Medical Monitoring Project

OMB #0920-0740

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 May 31, 2024). 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 the same as the burden shown in the current inventory.

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

- 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 (see Attachment 5d). These changes did not affect the average burden per response.
- Revisions to the medical record abstraction data elements were made to streamline the information collected and add important questions related to MPox vaccination (see Attachment 6). Because the medical records are abstracted by MMP staff, these

changes do not affect the burden of the project.

- The interview and medical record data collection system were integrated to improve project efficiency and enhance data quality.
- Video interviewing was removed as a mode of questionnaire administration due to extremely low uptake.

Background

MMP is a supplemental surveillance project designed to collect nationally representative data about people with diagnosed 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.

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. NAM 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 therapy (ART) dramatically reduces the probability of HIV transmission (**Attachment 7, 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. Increasing access to care is one of the key strategies of the federal Ending the HIV Epidemic, and the NAM 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 (formerly 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. 02/28/2026), 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 is more representative of persons living with HIV than was the case when MMP only sampled 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 to improve operational efficiency and enhance the quality and usefulness 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 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 with diagnosed 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. Project staff will continue to use the previously approved model recruitment letter, project area and facility recruitment scripts, and recruitment text and e-mail scripts (**Attachments 8a, 8b, 8c, and 8d)**. Making contact with individuals based on information reported to HIV case surveillance at their time of diagnosis can be problematic because 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** 9 for a copy of the agreement

form). As described above in section A1. Background, because the sampling frame does not systematically maintain residence information that is current as of the date of sampling, the MMP sample is likely to include a number of persons who have moved out of the jurisdiction where they are presumed to be living when they were sampled. In the 2021 MMP cycle, approximately 6% of sampled persons did not reside in the project area of sampling at the time of recruitment. Recruitment of 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, 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 tracking process does not involve collection of data from the public. Tracking data reports from the project areas are not sent to CDC, as this information is not useful for improving performance or efficiency among staff. For contacting sampled individuals, the MMP staff use contact information for sampled persons (i.e., phone number, street level address, etc.) that is collected by a different data system, the National HIV Surveillance System (NHSS, OMB Control No. 0920-0573, Exp. 02/28/2026). This contact information is not 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 40-minute face-to-face or telephone interview. Videoconference interviews were removed as a mode of questionnaire administration due to extremely low uptake. Three videoconference interviews have been conducted since implementation of this mode during MMP's 2022 cycle. Considering the effort required to train interviewers, monitor security and operational procedures, and maintain equipment to support videoconference interviews, we are requesting to drop this mode for MMP's 2024 cycle. 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 5a and 5b**). Sections of the previously approved questionnaire were modified to improve the efficiency of administration and the quality of the data collected. For example, questions about unmet needs for ancillary services were improved to ease participant comprehension and provide more useful information. 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 40 minutes, which is the same administration time as in the previously approved questionnaire. In addition, cognitive testing was performed to improve questions on gender identity, sexual orientation, and patient-provider communication. Detailed information on changes to the interview can be found in **Attachment 5d** and specific questions that will be removed can be found in the previously approved interview questionnaire in **Attachment 5c**.

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 6**). Eleven data elements were added to the MRA, including information about M-pox vaccination, anal pap testing, and HPV testing. Sixty-one previously approved data elements were deleted to remove information that is no longer useful, for example MAC prophylaxis, which is no longer recommended for people with HIV. The details of the changes to the MRA are provided in **Attachment 6**.

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. 02/28/2026). 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. 02/28/2026) (**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. No changes to the previously approved Minimum Dataset are requested. As for the currently approved project, the minimum dataset will contain extracted data for 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 can be a predictor of non-response, but we have determined that full date of birth is not needed. We will continue to use month and year of birth from NHSS for non-response bias adjustment, if needed. Employment status (collected via the interview) 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.

