Justification for the modification of 0920-0740, Medical Monitoring Project (MMP)

The Centers for Disease Control and Prevention (CDC) requests to make non-substantive changes to the currently approved Medical Monitoring Project (MMP) OMB No. 0920-0740; expiration date 5/31/2015). The proposed changes are for the questionnaire, as well for the medical record abstraction (MRA) and the minimum data set (MDS) list of data elements to be extracted from the National HIV Surveillance System (NHSS, OMB Control No. 0920-0573: Adult and Pediatric Confidential HIV/AIDS Case Report). MRA and MDS have no associated respondent burden. All other project activities and methods remain the same as in the previously approved information collection request. The proposed changes do not change the burden shown in the current inventory.

This submission includes "redlined" and "clean" versions of the MMP questionnaire. The MRA form will be completed using a new web-based application that replaces the four forms that were previously used; the MRA data elements and the changes from 2012 are detailed in "MMP 2013 Summary of Changes to Data Collection," and accompanying screenshots for the new MRA application are attached in "MRA 2013 Screenshots." The list of MDS elements and changes from 2012 are also detailed in "MMP 2013 Summary of Changes to Data Collection."

Please see the following attachments for additional detail as needed:

MMP 2013 Interview v. v 9. 5. 0_Clean.docx
MMP 2013 Interview v.9.5.0_Redlined.docx
MMP 2013 Summary of Changes to Data Collection.docx
MRA 2013 Screenshots.pdf
MMP 2013 Burden Table.docx

Overview of MMP

MMP's data collection supplements the HIV/AIDS surveillance programs in 23 selected state and local health departments, which collect information on persons diagnosed with, living with, and dying from HIV infection and AIDS. MMP is designed to obtain locally and nationally representative data on behaviors and clinical outcomes of a national probability sample of patients in care for HIV infection. 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.

Data collected from in-person and telephone interviews with HIV-infected patients include patient demographics and behaviors that may facilitate HIV transmission, such as sexual and drug use behaviors; patients' access to, use of and barriers to receiving HIV-related secondary prevention services; utilization of HIV-related medical services; and adherence to drug regimens. Data abstracted from patient medical records 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 Public Health Service guidelines. A minimum dataset that contains demographic and HIV-

related laboratory information on sampled participants is extracted from an existing HIV case surveillance database (NHSS, OMB Control No. 0920-0573: Adult and Pediatric Confidential HIV/AIDS Case Report). CDC's current goal remains the same as for the past cycle: to interview 80% of 9,400 sampled patients (7,520 total). The data collected for this project are protected under a Federal Assurance of Confidentiality.

No other Federal agency collects national population-based behavioral and clinical information from HIV-infected adults in care. The data are expected to have significant implications for policy, program development, and resource allocation at the state/local and national levels.

Proposed Changes and Justification

The estimated burden of the MMP interview is expected to be same in 2013 as in 2012 (45 minutes on average). The short form of the questionnaire has been discontinued to streamline data management by limiting the numbers of forms used and asking the same questions of all participants, whether or not they are able to answer all of the questions. The short form was originally intended to collect information from: 1) sampled persons unable to participate in the standard 45-minute interview because of illness; and 2) persons who speak a language other than English or Spanish, which necessitated translation of questions. However, experience indicates that the small number of short interview respondents (4% of the total number of interviews in the 2009 cycle) as well as the lack of key data elements in the short form precluded using data from the short interview in national analyses. Yet, substantial project resources have been required to collect data using the short questionnaire, including resources for questionnaire development; interview application programming and testing; and data management and weighting. All patients will be offered the standard interview and informed that they may stop the interview if they become fatigued. We estimate that less than half of the standard interview (about 20 minutes) will be completed by patients in the subgroups previously offered the short questionnaire. Therefore, the overall interview burden will remain the same. See attachment "MMP Burden Table".

As for the currently approved MMP data collection, the MRA and MDS data collection activities are conducted by MMP project staff and thus do not affect the overall burden of the project. The proposed changes to the interview questionnaire are detailed below:

Interview questionnaire

We propose non-substantive changes to the OMB-approved questionnaire. The proposed changes are based on: 1) experiences with implementation of previous cycles of data collection, weighting, and analysis; 2) new Office of Minority Health guidelines for data collection elements; and 3) recommendations from subject matter experts and CDC programs. Sixty-six questions have been deleted, 68 questions have been added, and eight questions have undergone minor modifications. The overall increase of 2 questions is not expected to change the estimated average time it takes for respondents to complete the interview (45 minutes). All proposed changes are consistent with the purpose and use of the information collection as stated in the OMB-approved project and do not change the burden to respondents.

