

Medical Monitoring Project

CDC-RFA-PS15-1503

National Center for HIV/AIDS, Viral Hepatitis,
Sexually Transmitted Diseases, and
Tuberculosis Prevention

Version 2.0

Issued 08/30/2013



Amendment II, dated 10-31-2014, is being done to add the following information to this FOA:

- 1) Additional FOA Questions and Answers from e-mails and the October informational conference call with applicants (Attached at the end of the FOA)***

And to remove:

- 2) A paragraph from FOA Questions and Answers on page 36: "The deadline for questions about this FOA will be Wednesday, December 3, 2014. This list of questions and answers will be updated every four weeks, as needed (roughly October 27 and December 8)."***

Amendment I, dated 09-26-2014, is being done to add the following information to this FOA:

- 1) Informational conference call on October 22, 2014 from 2-3pm U.S. Eastern Standard Time, Toll-Free: 877-785-0798 Participant Passcode: 1978977***
- 2) Letters of Support, Memorandum of Agreement, Memorandum of Understanding, and Bona Fide Agent status documentation to the list of acceptable attachments***
- 3) FOA Questions and Answers from e-mails and the informational conference call with applicants (Attached at the end of the FOA)***

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Part I. Overview Information

Applicants must go to the synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notifications Emails" link to ensure they receive notifications of any changes to CDC-RFA-PS15-1503. Applicants also must provide an e-mail address to www.grants.gov to receive notifications of changes.

A. Federal Agency Name:

Centers for Disease Control and Prevention (CDC)

B. Funding Opportunity Title:

Medical Monitoring Project

C. Announcement Type: New—Type 1

This announcement is only for non-research domestic activities supported by CDC. If research is proposed, the application will not be considered. Research for this purpose is defined at <http://www.cdc.gov/od/science/integrity/docs/cdc-policy-distinguishing-public-health-research-nonresearch.pdf>.

D. Agency Funding Opportunity Number:

CDC-RFA-PS15-1503

E. Catalog of Federal Domestic Assistance (CFDA) Number:

93.944, Human Immunodeficiency Virus (HIV)/Acquired Immunodeficiency Syndrome (AIDS) Surveillance

F. Dates:

1. **Letter of Intent (LOI) Deadline:** N/A

2. **Application Deadline:** *January 8, 2015*

3. **Informational conference call for potential applicants:** September 17, 2014 from 2-3pm U.S. Eastern Standard Time, Toll-Free: **877-785-0798** Participant Passcode: **1978977**; and October 22, 2014 from 2-3pm U.S. Eastern Standard Time, Toll-Free: **877-785-0798** Participant Passcode: **1978977**

G. Executive Summary:

1. **Summary Paragraph:** HIV causes a chronic infection that leads to a progressive disease. Without treatment, most HIV-infected persons develop acquired immunodeficiency syndrome (AIDS) within 10 years of infection, which results in substantial morbidity and premature death. Prevention, care, and treatment efforts for HIV-diagnosed adults in the United States need to be informed by locally and nationally representative data. The Medical Monitoring Project (MMP) is an ongoing, locally and nationally representative surveillance system that collects data on a probability sample of HIV-diagnosed adults in the United States. MMP monitors sociodemographic variables, behavioral and clinical characteristics, supportive service needs, use of healthcare and prevention services, and adherence to clinical care guidelines among HIV-diagnosed persons. This FOA will fund awardees for activities related to preparing for and conducting data collection, data management and dissemination, quality assurance and evaluation, and collaboration. The goal of these activities is to produce high-quality locally and nationally representative data on the behavioral and clinical characteristics of HIV-diagnosed adults, develop a strong data dissemination plan targeted to potential local and national users, and enhance collaboration among federal and local partners responsible for HIV

surveillance, prevention and treatment. The short- and mid-term goal is for MMP data to inform local and national HIV prevention and treatment efforts, including monitoring the Division of HIV/AIDS prevention (DHAP) strategic plan as well as progress towards the National HIV/AIDS Strategy goals, and for key local and national users to employ the data to inform budgeting, planning, and service delivery decisions. In the long-term, evidence-based local and national decisions to improve HIV prevention and treatment programs and policies are expected to lead to a reduction in new HIV infections, HIV-associated morbidity and mortality, and disparities in health outcomes.
a. Eligible Applicants (select one): Limited
b. FOA Type (select one): Cooperative Agreement
c. Approximate Number of Awards: 26
d. Total Project Period Funding: \$96,000,000
e. Average One Year Award Amount: \$19,200,000
f. Number of Years of Award: 5
g. Approximate Date When Awards will be Announced: June 1, 2015
h. Cost Sharing and /or Matching Requirements: N/A

Part II. Full Text

A. Funding Opportunity Description
1. Background
a. Statutory Authorities: This program is authorized under Sections 317(k) (2) and 318(c) of the Public Health Service Act [42 U.S.C. Sections 247b (k) (2) and 247c(c)], as amended.
b. Healthy People 2020: This program specifically addresses or contributes to the following Healthy People 2020 goals: • HIV-2: (Measureable) Reduce new (incident) HIV infections among adolescents and adults. • HIV-3: (Measureable) Reduce the rate of HIV transmission among adolescents and adults. • HIV-9: (Measureable) Reduce the proportion of persons with a diagnosis of Stage 3 HIV (AIDS) within 3 months of diagnosis of HIV infection. • HIV-18: (Measureable) Reduce the proportion of men who have sex with men (MSM) who reported unprotected anal intercourse with a partner of discordant or unknown status during their last sexual encounter. • HIV-19: (Developmental) Increase the proportion of persons who are linked to HIV medical care (had a routine HIV medical visit) within 3 months of HIV diagnosis. • HIV-20: (Developmental) Increase proportion of persons with an HIV diagnosis who had at least one HIV medical care visit in each 6 month period of the 24 month measurement period, with a minimum of 60 days between medical visits. • HIV-21: (Developmental) Increase the proportion of persons with an HIV diagnosis in medical care prescribed ART for the treatment of HIV infection in the 12-month measurement period. • HIV-22: (Developmental) Increase the proportion of persons with an HIV diagnosis in medical care with a viral load <200 copies/mL during the last test in the 12-month measurement period. • HIV-23: (Developmental) Reduce the proportion of persons with an HIV diagnosis receiving

HIV services who were homeless or unstably housed in the 12-month measurement period.

For additional details on the Healthy People 2020 goals listed above, visit <http://www.healthypeople.gov/2020/topicsobjectives2020/objectiveslist.aspx?topicId=22>.

c. Other National Public Health Priorities and Strategies:

This program specifically addresses or contributes to the following National HIV/AIDS Strategy (NHAS) goals:

- Reducing new HIV infections;
- Increasing access to care and improving health outcomes for people living with HIV;
- Reducing HIV-related disparities and health inequities.

d. Relevant Work:

This new FOA for the Medical Monitoring Project (MMP) builds upon the work of the two previous MMP FOAs (PS04-155 and PS09-937) and the Case-Surveillance Based Sampling (CSBS) supplement funded under PS09-937. MMP is a surveillance system designed to produce locally and nationally representative estimates of sociodemographic variables, behavioral and clinical characteristics, supportive service needs, use of healthcare and prevention services, and adherence to clinical care guidelines among HIV-diagnosed persons. Additional information can be found at: <http://www.cdc.gov/hiv/statistics/systems/mmp>. In the previous FOAs (PS04-155 and PS09-937), MMP used a facility-based sampling strategy to generate representative data on adults living with HIV who are receiving care in the United States. However, since only an estimated 45% of HIV-diagnosed persons are retained in medical care, the Institute of Medicine has recommended that the MMP reference population be expanded to all HIV-diagnosed adults, including those receiving and not receiving medical care.

At the inception of MMP in 2005, facility-based sampling was used because a comprehensive list of all HIV-diagnosed persons in all states was unavailable. However, as of April 2008, name-based confidential data on persons diagnosed and living with HIV infection are available in the National HIV Surveillance System (NHSS), and thus CSBS for MMP is feasible, as is being demonstrated through the CSBS supplement funded under PS09-937. Using the NHSS as a sampling frame for MMP will allow MMP to monitor clinical and behavioral characteristics of all diagnosed HIV-infected persons, regardless of whether or not they are receiving medical care. This new sampling methodology will be implemented as part of this FOA.

2. CDC Project Description

a. Approach:

The logic model depicts the main activities and resulting outputs that constitute the strategies the awardee is to undertake, and the outcomes expected in the short and mid-term as a result of these efforts, and the long-term public health achievements to which these short- and mid-term outcomes will contribute.

Strategies		Outcomes (**outcomes to be accomplished in project period)	
Activities	Outputs	Short- and Mid-Term	Long(er)-Term
<u>Preparation:</u> • Obtain regulatory approvals • Develop local standard operating procedures • Hire and train professional staff to recruit participants and collect data • Facilitate cross jurisdictional data collection • Develop and maintain capacity for telephone interviewing • Provide input on operational documents and data collection instruments <u>Sampling and Data Collection:</u> • Conduct sampling • Locate, contact, and recruit sampled persons • Manage and report contact tracking data • Interview sampled persons • Conduct medical record abstraction on sampled persons • Facilitate access to HIV care linkage and retention services for participants • Extract NHSS data • Collect HIV care facility data • Support and conduct MMP provider survey activities <u>Data Management and Dissemination:</u> • Manage and transmit data • Analyze and disseminate data <u>Quality Assurance and Evaluation:</u> • Maintain HIV data security and confidentiality • Attend trainings and other meetings • Conduct quality assurance activities • Conduct evaluation activities <u>Collaboration:</u> • Maintain advisory boards • Strengthen NHSS • Strengthen local collaborations	• High quality locally and nationally representative data on the behavioral and clinical characteristics of HIV-diagnosed persons • Strong data dissemination plan targeted to potential local and national users • Enhanced collaboration among federal and local partners responsible for HIV surveillance, prevention, and treatment	• Local and national HIV prevention and treatment efforts are informed by MMP data** • Key local and national users employ the data to inform budgeting, planning, and service delivery decisions**	• Evidence-based local and national decisions to improve HIV prevention and treatment programs and policies, and thus lead to a reduction in new HIV infections, HIV-associated morbidity, and disparities in health outcomes.

i. Problem Statement:
HIV causes a chronic infection that leads to a progressive disease. Without treatment, most HIV-infected persons develop acquired immunodeficiency syndrome (AIDS) within 10 years of infection, which results in substantial morbidity and premature death. Prevention, care, and treatment efforts for HIV-diagnosed adults in the United States need to be informed by locally and nationally representative data. If data are not available, decision making for HIV prevention, care, and treatment will not be evidence-based.
ii. Purpose:
MMP is an ongoing, locally and nationally representative surveillance system that collects data on a probability sample of HIV-diagnosed adults in the United States. MMP monitors sociodemographic variables, behavioral and clinical characteristics, supportive service needs, use of healthcare and prevention services, and adherence to clinical care guidelines among HIV-diagnosed adults. The data from MMP and associated projects are used to help inform and guide local and national HIV prevention, care, and treatment efforts.
iii. Outcomes:
As depicted in the logic model (outcomes with **) the awardee will be expected to show progress on the following: - Local and national HIV prevention and treatment efforts are informed by MMP data: MMP data will be disseminated and made publically available in a timely manner. The information could be conveyed in the form of presentations, fact sheets, epidemiologic profiles, surveillance reports, peer-reviewed manuscripts or other formats as appropriate. Efforts should be made to customize data dissemination activities to inform key decisions regarding budgeting, planning, and service delivery. - Key local and national users employ the data to inform budgeting, planning, and service delivery decisions.
iv. Funding Strategy: N/A
v. Strategies and Activities:
As depicted in the logic model, there are 5 strategies awardees are expected to undertake. The activities encompassed by these strategies will result in three powerful outputs: - High quality locally and nationally representative data on the behavioral and clinical characteristics of HIV-diagnosed persons - Strong data dissemination plan targeted to potential local and national users - Enhanced collaboration among federal and local partners responsible for HIV surveillance, prevention, and treatment These outputs will be the result of the following component activities in each strategy. Note that all activities need to be implemented according to CDC-approved protocols and procedures. Preparation: <u>Obtain regulatory approvals:</u> Obtain regulatory approvals to conduct MMP as required locally, including, but not limited to Institutional Review Board approval, approval to

conduct MMP under surveillance authority, approvals to access medical record data, and approvals to conduct other MMP activities.

