Medical Monitoring Project

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Supporting Statement A

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- 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 23 participating project areas (16 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 prevention services.

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 June 30, 2018). The number of proposed data collection sites (project areas), one criterion for eligibility, the token of appreciation, and the information elements for the minimum dataset (MDS) 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:

- Three project areas previously approved for data collection but who never collected data due to lack of funding will be dropped, resulting in a total of 23 project areas.
- Sampled persons found to have resided in a non-funded project area on the date of sampling will be considered ineligible for the project, because non-funded project areas were deemed ineligible in the first stage of sampling.

- Tracking data reports will no longer be sent to CDC, as this information is no longer needed.
- The token of appreciation for participants has been increased from approximately $25 to $50.
- Non-substantive changes have been made to the respondent consent form to decrease the reading comprehension level, ensure incarcerated persons understand that participation will not affect their parole, and clarify whom participants should contact for different concerns (see Attachments 3a and 3b).
- Non-substantive changes have been made to the model recruitment letter, project area recruitment script, and recruitment text and e-mail scripts to decrease the reading comprehension level, simplify and standardize procedures, and incorporate a user-friendly eligibility checklist (see Attachments 11a, 11b, 11d, 11e, 11f and 11g). The previously approved facility recruitment script (Attachment 11c) was not changed.
- Forty-three data elements were removed from and thirty-seven data elements were added to the Minimum Dataset (MDS) data elements (see Attachment 4). Because these data elements are extracted from the HIV surveillance system from which they are sampled, these changes do not affect the burden of the project.
- Revisions to the interview questionnaire were made to improve coherence, boost the efficiency of the data collection, and increase the relevance and value of the information. Based on an evaluation of the currently approved MMP interview instrument 118 questions were added to the interview form and 221 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 8d.
- Thirty-nine data elements were removed from the MRA data structure because they were not found to be useful. No new elements were added. 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 data structure are outlined in Attachment 13.
- The estimate of annualized burden hours for the proposed project has decreased from 7,140 hours in the current inventory to 6,354 hours as a result of the reduced number of project areas that will collect data (see Exhibit 12.A).

Background

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. 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. The following states received OMB approval to conduct MMP in 2015, but did not do so because funding was not available: Maryland, Massachusetts, and South Carolina. We propose to drop these states from the information collection request.

MMP was launched in 2007 following a National Academy of Medicine (NAM, formerly the 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 NAM, formally known as 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, population-based 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.

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 NAM, formally known as

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].” When limited to HIV-diagnosed persons receiving HIV care, MMP 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 NAM, formally known as 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.”

In response, beginning in 2015 MMP was redesigned to include all HIV-diagnosed persons regardless of care status by sampling persons directly from the National HIV Surveillance System (NHSS, OMB Control No. 0920-0573, exp. 6/30/2019), 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. MMP provides data to supplement HIV/AIDS case reporting that allows participation in MMP by a broader population that is more representative of persons living with HIV than was the case when MMP was sampling only persons receiving care, thus allowing MMP to supplement NHSS more effectively in addressing key information gaps regarding entry to care, engagement and retention in care. Further, MMP increases the value of NHSS by facilitating joint interpretation of trends in transmission risk behaviors, engagement in care, and clinical outcomes.

Only minor changes are requested to the project in order to improve operational efficiency and enhance the quality of the data collected.

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

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 uses a two-stage sampling design in which the first stage involved sampling geographic areas. The second stage involves annual probability-based selection, directly from NHSS, of a probability sample of HIV-diagnosed adults living in each of these geographic areas.

The procedures for contacting and recruiting persons for MMP will remain the same as in the previously approved information collection request. This involves both direct recruitment of respondents and recruitment through medical care providers. Non-substantive changes have been made to the model recruitment letter, project area recruitment script, and recruitment text and e-mail scripts to decrease the reading comprehension level to one more easily understood by sampled persons across educational levels, to simplify and standardize the steps and procedures required of local MMP staff, and to incorporate a user-friendly eligibility checklist. Revised and red-lined versions of these materials can be found in **Attachments 11a, 11b, 11d, 11e, 11f, and 11g**. The previously approved model facility recruitment script will continue to be used (**Attachment 11c**). 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 continue to search for contact information for sampled persons 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 continue to proceed if permitted by local laws and policies, according to inter-jurisdictional agreements. These agreements 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 4) cross-jurisdictional MMP recruitment activities are not permitted (see **Attachment 12** 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. However, as described in section A1, persons who were found to have resided in a non-MMP project area on the date of sampling will be ineligible, because their jurisdictions were not selected for the first stage of MMP sampling.

