Medical Monitoring Project

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Supporting Statement
Part B

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1. Respondent Universe and Sampling Methods

This request describes a proposed change to the sampling methods for the Medical Monitoring Project (MMP) that will broaden the respondent universe. In the currently approved project, sampling is facility-based. Respondents are HIV-infected adults receiving medical care from sampled HIV care facilities during the population definition period (January 1 – April 30) each year. The proposed respondent universe for prospective data collection is adults (>18 years old) who meet the HIV case definition, have been reported to the National HIV Surveillance System (NHSS, OMB Control No. 0920-0573, exp. 2/29/2016) and reside in one of the 26 participating project areas, including Puerto Rico, 19 sampled states, and 6 separately funded cities within the sampled states). The proposed respondent universe is estimated to number approximately 711,661 persons. Eligible adults must have been diagnosed with HIV as of a reference date, hereafter referred to as the sampling date, and must be living and be a resident of the jurisdiction according to the most recent address documented in NHSS records.

This request describes a proposed shift for MMP from three-stage to two-stage sampling. The first stage of sampling will remain the same as in the previously approved project. The first stage of sampling, conducted at the project's inception using probability proportional to size sampling methods, resulted in the selection of 20 of 52 eligible geographic primary sampling units (PSUs, defined as 50 states; Washington, DC; and Puerto Rico). The six cities separately funded for HIV/AIDS surveillance were included in the 20 selected PSUs and were, for administrative reasons, also funded separately to conduct MMP, resulting in a total of 26 project areas. Budget restrictions applied to the 2009 data collection cycle necessitated dropping 3 project areas. In preparation for the 2009 data collection cycle, three states were randomly selected to be removed from the PSU sampling frame in coordination with statisticians from the RAND Corporation, leaving 23 participating project areas (16 states, Puerto Rico, and six separately funded cities). This modification was approved by OMB. Sampling methods ensured representation of all regions of the US. Restoration of the original sample of 20 geographic primary sampling units is proposed in this request to reestablish the more complete coverage of the population of interest that was obtained through the original sample.

As stated in Part A, the decision to retain sampling of geographic areas as the first sampling stage was made to preserve operational efficiency and the ability of MMP to generate

representative estimates at the state and city level. It would be operationally inefficient and resource-intensive to sample directly from NHSS because this would require the establishment and maintenance of the infrastructure to collect MMP data in every state and territory, the majority of which would have very few cases sampled. Further, clustering the sample in geographic areas allows for a sample size sufficient to produce local estimates of HIV care and treatment that are needed for planning purposes.

Currently, the second stage of sampling for MMP involves selecting HIV care facilities from a sampling frame of facilities developed every other year in each participating state using data from local HIV/AIDS case surveillance, laboratory reporting, AIDS Drug Assistance Programs and other available data sources. For the third sampling stage, local HIV/AIDS surveillance staff work with each selected facility to develop a list of HIV-infected patients who received care from the facility at least once during the population definition period of the relevant calendar year. From this list, a sample of patients is chosen by systematic random sampling.

The proposed new method would skip the selection of facilities and instead employ systematic random sampling of eligible persons directly from NHSS. This new method allows for selection of HIV-diagnosed persons whether or not they are receiving HIV medical care. When MMP was initially designed, a facility-based multi-stage cluster sampling approach was chosen because no sampling frame existed from which to select a probability sample representing HIV-diagnosed persons in the United States. By April 2008, all states had implemented a confidential, name-based system for reporting HIV diagnoses to CDC. Reporting of HIV diagnoses is now sufficiently complete to serve as a sampling frame for MMP in place of facility-based sampling. Sampling using NHSS as a sampling frame is expected to reduce the costs and burden associated with the current complex sampling design, and increase the usefulness of MMP data by permitting monitoring of progress toward the National HIV/AIDS Strategy objectives, specifically with respect to HIV-diagnosed persons not receiving HIV medical care.

CDC HIV case surveillance staff will draw a sample from NHSS of eligible persons whose case records indicate they are residing in the 26 participating project areas. Health department staff in these jurisdictions will find and recruit sampled persons (i.e., screen them for eligibility and offer enrollment in the project), conduct interviews with consenting individuals, and abstract

their medical records. The use of NHSS as a sampling frame for MMP eliminates the need for sampling of facilities, as individuals will be sampled directly from NHSS.

