracted from the HIV surveillance system from which they will be sampled, these changes do not affect the burden of the project. The changes to the previously approved MDS data elements are outlined in **Attachment 10**.
- The estimate of annualized burden hours for the proposed project has decreased from 8,537 hours in the current inventory to 7,140 hours. This reduction resulted primarily from changes in project sampling methods that reduce the amount of time health care facility staff will spend on project activities (see Exhibit 12.A).

Background

MMP was launched in 2007 following an Institute of Medicine (IOM) review, requested by Congress, of the extent to which data currently collected by the HIV/AIDS case surveillance and supplemental surveillance systems were adequate for determining allocation of national resources for treatment and care of HIV infection. The IOM recommended that a population-based survey of HIV-infected persons be initiated to develop more accurate measures of need for prevention and care services. In response to this recommendation, MMP was designed to provide nationally representative estimates of clinical outcomes and HIV-related behaviors among HIV-infected adults receiving medical care for their HIV infection.

In addition, representative local estimates were needed for local resource allocation and planning for HIV prevention and care. MMP was designed to fill this data gap. For example, MMP allows for local estimation of unmet need for HIV care and services, and assessment of the quality of HIV care provided. MMP's unique design positions the project to be a valuable source of both national and local data.

MMP provides data to supplement HIV/AIDS case reporting to the National HIV Surveillance System (NHSS, OMB Control No. 0920-0573, exp. 2/29/2016), which 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.

Although HIV surveillance now provides a comprehensive sampling

frame of all HIV-diagnosed persons in all 50 states, at MMP's inception and until recently, HIV surveillance systems were not sufficiently mature in all states to support drawing a national probability sample directly from the surveillance system. However, it was possible to generate HIV patient lists from sampled medical facilities. Therefore, MMP's design to date has relied on a national probability sample of HIV-infected persons recruited from medical facilities where they are receiving HIV care.

The facility-based multistage cluster sampling approach employed by MMP has been successful in that it has provided the only national probability sample of persons living with HIV who are receiving HIV medical care. However, construction of a comprehensive list of HIV medical care facilities is expensive and time-intensive. Collecting data through facilities depends upon their voluntary participation, which has a large influence on response rates, because a facility that does not participate is, in effect, refusing participation for all of its patients. Most importantly, recruiting patients through medical facilities excludes HIV-infected persons not receiving care and treatment.

In the years since MMP was designed and launched, a growing body of scientific evidence has demonstrated that early initiation of HIV treatment and long-term adherence leads to better health outcomes and that antiretroviral (ART) therapy dramatically reduces the probability of HIV transmission (**Attachment 5, references 1-14**). Together, this evidence has prompted increasing public health emphasis on treatment as prevention via early linkage to and retention in HIV care. The National HIV/AIDS Strategy lists increasing access to care as one of three strategic areas of national focus, and the Institute of Medicine (IOM) cites "delayed linkage to care for HIV [and] poor retention in care" as "among the primary challenges to optimal health outcomes for [People Living With HIV/AIDS]."

Because the MMP sampling method used since 2007 excludes persons not receiving HIV care, MMP has had a limited ability to monitor delays in care entry and inform efforts to increase access to and utilization of care. Regarding this limitation of MMP, the IOM recommended in a 2012 review of HIV data systems that "steps might be taken either to make the population more representative of the national population of people living with HIV or to include groups… who are less apt to be represented in other data systems."

MMP's first stage of sampling had to be retained to preserve operational efficiencies and because MMP is an important source of representative estimates at the state and city level for guiding allocation of prevention and care resources. Resampling the primary sampling units was considered and rejected because the epidemiology of HIV infection had not changed sufficiently from the time of the original sample to outweigh operational considerations and the need to preserve the continuity of data in participating areas.
Recognizing that changing MMP's sampling methods to effectively include all HIV-diagnosed persons would position MMP to meet these critical needs, CDC has been conducting formative research to prepare for such a change. Specifically, CDC investigators have been working to identify implementation challenges associated with sampling directly from NHSS as a potential replacement for MMP's current facility-based sampling, and to field test solutions to these challenges (Formative Research and Tool Development for the Medical Monitoring Project: Testing Solutions for Challenges of Sampling, OMB Control No. 0920-0840, expiration 2/29/2016). This work has demonstrated the feasibility of sampling from NHSS and has led to the development of protocols to address the potential methodological and operational challenges associated with implementing the new sampling methodology. These protocols provide a foundation for the change in MMP's sampling methods described in this request.

The proposed change in MMP's sampling method is justified because it:

- allows participation in MMP by a broader population that is more representative of persons living with HIV than under the current sampling method, thus allowing MMP to supplement NHSS more effectively in addressing key information gaps regarding entry to care, engagement and retention in care;
- increases the value of MMP by facilitating joint interpretation of trends in NHSS data on diagnoses and trends in MMP data on transmission risk behaviors, engagement in care, and clinical outcomes;
- increases efficiency, i.e., by utilizing an existing comprehensive sampling frame, NHSS, rather than expending cost/effort to create two additional sampling frames (facility and patient);
- decreases the burden on medical facilities associated with MMP's current facility-based sampling.

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

2. Purpose and Use of Information Collection

MMP's aim has been to facilitate understanding of health-related behaviors, experiences, and needs of people diagnosed with HIV infection who are receiving HIV care across the U.S. and in specific jurisdictions. The objectives of MMP have been to assess prevalence of and trends in: 1) risk behaviors for HIV transmission, 2) HIV care and treatment, and 3) exposure to, use of, and impact of HIV prevention services. An expansion of the sampled population to include HIV-diagnosed persons not receiving care as well as those in care is proposed. The aim and objectives remain the same.

The initial 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 National HIV Surveillance System (NHSS, OMB Control No. 0920-0573, Exp. 2/291/2016) provides information on core demographics of HIV-infected persons in the US and prognostic markers that serve as proxy indicators of receipt of medical care, MMP has provided 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. 3/31/2017), which collects information from persons at risk of HIV infection, whereas MMP collects information from persons who have been diagnosed with HIV infection.