- Develop local standard operating procedures: Develop local standard operating procedures for contacting and recruiting sampled persons, including management of adverse events, strategies to address urgent needs identified during contact with participants such as linkage to and re-engagement in HIV care, methods to conduct cross jurisdictional data collection, safeguards to preserve patient confidentiality, and tools to assess quality of local HIV case surveillance and lab reporting data.
- Hire and train professional staff to recruit participants and collect data: Hire and train required staff needed to conduct all activities.
- Facilitate cross jurisdictional data collection: Develop and maintain collaborations with other HIV surveillance jurisdictions to the extent allowable by local laws and regulations to allow for cross-jurisdictional recruitment, interview, and medical record abstraction on sampled persons who have migrated across jurisdictional borders. Facilitate development of a policy that allows data collection on persons sampled in other project areas who have moved into the awardee's project area.
- Develop and maintain capacity for telephone interviewing: Develop procedures and train staff to conduct telephone interviews.
- Provide input on operational documents and data collection instruments: Provide input on all operational documents and data collection instruments, including, but not limited to protocol, operations manual, interview instrument, medical record abstraction instrument, interview guide, medical record abstraction guide, data management manuals and other documentation of standard operating procedures.

Sampling and Data Collection:

- Conduct sampling: Draw or receive a sample of eligible HIV-diagnosed persons from NHSS.
- Locate, contact and recruit sampled persons: Locate, contact, and recruit sampled persons for participation in MMP.
- Manage and report contact tracking data: Utilize a contact tracking database to integrate location information for all sampled persons. Report de-identified summary statistics about recruitment progress from this database to CDC via secure data transfer mechanism.
- Interview sampled persons: Conduct face-to-face or telephone interviews on all sampled persons who agree to participate in MMP. Interviews will be conducted using electronic data collection software with capacity for complex skip patterns and logic checks.
- Conduct medical record abstraction on sampled persons: Conduct detailed medical record abstractions on all sampled persons who agree to participate in MMP. Medical record abstractions will be conducted using an electronic data collection system with capacity for complex skip patterns and logic checks. Continue to maintain relationships with HIV medical care providers to facilitate access to medical records for abstraction.
- Facilitate access to HIV care linkage and retention services for participants: Ensure that all interviewed persons identified as not currently receiving HIV care are assessed for HIV care service needs and are linked or re-engaged in HIV medical care..
- Extract NHSS data: Extract NHSS data using CDC-supplied programs and submit to CDC via

secure data transfer as needed for purposes such as creating the minimum dataset (MDS), weighting, and quality assurance.

- Collect HIV care facility data: Maintain HIV care facility sampling frame and collect data on all facilities attended by sampled persons using an electronic data collection system.
- Support and conduct MMP provider survey activities: Support and conduct MMP provider survey activities, including creating a provider sampling frame, collecting data on providers using a survey instrument, contacting non-responding providers via mail, telephone, email, or other means as appropriate to improve overall participation, managing data as needed, conducting data analysis, and disseminating data to key local and national users.

Data Management and Dissemination:

- Manage and transmit data: Manage all data locally and transmit to CDC according to CDC-approved protocols and timelines, including but not limited to interview, medical record abstraction, MDS, facility frame, facility attributes, and provider survey data. Conduct data cleaning activities according to CDC timelines including reconciliation, reviewing and responding to error reports, and other activities as needed to maintain data quality.
- Analyze and disseminate data: Conduct local and national data dissemination in the form of presentations, fact sheets, epidemiologic profiles, surveillance reports, peer-reviewed manuscripts or other formats as appropriate. Efforts should be made to customize data dissemination activities to inform key decisions regarding budgeting, planning, and service delivery. Develop an annual data dissemination plan and report on data dissemination activities accomplished. Produce at least one surveillance summary report per data collection cycle, which should include prevalence estimates of sociodemographic, behavioral, and clinical factors.

Quality Assurance and Evaluation:

- Maintain HIV data security and confidentiality: Adhere to all local and national guidelines to maintaining HIV data security and confidentiality, including but not limited to the Centers for Disease Control and Prevention's Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs: Standards to Facilitate Sharing and Use of Surveillance Data for Public Health Action available at <http://www.cdc.gov/nchhstp/programintegration/docs/PCSIDataSecurityGuidelines.pdf>.
- Attend trainings and other meetings: Attend all required trainings, meetings, site visits, webinars and conference calls, including but not limited to the MMP annual meeting as well as the following trainings: operations, interview, medical record abstraction, data management, and data analysis.
- Conduct quality assurance activities: Conduct quality assurance activities to maintain data integrity including, but not limited to observation of 5% of all interviews conducted, re-abstraction of 5% of all medical record abstractions conducted, and adherence to all data management procedures.
- Conduct evaluation activities: Support and conduct evaluation activities as needed including, but not limited to enhanced data collection on deaths among HIV-diagnosed persons, qualitative and mixed methods data collection on HIV-diagnosed persons, pilot

activities of new data collection or sampling methods (e.g. web-based data collection), and process and other quality surveys.

Collaboration:

- **Maintain advisory boards:** Maintain a Community Advisory Board representative and a Provider Advisory Board representative to support and inform MMP. Consult with advisory board members on data collection, data dissemination, and other activities as needed.
- **Strengthen NHSS:** Collaborate with local case surveillance staff to update NHSS with data obtained through MMP, including but not limited to data on residency, laboratory test results, and transmission risk. Support improvement in HIV-related laboratory reporting, including expanding the authority to collect all values of CD4+ T-lymphocyte tests, HIV viral load measurements, and other HIV-related laboratory tests (e.g., HIV nucleotide sequence data) as well as the complete reporting of all values to the jurisdiction; data should be uploaded into surveillance software (e.g. eHARS) and submitted to CDC via CDC-approved protocols.
- **Strengthen local collaborations:** Strengthen local collaborations with HIV case surveillance staff, CDC-funded health department program staff, and other HIV prevention and treatment program staff, as appropriate. Collaboration between MMP staff and other groups could be used to strengthen data collection systems, support data sharing and integration, improve linkage and retention programs, or other areas as appropriate.

1. Collaborations

a. With CDC funded programs:

Maintain local collaborations with HIV case surveillance staff, CDC-funded health department program staff, and other CDC-funded surveillance or prevention program staff, as appropriate.

b. With organizations external to CDC:

Maintain local collaborations with non-CDC-funded HIV prevention and treatment program staff, including Health Resources and Services Administration (HRSA)- or Substance Abuse and Mental Health Services Administration (SAMHSA)-funded HIV prevention programs, as appropriate.

2. Target Populations:

All living adults diagnosed with HIV who reside in the United States

Inclusion:

All adults diagnosed with HIV and living in the United States as of the sampling reference date who have been reported to CDC and meet the CDC case definition for HIV disease

b. Evaluation and Performance Measurement:

i. CDC Evaluation and Performance Measurement Strategy:

CDC will work with awardees to develop a feasible scheme for measurement and evaluation that ensures successful monitoring of the implementation of the strategies and activities (process evaluation and measures) and assesses progress in achieving the project period outcomes and/or understanding of the barriers to such progress (outcome evaluation and measures).

Awardees must meet the following benchmarks yearly in order to meet the overall goals and

outcomes for MMP:

Preparation:

- Obtain regulatory approvals: All local approvals obtained by June 15 of each data collection year.
- Develop local standard operating procedures: Develop all standard operating procedures by June 15 of each data collection year.
- Hire and train professional staff to recruit participants and collect data: Hire and train required staff needed to conduct all activities by June 15 of each data collection year.
- Facilitate cross jurisdictional data collection: By end of data collection cycle, request permission from the jurisdiction of residence for recruitment, interview, and medical record abstraction on all sampled persons identified as migrating out of the sampling jurisdiction. Facilitate development of a policy that allows data collection on persons sampled in other project areas who have moved into the awardee's project area.
- Develop and maintain capacity for telephone interviewing: Develop capacity for telephone interviewing by June 15 of each data collection year.
- Provide input on operational documents and data collection instruments: Provide input on all operational documents and data collection instruments, including, but not limited to protocol, operations manual, interview instrument, medical record abstraction instrument, interview guide, medical record abstraction guide, data management manuals and other documentation of standard operating procedures as required.

Sampling and Data Collection:

- Conduct sampling: Draw or receive a sample of eligible persons by June 1 of each data collection year.
- Locate, contact, and recruit sampled persons: Contact attempts made on 95% of sampled persons by October 1st of each data collection cycle year.
- Manage and report contact tracking data: Report up-to-date contact attempt data to CDC project officer on a biweekly basis. Transmit de-identified recruitment summary statistics to CDC or its designee twice during the data collection year.
- Interview sampled persons: First interview conducted by July 1 of each data collection cycle year. Sample sizes per project area will be set annually; the expected number of sampled person per project area for the 2015 data collection cycle is in Table 1.
- Conduct medical record abstraction on sampled persons: First medical record abstraction conducted by September 1 of each data collection cycle year. Sample sizes per project area will be set annually; the expected number of sampled persons per project area for the 2015 data collection cycle is in Table 1.
- Facilitate access to HIV care linkage and retention services for participants: Plan for facilitating linkage and re-engagement in HIV care submitted and approved by CDC by the start of data collection.
- Extract NHSS data: Data extract submitted by end of each data collection cycle year.
- Collect HIV care facility data: Data submitted by end of each data collection cycle year.
- Support and conduct MMP provider survey activities: Support and conduct all MMP

provider survey activities as required.

Data Management and Dissemination:

- Manage and transmit data: Adhere to all data management procedures and timelines per protocols provided by CDC. Submit data to CDC via secure transfer mechanism.
- Analyze and disseminate data: Submit a data dissemination plan at start of data collection year and a report on data dissemination activities accomplished at end of data collection year. Produce at least one surveillance summary report per data collection cycle.

Quality Assurance and Evaluation:

- Maintain HIV data security and confidentiality: Adhere to all data security and confidentiality guidelines, and document compliance annually.
- Attend trainings and other meetings: Attend all required trainings, meetings, site visits, webinars, and conference calls.
- Conduct quality assurance activities: Conduct all required data quality assurance activities, including supervised interview on 5% of interviewed persons and re-abstraction on 5% of medical record abstractions by end of data collection year.
- Conduct evaluation activities: Conduct all evaluation activities as required.