Sampled states will have a minimum sample size of 400 persons after combination with separately funded cities, if applicable (**Attachment 18**). Some states will enroll more than 400, because the sample size in the project area is roughly proportional to the number of persons living with HIV in each state. A minimum sample size of 400 will allow the description of outcomes of interest, e.g., the proportion of participants with an undetectable viral load, with sufficient statistical precision.

These methods are expected to yield a representative sample of persons diagnosed with HIV in the nation and in each project area. More detail about each of the stages of sampling is provided below.

Primary Sampling Unit Selection Methods

The first stage of sampling, conducted in 2005 (and not to be repeated in the next three years) employed a random, stratified sample. Because the goal of MMP was to obtain a national probability sample of adults receiving HIV medical care in the US, all 50 states plus the District of Columbia (DC) and Puerto Rico (PR) were considered eligible to participate. Systematic sampling with probability proportional to size was used, with the measure of size being the total number of persons living with AIDS reported to the national HIV/AIDS Reporting System [HARS]), (OMB Control No. 0920-0573: Adult and Pediatric Confidential HIV/AIDS Case Reports for National HIV/AIDS Surveillance) at the end of 2002. Given available funding, 20 PSUs were selected at the first stage of sampling. In 2009, in coordination with statisticians from the RAND Corporation, the first stage of sampling was revised and three states were removed from the PSU sampling frame. This modification was approved by OMB. Twenty-three project areas (16 states, Puerto Rico, and 6 separately funded cities within sampled states) have been funded to conduct MMP since 2009. Restoration of the original sample of primary sampling units is proposed in this request, to include the three states defunded in the 2009 cycle, which would result in 26 project areas. We estimate that the current 23 project areas contain 73% of all persons with an HIV diagnosis in the United States. Expansion to the original 26 project areas would expand MMP’s coverage to 80% of HIV-diagnosed persons.
As discussed in Part A, resampling the primary sampling units was considered and rejected. At the inception of MMP, AIDS prevalence

in 2002 was the most comprehensive proportional measure of size of the population of interest available in all 52 jurisdictions. A comparison of AIDS prevalence in 2002 and HIV prevalence in 2010 showed the two distributions to be highly similar, although Maryland (dropped from the sampling frame in 2009 and proposed for re-inclusion in this request) constituted a larger proportion of cases. The value of preserving the existing project area infrastructure and of maintaining the capacity to track trends in locally representative estimates were judged to outweigh the potential the benefits to be gained, i.e., with regard to optimizing the sampling design, from resampling primary sampling units.

Respondent Sampling Methods

For the currently approved project, sampling involves selection of HIV care facilities in participating areas with probability proportional to the number of HIV patients; patients are then selected from among those seen in selected facilities during a four-month period (January-April) each year. The revised sampling method proposed in this request will involve the construction, by CDC staff, of respondent sampling frames for each of the 26 participating areas from the aggregated National HIV Surveillance System dataset, which combines data from 56 states and dependent areas.

The proposed changes to the sampling method for the project have been informed by formative research conducted by CDC, the purpose of which was to identify implementation challenges associated with sampling directly from NHSS as a potential replacement for MMP's current facility-based sampling, and to field-test solutions to these challenges (Formative Research and Tool Development for the Medical Monitoring Project: Testing Solutions for Challenges of Sampling, OMB Control No. 0920-0840, expiration 2/29/2016). The formative research indicated that sampling from NHSS (would allow access to more accurate information about residence at the time of sampling than would sampling from the local HIV surveillance data in each MMP project area. The national HIV surveillance data include reported residential location information from all 56 NHSS jurisdictions, which is obtained via ongoing reporting of HIV-related laboratory tests (CD4+ T-lymphocyte and viral load tests) mandated in 36 states and the District of Columbia. In contrast, residential information in the project area surveillance data is more limited.