MMP will continue to address these important data needs related to persons receiving HIV medical care. However, to remain relevant during a time when treatment for HIV infection is a national priority, MMP's fundamental aim and objectives must be pursued for all HIV-diagnosed persons, not only those receiving HIV medical care.

Changes in sampling methods and data collected are proposed in this request to meet this current need and enhance the value of MMP data while remaining concordant with the project's purpose i.e.,

- Current need: Information about care patterns of all HIV-diagnosed persons in the U.S. to whom care services are directed, not just persons already in care, is needed to

guide strategies to improve care access and utilization, and to maximize the impact of antiretroviral therapy.

- Enhanced value: Using the NHSS as a sampling frame and sampling from all persons reported with HIV diagnoses is expected to facilitate the interpretation of results from MMP relative to the entire population of HIV-diagnosed individuals, enhancing the value of MMP data for resource allocation and/or programmatic decision-making.

To maximize the value and use of data from MMP, new questions have been added to the interview to elicit information that is specific to HIV-diagnosed persons not receiving HIV care. Information from interviews of HIV-diagnosed person not receiving HIV medical care is needed to validate estimates from NHSS of the number of HIV-diagnosed people missing the substantial benefits of antiretroviral therapy, to understand the reasons for not receiving medical care, and to investigate whether changes in care facilitation services and financing of medical services are or are not effectively addressing this problem. This information, taken together with data from NHSS, allows for a more complete assessment of progress toward the National HIV/AIDS Strategy objectives for immediate linkage of HIV-diagnosed persons to continuous, quality care.

MMP's unique features have included and continue to include that it provides, at both the national and local level, both interview and medical record data for respondents, and links to the population-based HIV case reporting system. These three components, and their specific purposes and associated uses are detailed below.

- Through the interview, MMP provides population-level data on behavior (such as sex without a condom and injection drug use) that is directly related to HIV transmission and that is amenable to intervention through prevention programs. The explicit ability to identify gaps in HIV prevention services for all persons diagnosed with HIV/AIDS in the US who are engaging in behaviors that increase the risk of HIV transmission is a unique aspect of MMP, and one that is critical for monitoring the uptake and impact of CDC's national HIV prevention initiatives. Through medical record abstraction, MMP provides data on clinical outcomes and receipt of medical services. Although other studies provide such data for specific cohorts, MMP alone does so for locally representative and nationally representative samples of persons

receiving care in public and private facilities. Changing MMP's sampling methods as proposed in this request will position MMP to collect this information also from HIV-diagnosed persons who have dropped out of care or are intermittently in care. These data are expected to facilitate an understanding of the costs and consequences of delayed and inconsistent engagement in HIV medical care.

- In addition, because it collects data via linked interview and medical record abstraction, MMP allows description of risk behaviors among HIV-diagnosed persons by clinical characteristics, and assessment of the associations between care-seeking behavior, quality of care received, and clinical characteristics.
- Finally, the MMP minimum dataset containing data extracted from each project area's electronic HIV/AIDS Reporting System (eHARS) provides a link between the data collected from MMP participants and the entire MMP sample, including data describing nonparticipants. The MMP minimum dataset includes information on persons sampled for MMP that is collected by all states and six separately funded cities as part of HIV case reporting, and is sent de-identified to CDC for aggregation to make national estimates. The minimum dataset is a unique feature of MMP previously approved to ensure that individuals were not sampled for participation in MMP more than once, and for non-response bias analysis. If sampling of persons not receiving HIV care is approved as proposed, the minimum dataset can be used to make inferences to all persons diagnosed with HIV. Because CD4 t-lymphocyte counts and viral load test results used to stage HIV disease and as proxies for receipt of care are reported to states through NHSS prospectively, the link to case surveillance data through the minimum dataset also permits monitoring of receipt of care services, progression of HIV disease, and the potential for ongoing transmission of HIV over time. (also described in Supporting Statement B, section 2, "Procedures for the Collection of Information.") 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.

With its national scope and updated, unique design, as

reflected in this request, MMP will allow CDC to monitor national progress toward ensuring high quality care for all people diagnosed with HIV and maximizing. Specifically, at the national level, MMP data will be 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. CDC is responsible for issuing policies and recommendations for HIV-related medical and prevention services, and MMP provides an evidence base for these activities as well as a means to monitor the uptake and impact of the guidelines. If MMP data were not collected, CDC would be limited in its ability to provide recommendations and guidance regarding HIV treatment, care, and prevention.

At the local health jurisdiction level, MMP data are used for 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 prevention, care, and treatment. MMP has been providing information to evaluate local care and prevention services for persons receiving HIV medical care. With its updated sampling design, MMP will be positioned to provide information that describes a representative sample of all HIV-diagnosed persons and the types of prevention and care services they have needed and received. This information is expected to be useful for improving local care and prevention services for underserved people living with HIV as well as those who are receiving medical care.

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 population-based data to community planning groups and Ryan White Comprehensive AIDS Resources Emergency (CARE) Act planning consortia and councils for use in prioritizing local resources for HIV prevention and care and 2) by allowing estimation of 95% confidence intervals that reflect the precision of point estimates.

Publication highlights from MMP in the past three years include a CDC *Vital Signs* report on HIV prevention through care and treatment (2011), and reports on the impact of the Affordable Care Act on health insurance coverage of people with HIV, (2014) and on use of and adherence to antiretroviral therapy

among HIV-infected adults in care (2012). In addition, last year, the following important recent publications included MMP data: a Journal of the American Medical Association article on "Differences in Human Immunodeficiency Virus Care and Treatment among Subpopulations in the United States," the National HIV Prevention Progress Report, CDC's Health Disparities and Inequalities Report. Numerous national and area-specific analyses of MMP data have also been disseminated through peer-reviewed scientific journals, reports, and at national meetings (**Attachment 11**).