No information in identifiable form (IIF) will be collected for MMP. No audio recordings will be made of the interviews obtained by telephone. 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. 02/28/2026). 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 Data Coordinating Center (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 can be a 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. 02/28/2026) 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. 04/30/2026), 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 U.S. persons with diagnosed HIV 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 persons with diagnosed HIV, 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 U.S. persons with diagnosed HIV 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 NHSS 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 with diagnosed 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 that have quantified unmet needs for housing services among people with diagnosed HIV (2023), evaluated geographic differences in reaching selected national HIV strategic targets among people with diagnosed HIV (2022), and documented the association between unmet ancillary service needs and HIV clinical outcomes (2021). Numerous national and area-specific analyses of MMP data have also been disseminated through peer-reviewed scientific journals, reports, and at national meetings (**Attachment 10**).

Without MMP data, the best source of behavioral and clinical data would be the National HIV Surveillance System (NHSS, OMB No. 0920-0573, exp. 02/28/2026), which only collects a limited amount of information from medical records of persons 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. The interview and medical record data collection were integrated into a web-based integrated surveillance management system

(WISMS) to improve project efficiency and enhance data quality. 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 system “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.

The CDC Division of HIV Prevention (DHP) has implemented the use of handheld and laptop devices for other national surveillance systems. All state and local health departments participating in MMP 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 a secure web-based data portal system through which project area data are submitted, 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 track project area activities and retrieve data sets and reports. This system helps 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. 04/30/2026), 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. 02/28/2026).

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. 04/30/2026) collects data on specific populations at increased risk for HIV infection (men who have sex with men, persons who inject drugs and sexually active 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 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

In light of the new OMB Race/ethnicity guidelines we are requesting to use the current format for the following reasons, (1) changing MMP’s race/ethnicity questions in May 2024 is not possible without substantial harm to the data collected. MMP’s 2024 cycle is scheduled to begin on June 1. Any changes to the questionnaire would require reprogramming the data collection instrument, testing the changes, and integrating any changes and additions to align with the project’s data collection structure (e.g., creation of variable names, coding structure for response sets, etc.). These activities would substantially delay the start of data collection and shorten the data collection cycle given that MMP operates on annual 12-month cycles that are tied

to funding for the project, and (2) the benefits of early adoption of the new race/ethnicity questions would be outweighed by the harms caused because the loss of data would negatively affect the accuracy of estimates produced. Having fewer respondents would result in less precise estimates and potentially affect MMP's ability to produce robust estimates for smaller populations. This is crucial for MMP because it is the data source for National HIV/AIDS Strategy indicators that monitor important HIV outcomes among smaller priority populations, such as transgender women and people who inject drugs.

However, MMP staff are actively exploring how to implement the new race/ethnicity questions and plan to do so as soon as is feasible. Ensuring the new race/ethnicity questions meet OMB requirements in a way that will minimize the impact of the changes on our ability to assess trends in important HIV clinical and behavioral factors for national and local HIV initiatives and programs is important to ensure the value of the data are retained.

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 04/24/2023, Volume 88, Number 78, Pages 24799-24800 (**Attachment 2**). CDC received 1 public comment (**Attachment 2a**). The response to the comment is provided in **Attachment 2b**.

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 11**, 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 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 between $50-$75 in cash as a token of appreciation for participation, depending on local regulations,

practices, and characteristics such as cost of living. 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 amount of the token of appreciation is justified by the difficulties in recruiting hard to reach groups like persons with diagnosed HIV—particularly those who are not receiving medical care and whose HIV virus is not suppressed—in addition to the sensitive nature of the questions asked during interview and the medical record data abstracted. Response rates for all epidemiologic studies and many federal surveys have declined in recent decades **(Attachment 7 references 15 and 16)**. Multiple reviews have found that monetary incentives improve participant questionnaire response **(Attachment 7, references 17-20).**

Persons diagnosed with HIV but who are not retained 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, because MMP samples participants from the national HIV registry rather than through medical care facilities, this limits the ability of medical providers to support recruitment of 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 not retained in care and/or not achieving viral suppression. Small cell sizes somewhat limit our ability to make representative inferences about this population. Response rates among persons not known to be in care based on NHSS have remained relatively low from 2018 to 2021(range: 18% to 21%).