Each project area's sampling frame will include adults diagnosed with HIV and reported to the project area and CDC NHSS as of the

sampling date. Persons whose death preceded the sampling date and persons not residing in the jurisdiction, according to the most recently recorded address in NHSS, will be excluded from each project area sampling frame. Random samples will be selected independently from each project area sampling frame.

Sample size

A combined total of 10,900 participants per year will be sampled from the project area sampling frames (**Attachment 18**). To determine a minimum sample size, the expected precision of estimates derived from the entire sample and from subpopulations were considered for different sample size options. A sample size of 400 persons per state or 10,900 persons overall would have both acceptable precision and feasibility.

In calculating the precision of estimates from project area samples of 400 persons and a total combined sample of 10,900, the impact of weighted data analysis on precision was taken into account. Weighted analysis is necessary because the use of systematic random sampling within project areas and adjustment for non-response bias cause unequal selection probabilities. Both unequal selection probabilities across project areas and correlation of observations within project areas produce variance estimates that are larger than they would be for a simple random sample of the same size. This variance inflation is called design effect. A design effect of 2 is used in the calculations because this level of design effect is commonly encountered in national surveys.

The following table shows the expected precision of an estimate from these data, e.g., the proportion of persons who identified insufficient financial resources as a barrier to receiving care. The confidence interval (CI) half-widths in the table are the maximum that would be expected for estimates based on sample sizes of 400 and 10,900 for project area and aggregated estimates, respectively.

The table shows the level of precision to be expected not only for estimates for the entire population (column 2), but also for subpopulations that comprise 50%, 33%, and 10% of the total population (column 3, 4, and 5 respectively).

N	CI half-width total	CI half-width subpopn = 50%	CI half-width subpopn = 33%	CI half-width subpopn = 10%

400	6.93%	9.81%	12.09%	22.06%
10,900	1.33%	1.89%	2.31%	4.20%

As stated above, the sampling frame will be restricted to persons with presumed current residence in the project area, according to NHSS records. During the formative research, 39% of persons sampled from NHSS could not be located or did not respond to project area attempts to contact them, which reduced the yield of analyzable data. One option to address this problem would have been to increase project area sample sizes. However, response rates will likely vary from area to area, and some areas will lack the resources to pursue a larger sample. To allow a larger sample where this is needed and feasible, a supplementary sample no larger than the original sample will be drawn, without replacement, at the same time as the original sample, using the same systemic random sampling scheme. The original sample will be supplemented as necessary, by no more than the number of persons who do not respond to contact attempts, and the public burden will not exceed the total presented in Exhibit A.12.A.

Expected Response Rate

Current facility-based MMP methods require medical facilities to participate in MMP as a prerequisite for patient participation. Facilities that refuse participation refuse on behalf of all of their patients, and thus affect overall response rates. The facility response rate for MMP was 83% in 2011. Because some facilities choose to recruit their own patients, even if facilities participate, patient response rates were sometimes reduced, depending on the effort spent on recruitment for MMP. In 2011, 53% of eligible persons sampled for MMP were interviewed. Because both facility and patient participation must be taken into account in a multi-stage sample design, the combined response rate for the MMP interview in 2011 was 43%.

Using NHSS as a sampling frame and recruiting patients directly, rather than through health care facilities, is expected to increase the response rate among HIV-diagnosed persons receiving care. This higher response rate from the HIV patient population is necessary to balance the lower response rate expected from HIV-diagnosed persons not receiving care, which will be included in MMP starting with the 2015 data collection cycle, pending approval of this request. Formative research for MMP indicated that a 44% response rate among HIV-diagnosed persons can be achieved when these patients are selected from NHSS and recruited directly. Based on the formative research, the overall response rate for the proposed MMP project is expected to be the same as