Without MMP data, the best source of behavioral and clinical data would be the National HIV Surveillance System (NHSS, OMB No. 0920-0573, exp. 2/29/2016), which only collects a limited amount of information from medical records of persons infected with HIV) or cohort studies. Although some cohort studies are large, they do not provide nationally representative data because they generally collect information on persons receiving care at large HIV specialty care facilities in metropolitan areas. No large national systems collect data from a representative sample of all HIV-diagnosed individuals, including those not receiving HIV medical care as well as HIV patients. Not collecting MMP data would adversely affect the ability to monitor the HIV/AIDS epidemic both locally and nationally.

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. Interview data is collected using the Questionnaire Development Software (QDS), NOVA Research Company, Bethesda, Maryland. Medical record abstraction data are collected using Discover*e* software developed by Cerner Corporation, Kansas City, Missouri. 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.

The use of an electronic questionnaire may reduce the burden on respondents by improving comprehension and reducing the amount of time needed to complete the survey, as compared with a paper-administered survey. 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.

Transfer of data collected electronically will eliminate the need for data entry at the state/local sites. An evaluation of supplemental surveillance data using electronic data collection 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.

The 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.
The purpose of the Data Coordinating Center (DCC), managed by ICF International through a contract with CDC, is to implement a data management system (DMS) to provide participating project areas with a secure web-based data portal system through which project areas can easily submit data to CDC, revise submitted data sets, and receive final data from CDC. The system also allows the project areas and CDC staff to track critical respondent and medical record abstraction (MRA) activities. The system incorporates a secure web-based interface that allows CDC and project area staff to easily submit data, track project area activities, and retrieve data sets and reports. This system will help to streamline the data collection and management process.

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 persons diagnosed with HIV infection who are and are not receiving HIV medical care.

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. 3/31/2017), 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 National HIV Surveillance System (NHSS, OMB No. 0920-0573, exp. 2/29/2016).

These existing information collections listed above cannot be modified, used partially, nor in aggregate format to satisfy the needs of MMP. 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-diagnosed persons. HOPS, which is ongoing, and SUN, which ended in 2013, have collected information from HIV-infected adults receiving care in a limited number of HIV specialty care facilities, consequently, the data collected are limited for monitoring national or local care and prevention efforts, and for assessing the needs of persons not receiving medical care. The National HIV/AIDS Surveillance System covers all persons diagnosed with HIV, but provides information on a smaller set of demographic and HIV-related laboratory data elements than are collected through MMP.

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, the 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 diagnosed 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

Patients who attend small medical facilities that provide HIV care have a chance of being selected for MMP, and in those cases, small medical facilities may be asked to provide medical

records. In some cases, facilities may be asked to look up contact information for patients or, less commonly, to make the first contact with patients. These types of facility participation are voluntary. On average, it is estimated that looking up contact information will take 2 minutes per patient and making first contact with patients will take an average of 5 minutes per patient. Project staff will request the medical records of eligible sampled patients. It is estimated to take an average of 3 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 year, HIV-diagnosed persons will be sampled from NHSS for participation in MMP. It is possible that a person will be selected for participation in MMP in more than one year, as people will have some probability of being selected each project year. Persons 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 the 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 9/16/2014, Volume 79, Number 179, Pages 55496-55497 (**Attachment 2**). No public comments were received.

8B. Several consultations were conducted with various scientists and public health practitioners outside the agency.

A description of consultations conducted before 2010 is

included as **Attachment 14**, along with the names and contact information of the persons consulted. Consultations that occurred from 2010 to the present are described below.

Biweekly consultation calls to discuss design, sampling methods, and analytic considerations for clinical outcomes surveillance have been held with ICF Macro from June 2010 to the present.

Beginning in early 2013, CDC began an evaluation of the MMP questionnaire that involved consultation with external stakeholders, including grantees, MMP's Provider and Community Advisory Boards, subject matter experts, and colleagues from other federal agencies. The evaluation focused on examination of the relevance, coherence, and scientific contribution of interview questions. All new sections of the questionnaire were tested for clarity through test interviews and presentation to MMP's Community Advisory Board. The result is a modified interview questionnaire (**Attachments 8a and 8b**). Changes that were determined to be necessary given the inclusion in MMP of persons not receiving care were the expansion of the HIV testing, linkage to care, and reengagement in care sections, as well as the addition of questions that elicit detailed information on reasons for not being in care. Other sections were modified to improve the efficiency of administration and the quality of data collected, for example by changing open-ended questions to close-ended questions. The changes to the questionnaire are described in **Attachment 3b**.

CDC investigators also conducted a pilot project to identify implementation challenges associated with sampling directly from NHSS as a potential replacement for MMP's current facility-based sampling, and to field test solutions to these challenges (Formative Research and Tool Development for the Medical Monitoring Project: Testing Solutions for Challenges of Sampling, OMB Control No. 0920-0840, expiration 2/29/2016). Input from a large number of stakeholders was solicited to develop an optimal sampling design that did not duplicate or impinge upon existing efforts. Input was obtained on the sampling from MMP project area principal investigators and project coordinators individually and together at the MMP annual meeting. Each MMP project area evaluated their local HIV surveillance data to assess the quality of key information elements, and the expected population size and characteristics. Input was solicited from the MMP community and provider advisory boards about sampling from NHSS, the inclusion of HIV-diagnosed persons not receiving care, and direct recruitment of

MMP participants by MMP staff in the project areas. MMP project area investigators, state HIV surveillance coordinators, and CSTE consulted on cross-jurisdictional recruitment. David Evans of Project Inform, a national HIV advocacy group that includes consumers of HIV care and HIV care providers also consulted on the MMP sampling and recruitment changes. Finally, CDC staff throughout the Division of HIV/AIDS Prevention provided input on coordinating MMP with other CDC-funded initiatives to standardize operating procedures and to minimize the burden on respondents.