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 continue to track their recruitment and contact activities. This process tracking does not involve collection of data from the public. As described in section A1, tracking data reports from the project areas will no longer be sent to CDC, as this information was not found to be useful to improve performance or efficiency among staff. No contact information for sampled persons (i.e. phone number, street level address, etc.) is sent to CDC, it is all kept locally at the local project areas.

MMP's data collection continues to have two primary components: an interview and medical record abstraction. 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.
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, access to medical care, 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**). Sections of the previously approved questionnaire were modified to improve the efficiency of administration and the quality of the data collected. For

example, acquisition risk questions were removed because that data can be collected more effectively using the minimum dataset (MDS), and some injection drug use questions were removed because that data can be collected more comprehensively through the National HIV Behavioral Surveillance System (NHBS) (OMB 0920-0770, exp. 5/31/2020). In addition, questions about residence, reproductive health, gynecological care, and other topics were improved to ease participant comprehension. All new sections of the questionnaire were tested for comprehension through mock interviews. CDC staff conducted test interviews of the revised questionnaire using scenarios involving hypothetical respondents with different characteristics, and determined the average time to complete the interview was 45 minutes, which is the same administration time as the previously approved questionnaire. In addition, cognitive testing was performed to improve questions on HIV care experiences and barriers to care. Detailed information on changes to the interview can be found in **Attachment 8d** 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 13**). For 2018, 39 data elements were removed from the previously approved MRA data elements. No new data elements were added. Nadir CD4 count was deleted because MMP abstracts over a 2 year observation period and therefore cannot ascertain this information in most cases. In the encounter section, whether a physical exam was documented and whether antiretroviral medications were prescribed, refiled, or continued were deleted because that information is not needed to assess engagement in HIV care. Six month time blocks for documenting medications, diagnoses, and prophylaxis offer no advantage over 12 month time blocks. Therefore the date of the beginning of the 7th and 19th months were deleted. Five labs were deleted because they were determined not to be critical data elements: parathyroid hormone, INR, and TSH, HIV phenotype, and tropism assay. Mammogram information will no longer be collected because of frequent missing data and pregnancy information, including number of pregnancies and delivery method will be deleted because that information is more reliably captured in the patient interview. Date of death information will no longer be collected due to high prevalence of missing information. The details of

these changes to the MRA are provided in **Attachment 13**.

Demographic and HIV-related laboratory information associated with sampled participants will continue to be extracted from the existing HIV case surveillance database, the National HIV Surveillance System (NHSS, OMB Control No. 0920-0573, Exp. 6/30/2019). This minimum dataset (MDS) (**Attachment 4**) 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.

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. 6/30/2019) (Attachment 4) 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 age is a strong predictor of non-response, but we have determined that full date of birth is not needed. We will use month and year of birth from NHSS for non-response bias adjustment. Employment status 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 continue to 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 2015 MDS contained 82 data elements. The proposed 2018 MDS contains 76 data elements. The net change is a 6-element reduction. Forty-three data elements that were not found to be useful for making adjustments to account for non-participation bias, or are no longer collected by NHSS, were dropped from the 2018 MDS dataset. Thirty-seven data elements were added to the 2018 MDS dataset. These additions were necessary due to changes in the data structure of NHSS and the availability of more detailed information for non-response analysis. The variables retained in, deleted from, and added to the 2018 MDS are listed in **Attachment 4**.

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. Employment status is the only personally identifiable information collected that will be sent to CDC. Month and year 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. 6/30/2019). In addition, the NHSS coded identifier (STATENO) will be included in sampling frames drawn from CDC's NHSS database. Month and year 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 month and year 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.

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 4**) 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 month and year of birth. Past experience with MMP has shown that age is a strong predictor of non-response, but month and year of birth will be sufficient for non-response bias adjustment.

MMP's aim is to facilitate understanding of health-related behaviors, experiences, and needs of people diagnosed with HIV infection across the U.S. and in specific jurisdictions. The objectives of MMP are 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. The aim and objectives remain the same as in the previously approved information collection.