or better than the current overall response rate for MMP. Further, because MMP response rates have improved over time as the project has become more routinized, response rates for the proposed project are also expected to improve over time. Response rates for all epidemiologic studies have declined in recent decades (**Attachment 5 reference 21**). Although MMP's response rates have been lower than desired, the quality of estimates obtained from MMP is strengthened by unbiased sampling methods from well-defined sampling frames (**Attachment 5 reference 22**). The proposed method of drawing MMP annual samples from the NHSS database maintained by CDC (NHSS, OMB Control No. 0920-0573, exp. 2/29/2016), will ensure that MMP has better information about nonrespondents than most household and phone surveys, allowing adjustment of the data for nonresponse bias. Through the efforts of CDC's MMP staff and the project areas, MMP response rates have continued to improve each year. The maximum combined response rate obtained to date by an MMP project area is 75%; in this project area, the response rate improved from a baseline of 51%. This area's performance suggests that other areas may achieve a response rate at least as high as 75%, and that the response rate of this particular area may improve further. Therefore, the objective for future cycles of MMP is to interview 80% of 10,900 sampled persons.

2. Procedures for the Collection of Information

The proposed project will employ a new method for sampling participants directly from NHSS. In a departure from the procedures for the currently approved project, participants will be sampled from NHSS and recruited primarily by project area MMP staff, rather than sampled from health care facilities and recruited primarily through health care providers. However, if direct contact cannot be made, and a sampled person has a known health care provider, contact through the provider may be employed as a back-up mechanism. Otherwise, data collection procedures, described below, will be exactly the same as those currently approved for MMP.

All interviews will be conducted by trained project area staff. Participation in the project is voluntary. Respondents may refuse to participate at all or in part. Respondents may refuse to answer questions or discontinue participation at any time without penalty.

The National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), CDC, has determined that MMP is not research and that it is a routine disease surveillance activity,

with data being used for disease control program monitoring or policy purposes (non-research status approved [date] (**Attachment 15**). Because NCHHSTP has determined that MMP is not research, federal institutional review board (IRB) review and approval is not required. All applicable Federal and state privacy laws must be followed.

Project areas should follow state and/or local procedures to determine whether the proposed data collection is subject to state and/or local human subject regulations. The need for state/local IRB review, and the IRB approval and renewal dates, if applicable, must be kept on file in every project area. Copies of this documentation should be provided to CDC on an annual basis.

All federal, state, and local MMP staff must adhere to the ethical principles and standards by respecting and protecting the privacy, confidentiality, and autonomy of participants to the maximum extent possible.

Sampled persons will be offered enrollment primarily through contact with MMP project area staff. However, some providers may prefer to notify the patient before MMP staff initiate contact. Otherwise, potential participants will be initially contacted using letters or telephone, text, and E-mail-contact scripts developed using CDC templates (**Attachments 4a, 4b, 4c, and 4d**).

Contact information for sampled persons being sought for recruitment will be obtained from project area NHSS records. Before making phone contact, project areas may send information about the project by mail. To protect the confidentiality of persons recruited, such mailings will refer in general to a health survey rather than specifically mentioning HIV. The nature of the survey will be revealed through the informed consent process (**Attachment 17**) when contact is established with the sampled person. Local project staff will use patient contact information to initiate mail and/or phone contact with eligible persons to describe the project and offer enrollment. Persons for whom contact by mail or telephone fails may be approached at their home or their current HIV medical care facility. Model patient recruitment materials are included as **Attachments 4a, 4b, 4c, and 4d**). Project areas may modify the model patient recruitment materials to meet their specific needs, but must include the required elements of informed consent. Unless the elements in CDC model recruitment materials are modified, additional OMB approval will not be sought for modifications made by individual project areas. Based on experiences with MMP and

during the pilot test of new sampling methods, any modifications made by the individual project areas will likely be minor.

All patient interviews (**Attachments 8a and 8b**) will be conducted by trained project staff in a private location, either as part of a routine visit to a medical facility, in a hospital or clinic or at the respondent's home, or in another mutually agreed-upon location. Interviews may also be conducted over the telephone or by videoconference. The expected duration of the interview is approximately 45 minutes.

The interview instrument (**Attachments 8a and 8b**) will be provided by CDC in a Computer Assisted Personal Interview format to allow data to be collected electronically. The interview will be administered face-to-face, through the telephone, or by videoconference using electronic tablet devices or computers. The interview instrument was developed using Questionnaire Development System (QDS) software (NOVA Research Company, Bethesda, Maryland).