We describe the types of proposed changes and provide examples for each below. They are detailed in "MMP 2013 Summary of Changes to Data Collection" and noted in the tracked changes version of the questionnaire.

1. Changes based on experiences with implementation of previous cycles of data collection, weighting, and analysis

A major source of questions deleted from the 2013 questionnaire is the Access to Care module. Based on experience with weighting MMP data and the recommendations of our statistical consultants, forty-nine questions about sources of care for HIV (e.g., OB/GYN clinic, prison, etc.) are no longer necessary for weighting the data to insure a nationally representative patient population.

The following questions were added to the Access to Care module for data weighting purposes:

- "Was your usual place of general medical care the same as your usual place of HIV medical care?"
- "What is the name of your usual place of HIV care?" The respondent's answer is not recorded but is used by the interviewer to answer "Is the respondent's usual place of care the same as the sampled facility?"

Based on feedback from subject matter experts in reproductive health, seven questions about pregnancies among HIV-positive women have been deleted and replaced by a series of questions designed to better understand pregnancy intentions and outcomes by enumerating up to 5 pregnancies after a women's HIV infection. There are 25 questions in the series (5 for each of 5 pregnancies). Some women will have no pregnancies to report, and few women will have as many as 5. There are skip patterns which differentiate past pregnancy and current pregnancy, so the maximum number of questions per pregnancy is 4. Therefore, the maximum number of questions would be 20 for a woman with 5 post-HIV infection pregnancies and 4 for a woman with 1 pregnancy. No woman will ever answer all 25 questions, and many women will answer 0.

Analysis of MMP data has shown that text value data obtained from certain questions that include an "other, specify" response option do not yield any meaningful responses or produce information that should be used to augment an existing response set. For these reasons, we have deleted the "other, specify" option for 3 questions, including: Met and Unmet Needs (Access to Care); place respondent went for STI testing, diagnosis, or treatment (Gynecological and Reproductive History); and sexual orientation (Demographics). Vision and legal services were added to the list of HIV Met and Unmet Needs (Access to Care) based on previous "other, specify" data.

Some questions were determined to yield unreliable data or data not useful for national estimates and were deleted. These include: interview setting; date and result of first viral load test; and language use (optional acculturation scale). An additional question for participant ID was added given input errors in previous cycles; this does not change the burden since this information is entered by interviewers prior to the interview.

The following were added to enhance data analysis:

- A question was borrowed from the Behavioral Risk Factor Surveillance System about employment status for a richer description of socioeconomic status

- Number of household dependents under 18 years of age for categorization of a respondent's household income relative to Federal Poverty Level

Minor modifications producing no burden change include:

- Removed reference to handheld devices, which will no longer be used for data collection, from an item in the Preliminary Information module completed by the interviewer.
- Added "city, county, state of other publicly funded insurance" to list of health insurance types to minimize use of "other" category.
- Changed income categories for a finer gradation among lower incomes.
- Returned to exact wording of Pap smear question from previous cycle for clarity (omitted "vaginal" and retained "cervical" in the description of the test.
- Day of birth omitted since it is not necessary for the purpose for which this data element is collected.
- Provided additional instructions to programmers who program the interview software application (e.g., removed references to the use of "??" to denote "don't know" responses for entering data in handheld devices). These are not read by interviewers or respondents.
- Added text for interviewers to clarify the meaning of some questions and ensure correct responses (e.g., added language to the "SAY" box in the Sources of Care section to clarify the meaning of "HIV outpatient care"): "Now I'm going to ask you about the places where you get HIV outpatient medical care. By HIV outpatient medical care I mean care not in an emergency room, urgent care center, or while staying overnight in the hospital. If you don't remember everything, that's okay. Tell me what you remember."
- Added validity checks and confirmation messages which are employed only if responses are outside the range of valid responses (e.g., the date of the 2nd pregnancy must be after the date of the 1st pregnancy and the date of all pregnancies must be after the date of the respondent's first positive HIV test.