Additionally, not only are MMP participants providing highly sensitive data during the survey, they must also 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.

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. 02/28/2026) as part of the minimum dataset (MDS)**Attachment 4**. Age has previously been a predictor of non-response in MMP, and it will be used to adjust for non-response bias if found to be associated with non-response.

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 data collection tool called Web-based Integrated Surveillance Management System (WISMS). Data is automatically saved to a secure CDC cloud-based server. Preapproved users access WISMS via CDC’s Secure Access Management System (SAMS) authentication, which is user name and password protected, such that users can only see data they input into the system. Cumulative surveillance data is housed on secure cloud servers that have been configured to CDC IT Security Program Implementation

Standards following the National Institute of Standards and Technology (NIST) United States Government Configuration Baseline (USGCB), which adhere to the most restricted security settings consistent with operational requirements. WISMS servers are located and housed within CDC Azure Cloud environment that meets the stringent security requirements from NIST Special Publication (SP) 800-53 revision 5, Security and Privacy Controls for Information Systems and Organizations. The data is protected by multiple layers of security that ensure confidentiality, integrity, and availability.

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 12)** when it was granted authority to operate in 2022 during the SA&A process (Enterprise Systems Catalog, IT Record ID: 2288). The NCHHSTP security steward and the program data steward annually reviews the PIA for changes to privacy data and has not found any changes since approval.

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 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 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.

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.

A Privacy Impact Assessment (PIA) has been completed for the interview and medical record data collection system in accordance with CDC, HHS, and OMB requirements (**Attachment 12**). 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 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 15**). 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).

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 approved for telephone interviewing include ensuring that the participant and the interviewer each has a private location in which to conduct the interview. No audio recordings will be made of the interviews obtained through telephone.

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 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 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 Office of Grants Services will require the inclusion of 308(d) clauses in any HIV 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 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 electronically attest to the respondent’s verbal consent. An example model consent document is included as **Attachment 3**. No modifications from the previously approved consent have been made. All sites must obtain consent from respondents and store consent forms in a secure location. Respondents will be told that they may decline to participate without penalty or, if they agree to participate, they may refuse to answer any question. 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

IRB

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 in August of 2023 (**Attachment 14**-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 begins, if required in the jurisdiction. All applicable Federal and state privacy laws must be followed.

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 will be administered in a private location that ensures the confidentiality of responses. No audio recordings will be made of the interviews obtained through telephone. 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 is the same as for the currently approved project, 5,707 hours.

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 40 minutes **(Attachment 5a)**. Thus, the total annual burden (in hours) associated with the interview is 5,173. 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 **(Attachment 8e)**. 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 **(Attachment 8c)**. Medical records are only pulled once for each abstraction, the estimate to pull 7,760 medical records is 3 minutes per record **(Attachment 8f)**.

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. 5a)	7,760	1	40/60	5,173
Facility office staff looking up contact information	Look up contact information (Att. 8e)	1,940	1	2/60	65
Facility office staff approaching sampled persons for enrollment	Model Patient Recruitment Script-Facility (Att. 8c)	970	1	5/60	81
Facility	Pull medical	7,760	1	3/60	388

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Hours Per Response	Total Response Burden (Hours)
office staff pulling medical records	records (Att. 8f)				
Total					**5,707**

B. Estimated Annualized Cost to Respondents

The annualized cost to respondents for the burden hours is estimated to be $169,392; details are provided in Exhibit A.12.B. The 2020 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	5,173	$29.70	$153,638
Facility office staff looking up contact information	65	$29.50	$1,918
Facility office staff approaching sampled patients for recruitment	81	$29.50	$2,390
Facility office staff pulling medical records	388	$29.50	$11,446

Total	**5,707**		**$169,392**

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 $18,516,962. 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			$3,361,859
	Epidemiologist-14 $278,586	2	100%	
	Health Scientist-14 $139,293	1	100%	
	Medical Officer-14 $400,000	2	100%	
	Nurse Consultant-14 $139,293	1	100%	
	Epidemiologist-13 $943,000	8	100%	
	Health Scientist-13 $235,750	2	100%	
	Health Scientist-12 $198,256	2	100%	
	Statistician-13 $17,681	1	15%	
	Support Staff			
	Data Managers/Analysts $700,000	6	100%	
	Project Coordinator $150,000	1	100%	
	ORISE Fellows $160,000	2	100%	
	Cooperative agreement funds to project areas			$13,587,963