At the end of the interview, participants will receive HIV prevention materials, referrals to local prevention and care services, and prevention information from the project staff, as requested.

To avoid data loss, and to ensure data security, at the end of each field visit the interviewers will be responsible for downloading and saving all data records into the health department secure MMP database. Interviewers will be instructed to delete all patient records from the data collection computer's hard drive after downloading the records and before leaving for the next interview.

Local project staff trained in the abstraction of clinical variables from medical charts will abstract the medical records of persons who have received HIV medical care (**Attachment 9** for abstraction data elements) Staff will use standardized web-based software accessed from a secure laptop computer for medical record abstraction. The information to be collected is primarily related to the diagnosis of opportunistic infections, provision of preventive therapies, prescription of antiretroviral medications, adverse events due to medications, and health services utilization.

Minimal data on all sampled persons from the National HIV Surveillance System (NHSS, OMB Control No. 0920-0573, exp. 2/29/2016) will be extracted using a computer program run by

project staff in each project area or at CDC (data to be extracted are listed in **Attachment 10**). These data on respondents and non-respondents will be compared to assess non-response bias. Additionally, because CD4 t-lymphocyte counts and viral load test results used to stage HIV disease and as proxies for receipt of care are reported to states through NHSS prospectively, the link to case surveillance data through the minimum dataset can also be used to monitor MMP respondents' receipt of care services, progression of HIV disease, and potential for ongoing transmission of HIV over time.

The personally identifying information used to select participants (i.e., date of birth) will not be collected on the interview and medical record abstraction forms; instead, each person will be assigned a unique coded identifier.

The tablet and laptop computers used for data collection will be password protected and the data on them will be encrypted using standard, 128-bit encryption software. No personal identifiers will be collected or included. All data will be downloaded onto a secure computer at the health department and deleted from the field computers upon return to the health department.

Quality Control

For quality assurance purposes, a 5% subset of interviews will be observed by the project coordinator to determine accuracy and completeness. Additionally, interviewers will discuss each other's interviews to facilitate consistency in administration techniques across interviewers.

CDC will regularly train the interviewers and convene lessons learned meetings to understand the problems that can occur with the software and hardware used for conducting the interviews. Training topics will include how to use the CDC-provided software and hardware, conduct the interviews, archive the collected data, and transfer the data. CDC will also provide written, detailed instructions on conducting interviews to participating health departments. Computer applications will have automated edit checks built in for quality control.

CDC is responsible for overseeing a contract with the Cerner Corporation for the development and distribution of the medical record abstraction software to the participating health departments. CDC provides the medical record abstraction data elements and rules for entry, and Cerner develops the software. CDC will conduct abstractor training, and also provide a manual

with detailed instructions for data abstraction to participating health departments.

CDC will ensure regular training of abstractors and convene lessons learned meetings to understand the problems that can occur with the software and hardware that are used for conducting the abstraction. The software application for medical record abstraction will have built in edit checks for quality control.

Electronic abstraction records (**Attachment 9**) will be visually scanned to check for completeness. A 5% subset of medical records will be re-abstracted by a second, independent reviewer and compared to the original abstraction data to determine completeness and discrepancies. The medical records selected for re-abstraction should be from a variety of facilities, abstractors, and time periods.

CDC regularly conducts site visits to each project area. The purpose of the site visit is to monitor adherence to the project protocol, observe interviews and medical record abstractions, and obtain feedback on study procedures. Additional site visits specific to the proposed data collection will be conducted as needed.

Because MMP is primarily a descriptive project, power calculations, which are used in sample size determinations for studies that test specific hypotheses, were not performed. Instead, the level of precision (i.e., the estimated 95% confidence interval half-width) was the criterion for determining sample sizes in individual project areas. Ninety-five percent (95%) confidence interval half-widths were calculated for a variety of sample sizes and design effects.