Collaboration:

- Maintain advisory board: Maintain a Community Advisory Board representative and a Provider Advisory Board representative.
- Strengthen NHSS: Input all residency, laboratory test result, transmission risk, and other data as required on sampled persons obtained through MMP into local case surveillance systems by 2 months after the end of data collection. Support improvement in HIV-related laboratory reporting, including expanding the authority to collect all values of CD4+ T-lymphocyte tests, HIV viral load measurements, and other HIV-related laboratory tests (e.g., HIV nucleotide sequence data) as well as the complete reporting of all values to the jurisdiction; data should be uploaded into surveillance software (e.g. eHARS) and submitted to CDC. Provide status report on progress towards complete laboratory reporting annually per HIV case surveillance standards.
- Strengthen local collaborations: Strengthen local collaborations with HIV case surveillance staff, CDC-funded health department program staff, and other CDC-funded surveillance or prevention program staff, as appropriate. Strengthen local collaborations with non-CDC-funded HIV prevention and treatment program staff, including Health Resources and Services Administration (HRSA)- or Substance Abuse and Mental Health Services Administration (SAMHSA)-funded HIV prevention programs, as appropriate.

Outcomes:

- Inform local HIV prevention and treatment efforts: Document how MMP data were used to inform local HIV prevention and treatment programs and policies.

Table 1: Expected minimum number of sampled persons for the 2015 data collection cycle by Medical Monitoring Project area*

Project area	Minimum persons sampled
New York State	200
New York City	800
California	500
Los Angeles County	400
San Francisco	400
Texas	400
Houston	400
Florida	800
New Jersey	500
Pennsylvania	200
Philadelphia	400
Georgia	500
Illinois	200
Chicago	400
Puerto Rico	400
Virginia	400
North Carolina	400
Michigan	400
Washington	400
Indiana	400
Mississippi	400
Oregon	400
Delaware	400
Maryland	400
Massachusetts	400
South Carolina	400
Total	10900

*Sample sizes per project area will be revised annually; the expected number of sampled persons per project area for the 2015 data collection cycle is presented here.

ii. Applicant Evaluation and Performance Measurement Plan:

Applicants must describe the types of evaluation that will be conducted locally and key evaluation questions to be asked. This plan should include but is not limited to the performance measures listed in section 2.b.i. and should incorporate local area performance measurement plans. Applicants must also describe how evaluation results will be used for quality improvement in their local area.

c. Organizational Capacity of Awardees to Execute the Approach:

Applicants must also have the capacity to access the Enhanced HIV/AIDS Reporting System

(eHARS) and run SAS programs for sampling and analysis. Applicants must have experience with conducting interviews and medical record abstractions. Applicants should have a staffing plan and structure to include a principal investigator (25% or less), project coordinator (1 FTE or less), data manager (1 FTE or less), and one interviewer/abstractor per 100 sampled persons. Please include CVs for key staff or note whether hiring new staff will be required. Applicants should state whether key staff members have experience with or knowledge of HIV case surveillance and/or sampling and recruiting patients from eHARS. In addition to staffing plans and management, applicants must have the capacity to support all strategies and activities outlined in Section 2 a. v. This includes submitting a budget with resources for all activities including support for in- and out-of-state travel; incentives for participants; funds to support Community and Advisory Board activities; and necessary equipment and software needed to conduct MMP.

d. Work Plan:

Applicants must provide a detailed work plan for the first year of this award and a high level work plan for the subsequent years of the award. The detailed work plan must include discussion of their approach to conduct the strategies and activities needed for MMP and their ability to meet each benchmark. The work plan must also include a timeline and person responsible for completing each activity. The budget submitted must be consistent with the work plan and include resources needed to conduct these activities based on the number of sampled persons for each project area as listed above.

e. CDC Monitoring and Accountability Approach:

Monitoring activities include routine and ongoing communication between CDC and awardees, site visits, and awardee reporting (including work plans, performance, and financial reporting). The HHS Awarding Agency Grants Administration Manual (AAGAM)* specifies the following HHS expectations for post-award monitoring for grants and cooperative agreements:

- Tracking awardee progress in achieving the desired outcomes.
- Insuring the adequacy of awardee systems that underlie and generate data reports.
- Creating an environment that fosters integrity in program performance and results.

Monitoring may also include the following activities:

- Ensuring that work plans are feasible based on the budget and consistent with the intent of the award.
- Ensuring that awardees are performing at a sufficient level to achieve objectives within stated timeframes.
- Working with awardees on adjusting the work plan based on achievement of objectives and changing budgets.
- Monitoring performance measures (both programmatic and financial) to assure satisfactory performance levels.
- Participating in mandatory training and project meetings.

Other activities deemed necessary to monitor the award, if applicable.

These may include monitoring and reporting activities as outlined in Chapter 2.01.101 of the

HHS AAGAM* that assists grants management staff (e.g., grants management officers and specialists, and project officers) in the identification, notification, and management of high-risk awardees.

Progress towards benchmarks will be reviewed using a monthly progress indicator table submitted to project areas monthly.

*Beginning 10/01/2014, AAGAM will be replaced with GPAM.

f. CDC Program Support to Awardees:

In a cooperative agreement, CDC staff are substantially involved in the program activities, above and beyond routine grant monitoring. CDC staff will provide support by:

- In collaboration with leadership from participating project areas and the Divisions in NCHHSTP, developing national procedures for sampling, recruitment, and data collection.
- Evaluating and providing feedback on any significant differences between national and local procedures
- Developing and distributing model SAS code for drawing a sample of eligible persons from NHSS, as required by national MMP procedures or by directly providing the sample to project areas.
- Providing guidance and technical support for sampling eligible persons from NHSS.
- Participating in joint conference calls, awardee meetings, and site visits.
- Disseminating findings jointly with participating project areas.
- Monitoring progress in participant recruitment, interview, and abstraction for all sites.
- Developing methods and process indicators
- Providing guidance and technical support for project management.
- Providing training and technical support for data abstractors and interviewers, including technical support for electronic data collection and data transfer to CDC.
- Providing training and technical support for data management and data analysis.
- Obtaining national-level approval for conducting MMP, including Paperwork Reduction Act review and CDC non-research determination.
- On an annual basis, sharing and discussing National outcome data from MMP with HRSA and all respective Divisions in NCHHSTP.

B. Award Information

1. **Type of Award:** Cooperative Agreement
CDC's substantial involvement in this program appears in the CDC Program Support to Awardees section.
2. **Award Mechanism:** U62; Prevention/Surveillance Activities/Studies of AIDS
3. **Fiscal Year:** 2015
4. **Approximate Total Fiscal Year Funding:** \$16,000,000
5. **Approximate Total Project Period Funding:** \$96,000,000
6. **Total Project Period Length:** 5

7. Approximate Number of Awards: 26
8. Approximate Average Award: \$615,384 (this amount is for the first budget period)
9. Floor of Individual Award Range: \$300,000
10. Ceiling of Individual Award Range: \$1,800,000
11. Anticipated Award Date: June 1, 2015
12. Budget Period Length: 12 months Throughout the project period, CDC will continue the award based on the availability of funds, the evidence of satisfactory progress by the awardee (as documented in required reports), and the determination that continued funding is in the best interest of the federal government. The total number of years for which federal support has been approved (project period) will be shown in the "Notice of Award." This information does not constitute a commitment by the federal government to fund the entire period. The total project period comprises the initial competitive segment and any subsequent non-competitive continuation award(s). *Beginning FY 14, AAGAM will be replaced with GPAM.
13. Direct Assistance: Direct Assistance (DA) is available through this FOA. An official state, local or territorial government applicant may request that CDC provide DA in the form of federal personnel as a part of the grant awarded through this FOA. If the request for DA is approved as a part of the award, CDC will reduce the funding amount provided directly to the awardee as a part of the award. The amount by which the award is reduced will be used to provide DA; the funding shall be deemed part of the award and as having been paid to the awardee. Moreover, DA may include provision of material support, including but not limited to computer hardware, software, or other materials as needed. Please review CDC's policy on direct financial assistance to Grant and Cooperative Agreement Recipients (http://www.cdc.gov/stltpublichealth/GrantsFunding/direct_assistance.html)

C. Eligibility Information
1. Eligible Applicants: Government Organizations: • State or their bona fide agents (includes the District of Columbia) • Local governments or their bona fide agents • Territorial governments or their bona fide agents in the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau)
2. Special Eligibility Requirements: N/A
3. Justification for Less than Maximum Competition:
The Medical Monitoring Project or MMP is a national public health surveillance program

designed to collect clinical and behavioral information on those diagnosed with HIV or AIDS. Competition for MMP funds is limited to the twenty-six (26) established MMP sites originally selected in 2004. These particular sites were selected to represent the HIV epidemic in the United States. Process for the selection and establishment of MMP sites has been published in a scientific journal; a detailed description of the process used for selection is available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3462615/pdf/TOAIDJ-6-67.pdf>. The established MMP sites have enabled CDC to obtain data that represent the country as a whole starting in 2004. Ascertainment of representative national data is the goal of MMP.

Twenty States or territories, including six jurisdictions which are separately funded for other HIV/AIDS program activities within states, were selected to participate in MMP in 2004. These 26 sites have built the capacity to successfully perform MMP and enable CDC to meet surveillance goals by producing national estimates characterizing the US epidemic. The selected sites were: California Department of Health Services; Chicago Department of Public Health; Delaware Department of Health and Social Services; Florida Department of Health; Georgia Department of Public Health; Houston Department of Health and Human Services; Illinois Department of Public Health; Indiana State Department of Health; Los Angeles County Health Department; Maryland Department of Health and Mental Hygiene; Massachusetts Department of Public Health; Michigan Department of Community Health; Mississippi Department of Health; New Jersey Department of Health and Senior Services; New York City Department of Health and Mental Hygiene; New York State Department of Health; North Carolina Department of Health and Human Services; Oregon Department of Human Services; Pennsylvania Department of Health; Philadelphia Department of Public Health; Puerto Rico Health Department; San Francisco Department of Public Health; South Carolina Department of Health and Environmental Control; Texas Department of State Health Services; Virginia Department of Health; and Washington State Department of Health. These are the twenty-six areas eligible to apply and continue to conduct MMP activities.

In order to appropriately use MMP data for prevention and to evaluate national HIV-related health care initiatives including portions of the Affordable Care Act, the data collected in MMP must be nationally representative. If competition is not limited to the 26 established sites listed above, MMP would not be adhering to the scientific sampling strategy chosen for its project design. Without this adherence, MMP data would not be nationally representative and would no longer produce reports that represent the HIV epidemic in the United States.

4. Cost Sharing or Matching:

Cost sharing or matching funds are not required for this program. Although no statutory matching requirement for this FOA exists, leveraging other resources and related ongoing efforts to promote sustainability is strongly encouraged.

5. Maintenance of Effort:

Maintenance of effort is not required for this program.

D. Application and Submission Information

Additional materials that may be helpful to applicants:

<http://www.cdc.gov/od/pgo/funding/docs/FinancialReferenceGuide.pdf> .