Contractor and Other Expenses	Data Coordinating Center (CDC Contractor for data collection)	$1,500,000
	Contracted Recruitment Services for Cognitive Interviews	$20,640
	Travel	$41,000
	Spanish language translation	$5,500
	TOTAL COST TO THE GOVERNMENT	$18,516,962

*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/2020/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, medical officers, health scientists and a nurse consultant) at the GS-13 and 14 levels, a GS-13 level statistician, GS-13 level health scientist, a project coordinator, 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

No changes to the burden of the project are requested. 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**
Sample distributed to project areas(2024 cycle)	Immediately upon OMB approval
Sampled cases interviewed	1-11 months after OMB approval: Data collection needs to begin on June 1, 2024 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
Sample distributed to project areas (2025 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
Sample distributed to project areas (2026 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/library/reports/hiv-surveillance-special-reports/no-29/index.html). 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/library/reports/hiv-surveillance/vol-27-no-3/index.html) and the National HIV/AIDS Strategy Federal Implementation Plan: 2022-2025 (https://files.hiv.gov/s3fs-public/2022-09/NHAS_Federal_Implementation_Plan.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 non-injection drug use in past 12 months;
- Prevalence of use of antiretroviral therapy;

- Prevalence of detectable HIV viral load;
- Prevalence of HIV stigma;
- Prevalence of good or better self-rated health;
- Prevalence of unmet need for mental health services;
- Prevalence of food insecurity;
- Prevalence of unemployment;
- Prevalence of unstable housing or homelessness.

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. However, the program is requesting a May 31, 2027 expiration date for this data collection. The reason for this is that MMP is charged with providing annual estimates of behavioral and clinical factors among U.S. persons with diagnosed HIV, which are used to monitor trends in the burden of disease and associated factors. To achieve this, we need to sample persons using a consistent date of sampling and complete a 12-month data collection cycle every year.

- MMP design
  - MMP's design entails annual random sampling of adults with diagnosed HIV reported to the National HIV Reporting System (NHSS) by December 31 of the year prior to data collection. To account for reporting and processing delays, the samples are drawn a few months later. Data collection begins on June 1 of the cycle year and ends on May 31 of the following year. For example, for the 2024 cycle, the date of sampling is December 31, 2023 and the data collection cycle runs June 1, 2024 through May 31, 2025.
- Importance of maintaining consistent OMB approval and expiration dates that are aligned with MMP data collection cycle start/end dates
  - A full 12-month data collection period is needed to maximize response rates, allow time for processing of the sample and data closeout, and ensure consistency of methods across cycles.
  - Having the same sampling date each year is crucial for ensuring comparability across cycles so that MMP data can be used to assess trends (e.g., needed for national prevention indicator reports).
  - MMP requests OMB approval beginning on June 1, 2024 and expiring on May 31, 2027

- If approval begins after June 1, the start of the 2024 data collection cycle is delayed. This decreases the amount of recruitment and data collection time available for the 2024 cycle, which negatively affects response rates and results in inconsistent methods across cycles.
- If approval begins before June 1, this will be problematic because the 3-year OMB approval will expire before the end of the 2026 data collection cycle (ending May 31, 2027), thus shortening the amount of recruitment and data collection time available for that cycle. Again, this will negatively affect response rates and the consistency of methods across cycles.
- In addition to effects on the quality and consistency of MMP data, having set OMB approval and expiration dates are important to our partners, who depend on predictable dates to plan effectively and not waste fiscal and other resources. The MMP funding awards have a June 1 start date, so having OMB approval before June 1 would mean lost time, as project areas will not have funding to conduct project activities. Having OMB approval after June 1 would result in a waste of federal resources, as project areas would have funding but be unable to conduct project activities.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.