The results of the pilot project demonstrated the feasibility of sampling from NHSS and have prompted the development of protocols to address the potential methodological and operational challenges associated with implementing the new sampling methodology. Questions added to the interview pertaining to persons not receiving care were also tested through the pilot. The five project areas that implemented the pilot were consulted regarding the challenges encountered with implementing the sampling, recruitment, and data collection, and how best to surmount these. The information obtained through the pilot and these consultations informed the development of the proposed project.

In 2014 we began consultations with Ms. Antigone Dempsey and Ms. Heather Hauck from HRSA to discuss common areas of scientific and public health interest and collaborate on analyses.

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

Participants will be given approximately $25 in cash as a token of appreciation for participation; the specific amount will be 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.

In his memorandum for the president’s management council dated January 20, 2006, the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget wrote, “Incentives are most appropriately used in Federal statistical surveys with hard-to-find populations or

respondents whose failure to participate would jeopardize the quality of the survey data (e.g., in panel surveys experiencing high attrition), or in studies that impose exceptional burden on respondents, such as those asking highly sensitive questions…"

The use of tokens of appreciation in MMP is appropriate according to this guidance. MMP involves conducting surveys with hard-to-reach and highly selective populations, including HIV-positive persons who have either never been linked to HIV care or who have fallen out of care. Many of these people will have characteristics that make them more difficult to enroll such as unstable housing, substance abuse, and poverty. The survey instrument also contains highly sensitive questions regarding sexual history, experience of stigma and discrimination, and income. Providing tokens of appreciation to respondents will be critical to achieving acceptable response rates in this hard-to-find population, as demonstrated in the survey literature (**Attachment 5 reference 15**).

The need for and amount of the tokens of appreciation is based, in part, on the fact that research projects that, like MMP, ask HIV risk behavior questions in many of the participating areas offer similar tokens of appreciation. 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 (**Attachment 5 references 16 and 17**). Research has shown that financial incentives are effective at increasing response rates among female residents in minority zip codes (**Attachment 5 reference 18**). 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 (**Attachment 5 reference 19**). Data from MMP's 2009 cycle indicate that 65% of respondents reported a race or ethnicity other than non-Hispanic white. Providing remuneration to respondents is critical to achieving 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. 3/31/2017) and the Feasibility of HIV Behavioral Surveillance for Young MSM (OMB 0920-0840, exp. 2/29/2016), both of which ask questions similar to those included in MMP and have a similar length of time for completing the interview. In both of these other projects,

tokens of appreciation were used to help increase participation rates; participants were offered approximately $25 as a token of appreciation. Other studies have also found that tokens of appreciation modestly improve response rates (**Attachment 5 reference 20**).

10. Assurance of Confidentiality Provided to Respondents

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). Previously collected date of birth will be extracted from the National HIV Surveillance System (NHSS, OMB No. 0920-0573, exp. 2/29/2016) as part of the minimum dataset (MDS). Date of birth has been shown to be a strong predictor of non-response in MMP, and it will be used to adjust for non-response bias.
The NHSS coded identifier (STATENO) will be extracted from NHSS and maintained with data collected for MMP. This identifier can be used by authorized project area staff to link to locally maintained NHSS data containing personal identifiers, which will be used by the project areas staff to recruit participants. CDC will not receive or have access to personal identifiers. Data collected in the project areas for MMP will be stored separately from personal identifiers.

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. MMP 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.

MMP is covered by an Assurance of Confidentiality for HIV/AIDS surveillance data (**Attachment 13**). 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.

MMP was determined by the National Center for HIV, Viral Hepatitis, STD and TB Prevention's Office of the Associate Director for Science at the Centers for Disease Control and Prevention (CDC) to be a non-research, public health surveillance activity used for disease control program or policy purposes (**Attachment 15**-Approved Project Determination). Because MMP is non-research, the project is not required to be reviewed by a Federal institutional review board (IRB). Nonetheless, CDC investigators/project officers are expected to adhere to ethical principles and standards by respecting and protecting to the maximum extent possible the privacy, confidentiality, and autonomy of participants. Participating health departments may obtain local IRB approval before data collection according if required in the jurisdiction. All applicable Federal and state privacy laws must be followed.

10.1 Privacy Impact Assessment

Overview of the Data Collection System

MMP is a supplemental surveillance project designed to collect nationally representative data about people diagnosed with HIV/AIDS 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; up to 26 grantees may be awarded funding to conduct MMP starting in June 2015 under a new Federal Opportunity Announcement. Current grantees include: 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. If funding is available, the following states may participate starting in 2015: Maryland, Massachusetts, and South Carolina.

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.

MMP has previously employed a three-stage sampling design, involving probability-based selection of 1) geographic areas based on AIDS prevalence, 2) HIV health care facilities based on numbers of patients, and 3) patients receiving care in the selected facilities. This request proposes a change to a two-stage sampling design which omits the sampling of HIV care facilities. The project will continue to involve the previously sampled geographic areas. However, the annual probability-based selection, directly from NHSS, of a representative sample of HIV-diagnosed adults living in each area will replace annual samples of HIV care facilities in the areas, with selection of patients from the sampled facilities. This change is expected to increase the value of MMP data because it will allow MMP to address critical data gaps regarding HIV care patterns, facilitate the joint interpretation of trends indicated by NHSS and MMP data, and increase efficiency by utilizing an existing comprehensive sampling frame rather than expending cost/effort to create two additional sampling frames (facility and patient).

Replacing current MMP methods with sampling from NHSS will expand the covered population of MMP from HIV-diagnosed persons in care to all HIV-diagnosed persons. However, it will also require procedures for contacting and recruiting HIV-diagnosed persons not receiving care, a population that is not currently sampled. Currently, MMP investigators sample patients from medical facilities and often, but not always, rely on the patient-provider relationship to facilitate enrollment. A consequence of the proposed change will be that project area staff may more often directly contact and recruit sampled persons, including all who are not receiving HIV medical care who cannot be reached through a health care provider.