1. Required Registrations: An organization must be registered at the three following locations before it can submit an application for funding at www.grants.gov.

- a. Data Universal Numbering System:** All applicant organizations must obtain a Data Universal Numbering System (DUNS) number. A DUNS number is a unique nine-digit identification number provided by Dun & Bradstreet (D&B). It will be used as the Universal Identifier when applying for federal awards or cooperative agreements.

The applicant organization may request a DUNS number by telephone at 1-866-705-5711 (toll free) or internet at

<http://fedgov.dnb.com/webform/displayHomePage.do>. The DUNS number will be provided at no charge.

If funds are awarded to an applicant organization that includes sub-awardees, those sub-awardees must provide their DUNS numbers before accepting any funds.

- b. System for Award Management (SAM):** The SAM is the primary registrant database for the federal government and the repository into which an entity must submit information required to conduct business as an awardee. All applicant organizations must register with SAM, and will be assigned a SAM number. All information relevant to the SAM number must be current at all times during which the applicant has an application under consideration for funding by CDC. If an award is made, the SAM information must be maintained until a final financial report is submitted or the final payment is received, whichever is later. The SAM registration process usually requires not more than five business days, and registration must be renewed annually. Additional information about registration procedures may be found at www.SAM.gov.
- c. [Grants.gov](http://www.grants.gov):** The first step in submitting an application online is registering the organization at www.grants.gov, the official HHS E-grant Web site. Registration information is located at the "Get Registered" option at www.grants.gov.

All applicant organizations must register at www.grants.gov. The one-time registration process usually takes not more than five days to complete. Applicants must start the registration process as early as possible.

2. Request Application Package: Applicants may access the application package at www.grants.gov.

3. Application Package: Applicants must download the SF-424, Application for Federal Assistance, package associated with this funding opportunity at www.grants.gov. If Internet access is not available, or if the online forms cannot be accessed, applicants may call the CDC PGO staff at 770-488-2700 or e-mail PGO PGOTIM@cdc.gov for assistance. Persons with hearing loss may access CDC telecommunications at TTY 1-888-232-6348.

4. Submission Dates and Times: If the application is not submitted by the deadline published in the FOA, it will not be processed. PGO personnel will notify the applicant that their application did not meet the deadline. The applicant must receive pre-approval to submit a paper application (see Other Submission Requirements section for additional details). If the applicant is authorized to submit a paper application, it must be received by the deadline provided by PGO.
a. Letter of Intent (LOI) Deadline (must be emailed or postmarked by): N/A
b. Application Deadline: <i>January 8, 2015</i>
5. CDC Assurances and Certifications: All applicants are required to sign and submit “Assurances and Certifications” documents indicated at http://www.cdc.gov/od/pgo/funding/grants/foamain.shtm. Applicants may follow either of the following processes: • Complete the applicable assurances and certifications, name the file “Assurances and Certifications” and upload it as a PDF file at www.grants.gov • Complete the applicable assurances and certifications and submit them directly to CDC on an annual basis at http://wwwn.cdc.gov/grantsassurances/Homepage.aspx Assurances and certifications submitted directly to CDC will be kept on file for one year and will apply to all applications submitted to CDC within one year of the submission date.
6. Content and Form of Application Submission: Applicants are required to include all of the following documents with their application package at www.grants.gov.
7. Letter of Intent (LOI): LOI is not requested or required as part of the application for this FOA.
8. Table of Contents: (No page limit and not included in Project Narrative limit) Provide a detailed table of contents for the entire submission package that includes all of the documents in the application and headings in the “Project Narrative” section. Name the file “Table of Contents” and upload it as a PDF file under “Other Attachment Forms” at www.grants.gov.
9. Project Abstract Summary: (Maximum 1 page) A project abstract is included on the mandatory documents list and must be submitted at www.grants.gov. The project abstract must be a self-contained, brief summary of the proposed project including the purpose and outcomes. This summary must not include any proprietary or confidential information. Applicants must enter the summary in the “Project Abstract Summary” text box at www.grants.gov.
10. Project Narrative: (Maximum of 25 pages, single spaced, Calibri 12 point, 1-inch margins, number all pages. Content beyond 25 pages will not be considered. 25 page limit includes the work plan.) The Project Narrative must include all of the bolded headings shown in this section. The Project Narrative must be succinct, self-explanatory, and in the order outlined in this section. It must address outcomes and activities to be conducted over the entire project period as identified in

the CDC Project Description section.

Applicants must submit a Project Narrative with the application forms. Applicants must name this file “Project Narrative” and upload it at www.grants.gov.

- a. **Background:** Applicants must provide a description of relevant background information that includes the context of the problem. (See CDC Background.)
- b. **Approach**
 - i. **Problem Statement:** Applicants must describe the core information relative to the problem for the jurisdictions or populations they serve. The core information must help reviewers understand how the applicant’s response to the FOA will address the public health problem and support public health priorities. (See CDC Project Description.)
 - ii. **Purpose:** Applicants must describe in 2-3 sentences specifically how their application will address the problem as described in the CDC Project Description.
 - iii. **Outcomes:** Applicants must clearly identify the outcomes they expect to achieve by the end of the project period. Outcomes are the results that the program intends to achieve. All outcomes must indicate the intended direction of change (i.e., increase, decrease, maintain). (See the program logic model in the Approach section of the CDC Project Description.)

In addition to the project period outcomes required by CDC, applicants should include any additional outcomes they anticipate.

- iv. **Strategy and Activities:** Applicants must provide a clear and concise description of the strategies and activities they will to use to achieve the project period outcomes. Whenever possible, applicants should use evidence-based program strategies as identified by the Community Guide¹ (or similar reviews) and reference it explicitly as a source. Please note that a new toolkit designed to share information and resources to assist health departments and their partners in developing and implementing a Data to Care program is available at <http://www.effectiveinterventions.org>. Applicants may propose additional strategies and activities to achieve the outcomes. Applicants must select existing evidence-based strategies that meet their needs, or describe the rationale for developing and evaluating new strategies or practice-based innovations. (See CDC Project Description: Strategies and Activities section.)
- c. **Applicant Evaluation and Performance Measurement Plan:** Applicants must provide an overall jurisdiction or community-specific evaluation and performance measurement plan that is consistent with the CDC Evaluation and Performance Measurement Strategy section of the CDC Project Description of

¹ <http://www.thecommunityguide.org/index.html>

this FOA. Data collected must be used for ongoing monitoring of the award to evaluate its effectiveness, and for continuous program improvement.

The plan must:

- Describe how key program partners will be engaged in the evaluation and performance measurement planning processes.
- Describe the type of evaluations to be conducted (i.e., process and/or outcome).
- Describe key evaluation questions to be answered.
- Describe other information, as determined by the CDC program (e.g., performance measures to be developed by the applicant) that must be included.
- Describe potentially available data sources and feasibility of collecting appropriate evaluation and performance data.
- Describe how evaluation findings will be used for continuous program and quality improvement.
- Describe how evaluation and performance measurement will contribute to development of that evidence base, where program strategies are being employed that lack a strong evidence base of effectiveness.

Awardees will be required to submit a more detailed evaluation and performance measurement plan within the first six months of the project, as outlined in the reporting section of the FOA.

d. Organizational Capacity of Applicants to Implement the Approach:

Applicant must address the organizational capacity requirements as described in the CDC Project Description. Applicants must name this file “CVs/Resumes” or “Organizational Charts” and upload it at www.grants.gov.

11. Work Plan: *(Included in the Project Narrative’s 25 page limit)*

Applicants must prepare a work plan consistent with the CDC Project Description Work Plan section. The work plan integrates and delineates more specifically how the awardee plans to carry out achieving the project period outcomes, strategies, and activities, evaluation and performance measurement, including key milestones.

Applicants must name this file “Work Plan” and upload it as a PDF file at www.grants.gov.

12. Budget Narrative:

Applicants must submit an itemized budget narrative, which may be scored as part of the Organizational Capacity of Awardees to Execute the Approach. When developing the budget narrative, applicants must consider whether the proposed budget is reasonable and consistent with the purpose, outcomes, and program strategy outlined in the project narrative. The budget must include:

- Salaries and wages
- Fringe benefits

- Consultant costs
- Equipment
- Supplies
- Travel
- Other categories
- Total Direct costs
- Total Indirect costs
- Contractual costs

For guidance on completing a detailed budget, see Budget Preparation Guidelines at: <http://www.cdc.gov/od/pgo/funding/grants/foamain.shtm>.

If applicable and consistent with statutory authority, applicant entities may use funds for activities as they relate to the intent of this FOA to meet national standards or seek health department accreditation through the Public Health Accreditation Board (see: <http://phaboard.org>). Applicant entities include state, local, territorial governments (including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau), or their bona fide agents, political subdivisions of states (in consultation with states), federally recognized or state-recognized American Indian or Alaska Native tribal governments, and American Indian or Alaska Native tribally designated organizations. Activities include those that enable a public health organization to deliver public health services such as activities that ensure a capable and qualified workforce, up-to-date information systems, and the capability to assess and respond to public health needs. Use of these funds must focus on achieving a minimum of one national standard that supports the intent of the FOA. Proposed activities must be included in the budget narrative and must indicate which standards will be addressed.

Applicants must name this file “Budget Narrative” and upload it as a PDF file at www.grants.gov. If requesting indirect costs in the budget, a copy of the indirect cost-rate agreement is required. If the indirect cost rate is a provisional rate, the agreement must have been made less than 12 months earlier. Applicants must name this file “Indirect Cost Rate” and upload it at www.grants.gov.

13. Tobacco and Nutrition Policies:

Awardees are encouraged to implement tobacco and nutrition policies.

Unless otherwise explicitly permitted under the terms of a specific CDC award, no funds associated with this FOA may be used to implement the optional policies, and no applicants will be evaluated or scored on whether they choose to implement these optional policies.

CDC supports implementing evidence-based programs and policies to reduce tobacco use and secondhand smoke exposure, and to promote healthy nutrition. CDC encourages all awardees to implement the following optional recommended evidence-based tobacco and nutrition

policies within their own organizations. The tobacco policies build upon the current federal commitment to reduce exposure to secondhand smoke, specifically The Pro-Children Act, 20 U.S.C. 7181-7184, that prohibits smoking in certain facilities that receive federal funds in which education, library, day care, health care, or early childhood development services are provided to children.

Tobacco Policies:

1. Tobacco-free indoors: Use of any tobacco products (including smokeless tobacco) or electronic cigarettes is not allowed in any indoor facilities under the control of the awardee.
2. Tobacco-free indoors and in adjacent outdoor areas: Use of any tobacco products or electronic cigarettes is not allowed in any indoor facilities, within 50 feet of doorways and air intake ducts, and in courtyards under the control of the awardee.
3. Tobacco-free campus: Use of any tobacco products or electronic cigarettes is not allowed in any indoor facilities or anywhere on grounds or in outdoor space under the control of the awardee.