95% Confidence Interval half-widths for total population estimates for various sample sizes and design effects

N	CI half-width design effect = 1	CI half-width Design effect = 2	CI half-width design effect = 3	CI half-width design effect = 4	CI half-width design effect = 5
100	9.80%	13.86%	16.97%	19.60%	21.91%
200	6.93%	9.80%	12.00%	13.86%	15.50%
300	5.66%	8.00%	9.80%	11.32%	12.65%
400	4.90%	6.93%	8.49%	9.80%	10.96%
500	4.38%	6.20%	7.59%	8.77%	9.80%
600	4.00%	5.66%	6.93%	8.00%	8.95%
700	3.70%	5.24%	6.42%	7.41%	8.28%
800	3.46%	4.90%	6.00%	6.93%	7.75%

900	3.27%	4.62%	5.66%	6.53%	7.30%
1000	3.10%	4.38%	5.37%	6.20%	6.93%
1200	2.83%	4.00%	4.90%	5.66%	6.33%

Four hundred was determined to be the minimum sample size for a state to obtain total population estimates with an acceptable level of precision (assuming a design effect, or increase in variance of estimates due to using a multistage sampling design, of 2). This sample size was assigned to most of the states with the lowest AIDS prevalence. Sample sizes for states with moderate to high AIDS prevalence were determined based on the distribution of cases among the 20 sampled states and the 6 separately funded cities in those states, to achieve a national sample size of approximately 10,000. These project area sample sizes will allow national estimates at an acceptable level of precision for subpopulations as small as 10% of the total population of interest (as shown in the table in the section “Sample size” above).

3. Methods to Maximize Response Rates and Deal with Non response

The proposed project will employ the same methods to maximize response rates and to address nonresponse as was previously approved for the project. Because the MMP interview takes approximately 45 minutes to administer, contains sensitive questions, and a significant portion of the population of HIV-infected adults in care are members of racial and ethnic minorities, participants will be offered tokens of appreciation for their participation to increase response rates. Participants will receive approximately $25 as a token of appreciation for participation in the interview. If local regulations prohibit offering cash, personal gifts, gift certificates, or bus or subway tokens of equivalent value may be offered.

Research indicates that providing tokens of appreciation to respondents helps raise response rates for long, sensitive, in-person surveys (**Attachment 5 reference 15**). In addition, persons at risk for HIV infection have frequently been the focus of health-related data collections, in which tokens of appreciation are the norm (**Attachment 5 references 16 and 17**). Research has shown that financial tokens of appreciation are effective at increasing response rates among female residents in minority zip codes (**Attachment 5 reference 18**). A meta-analysis of 95 studies published between January 1999 and April 2005 describing methods of increasing minority enrollment and retention in research studies found that tokens of appreciation enhanced retention among this group (**Attachment 5 reference 19**). Data from MMP’s

2007 cycle indicate that 65% of respondents reported a race or ethnicity other than non-Hispanic white. Providing tokens of appreciation to MMP respondents is critical to achieve acceptable response rates.

Tokens of appreciation are also provided to persons who participate in CDC's HIV-related data collections among other populations, such as the National HIV Behavioral Surveillance System (NHBS) (OMB 0920-0770, exp. 3/31/2017) and the Feasibility of HIV Behavioral Surveillance for Young MSM (OMB No. 0920-0840, exp. 2/29/2016). Tokens of appreciation were also used in the Supplement to HIV/AIDS Surveillance (SHAS) project (OMB 0920-0262, exp. 06/30/2004) (described in A.1.), for persons who agreed to participate in the interview. Participants were offered $25 as a token of appreciation.

A national provider advisory board, made up of providers of HIV care, gives input on the project to CDC, specifically regarding how data are collected and how to increase participation. Members of a national community advisory board (CAB), with a representative from each project area, serve as sources of information for participants about the relevance of the project for HIV-infected persons in the local area. The national CAB shares information about the project and provides feedback to CDC about participant recruitment, data collection, and how the project is perceived by the community. Input from these two groups helps to maximize participant response.

For the proposed project, project staff will continue to employ face-to-face interviews, will continue to offer telephone interviewing and will add videoconferencing as an optional mode of questionnaire administration, to increase ease of participation, and thereby increase response rates. Use of mixed modes for survey administration has been found to result in improved response rates (**Attachment 5 reference 23**). In addition, conference calls between CDC and the project areas are held on a monthly basis to review response rates and provide technical assistance to improve participant response rates. Project staff will also be encouraged to offer evening and weekend interview hours to maximize the convenience of participation.