The change in sampling methodology does not involve contact and recruitment methods that are new to MMP, as the project has always employed both direct recruitment of respondents and

recruitment through medical care providers. However, making contact with individuals based on information reported to HIV case surveillance at their diagnosis can be problematic, as the contact information in NHSS may be out-of-date, especially for those who have had no medical care after diagnosis or who have discontinued care. Therefore, MMP project area staff will search for contact information for persons sampled in other databases used routinely for public health work. Such databases include health department surveillance and intervention databases for other diseases such as tuberculosis or sexually transmitted diseases, electronic medical record systems to which health departments have access, as well the Social Security Death Index.

Cross-jurisdictional recruitment of MMP participants who have moved out of the project area where they were presumed to be residing when sampled will proceed if permitted by local laws and policies, according to inter-jurisdictional agreements. These agreements will specify one of 4 options: 1) recruitment by the project area for which the sampled person was selected, with no notification of the health department in the area to which the person has relocated; 2) recruitment with notification after contact with the sampled person; 3) recruitment with notification before contact with the sampled person; and cross-jurisdictional MMP recruitment activities are not permitted (see **Attachment 6** for a copy of the agreement form). As described above in section A1. Background, because the sampling frame does not maintain residence information that is current as of the date of sampling, the MMP sample is likely to include a substantial number of persons who have moved out of the jurisdiction where they are presumed to be living when they were sampled. The formative research found that approximately 20% of sampled persons with known eligibility did not reside in the project area of sampling at the time of recruitment. Recruitment of these persons who have relocated is necessary to ensure that the MMP sample represents the population of all HIV-diagnosed persons in the United States.

To facilitate recruitment of persons who cannot be contacted through a health care provider because they are not receiving care, and to maximize response rates, local staff in the project areas will institute new contact tracking processes, described briefly in section A1. This process tracking will not involve collection of data from the public.

MMP’s data collection has had and will continue to have two primary components: an interview and medical record abstraction

(**Attachments 8a, 8b, and 9**). Trained health department personnel invite each selected individual to participate in a 45-minute face-to-face, telephone, or videoconference interview. For patients who have received HIV medical care, additional clinical information will continue to be abstracted from patient medical records.

Demographic and HIV-related laboratory information associated with sampled participants is currently and will continue to be extracted from the existing HIV case surveillance database, the National HIV Surveillance System (NHSS, OMB Control No. 0920-0573, Exp. 2/29/2016). This minimum dataset (MDS) (**Attachment 10**) is used to adjust for participant nonresponse bias and contains the NHSS coded identifier, which allows CDC staff to convey a list of persons sampled from NHSS to project area staff without using respondent personal identifiers. This link to NHSS data also allows monitoring of ongoing care and treatment of MMP respondents through CD4+ T-lymphocyte counts and viral load test results reported prospectively to NHSS.

Description of the information to be collected

As mentioned above, project area staff will track their attempts to contact potential respondents to recruit them to participate in MMP. The contact attempts tracking database (**Attachment 7**) will include the time, date, method, and outcome of the staff's recruitment attempts. These data will be recorded by project staff about their work processes, and will not be collected from the public. Although the project area database will contain the sampled person's contact information, no patient identifiers or contact information will be sent to CDC. Rather, the contact attempt tracking data will be sent to CDC in report form and will be limited to the elements listed in **Attachment 7**. These reports will be used to evaluate the most effective times and days of the week to recruit participants as well as the most effective methods (phone, letter, etc.).

The information to be collected through English and Spanish interviews with sampled HIV-diagnosed adults will continue to include: information to determine eligibility, demographic characteristics, stigma and discrimination, adherence to antiretroviral therapy, 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 (**Attachments 8a and 8b**). To collect data needed from HIV-diagnosed persons who are

not receiving HIV care, questions have been added on HIV testing, linkage to care, and facilitators of engagement in care, as well as questions eliciting reasons for not being in care. Questions about insurance have been modified and new questions have been added to monitor changes in HIV care related to implementation of the Patient Protection and Affordable Care Act of 2010. Questions about intimate partner violence and productivity loss were added. Other sections have been modified to improve the efficiency of administration and the quality of data collected, for example by changing open-ended questions to closed-ended questions. Because questions have been added, questions that are no longer needed have been removed to maintain the average 45-minute length of the questionnaire (Detailed information on changes to the interview can be found in **Attachment 3b** and specific questions that will be removed can be found in the previously approved interview questionnaire in **Attachment 8c**).

Information to be collected through abstraction of sampled individuals' medical records will continue to include: demographics and insurance status; the prevalence and incidence of AIDS-defining opportunistic illnesses and co-morbidities related to HIV disease; the receipt of prophylactic and antiretroviral medications; and whether patients are receiving screening and treatment according to U.S. Public Health Service guidelines (**Attachment 9**). One data element about Pap smear specimen adequacy was removed because it was not useful analytically. Five laboratory test result data elements were removed because they were of limited analytic value and required substantial time to abstract. One data element assessing whether a facility where an MMP participant accessed HIV care receives Ryan White HIV/AIDS Program funding was added to allow MMP to monitor funding-associated changes in the delivery and quality of HIV care. A second data element, which assesses whether an MMP participant accessed HIV care in the MMP project area where he/she was sampled, or in another US state), has been added to permit MMP project areas to monitor care provided in their own jurisdictions. This data element is now necessary because MMP no longer samples persons according to where they received HIV care. The details of these changes to the MRA are provided in **Attachment 3b**.