Nutrition Policies:

1. Healthy food-service guidelines must, at a minimum, align with HHS and General Services Administration Health and Sustainability Guidelines for Federal Concessions and Vending Operations. These guidelines apply to cafeterias, snack bars, and vending machines in any facility under the control of the awardee and in accordance with contractual obligations for these services (see: [http://www.gsa.gov/graphics/pbs/Guidelines for Federal Concessions and Vending Operations.pdf](http://www.gsa.gov/graphics/pbs/Guidelines%20for%20Federal%20Concessions%20and%20Vending%20Operations.pdf)).
2. Resources that provide guidance for healthy eating and tobacco-free workplaces are:
<http://www.cdc.gov/nccdphp/dnpao/hwi/toolkits/tobacco/index.htm>
<http://www.thecommunityguide.org/tobacco/index.html>
<http://www.cdc.gov/chronicdisease/resources/guidelines/food-service-guidelines.htm>.

14. Health Insurance Marketplaces:

A healthier country is one in which Americans are able to access the care they need to prevent the onset of disease and manage disease when it is present. The Affordable Care Act, the health care law of 2010, creates new Health Insurance Marketplaces, also known as Exchanges, to offer millions of Americans affordable health insurance coverage. In addition, the law helps make prevention affordable and accessible for Americans by requiring health plans to cover certain recommended preventive services without cost sharing. Outreach efforts will help families and communities understand these new options and provide eligible individuals the assistance they need to secure and retain coverage as smoothly as possible. For more information on the Marketplaces and the health care law, visit: www.HealthCare.gov.

15. Intergovernmental Review:

Executive Order 12372 does not apply to this program.

16. Funding Restrictions:

Restrictions that must be considered while planning the programs and writing the budget are:

- Awardees may not use funds for research.
- Awardees may not use funds for clinical care.
- Awardees may use funds only for reasonable program purposes, including personnel, travel, supplies, and services.
- Generally, awardees may not use funds to purchase furniture or equipment. Any such proposed spending must be clearly identified in the budget.
- Reimbursement of pre-award costs is not allowed.
- Other than for normal and recognized executive-legislative relationships, no funds may be used for:
 - publicity or propaganda purposes, for the preparation, distribution, or use of any material designed to support or defeat the enactment of legislation before any legislative body
 - the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before any legislative body
- See [Additional Requirement \(AR\) 12](#) for detailed guidance on this prohibition and [additional guidance on lobbying for CDC awardees](#).
- The direct and primary recipient in a cooperative agreement program must perform a substantial role in carrying out project outcomes and not merely serve as a conduit for an award to another party or provider who is ineligible.
- Data collection initiated under this cooperative agreement has been approved by the Office of Management and Budget. Any changes to the existing data collection will be subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

17. Other Submission Requirements:

- a. Electronic Submission:** Applications must be submitted electronically at www.grants.gov. The application package can be downloaded at www.grants.gov. Applicants can complete the application package off-line and submit the application by uploading it at www.grants.gov. All application attachments must be submitted using a PDF file format. Directions for creating PDF files can be found at www.grants.gov. File formats other than PDF may not be readable by PGO Technical Information Management Section (TIMS) staff.

Applications must be submitted electronically by using the forms and instructions posted for this funding opportunity at www.grants.gov.

If Internet access is not available or if the forms cannot be accessed online, applicants may contact the PGO TIMS staff at 770- 488-2700 or by e-mail at pgotim@cdc.gov, Monday through Friday, 7:30 a.m.–4:30 p.m., except federal holidays. Electronic applications will be considered successful if they are

available to PGO TIMS staff for processing from www.grants.gov on the deadline date.

- b. Tracking Number:** Applications submitted through www.grants.gov are time/date stamped electronically and assigned a tracking number. The applicant's Authorized Organization Representative (AOR) will be sent an e-mail notice of receipt when www.grants.gov receives the application. The tracking number documents that the application has been submitted and initiates the required electronic validation process before the application is made available to CDC.
- c. Validation Process:** Application submission is not concluded until the validation process is completed successfully. After the application package is submitted, the applicant will receive a "submission receipt" e-mail generated by www.grants.gov. A second e-mail message to applicants will then be generated by www.grants.gov that will either validate or reject the submitted application package. This validation process may take as long as two business days. Applicants are strongly encouraged to check the status of their application to ensure that submission of their package has been completed and no submission errors have occurred. Applicants also are strongly encouraged to allocate ample time for filing to guarantee that their application can be submitted and validated by the deadline published in the FOA. Non-validated applications will not be accepted after the published application deadline date.

If a "validation" e-mail is not received within two business days of application submission, please contact www.grants.gov. For instructions on how to track the application, refer to the e-mail message generated at the time of application submission or the Application User Guide, Version 3.0, page 57.

- d. Technical Difficulties:** If technical difficulties are encountered at www.grants.gov, applicants should contact Customer Service at www.grants.gov. The www.grants.gov Contact Center is available 24 hours a day, 7 days a week, except federal holidays. The Contact Center is available by phone at 1-800-518-4726 or by e-mail at support@www.grants.gov. Application submissions sent by e-mail or fax, or on CDs or thumb drives will not be accepted. Please note that www.grants.gov is managed by HHS.
- e. Paper Submission:** If technical difficulties are encountered at www.grants.gov, applicants should call the www.grants.gov Contact Center at 1-800-518-4726 or e-mail them at support@www.grants.gov for assistance. After consulting with the Contact Center, if the technical difficulties remain unresolved and electronic submission is not possible, applicants may e-mail or call CDC GMO/GMS, *before the deadline*, and request permission to submit a paper application. Such requests are handled on a case-by-case basis.

An applicant's request for permission to submit a paper application must:

1. Include the www.grants.gov case number assigned to the inquiry;

2. Describe the difficulties that prevent electronic submission and the efforts taken with the www.grants.gov Contact Center to submit electronically; and
3. Be postmarked at least three calendar days before the application deadline. Paper applications submitted without prior approval will not be considered. If a paper application is authorized, PGO will advise the applicant of specific instructions for submitting the application (e.g., original and two hard copies of the application by U.S. mail or express delivery service).

E. Application Review Information

1. Review and Selection Process: Applications will be reviewed in three phases.

a. Phase I Review:

All applications will be reviewed initially for completeness by CDC PGO staff and will be reviewed jointly for eligibility by the CDC OID and PGO. Incomplete applications and applications that do not meet the eligibility criteria will not advance to Phase II review. Applicants will be notified that their applications did not meet eligibility or published submission requirements.

b. Phase II Review:

A review panel will evaluate complete, eligible applications in accordance with the "Criteria" section of the FOA. (See CDC Project Description)

1. Approach: (45 points) Describes an overall strategy to achieve the outcomes, with specific and appropriate time lines. Describes activities that are evidence-based, achievable, and appropriate to achieve the outcomes of the project. Describes clear monitoring and evaluation procedures and how evaluation and performance measurement will be incorporated into planning, implementation, and reporting of project activities. □ Feasibility of the applicant's plan to meet the outcomes, the extent to which the specific methods described are likely to achieve the outcomes, and whether the proposed use of funds is efficient.
2. Evaluation and Performance Management: (25 points) Describes an evaluation plan that clearly identifies key evaluation questions, type(s) of evaluations to be conducted, how and by whom evaluation will be conducted, data collection and analysis plans, how data will be reported, and how evaluation and performance measurement findings will be used to demonstrate the outcomes of the FOA and for continuous program quality improvement. Provides an evaluation plan that is feasible, ethical, methodologically sound, and engages key stakeholders. Describes how evaluation and performance measurement will contribute to developing an evidence base for programs that lack a strong effectiveness evidence base.
3. Applicant's Organizational Capacity to Implement the Approach: (30 points) Demonstrates relevant experience and capacity (both management, administrative, and technical) to achieve the goals of the project. Demonstrates experience and capacity to implement the evaluation plan. Provides a staffing plan and project management structure that will be sufficient to meet the goals of the proposed project and which clearly defines staff roles. Provides an organizational chart.

4. Budget (not scored): The extent to which the budget is reasonable, clearly itemized and justified, consistent with the intended use of funds and demonstrates the capacity to support project activities.
c. Phase III Review:
The following factors also may affect the funding decision: Available fiscal year funding may limit the number of awards made each year. Funding preference will be given to those MMP project areas who have been conducting MMP for seven years or longer.
2. Announcement and Anticipated Award Dates:
CDC will notify selected awardees by phone call prior to distribution of official award notice. Anticipated award date is June 1, 2015.

F. Award Administration Information
1. Award Notices:
Awardees will receive an electronic copy of the Notice of Award (NoA) from CDC PGO. The NoA shall be the only binding, authorizing document between the awardee and CDC. The NoA will be signed by an authorized GMO and e-mailed to the awardee program director. Any applicant awarded funds in response to this FOA will be subject to the DUNS, SAM Registration, and Federal Funding Accountability And Transparency Act Of 2006 (FFATA) requirements. Unsuccessful applicants will receive notification of these results by e-mail with delivery receipt or by U.S. mail.
2. Administrative and National Policy Requirements:
Awardees must comply with the administrative requirements outlined in 45 C.F.R. Part 74 or Part 92, as appropriate. Brief descriptions of relevant provisions are available at http://www.cdc.gov/od/pgo/funding/grants/additional_req.shtm . The following Administrative Requirements (AR) apply to this project: • AR-7: Executive Order 12372 • AR-9: Paperwork Reduction Act • AR-10: Smoke-Free Workplace • AR-11: Healthy People 2010 • AR-12: Lobbying Restrictions • AR-14: Accounting System Requirements • AR-21: Small, Minority, And Women-owned Business • AR-24: Health Insurance Portability and Accountability Act • AR-25: Release and Sharing of Data

- AR-29: Compliance with EO13513, “Federal Leadership on Reducing Text Messaging while Driving,” October 1, 2009
- AR-30: Compliance with Section 508 of the Rehabilitation Act of 1973
- AR-33: Plain Writing Act of 2010
- AR-34: Patient Protection and Affordable Care Act (e.g., a tobacco-free campus policy and a lactation policy consistent with S4207)

ARs applicable to awards associated with HIV/AIDS issues:

- AR-4: HIV/AIDS Confidentiality Provisions
- AR-5: HIV Program Review Panel
- AR-6: Patient Care

Organization-specific ARs:

- AR-8: Public Health System Reporting (community-based, nongovernment organizations)
- AR-15: Proof of Non-profit Status (nonprofit organizations)
- AR 23: Compliance with 45 C.F.R. Part 87 (faith-based organizations)]

For more information on the C.F.R., visit the National Archives and Records Administration at <http://www.access.gpo.gov/nara/cfr/cfr-table-search.html>.

3. Reporting

a. CDC Reporting Requirements:

Reporting provides continuous program monitoring and identifies successes and challenges that awardees encounter throughout the project period. Also, reporting is a requirement for awardees who want to apply for yearly continuation of funding. Reporting helps CDC and awardees because it:

- Helps target support to awardees, particularly for cooperative agreements;
- Provides CDC with periodic data to monitor awardee progress towards meeting the FOA outcomes and overall performance;
- Allows CDC to track performance measures and evaluation findings to validate continuous program improvement throughout the project period and to determine applicability of evidence-based approaches to different populations, settings, and contexts; and
- Enables CDC to assess the overall effectiveness and influence of the FOA.