2. Changes based on The Office of Minority Health (OMH) guidelines

We made the following language changes and added questions to comply with OMH guidelines for data collection elements as follows:

- Added a question to describe Hispanic origin
- Added "or Spanish origin" to the question "Do you consider yourself to be of Hispanic or, Latino/a or Spanish origin?"
- Added 3 language questions: How well do you speak English? Do you speak a language other than English at home? What is this language?
- Added 6 questions to capture disability status

3) Changes based on recommendations from subject matter experts and CDC programs

The following questions were added to enhance MMP's ability to produce important behavioral and clinical estimates affecting health outcomes and engagement in medical care:

- Respondent's regular HIV healthcare provider

- Two questions to elicit respondents' satisfaction with HIV care
- New antiretroviral medication (Stribild)
- Whether respondent's healthcare professional asked about HIV medication adherence in past 12 months
- Ever use of injection drugs
- HIV acquisition behaviors to supplement National HIV/AIDS Surveillance System transmission risk categories
- Exposure to prevention materials in past 12 months
- Lowest CD4 count
- TB testing and results
- Pelvic examination in past 12 months
- Use of contraceptive methods among HIV-infected women
- HIV care received at Obstetric /gynecology or gynecology clinics

Medical Record Abstraction (MRA)

As for the previously approved information collection request, MMP medical record abstraction will continue to be conducted by MMP staff, and thus will not contribute to the overall burden of the project. Changes to the MRA are proposed based on the desire to maximize efficiency in the collection of MRA data and the limited utility of collecting historical data due to incompleteness. The previously approved MRA forms (Medical History Form, Surveillance Period Summary Form, Surveillance Period Visit Form, and Surveillance Period Inpatient Form) will be consolidated into one web-based data abstraction form. The web-based form was developed by Cerner Corporation, Kansas City, Missouri, for abstraction of medical record data focused on the prior two years of care. The web-based platform for this form is called Discovere™ and is currently used by other CDC projects for medical record abstraction. The data domains for the abstraction remain consistent with the previously approved medical record abstraction and will include data on demographics, medications, diagnoses, procedures, out-patient visits, in-patient visits, laboratory results, prophylaxis, pregnancy, and screening. See "MMP 2013 Summary of Changes to Data Collection" for the list of the 2013 data elements and changes relative to 2012 and "MRA 2013 Screenshots" for information about the web-based application.

With the current MMP MRA application, project areas enter data to an electronic data collection instrument and periodically upload the data to the MMP Data Coordinating Center (DCC) web portal for further processing and analysis. With the new web-based MRA application, data will automatically be uploaded to a secure Cerner Corporation server each time data is entered into the application and saved. Cerner will subsequently upload the MRA data to the DCC portal on a monthly basis using approved encryption software. Access to the web-based MRA application will be username- and password-protected such that unauthorized users will not be able to view, export, or modify the collected data.

Implementation will not proceed until the Cerner web-based application undergoes certification and accreditation by CDC. The security of the system will meet all Federal Information Systems Management Act (FISMA), OMB, HHS, and CDC IT Security requirements which ensure the confidentiality, integrity, and availability of data on federal information systems. The MRA data will be housed on servers that have been configured with the current National Institute of Standards and Technology (NIST) Configuration baselines which adhere to the most restricted security settings consistent with operational requirements. The servers are located within a facility that meets the stringent physical security requirements from NIST Special Publication (SP) 800-53 Revision 3, Recommended Security Controls for Federal Information Systems and Organizations. The data is 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 limit access to the system.

The MMP MRA system has had a Privacy Impact Assessment (PIA) completed in accordance with CDC, HHS, and OMB requirements. The data within this system has been categorized as "Low" using the Federal Information Processing Standards (FIPS) Publication 199. There is no Personally Identifiable Information (PII) data collected by the system and there are no significant privacy impacts anticipated for the MMP MRA system. The data collected for this project are protected under a Federal Assurance of Confidentiality.

Minimum Data Set (MDS)

As for the previously approved information collection request, MMP minimum data set collection will continue to be conducted by MMP staff through an electronic extract of existing NHSS data (OMB Control No. 0920-0573: Adult and Pediatric Confidential HIV/AIDS Case Report), and thus will not contribute to the overall burden of the project. Based on recommendations from NHSS staff, we propose adding 34 data elements to this extract in order to increase the completeness and quality of MDS data. Some added data elements are needed to ensure that calculated variables already approved for collection from NHSS can be disaggregated accurately (e.g., breakdowns of HIV acquisition risk information). Other data elements added will be used as data quality indicators (e.g., the date record entered in NHSS, quality flag entered by local NHSS staff). See "MMP 2013 Summary of Changes to Data Collection."

Impact of Revisions on the Estimated Burden

The proposed non-substantive changes to the data collection instruments will not change the overall estimated burden of this project. The changes are consistent with the previously approved domains and with the purpose and use of the currently approved data collection. The average burden per participant will remain the same as will the number of participants and the annual reporting and recordkeeping burden.