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. 6/30/2019) 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. 5/31/2020), 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. MMP provides 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, which is needed to guide strategies to improve care access and utilization, and to maximize the impact of antiretroviral therapy. Further, using the NHSS as a sampling frame and sampling from all persons reported with HIV diagnoses facilitates 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.

MMP's unique features 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, as well as those who have dropped out of care or are intermittently in care. These data 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 the HIV/AIDS Reporting System (eHARS) is used for non-response bias analysis and allows for 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 by 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 unique design, MMP allows CDC to

monitor national progress toward ensuring high quality care for all people diagnosed with HIV. Specifically, 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. 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 that 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. MMP also provides information that describes HIV-diagnosed persons and the types of prevention and care services they have needed and received. This information is useful to improve local care and prevention services for people living with HIV who are not 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 publications on improvements in antiretroviral therapy prescription and viral suppression among HIV patients (2016), increased sexually transmitted disease testing among sexually active HIV patients (2016), and an assessment of service delivery and patient outcomes in different care settings (2015). In addition, MMP was used as a data source for an influential Journal of the American Medication Association Internal Medicine publication that estimated HIV transmission at each step of the

care continuum in the United States (2015). Numerous national and area-specific analyses of MMP data have also been disseminated through peer-reviewed scientific journals, reports, and at national meetings (**Attachment 6**).

Without MMP data, the best source of behavioral and clinical data would be the National HIV Surveillance System (NHSS, OMB No. 0920-0573, exp. 5/31/2020), 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 population-based local and national 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. 5/31/2020), 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. 6/30/2019).

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 (OMB 0920-0770, exp. 5/31/2020) 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 8/22/2017, Volume 82, Number 161, Pages 39788-39790 (**Attachment 2**). One public comment was received **(Attachment 2a**.

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 7**, 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. Names and contact information for ICF staff are listed in Section 5 of Supporting Statement Part B.

To prepare for the change from facility-based sampling to sampling directly from NHSS in 2015, in 2013 CDC investigators conducted a pilot project to identify implementation challenges 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. Names and contact information for the MMP project area principal investigators can be found at https://www.cdc.gov/hiv/statistics/systems/mmp/projectareas.html. 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 (1-877-435-7443), 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 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 revisions to the project made in 2015.

In 2014 we began consultations with Ms. Antigone Dempsey (1-301-443-0360) and Ms. Heather Hauck (1- 301-443-3613) 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 $50 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. The token of appreciation will be increased to $50 from an approximate amount of $25. This change is needed due to difficulties in recruiting persons with diagnosed HIV who are not receiving medical care and whose HIV virus is not suppressed.

MMP's response rate declined from 2014 – 2015 and remained depressed in 2016 (see Supporting Statement B, Table 1a). The national response rate for the most recent completed data collection cycle year (2016 cycle) was 44% and ranged from 42% to 53% in our project areas. This response rate is much lower than 4 years earlier (2012 cycle) when the national response rate among participants was 53% and ranged from 40% to 65% in our project areas.

We believe the primary reasons for this precipitous fall in patient response rate is due to the change in our sampling methods from including HIV positive persons in care to include all persons diagnosed with HIV in 2015. Persons diagnosed with HIV but who are not in care are known to be a much more challenging population to locate and to recruit to participate in a system such as MMP. Additionally, the change in methods limited the ability of medical providers to support recruitment of participants which always proved a tremendous help when recruiting participants.

However, understanding this population is critical to our nation's efforts to reduce HIV infection. In order to reduce new HIV infections, persons already diagnosed must be linked to care, prescribed antiretroviral medications, and achieve viral suppression. Understanding the barriers to care, reasons for not being prescribed antiretroviral medications, and why viral suppression is not attained or maintained are the primary objectives of MMP and the reason for change in sampling methods to include this new population. Weighting the MMP sample to be nationally representative of all persons with diagnosed HIV – both persons in and out of care – would be more robustly accomplished with higher response rates among persons who are out of care. Currently, small cell sizes somewhat limit our ability to make representative inferences about this population.

Our non-response analysis for the 2016 cycle demonstrated that we have much lower response rates among persons not in care (17%) compared to those persons retained in care (55%) as well as lower response rates among persons not virally suppressed (29%) compared to persons virally suppressed (54%). There were similar findings for the 2015 cycle (see Supporting Statement B, Table 1b).