As described in Section 1 "Expected response rate" above, the response rate for the proposed project is expected to be the same as or better than the most recent MMP response rate for diagnosed persons receiving HIV care. Nevertheless, the goal of MMP is to interview 80% of eligible persons sampled.

Assessing Non-Response Bias

The same procedures for assessing non-response bias that are currently used for MMP will be used for the proposed project. Minimal data (**Attachment 10**) on all sampled persons from NHSS will be extracted using a computer program run by project staff in each project area or at CDC. Minimal data on respondents and non-respondents will be compared to identify predictors of non-response. Predictors with statistically significant effects will be used in the development of weight adjustment classes. Along with selection probabilities based on the sampling design, non-response data will factor into calculation of analytic weights so as to increase the generalizability of results to the universe of HIV-diagnosed adults.

Weights will be developed based on the assessment of non-response bias for each cycle. In the analysis of non-response that was completed for the 2011 MMP data collection cycle, the most significant predictors of patient response were facility size, facility ownership (e.g., public, non-profit, private), race/ethnicity, years since diagnosis and age group. The ability to assess and adjust for nonresponse is a strength of probability surveys that may compensate for lower than desired response rates (**Attachment 5 reference 22**).

Recruitment will be monitored through on-going data reports generated weekly and monthly from the data submitted to CDC. The project area staff and CDC will use the data in these reports to identify problems with recruitment. When a problem with response or recruitment arises during data collection, field staff will be instructed to consult with local stakeholders and facility staff to identify solutions to the problem.

4. Tests of Procedures or Methods to be Undertaken

CDC investigators conducted formative research to identify implementation challenges associated with sampling directly from NHSS as a potential replacement for MMP's current facility-based sampling, and to field test solutions to these challenges (Formative Research and Tool Development for the Medical Monitoring Project: Testing Solutions for Challenges of Sampling, OMB Control No. 0920-0840, expiration 2/29/2016). This work demonstrated the feasibility of sampling from NHSS and has led to the development of protocols to address the potential methodological and operational problems associated with implementing the new sampling methodology. For example, procedures for interviewing persons who have moved away from the jurisdiction from which they were sampled have been developed,

and methods of contacting sampled persons have been refined to yield a higher contact rate. Results from formative research also indicated that sampling from the NHSS database yielded more complete address information than sampling from the local jurisdiction's HIV surveillance database.

Beginning in early 2013, CDC began an evaluation of the MMP questionnaire that included consultation with external stakeholders, including grantees, subject matter experts, and colleagues from other federal agencies. The evaluation focused on examination of the relevance, coherence, and scientific contribution of interview questions. The result is a modified interview form (**Attachments 8a and 8b**).

With the inclusion in MMP of HIV-diagnosed persons not receiving HIV care, the following changes to the interview questionnaire were necessary: the expansion of the HIV testing, linkage to care, and re-engagement in care sections, as well as the addition of questions that elicit detailed information on reasons for not receiving care. These questions were tested through the formative research mentioned earlier, and were refined based on input received through consultation with stakeholders and experience with the formative research. Other sections of the interview instrument were modified to improve the efficiency of administration and the quality of data collected, for example, by changing open-ended questions to close-ended questions. All new sections of the questionnaire were tested for clarity through role-playing the interview and presentation to MMP's Community Advisory Board. CDC staff conducted test interviews of the revised questionnaire using scenarios involving hypothetical respondents with different characteristics. The average time to complete the interview is estimated as 45 minutes, the same amount of time required to complete the previously approved questionnaire. The changes to the questionnaire are described in **Attachment 3b**.

OMB will be informed of any further changes to data collection procedures or instruments as quickly as possible.

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

Consultants on Statistical Aspects

The following individuals consulted on statistical aspects:

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Individuals Collecting and/or Analyzing Data

CDC is not directly engaged with human subjects during data collection. However, CDC Project Staff below will train health department staff in data collection methods, monitor the progress of recruitment by health department staff, and analyze the data.

CDC Project Staff

All CDC project staff can be reached at the following address and phone number:
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