The Minimum Dataset for MMP will continue to consist of data extracted from the National HIV Surveillance System (NHSS, OMB Control No. 0920-0573, exp. 2/29/2016) (Attachment 10) including the NHSS coded identifier, demographics, HIV diagnosis date, and HIV-related laboratory tests--i.e., CD4+ T-

lymphocyte and HIV viral load tests used to monitor the progression of HIV disease and the potential for ongoing transmission. As for the currently approved project, the minimum dataset will contain extracted data relating to all sampled persons (both respondents and non-respondents). The characteristics of persons who did and did not participate are needed to assess non-response bias affecting inferences from MMP data to the entire population of persons diagnosed with HIV in the U.S. Experience with MMP to date has shown that date of birth is a strong predictor of non-response, making date of birth necessary for non-response bias adjustment. Date of birth, extracted from the NHSS database, is the only information in identifiable form that will be included with MMP data maintained at CDC. Indirect identification of individuals through the de-identified data that CDC receives will not be possible.

As described above, the NHSS coded identifier (STATENO) will also be included with MMP data at CDC. CDC staff will draw annual samples from the CDC's NHSS dataset for each project area, and will send the sample to the appropriate project area, including this coded identifier. Project areas will then use the coded identifier to access the names and contact information for sampled persons, which are collected in their local NHSS databases under strict access controls, and use this information to contact and recruit sampled persons, along with information available from other sources, as needed.

The 2014 MDS contained 118 data elements. The proposed 2015 MDS contains 88 data elements. The net change is a 30-element reduction. Seventy-four data elements that were not found to be useful for making adjustments to account for non-participation bias were dropped from the 2015 MDS dataset. With the change in MMP sampling methodology to include HIV-diagnosed persons not receiving HIV care, factors associated with participation among persons not receiving care are needed. HIV care utilization is expected to be correlated with participation, and HIV-related laboratory tests reported to HIV surveillance are a proxy for care utilization. Therefore, 14 laboratory testing-related data elements were added to the MDS variable list, to allow for adjustment for differences in care utilization. In 2014 the MDS was transferred to CDC by project areas from local eHARS (HIV case surveillance) databases. In 2015, the MDS will primarily be drawn from the National HIV Surveillance System database, which is created from merged reports from all US jurisdictions. This change made necessary the addition of 27 data elements that account for the multiple

sources of data. For instance, a data element was added to indicate the number of jurisdictions whose data were merged to create the MDS record. Three additional variables pertaining to the recency of contact information for the sampled person were added that will be transferred to CDC by project areas from local eHARS, as the information is only retained locally. The variables retained in, deleted from, and added to the 2015 MDS are listed in **Attachment 10**.

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

The information collection system will not collect data from the public via a website, nor will it host a public website. There is no website content directed at children under 13 years of age.

No information in identifiable form (IIF) will be collected for MMP. No audio or audiovisual recordings will be made of the interviews obtained by telephone and videoconferencing. Data will not be collected on paper forms. However, date of birth will be included as part of the sampling frame, which will be drawn from the NHSS database at CDC (NHSS, OMB Control No. 0920-0573, exp. 2/29/2016). In addition, the NHSS coded identifier (STATENO) will be included in sampling frames drawn from CDC's NHSS database. Date of birth and the NHSS coded identifier are also present in the project areas' NHSS data, and will be stored, along with a survey identification number, with data collected for MMP both locally and at CDC.

Although individuals cannot be directly or indirectly identified through MMP data stored at the DCC and at CDC, project areas do keep personal identifiers in project area NHSS databases, such as names and contact information. In the project areas, NHSS databases containing personal identifiers are maintained under strict access controls. Maintaining date of birth and the NHSS coded identifier in the sampling frames for MMP at CDC will allow CDC staff to communicate with project areas about which persons have been selected to participate. Authorized project area staff will use the names and contact information in the project area NHSS database as well as other data sources routinely used by health departments to contact and recruit sampled persons, and will track their attempts to do so in a contact tracking database containing this information. No data in this database will be collected from the public. The database will be used to document dates and modes of contact attempted and sources of contact information.

These data will be maintained under the same strict access controls as are NHSS data (described above).

Contact tracking data will be sent to CDC in report form and will not include patient identifiers or contact information. The data elements that will be reported to CDC are included in **Attachment 7**. Project area MMP staff will remove all PII in the contact tracking database by two years from the end of the data collection cycle, or by May 31, 2022, whichever occurs earlier. Data from other information sources consulted to confirm vital status, identify area of current residence or update contact information will not be transferred to CDC, nor will CDC staff have access to these data. Such sources include health department surveillance and intervention databases for other diseases such as tuberculosis or sexually transmitted diseases, electronic medical record systems to which health departments have access, as well the Social Security Death Index. In the project areas, data collected for MMP will be stored separately from personal identifiers. Project areas will not transmit personal identifiers to CDC, nor will CDC staff have access to them.

Retaining the NHSS coded identifier (STATENO) along with data collected for MMP will allow linkage between data collected for MMP and data collected for NHSS, which is essential for accomplishing the purposes of MMP. The coded NHSS identifier will allow specified demographic and HIV-related laboratory information for sampled participants to be extracted from NHSS. This minimum dataset (MDS) (**Attachment 10**) will be used to compare persons recruited and not recruited for MMP and to adjust for participant nonresponse bias. One of the variables that is extracted from NHSS and maintained in the MDS for MMP is participant date of birth. Past experience with MMP has shown that date of birth is a strong predictor of non-response, and is thus essential information for non-response bias adjustment.

The 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.

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

Medical record data are abstracted by MMP staff via a web-based application called Discovere™ (Cerner Corporation). Data are automatically uploaded to a secure Cerner Corporation server when they are entered into the application and saved. Cerner will subsequently upload the MRA data to the DCC portal on a monthly basis using approved encryption software. Access to the web-based MRA application will be username- and password-protected, such that unauthorized users will not be able to view, export, or modify the collected data. Discovere™ has undergone certification and accreditation by CDC. The security of the system meets all Federal Information Systems Management Act (FISMA), OMB, HHS, and CDC IT Security requirements which ensure the confidentiality, integrity, and availability of data on federal information systems. The MRA data are housed on servers that have been configured with the current National Institute of Standards and Technology (NIST) Configuration baselines, which adhere to the most restricted security settings consistent with operational requirements. The servers are located within a facility that meets the stringent physical security requirements from NIST Special Publication (SP) 800-53 Revision 3, Recommended Security Controls for Federal Information Systems and Organizations. The data are protected by multiple layers of security that ensure confidentiality, integrity, and availability, with tools such as anti-virus protection, intrusion detection systems, and firewall rules strictly limiting access to the system.