As described in the following text, awardees must submit an annual performance report, ongoing performance measures data, administrative reports, and a final performance and financial report. A detailed explanation of any additional reporting requirements will be provided in the Notice of Award to successful applicants.

b. Specific reporting requirements:

- i. Awardee Evaluation and Performance Measurement Plan:** Awardees must provide a more detailed evaluation and performance measurement plan

within the first six months of the project. This more detailed plan must be developed by awardees as part of first-year project activities, with support from CDC. This more detailed plan must build on the elements stated in the initial plan, and must be no more than 25 pages. At a minimum, and in addition to the elements of the initial plan, this plan must:

- Indicate the frequency that evaluation and performance data are to be collected.
- Describe how data will be reported.
- Describe how evaluation findings will be used to ensure continuous quality and program improvement.
- Describe how evaluation and performance measurement will yield findings that will demonstrate the value of the FOA (e.g., effect on improving public health outcomes, effectiveness of FOA as it pertains to performance measurement, cost-effectiveness, or cost-benefit).
- Describe dissemination channels and audiences (including public dissemination).
- Describe other information requested and as determined by the CDC program.

When developing evaluation and performance measurement plans, applicants are encouraged to use the Introduction to Program Evaluation for Public Health Programs: A Self-Study Guide, available at:
<http://www.cdc.gov/eval/guide/index.htm>

ii. **Annual Performance Report:** This report must not exceed 45 pages excluding administrative reporting; attachments are not allowed, but Web links are allowed.

The awardee must submit the Annual Performance Report via www.grants.gov 120 days before the end of the budget period. In addition, the awardee must submit an annual Federal Financial Report within 90 days after the end of the calendar quarter in which the budget year ends.

This report must include the following:

- **Performance Measures** (including outcomes)—Awardees must report on performance measures for each budget period and update measures, if needed.
- **Evaluation Results**—Awardees must report evaluation results for the work completed to date (including any data about the effects of the program).
- **Work Plan**—Awardees must update work plan each budget period.
- **Successes**
 - Awardees must report progress on completing activities outlined in the work plan.
 - Awardees must describe any additional successes (e.g., identified

through evaluation results or lessons learned) achieved in the past year.

- Awardees must describe success stories.
- **Challenges**
 - Awardees must describe any challenges that might affect their ability to achieve annual and project-period outcomes, conduct performance measures, or complete the activities in the work plan.
 - Awardees must describe any additional challenges (e.g., identified through evaluation results or lessons learned) encountered in the past year.
- **CDC Program Support to Awardees**
 - Awardees must describe how CDC could help them overcome challenges to achieving annual and project-period outcomes and performance measures, and completing activities outlined in the work plan.
- **Administrative Reporting** (No page limit)
 - SF-424A Budget Information-Non-Construction Programs.
 - Budget Narrative—must use the format outlined in “Content and Form of Application Submission, Budget Narrative” section.
 - Indirect Cost-Rate Agreement.

For year 2 and beyond of the award awardees may request that their estimated unobligated funds be carried over into the next budget period. The carryover request must:

- Express a bona fide need for permission to use an unobligated balance;
- Include a signed, dated, and accurate Federal Financial Report (FFR) for the budget period from which funds will be transferred (as much as 75% of unobligated balances); and
- Include a list of proposed activities, an itemized budget, and a narrative justification for those activities.

The awardee must submit the Annual Performance Report via www.grants.gov 120 days before the end of the budget period.

iii. Performance Measure Reporting: CDC programs must require awardees to submit performance measures annually as a minimum, and may require reporting more frequently. Performance measure reporting must be limited to data collection. When funding is awarded initially, CDC programs must specify required reporting frequency, data fields, and format.

iv. Federal Financial Reporting (FFR): The annual FFR form (SF-425) is required and must be submitted through eRA Commons² within 90 days after each budget period ends. The report must include only those funds authorized

²<https://commons.era.nih.gov/commons/>

and disbursed during the timeframe covered by the report. The final report must indicate the exact balance of unobligated funds, and may not reflect any unliquidated obligations. The final FFR expenditure data and the Payment Management System's (PMS) cash transaction data must correspond; no discrepancies between the data sets are permitted. Failure to submit the required information by the due date may affect adversely the future funding of the project. If the information cannot be provided by the due date, awardees are required to submit a letter of explanation and include the date by which the information will be provided.

- v. Final Performance and Financial Report:** At the end of the project period, awardees must submit a final report including a final financial and performance report. This report is due 90 days after the project period ends. (CDC must include a page limit for the report with a maximum of 40 pages).

At a minimum, this report must include:

- Performance Measures (including outcomes)—Awardees must report final performance data for all performance measures for the project period.
- Evaluation Results—Awardees must report final evaluation results for the project period.
- Impact/ Results—Awardees must describe the effects or results of the work completed over the project period, including success stories.
- Additional forms as described in the Notice of Award, including Equipment Inventory Report and Final Invention Statement.

Awardees must email the report to the CDC PO and the GMS listed in the "Agency Contacts" section of the FOA.

4. Federal Funding Accountability and Transparency Act of 2006 (FFATA):

The FFATA and Public Law 109-282, which amends the FFATA, require full disclosure of all entities and organizations that receive federal funds including awards, contracts, loans, other assistance, and payments. This information must be submitted through the single, publicly accessible Web site, www.USASpending.gov.

Compliance with these mandates is primarily the responsibility of the federal agency. However, two elements of these mandates require information to be collected and reported by applicants: 1) information on executive compensation when not already reported through SAM; and 2) similar information on all sub-awards, subcontracts, or consortiums for greater than \$25,000.

For the full text of these requirements, see:

<http://www.gpo.gov/fdsys/browse/collection.action?collectionCode=BILLS>.

G. Agency Contacts

CDC encourages inquiries concerning this FOA.

For **programmatic technical assistance**, contact:

Catherine Sanders, Project Officer
Department of Health and Human Services
Centers for Disease Control and Prevention
1600 Clifton Road NE, MS E-46
Atlanta, GA 30329
Telephone: (404) 639-0959
Email: hge3@cdc.gov

For **financial, awards management, or budget assistance**, contact:

Gladys Gissentanna, Grants Management Specialist
Department of Health and Human Services
CDC Procurement and Grants Office
2920 Brandywine Road, MS E-15
Atlanta, GA 30341
Telephone: (770) 488-2741
Email: gcg4@cdc.gov

For assistance with **submission difficulties related to** www.grants.gov, contact the Contact Center by phone at 1-800-518-4726.

Hours of Operation: 24 hours a day, 7 days a week, except on federal holidays.

For all other **submission** questions, contact:

Technical Information Management Section
Department of Health and Human Services
CDC Procurement and Grants Office
2920 Brandywine Road, MS E-14
Atlanta, GA 30341
Telephone: 770-488-2700
E-mail: pgotim@cdc.gov

CDC Telecommunications for persons with hearing loss is available at: TTY 1-888-232-6348.

H. Other Information

MMP website: <http://www.cdc.gov/hiv/statistics/systems/mmp/index.html>

Following is a list of acceptable attachments that applicants can upload as PDF files as part of their application at www.grants.gov. Applicants may not attach documents other than those listed; if other documents are attached, applications will not be reviewed.

- Project Abstract

- Project Narrative
- Budget Narrative
- CDC Assurances and Certifications
- Work Plan
- Table of Contents for Entire Submission
- Resumes/CVs
- Organizational Charts
- Indirect Cost Rate , if applicable
- Letters of Support
- Memorandum of Agreement (MOA)
- Memorandum of Understanding (MOU)
- Bona Fide Agent status documentation

I. Glossary

Administrative and National Policy Requirements, Additional Requirements (ARs): Administrative requirements found in 45 CFR Part 74 and Part 92 and other requirements mandated by statute or CDC policy. All ARs are listed in the Template for CDC programs. CDC programs must indicate which ARs are relevant to the FOA; awardees must comply with the ARs listed in the FOA. To view brief descriptions of relevant provisions, see http://www.cdc.gov/od/pgo/funding/grants/additional_req.shtm.

Award: Financial assistance that provides support or stimulation to accomplish a public purpose. Awards include grants and other agreements (e.g., cooperative agreements) in the form of money, or property in lieu of money, by the federal government to an eligible applicant.

Budget Period or Budget Year: The duration of each individual funding period within the project period. Traditionally, budget periods are 12 months or 1 year.

Carryover: Unobligated federal funds remaining at the end of any budget period that, with the approval of the GMO or under an automatic authority, may be carried over to another budget period to cover allowable costs of that budget period either as an offset or additional authorization. Obligated but liquidated funds are not considered carryover.

Catalog of Federal Domestic Assistance (CFDA): A catalog published twice a year that describes domestic assistance programs administered by the federal government. This catalog lists projects, services, and activities that provide assistance or benefits to the American public. This catalog is available at <https://www.cfda.gov/index?s=agency&mode=form&id=0bebbc3b3261e255dc82002b83094717&tab=programs&tabmode=list&subtab=list&subtabmode=list>.

CFDA Number: A unique number assigned to each program and FOA throughout its lifecycle that enables data and funding tracking and transparency.

CDC Assurances and Certifications: Standard government-wide grant application forms.

Competing Continuation Award: A financial assistance mechanism that adds funds to a grant and adds one or more budget periods to the previously established project period (i.e., extends the “life” of the award).

Continuous Quality Improvement: A system that seeks to improve the provision of services with an emphasis on future results.

Contracts: An award instrument that establishes a binding, legal procurement relationship between CDC and a recipient, and obligates the recipient to furnish a product.

Cooperative Agreement: A financial assistance award with the same kind of interagency relationship as a grant except that it provides for substantial involvement by the federal agency funding the award.

Cost Sharing or Matching: Refers to program costs not borne by the federal government but by the awardees. It may include the value of allowable third-party, in-kind contributions, as well as expenditures by the awardee.

Direct Assistance: An assistance support mechanism, which must be specifically authorized by statute, whereby goods or services are provided to recipients in lieu of cash. Direct assistance generally involves the assignment of Federal personnel or the provision of equipment or supplies, such as vaccines.
<http://intranet.cdc.gov/ostlts/directassistance/index.html>.

DUNS: The Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number is a nine-digit number assigned by Dun and Bradstreet Information Services. When applying for Federal awards or cooperative agreements all applicant organizations must obtain a DUNS number as the Universal Identifier. DUNS number assignment is free. If requested by telephone, a DUNS number will be provided immediately at no charge. If requested via the internet, obtaining a DUNS number may take one to two days at no charge. If an organization does not know its DUNS number or needs to register for one, visit Dun & Bradstreet at <http://fedgov.dnb.com/webform/displayHomePage.do>.

Federal Funding Accountability and Transparency Act of 2006 (FFATA): Requires that information about federal awards, including awards, contracts, loans, and other assistance and payments, be available to the public on a single Web site at www.USAspending.gov.

Fiscal Year: The year for which budget dollars are allocated annually. The federal fiscal year starts October 1 and ends September 30.

Grant: A legal instrument used by the federal government to transfer anything of value to a recipient for public support or stimulation authorized by statute. Financial assistance may be money or property. The definition does not include a federal procurement subject to the Federal Acquisition Regulation; technical assistance (which provides services instead of money); or assistance in the form of revenue sharing, loans, loan guarantees, interest subsidies, insurance, or direct payments of any kind to a person or persons. The main difference between a grant and a cooperative agreement is that in a grant there is no anticipated substantial programmatic involvement by the federal government under the award.