Our request to increase the tokens of appreciation is intended to improve response rates among persons not in care or who are not virally suppressed. Although we do not have published data to support the increase, we have expert advice from public health practitioners in the field that a higher token of appreciation would result in better response rates especially among the most disadvantaged, which are often the persons not in care or not virally suppressed.

Additionally, we should note that not only are MMP participants providing highly sensitive data during the survey they complete but they also must agree to allow us to perform a 2 year medical chart abstraction. The data from their medical records are highly sensitive and our participants clearly see the token of appreciation as acknowledgement of their responses to the survey as well as their consent for us to review and abstract medical record data. Because the response rates during the past year were obtained with the incentive, they cannot be used to make inferences about the effectiveness of the incentives; inferences about the effectiveness of the incentives require that data be collected without incentives.

Because we cannot confirm receipt of care prior to the survey, the token amount needs to be increased for all eligible participants. We plan to reassess our response rates following the increase in token of appreciation to evaluate its effects on participation, particularly among persons not receiving care. As part of this reassessment, we will submit response rates pre- and post-increase of the token of appreciation amount to OMB.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The CDC Privacy Officer has assessed this package for applicability of 5 U.S.C. § 552a, and determined that the Privacy Act does apply to the overall information collection. This activity is covered under the Privacy Act System of Records

Notice (SORN) #09-20-0136, “Epidemiologic Studies and Surveillance of Disease Problems. HHS/CDC”, which enables the Centers for Disease Control and Prevention (CDC) officials to collect information to better understand disease patterns in the United States, develop programs for prevention and control of health problems, and communicate new knowledge to the health community.
MMP is anonymous (neither names nor social security numbers are collected). Previously collected month and year of birth will be extracted from the National HIV Surveillance System (NHSS, OMB No. 0920-0573, exp. 6/30/2019) as part of the minimum dataset (MDS). Age 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. Data collected in the project areas for MMP will be stored separately from personal identifiers. All patient information is labelled with a unique MMP coded participant identifier (STATENO) only. The MMP database maintained at CDC has received Data Security Assessment and Authorization (SA&A) from the CDC Information Technology Office.

Medical record data are abstracted by MMP staff via a web-based application called Discovere™ (Cerner Corporation). This system is called MMP-MRA – Discovere (MMPMRAD). Data are automatically uploaded to a secure Cerner Corporation server when they are entered into the application and saved. Cerner will subsequently upload the MMPMRAD data to the DCC portal on a monthly basis using approved encryption software. Access to the web-based MMPMRAD application will be username- and password-protected, such that unauthorized users will not be able to view, export, or modify the collected data. The MMPMRAD 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 Current Edition, 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.

The NCHHSTP IT Security Information System Security Officer (ISSO), consulted on the system security described in this section. The data system for this collection underwent a Privacy Impact Assessment (PIA) (**Attachment 17)** when it was granted authority to operate in 2013 during the SA&A process (Enterprise Systems Catalog, IT Record ID: 2288).

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. 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 9**). 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 10**-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.

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). This system is called MMP-MRA – Discovere (MMPMRAD). Data are automatically uploaded to a secure Cerner Corporation server when they are entered into the application and saved. Cerner will subsequently upload the MMPMRAD data to the DCC portal on a monthly basis using approved encryption software. Access to the web-based MMPMRAD 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 Security Assessment and Authorization (SA&A)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 MMPMRAD 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 Current Edition, 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 – Discovere (MMPMRAD) 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 are no significant privacy impacts anticipated for the MMPMRAD 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 Security Assessment and Authorization (SA&A) Guidelines outlined in NIST SP 800-37 Current Edition (Guide for Applying the Risk Management Framework to Federal Information Systems: A Security Life Cycle Approach). The DCC has received approval through the Security Assessment and Authorization (SA&A) process (**Attachment 14**). 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 Security Assessment and Authorization (SA&A)Guidelines outlined in NIST SP 800-37 Current Edition (Guide for Applying the Risk Management Framework to Federal Information Systems: A Security Life Cycle Approach).

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 9**).