A Privacy Impact Assessment (PIA) has been completed for the MMP MRA system in accordance with CDC, HHS, and OMB requirements. The potential impact of a loss of confidentiality of the data within this system is low, according to the Federal Information Processing Standards (FIPS) Publication 199. There is no personally identifiable information collected by the system and there are no significant privacy impacts anticipated

for the MMP MRA system.

CDC awarded a contract in 2008 to maintain a Data Coordinating Center (DCC), which is a system with a secure data server to which project area staff transmit MMP data and where the data are 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 12**). In addition to the technical requirements listed above, data management processes are required to be in compliance with Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs: (http://www.cdc.gov/nchhstp/programintegration/docs/PCSIDataSecurityGuidelines.pdf).

Grantees will transmit interview data files to Data Coordinating Center contractor, ICF International, through a secure web-based data portal. This 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).

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 MMP 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 (**Attachment 13**).

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

and controlling access to hardware.

Confidentiality precautions currently approved for telephone interviewing will be applied to videoconference interviewing, which include ensuring that the participant and the interviewer each has a private location in which to conduct the interview. No audio/audiovisual recordings will be made of the interviews obtained through telephone and videoconferencing. Videoconferencing may improve privacy by removing the need to mail project materials such as response cards to participants, as these can be shown to the participant during the videoconference. Additionally, project interviewers may only conduct videoconference interviews on desktop or laptop computers that have password protection, encryption, and controlled access via a secure network.

Data collectors will complete project area-specific security and confidentiality training and sign the statement used in their jurisdiction indicating their understanding of security and confidentiality policies related to HIV surveillance data. Interviewers and abstractors will also receive training from CDC staff on how to protect the security and confidentiality of the information collected.

The Assurance of Confidentiality will be 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 will be subject to the confidentiality obligations described in the CDC guidelines for the security and confidentiality of National HIV Surveillance System data (www.cdc.gov/nchhstp/programintegration/docs/PCSIDataSecurityGuidelines.pdf) and will be required to undergo security and confidentiality training.

Data collectors and data managers will undergo annual security and confidentiality training consistent with the guidelines set forth in the document “Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs” available at (www.cdc.gov/nchhstp/programintegration/docs/PCSIDataSecurityGuidelines.pdf). 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, local area network [LAN] support). All CDC permanent employees and their contractors will be required to attend annual confidentiality training, to sign a Nondisclosure Agreement (**Attachment 16**), 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 project data maintained at CDC that are released to persons other than project staff will not include full date of birth.

Project area MMP staff will obtain informed consent 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. An example model consent document is included as **Attachment 17**. All sites must obtain consent from respondents and store the consent forms in a secure location. 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.

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 anxiety, and history of arrest.

Although the information requested is highly sensitive, the purposes of MMP cannot be accomplished without their collection. This information is needed to understand differences in health outcomes among demographic groups to guide direction of services to those who need them, a fundamental reason for collecting MMP data. These data will be used to understand and direct improvements to HIV care and

treatment access, and to understand 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 suppression of viral load. These data will also be used to enhance HIV prevention programs designed to reduce high-risk behaviors among persons most likely to transmit HIV. 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 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 respondent’s home, in a hospital or clinic, or other mutually agreed-upon location. Telephone interviews and those conducted via video conferencing will be administered in a private location that ensures the confidentiality of responses. No audio/audiovisual recordings will be made of the interviews obtained through telephone and videoconferencing. 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 for the proposed project has decreased by 16%, from 8,537 to 7,140 hours, due to changes in project sampling methods. Some of the proposed changes increase the burden, while others decrease the burden; the changes result in a net decrease in overall burden.

Adding three former MMP project areas (Maryland, Massachusetts, and South Carolina) that were dropped in the 2009 MMP cycle due to budget limitations and increasing the sample size in three areas that were previously allocated comparatively small samples (Georgia, Illinois, and Pennsylvania) is expected to improve national representativeness and the ability to collect enough data to produce representative local estimates in these areas. These changes would result in an increase in total sample size from 9,400 to 10,900 and an increase in burden associated with interviews and medical record abstraction. Although revisions were made to the previously approved data collection instruments (**Attachment 3b**), these revisions did not result in a change in the average time required to complete the data collections. The increases in burden associated with the interview and medical record abstraction are solely attributable to increasing the sample size—the numbers of persons to be interviewed and the numbers of medical records that facilities would be asked to pull. Because medical record abstraction is conducted by MMP staff, increasing the number of medical record abstractions will not affect burden on the participants.

The change in sampling methods is also associated with an increase in burden because health care facility staff may be asked to look up contact information on sampled persons with incomplete or incorrect contact information in NHSS. This was not necessary in prior MMP cycles because the patient samples were drawn from facility records.

The following are proposed changes resulting from the change in

sampling methods that decrease project burden: 1) facility office staff will no longer be asked to provide an estimate of the number of HIV patients seen at the facility, given that the sample will be drawn from NHSS; 2) fewer facilities will be asked to recruit sampled persons because the sample will include persons who are not receiving care instead of consisting entirely of sampled facilities' patients. We estimate that 10% of sampled persons will be approached by facility staff, who will inform them that they have been selected to participate in MMP and refer them to the health department MMP staff. Model patient recruitment scripts are included (**Attachments 4a, 4b, 4c, and 4d**).

CDC's current goal is to interview 80% of 10,900 patients or 8,720, all of whom will complete the standard interview, which will take approximately 45 minutes. Thus, the total annual burden (in hours) associated with the interview is 6,540. 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 the time required to look up patient contact information, approach persons for enrollment, and pull patient medical records. Facility staff will be asked to look up contact information for an estimated 20% of sampled persons (2,180 persons), which will take 2 minutes per person. We estimate that 10% of sampled persons (1,090) will be approached by facility staff to participate in the project; this process is estimated to take 5 minutes per person. Medical records are only pulled once for each abstraction, the estimate to abstract each of 8,720 medical records is 3 minutes per record.