Grants.gov: A "storefront" Web portal for electronic data collection (forms and reports) for federal

grant-making agencies at www.grants.gov.

Health Disparities: Differences in health outcomes and their determinants among segments of the population as defined by social, demographic, environmental, or geographic category.

Healthy People 2020: National health objectives aimed at improving the health of all Americans by encouraging collaboration across sectors, guiding people toward making informed health decisions, and measuring the effects of prevention activities.

Inclusion: Both the meaningful involvement of a community's members in all stages of the program process and the maximum involvement of the target population that the intervention will benefit. Inclusion ensures that the views, perspectives, and needs of affected communities, care providers, and key partners are considered.

Indirect Costs: Costs that are incurred for common or joint objectives and not readily and specifically identifiable with a particular sponsored project, program, or activity; nevertheless, these costs are necessary to the operations of the organization. For example, the costs of operating and maintaining facilities, depreciation, and administrative salaries generally are considered indirect costs.

Intergovernmental review: Executive Order 12372 governs applications subject to Intergovernmental Review of Federal Programs. This order sets up a system for state and local governmental review of proposed federal assistance applications. Contact the state single point of contact (SPOC) to alert the SPOC to prospective applications and to receive instructions on the State's process. Visit the following Web address to get the current SPOC list: http://www.whitehouse.gov/omb/grants_spoc/.

Letter of Intent (LOI): A preliminary, non-binding indication of an organization's intent to submit an application.

Lobbying: Direct lobbying includes any attempt to influence legislation, appropriations, regulations, administrative actions, executive orders (legislation or other orders), or other similar deliberations at any level of government through communication that directly expresses a view on proposed or pending legislation or other orders, and which is directed to staff members or other employees of a legislative body, government officials, or employees who participate in formulating legislation or other orders. Grass roots lobbying includes efforts directed at inducing or encouraging members of the public to contact their elected representatives at the federal, state, or local levels to urge support of, or opposition to, proposed or pending legislative proposals.

Maintenance of Effort: A requirement contained in authorizing legislation, or applicable regulations that a recipient must agree to contribute and maintain a specified level of financial effort from its own resources or other nongovernment sources to be eligible to receive federal grant funds. This requirement is typically given in terms of meeting a previous base-year dollar amount.

Memorandum of Understanding (MOU) or Memorandum of Agreement (MOA): Document that describes a bilateral or multilateral agreement between parties expressing a convergence of will between the parties, indicating an intended common line of action. It is often used in cases where the parties either do not imply a legal commitment or cannot create a legally enforceable agreement.

New FOA: Any FOA that is not a continuation or supplemental award.

Nongovernment Organization (NGO): Any nonprofit, voluntary citizens' group that is organized on a local, national, or international level.

Notice of Award (NoA): The only binding, authorizing document between the recipient and CDC that confirms issue of award funding. The NoA will be signed by an authorized GMO and provided to the recipient fiscal officer identified in the application.

Performance Measurement: The ongoing monitoring and reporting of program accomplishments, particularly progress toward pre-established goals, typically conducted by program or agency management. Performance measurement may address the type or level of program activities conducted (process), the direct products and services delivered by a program (outputs), or the results of those products and services (outcomes). A “program” may be any activity, project, function, or policy that has an identifiable purpose or set of objectives.

Objective Review: A process that involves the thorough and consistent examination of applications based on an unbiased evaluation of scientific or technical merit or other relevant aspects of the proposal. The review is intended to provide advice to the persons responsible for making award decisions.

Outcome: The observable benefits or changes for populations or public health capabilities that will result from a particular program strategy.

Plain Writing Act of 2010: Requires federal agencies to communicate with the public in plain language to make information more accessible and understandable by intended users, especially people with limited health literacy skills or limited English proficiency. The Plain Writing Act is available at www.plainlanguage.gov.

Program Strategies: Public health interventions or public health capabilities.

Program Official: Person responsible for developing the FOA; can be either a project officer, program manager, branch chief, division leader, policy official, center leader, or similar staff member.

Project Period Outcome: An outcome that will occur by the end of the FOA’s funding period.

Public Health Accreditation Board (PHAB): National, nonprofit organization that improves tribal, state, local, territorial, and U.S. public health departments and strengthens their quality and performance through accreditation.

System for Award Management (SAM): The primary vendor database for the U.S. federal government. SAM validates applicant information and electronically shares secure and encrypted data with federal agencies' finance offices to facilitate paperless payments through Electronic Funds Transfer (EFT). SAM stores organizational information, allowing www.grants.gov to verify identity and pre-fill organizational information on grant applications.

Statute: An act of the legislature; a particular law enacted and established by the will of the legislative department of government, expressed with the requisite formalities. In foreign or civil law any particular

municipal law or usage, though resting for its authority on judicial decisions, or the practice of nations. *Black's Law Dictionary 2 Kent, Comma 450.*

Statutory Authority: Authority provided by legal statute that establishes a federal financial assistance program or award.

Technical Assistance: Advice, assistance, or training pertaining to program development, implementation, maintenance, or evaluation that is provided by the funding agency.

Work Plan: The summary of annual strategies and activities, personnel and/or partners who will complete them, and the timeline for completion. The work plan will outline the details of all necessary activities that will be supported through the approved budget.

J. Questions and Answers on FOA CDC-RFA-PS15-1503 Medical Monitoring Project

Question	Answer
Topic: Informational Conference Calls Will there be an informational conference call in November?	There will not be an additional informational conference call for this FOA.
Topic: Budget Are there specific budget items to consider for this FOA, especially with the change to using case surveillance based sampling?	This is not a comprehensive list, but some specifics items to consider are: • Subscription fees for people search websites like Lexis-Nexis • Percentage of staff time devoted to lead generation for sampled persons • Appropriate resources for staff or for time for locating sampled persons • Incentives for participants • Microsoft Access if interested in using a contact tracking database developed by CDC • Out of State travel for 2 staff members to 3 on-site meetings in Atlanta • Local Provider Advisory Board (PAB) Community Advisory Board (CAB) expenses • QDS software, if not already using version 2.6.1 • Web-connectivity for conducting medical record abstractions • Fees for copies of medical records • Equipment for conducting interview and MRAs • Cell phones for data collection staff • GPS for data collection staff • Percentage of staff time for data analysis and dissemination activities
Topic: Budget Should we budget for CAB or PAB travel to Atlanta?	Project areas should not budget for CAB or PAB travel to Atlanta. Any CAB or PAB expenses included in budgets should be for local costs associated with CAB and PAB activities.
Topic: Budget Are we allowed to budget for data analysis or dissemination activities?	Yes. The main focus of MMP is data collection, but data analysis and dissemination is also an important aspect and one that is highlighted in the FOA. However, depending on funding levels, budgets for data analysis and dissemination activities may be reduced.
Topic: Budget What are the details on expected out-of-state travel?	Refer to the previous answer about out-of-state travel. It has been revised and is on page 42.
Topic: Budget Is there a limit on the amount for patient incentives?	Regulatory documents for MMP say incentives are approximately \$25, but may vary by project area. Project areas may consider incentives of

Question	Answer																											
	approximately \$50 if allowed locally.																											
Topic: CAB and PAB Activities Are we expected to select members for National Advisory Board activities and also maintain a local advisory board?	Each project area should have one CAB and one PAB member who will be a part of MMP’s National Advisory Board. Project areas are not required to maintain their own local boards, although some areas have found it helpful.																											
Topic: Hardware and Software Specifications What are the specific equipment and software requirements for MMP?	• Able to support QDS computer-assisted personal interviews (CAPI) 2.6.1 • Able to support web connectivity in the field • Able to support encryption software without causing computer sluggishness or other problems. Note: Data security standards require device data encryption (FIPS- 140-2 compliance). • Has a battery life of at least 7 to 8 hours (preferred); Optional: Interchangeable battery for back-up. • Has a USB port to transfer data files (preferred); Optional: an SD card slot for back-up. • Rugged for field work (optional) • Easy to carry and discrete in the field Based on the requirements above, the following are the basic recommended hardware specifications. <table><tr><th>Item</th><th>Recommended</th><th>Comments</th></tr><tr><td>Operating system</td><td>Windows Vista, Windows XP, Windows 7 or 8 environment</td><td>XP tablets not recommended; QDS will not work with Windows RT systems</td></tr><tr><td>Processor</td><td>1.3 GHZ+ , low watts</td><td></td></tr><tr><td>RAM</td><td>2 GB+</td><td></td></tr><tr><td>Hard Drive</td><td>Solid State Drive, 64GB or larger</td><td>Solid state drives are smaller and consume less power</td></tr><tr><td>Input</td><td>Keyboard, Touch and Stylus (if tablet) for interview. Keyboard only for abstractions</td><td></td></tr><tr><td>Battery</td><td>>7-8 hrs.</td><td>Can be extended by adding extra battery packs</td></tr><tr><td>USB Port</td><td>At least one</td><td>For adding/removing data files</td></tr><tr><td></td><td></td><td></td></tr></table>	Item	Recommended	Comments	Operating system	Windows Vista, Windows XP, Windows 7 or 8 environment	XP tablets not recommended; QDS will not work with Windows RT systems	Processor	1.3 GHZ+ , low watts		RAM	2 GB+		Hard Drive	Solid State Drive, 64GB or larger	Solid state drives are smaller and consume less power	Input	Keyboard, Touch and Stylus (if tablet) for interview. Keyboard only for abstractions		Battery	>7-8 hrs.	Can be extended by adding extra battery packs	USB Port	At least one	For adding/removing data files			
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USB Port	At least one	For adding/removing data files																										

Question	Answer		
	SD Card Slot	1	For back up if problem with USB port occurs

Topic: Performance Measurement Will the performance measurement dates be different for the project areas not currently funded for MMP?	Project areas not currently funded for MMP will have the same time period for benchmarks, but the start date of activities for the first year would be delayed based on establishment of infrastructure. Those areas would also not be expected to meet the June 15 preparation benchmarks.
Topic: Evaluation and Performance Measurement Plan Are you envisioning evaluation will be conducted using existing resources for MMP or state and local health departments or conducted using outside sources?	Additional outside resources are not required to conduct evaluation and measurement of performance for MMP. For more details on expectations, refer to page 8-10 in the FOA and a previous answer to an Evaluation and Performance Measurement Plan question on page 44.
Topic: IRB Approval Is IRB approval still applicable and appropriate for MMP in 2015? What type of guidance should we give to facilities who may have required IRBs in the past?	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. It should be determined in your local area if MMP will need to go through an IRB process. Post-Award, your CDC Project Officer can assist you with discussion with facilities who have previously required IRBs but may not for MMP 2015.
Topic: HIV Care linkage and retention What HIV Care linkage and retention activities are expected?	One of the required activities noted in the FOA is to: Facilitate access to HIV care linkage and retention services for participants. We do not expect project areas to develop their own linkage programs, but rather to closely collaborate with existing programs and resources available in each local area.
Topic: HIV Care linkage and retention Should we have an objective about what percentage of people who will be linked and reengaged in care?	Setting a percentage linked to care goal is not necessary, but if your plan is to link your participants to another program, the goals of that program would be relevant. You many want to evaluate a percentage of your participants who are referred to another program to see what

	percentage are engaged in care in order to determine whether your linkage collaborations are adequate.
Topic: Principal Investigator Are there specific qualifications preferred or needed for the Principal Investigator?	Outside of what is in the FOA, we don't have specific guidance on Principal Investigator qualifications. Roles of Principal Investigators often vary from project area to project area.
Topic: Cross-Jurisdictional data collection Are cross-jurisdictional procedures something that each project area will need to develop or is that something that will be developed by CDC?	General guidelines for cross-jurisdictional data collection were developed collaboratively by CDC MMP and NHSS staff, the HIV subcommittee of the Council of State and Territorial Epidemiologists, and case surveillance coordinators from all jurisdictions. The guidelines take as a starting point that the public health jurisdiction in which the sampled person resides may decide whether and how cross-jurisdictional data collection for MMP takes place for that sampled person. The Overall Responsible Party (ORP) from each surveillance jurisdiction in the U.S. has selected procedures for cross-jurisdictional data collection from among four options: A.) Approval for interview and medical record data collection without any notification or contact of the jurisdiction of residence B.) General approval for interview and medical record data collection without case-by-case notification in advance of recruitment. Notification should occur following recruitment as legally permissible. C.) Case-by-case notification prior to an interview and/or abstraction when it is known in advance that the person resides in this jurisdiction D.) Refusal of all CSBS cross-jurisdictional data collection. If MMP staff become aware that a sampled person resides outside of the jurisdiction of sampling, they should identify the option selected by the ORP of the jurisdiction of residence and follow the indicated procedures.
Topic: SMART Objectives Do objectives have to be SMART (Specific; Measurable; Attainable; Relevant; Time-	The FOA does not explicitly state that objectives should be SMART, although that is preferable.