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 15**), 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 3a**. Modifications from the previously approved consent have been made to decrease the reading comprehension level, ensure incarcerated persons understand that participation will not affect their parole and clarify whom participants should contact for different concerns. A comparison of the 2018 consent form with the previously approved consent form is provided in Attachment 3b. 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. Institutional Review Board (IRB) and 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 11%, from 7,140 to 6,354 hours, due to the removal of three unfunded project areas, which reduced the sample size from 10,900 to 9,700. This reduces the number of interviews conducted and the number of persons for whom healthcare facility staff will be asked for contact information, assistance with approaching for participation, and pulling medical records.

CDC's current goal is to interview 80% of 9,700 patients or 7,760, all of whom will complete the standard interview, which will take approximately 45 minutes **(Attachment 8a)**. Thus, the total annual burden (in hours) associated with the interview is 5,820. 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 (1,940 persons), which will take 2 minutes per person. We estimate that 10% of sampled persons (970) 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 pull 7,760 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 Persons	Interview Questionnaire (att 8a)	7,760	1	45/60	5,820
Facility office staff looking up contact information	Look up contact information	1,940	1	2/60	65
Facility office staff approaching sampled persons for enrollment	Approach persons for enrollment	970	1	5/60	81
Facility office staff pulling medical records	Pull medical records	7,760	1	3/60	388
Total					**6,354**

B. Estimated Annualized Cost to Respondents

The annualized cost to respondents for the burden hours is estimated to be $152,037; details are provided in Exhibit A.12.B.

The 2017 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	5,820	$23.87	$138,923
Facility office staff looking up contact information	65	$24.56	$1,596
Facility office staff approaching sampled patients for recruitment	81	$24.56	$1,989
Facility office staff pulling medical records	388	$24.56	$9,529
Total	**6,354**		**$152,037**

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 annualized cost to the government is $17,838,614. The annualized cost is summarized in Exhibit 14.A.

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

Expense	Expense Explanation	Annual

Type		Costs (dollars)
Direct Costs to the Federal Government	MMP – Personnel Epidemiologist-14 2 100% $255,314 Health Scientist-14 1 100% $117,019 Medical Officer-14 2 100% $269,498 Epidemiologist-13 6 100% $594,150 Health Scientist-13 1 100% $96,024 Health Scientist-12 4 100% $312,916 Public Health Analyst-11 1 100% $63,161 Public Health Advisor-13 1 100% $108,027 Statistician-14 1 50% $62,055 Support Staff Business Support Spec-11 1 50% $34,738 Data Managers/Analysts 7 100% $490,000 Project Coordinator 1 100% $80,000 ORISE Fellows 2 100% $150,000	$2,632,902
	Cooperative agreement funds to project areas	$13,494,736
Contractor and Other Expenses	Data Coordinating Center (CDC Contractor for data collection)	$971,286
	Contracted Questionnaire Programming	$284,090
	Contracted Medical Record Abstraction Application development and maintenance	$422,100
	Travel	$30,000
	Spanish language translation	$3,500
	TOTAL COST TO THE GOVERNMENT	$17,838,614

*Salary estimates were obtained from the US Office of Personnel Management salary scale at https://www.opm.gov/policy-data-

oversight/pay-leave/salaries-wages/salary-tables/pdf/2017/ATL.pdf. Cooperative Agreement and contractual funding is not final and is an estimate based on previous years.

The personnel related to the MMP data collection include project officers (epidemiologists, a health 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 health 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 the number of persons sampled, the burden has decreased by 786 hours (see Exhibit 12.A). Specifically, the removal of three unfunded project areas reduces the number of interviews conducted and the number of persons for whom healthcare facility staff will be asked for contact information, assistance with approaching for participation, and pulling medical records. 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**
Sampling begins (2018 cycle)	1 month after OMB approval
Sampled cases interviewed	1-11 months after OMB approval: Data collection needs to begin on June 1, 2018 to avoid project delays.
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 (2019 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 (2020 cycle)	25 months after OMB approval
Sampled cases interviewed	25-35 months after OMB approval
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

https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-hssr-mmp-2014.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. CDC has contributed MMP data to several national reports, for example Monitoring Selected National HIV Prevention and Care Objectives by Using HIV Surveillance Data (https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-supplemental-report-vol-21-4.pdf) and the National HIV/AIDS Strategy for the United States: Updated to 2020, Indicator Supplement (https://www.aids.gov/federal-resources/national-hiv-aids-strategy/nhas-indicators-supplement-dec-2016.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.