Exhibit A.12.A: Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Hours Per Response	Total Response Burden (Hours)
Sampled, Eligible HIV-Infected	Interview Questionnaire (att 8a)	8,720	1	45/60	6,540

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Hours Per Response	Total Response Burden (Hours)
Persons					
Facility office staff looking up contact information	N/A	2,180	1	2/60	73
Facility office staff approaching sampled persons for enrollment	N/A	1,090	1	5/60	91
Facility office staff pulling medical records	N/A	8,720	1	3/60	436
Total					**7,140**

B. Estimated Annualized Cost to Respondents

The annualized cost to respondents for the burden hours is estimated to be $157,341; details are provided in Exhibit A.12.B. The estimates of hourly wages were obtained from the Department of labor (Bureau of Labor Statistics Wage Data (http://www.bls.gov/news.release/pdf/ecec.pdf).

Exhibit A.12.B. Annualized Cost to Respondents

Activity	**Total Burden Hours**	**Hourly Wage Rate**	**Total Respondent Cost**
Sampled persons completing interview	6,540	$21.77	$142,376
Facility office staff looking up	73	$24.94	$1,821

contact information			
Facility office staff approaching sampled patients for recruitment	91	$24.94	$2,270
Facility office staff pulling medical records	436	$24.94	$10,874
Total	**7,140**		**$157,341**

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 $48,776,430. 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 the Federal Government	MMP – Personnel Epidemiologist-14 5 100% $581,646 Epidemiologist-13 6 100% $569,946 Behavioral Scientist-13 1 75% $73,401 Statistician-14 1 50% $54,423 Nurse Coordinator-12 1 100% $77,461 Public Health Advisor-13 1 100% $94,991 IT Specialist-12 1 50% $36,310 Support Staff Business Support Spec-11 1 50% $31,303 Data Managers/Analysts 9 100% $540,000 Project Coordinator 1 100% $80,000 ORISE Fellows 4 100% $240,000	$2,379,481
	Cooperative agreement funds to project areas	$12,500,000

Contractor and Other Expenses	Data Coordinating Center (CDC Contractor for data collection)	$892,500
	Contracted Questionnaire Programming (2) 0.5 FTE	$60,000
	Contracted Medical Record Abstraction Application development and maintenance	$393,329
	Travel	$30,000
	Spanish language translation	$3,500
	TOTAL COST TO THE GOVERNMENT	$16,258,810

*Salary estimates were obtained from the US Office of Personnel Management salary scale at http://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/#url=2014. Cooperative Agreement funding for FY 2015 is not finalized. The estimate included is an average based on requested increase in previous cooperative agreement funds for MMP.

The personnel related to the MMP data collection include project officers (epidemiologists, a behavioral scientist and a nurse coordinator) at the GS-13 and 14 levels, a GS-14 level statistician, GS-13 level public health advisor, a project coordinator, a business support specialist, an Information Technology Specialist, and data managers/analysts. Travel is related to providing technical assistance and conducting site visits.

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 from medical record abstractions and questionnaires 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 managers and analysts will have responsibility for analyzing the final data set. They will work with MMP

epidemiologists, the behavioral scientist and nurse coordinator to create data tables to be displayed in surveillance reports and other products.

15. Explanation for Program Changes or Adjustments

Due to proposed changes in sampling methods, the burden has decreased by 1,397 hours (see Exhibit 12.A). Specifically, because MMP will sample directly from HIV/AIDS surveillance program records instead of from facility sampling frames, facility staff will no longer be asked to provide estimated HIV patient loads and patient lists. Changes to the proposed project are fully described above in section A.1 “Circumstances Making the Collection of Information Necessary.”

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.

Activity	**Time Schedule**
Case-based sampling begins (2015 cycle)	1 month after OMB approval
Sampled cases interviewed	1-11 months after OMB approval
Abstract medical records of sampled cases	3-12 months after OMB approval
Data management	1-12 months after OMB approval
Analysis of collected data	15-18 months after OMB approval
Publication	18 months after OMB approval
Case-based sampling begins (2016 cycle)	13 months after OMB approval
Sampled cases interviewed	13-23 months after OMB approval
Abstract medical records of sampled cases	15-24 months after OMB approval
Data management	13-24 months after OMB approval
Analysis of collected data	27-30 months after OMB approval
Publication	24 months after OMB approval
Case-based sampling begins (2017 cycle)	25 months after OMB approval
Sampled cases interviewed	25-35 months after OMB approval

Activity	Time Schedule
Abstract medical records of sampled cases	27-36 months after OMB approval
Data management	25-36 months after OMB approval
Evaluation of collected data	36 months after OMB approval

Data from MMP is expected to continue to inform prevention and care services and increase existing knowledge of receipt of HIV treatment and prevention services and clinical outcomes. National surveillance reports will be published for each annual cycle of MMP (for an example, see http://www.cdc.gov/hiv/pdf/research_mmp_MMWR2007.pdf). A 12-month period is required for data collection, and data collection will occur annually. Therefore, a 3-year clearance is requested.

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 reporting of MMP data collected in the project area. CDC has primary responsibility for the release of cycle-specific findings aggregated from all geographic areas. These data will be 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 2009 data collection cycle results (end of data collection September 2010) are in press as of March 2014. 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. CDC has contributed 2009 MMP data to several national reports, for example The National HIV Prevention Progress Report (http://www.cdc.gov/hiv/pdf/policies_NationalProgressReport.pdf) and the CDC Health Disparities & Inequalities Report (http://www.cdc.gov/mmwr/pdf/other/su6203.pdf).

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 HIV medical care receipt in the past 12 months;
- 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.