Based)?	
Topic: Preparation of Standard Operating Procedures (SOP) Should we provide the SOPs we have developed or instead provide information about how SOPs were or will be developed?	One of the required strategies and activities is the development of local standard operating procedures as described on page 6. At a minimum, you should document your intention to develop these SOPs and describe your intended development process. Alternatively, if SOP drafts have already been developed, you may describe the SOPs or include the actual SOPs as space allows.
Topic: Application attachments Are appendices or attachments included in the 25-page Project Narrative limit? The list of attachments on page 31 is confusing because it includes attachments that both do and don't count toward the Project Narrative 25-page limit. Is there a difference between attachments and appendices?	There is a difference between the mandatory attachments and additional attachments. Mandatory attachments are: Project Abstract; Project Narrative; Budget Narrative; CDC Assurances and Certifications; Work Plan; and Table of Contents. The Project Narrative and Work Plan are included in the Project Narrative 25-page limit. Acceptable attachments are listed on page 30-31 of the FOA. There are no appendices.
Topic: Application attachments Where would we attach Letters of Support or MOUs? They are not included in the list of attachments?	The FOA has been amended to add Letters of Support, Memorandum of Agreement, Memorandum of Understanding, and Bona Fide Agent status documentation to the list of attachments.
Topic: Application attachments We would like to include maps in our application but don't know if they can be an attachment or would count toward the 25-page limit?	This FOA template has been designed to limit the number of additional documents. It is preferable to provide a web-link to the maps or to any additional information referenced or the additional information should be included in the Project Narrative.
Topic: Work Plan Is CDC amenable to the work plan for this FOA being submitted in a table format?	Yes
Topic: Facility Sampling Frame What role does the facility sampling frame and facility attributes play in the methodology for MMP in 2015? And, is it going to be one of the requirements that we update our facility sampling frame?	One of the required activities noted in the FOA is to: <u>Collect HIV care facility data:</u> Maintain HIV care facility sampling frame and collect data on all facilities attended by sampled persons using an electronic data collection system. Maintaining a facility sampling frame is required. This will specifically help when conducting

	interviews and trying to figure out where to do the medical record abstraction. Maintaining the list of facilities may expedite matching the name given by the interviewee to the facility where the medical record is mostly likely found. There are not currently plans to leverage that frame in a way that it would need to be carefully maintained. Some of this will be evolving as we move forward with case-surveillance-based sampling. As it seems now, there is no need to update it in the same manner as before, but it may be something that is required in the future. Current plans for 2015 data collection do not include a separate facility attributes data collection component. In the future methods may be developed to achieve a more robust facility attributes and/or provider data collection component that may rely on a facility sampling frame. The first priority, however, is to validate the individual level data collection aspects of CSBS.
Topic: Budget Do we need to submit a 5-year budget or just the budget for the first 12 months?	An itemized budget narrative should be provided for the first 12-month budget period only. The estimated budgeted amounts for each of the five years in the project period should be included on form SF-424A and included with the application.
Topic: Budget Was the budgeted amount for the CSBS pilot sites higher than MMP?	It is not possible to make a comparison between the budgets for the CSBS pilot project which was funded as a smaller supplement to MMP and MMP budgets for 2015.
Topic: Budget What did the pilot sites budget for accessing medical records and what was the range for that type of activity?	Only one CSBS pilot project area budgeted for medical record copying and based that on one major provider's rate. For reference, here is a link to a document that shows medical record charges and relevant regulations or statutes by state: http://rarehealthexchange.org/news/wp-content/uploads/2012/01/7-Obtaining-Medical-Records.pdf. Project areas should budget a small percentage for potential medical record charges.
Topic: Budget Are we allowed to budget for facility expenses?	A small percentage of your budget may include facility expenses. Since recruitment will not be done directly through facilities and facilities will not be asked to generate a patient list, we would

	not expect facility expenses at the same level as previously budgeted for MMP during the last project period.
Topic: Budget Will there be out-of-state meetings and trainings that we should include in our budgets?	Yes. For the first year please budget for 2 people to attend a 2-day Principal Investigator/Project Coordinator Meeting. Also budget for 2 people to attend a 3-day MMP Operations Training and 2 people to attend a 3-day MMP Data Management Training. All meetings and trainings will be held in Atlanta.
Topic: Medical Record Abstraction We would like clarity on the strategy for medical record abstraction. In the interview, we will be asking about the place where they got the most care. Is there an expectation that we are abstracting just one medical record or multiple medical records?	You will abstract just one medical record. And, current plans for 2015 are to no longer collect medical records on people who are not interviewed, so the FOA requires applicants to collect medical records on people who are interviewed based on their response to the question about where they went most often for care in the year prior to their last visit.
Topic: Medical Record Abstraction If someone is out of care and they need to be connected care, then obviously there would be no abstraction and the only people who would get an abstraction are those who had care?	The reason the question in the interview is asked about where did you receive the most care in the year prior to your last care visit is because we recognize there are people who have had HIV care in the past, just not very recently. For those people, a limited medical record abstraction is required. Most of the abstraction concerns care delivered in the past 2 years, but there are some core and demographic variables that are more longer term and should be captured even if it has been beyond 2 years since the person received HIV care. If the person has never been in care then a medical record abstraction is not required.
Topic: Medical Record Abstraction Did the pilot sites encounter trying to find an old medical record and having it being archived and unavailable?	CSBS pilot sites report little to no experience with archived, unavailable medical records.
Topic: Sample Draw There is wording in the FOA that makes it sound like each site would be able to decide if the site draws the sample or if CDC draws the sample. Are we supposed to say whether we want to do one or the other?	At the time of writing the FOA, it was not certain how the sample would be drawn, but it was not meant to be determined by each site. The samples for each site will be drawn at CDC. The State Numbers and SAS programs will be sent to the sites to run.
Topic: Provider Survey	One of the required activities noted in the FOA is

Do we need to address the Provider Survey and how we plan to conduct that or will that be done in collaboration with CDC?	to: <u>Support and conduct MMP provider survey activities</u>: Support and conduct MMP provider survey activities, including creating a provider sampling frame, collecting data on providers using a survey instrument, contacting non-responding providers via mail, telephone, email, or other means as appropriate to improve overall participation, managing data as needed, conducting data analysis, and disseminating data to key local and national users. The Provider Survey is not conducted in 2015. Do not budget for these activities. This is an activity conducted in collaboration with CDC. The year or years that the Provider Survey is conducted will be due to the availability of funds.
Topic: Not-in-Care Estimates Do you have any information from the CSBS pilot on how well the people who are interviewed and out of care represent the universe of people who are out of care?	The data presented from the pilot are unweighted. When weighted the response rate of those who are out of care is probably lower than among the rest of the sample. The weighting of those data will be completed prior to the launch of MMP 2015. The probabilities of non-response will be dealt with in the weighting process and representative estimates developed. One important reason to go in the direction of sampling those both in and out of care is because there is not an authoritative source for what proportion are out of care, so MMP's future data collection activity seeks to develop this estimate.
Topic: NHSS Extraction There is a mention about extracting the NHSS data? Is that the minimum data set?	One of the required activities noted in the FOA is to: <u>Extract NHSS data</u>: Extract NHSS data using CDC-supplied programs and submit to CDC via secure data transfer as needed for purposes such as creating the minimum dataset (MDS), weighting, and quality assurance. Applicants should have the ability to extract NHSS data for these purposes.
Topic: NHSS Collaboration There is mention within 2 months of ending data collection that we would have a system set up for sharing certain data with the surveillance group for updating information in eHARS?	One of the required activities noted in the FOA is to: <u>Strengthen NHSS</u>: Collaborate with local case surveillance staff to update NHSS with data obtained through MMP, including but not limited to data on residency, laboratory test results, and

	transmission risk. Support improvement in HIV-related laboratory reporting, including expanding the authority to collect all values of CD4+ T-lymphocyte tests, HIV viral load measurements, and other HIV-related laboratory tests (e.g., HIV nucleotide sequence data) as well as the complete reporting of all values to the jurisdiction; data should be uploaded into surveillance software (e.g. eHARS) and submitted to CDC via CDC-approved protocols. People are sampled out of case surveillance, therefore potentially valuable information for NHSS could be collected in MMP. More specific guidance will be provided as the project progresses, but the idea is that feeding data back into that system would be of use.
Topic: Preparation Please clarify the June 15 date listed in the preparation section of the FOA.	June 15 of each year is the date listed in the FOA as when all regulatory approvals and operating procedures should be in place for data collection
Topic: Evaluation and Performance Measurement Plan Please explain more about Evaluation and Performance Measurement that is required as part of the Project Narrative and as part of future reporting.	The applicant's Evaluation and Performance Measurement Plan should be consistent with the CDC Evaluation and Measurement Strategy section of the FOA on pages 8-11. Each project area's plan should be based on plans and procedures to conduct MMP in their local area and should describe how their work and progress on MMP will be evaluated. Then, within the first 6-months of data collection with support from their CDC Project Officer, a revised, more detailed evaluation plan must be submitted.
Topic: Number of Sites funded Is there a chance that one of the current sites will not get funded?	Funding preference will be given to those MMP project areas who have been conducting MMP for seven years or longer. It is our intent to fund at least 23 project areas. However, that is subject to the availability of funds.
Topic: Communication of MMP impact/results to providers Does the project have a way of providing updates or information that we can share with providers on the progress of MMP and impact it is having?	A good resource for information about MMP is: http://www.cdc.gov/hiv/statistics/systems/mmp/. Under the resources tab of this website are links to many recent publications using MMP data and a link to a full bibliography of MMP publications and presentations by date.

