

**Formative Research and Tool Development for the Medical
Monitoring Project: Testing Solutions for Challenges of Sampling**

Generic Information Collection Request under 0920-0840

May 28, 2013

**Supporting Statement
Part A**

CONTACT:

Stanley Wei, MD, MPH
Medical Epidemiologist, Clinical Outcomes Team
Division of HIV/AIDS Prevention
Centers for Disease Control & Prevention
1600 Clifton Rd, NE, MS E-46
Phone (404) 639-4288
Fax (404) 639-8640
Swei1@cdc.gov

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94. A. JUSTIFICATION

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96. A.1 Circumstances Making the Collection of Information Necessary

97.

98. This request is for sub-collection under a generic approval (Formative Research and Tool Development, OMB Control No. 0920-0840, expiration 2/29/2016), for a one-year project to field test solutions to implementation challenges of a new sampling methodology, Case-Surveillance-Based Sampling (CSBS) as a potential replacement for current Medical Monitoring Project (MMP) sampling methodology. MMP (OMB Control No. 0920-0740, expiration 5/31/2015), is a supplemental surveillance project designed to monitor ongoing care and treatment of HIV-infected persons. Since MMP's sampling methodology was proposed in 2004, a growing body of scientific evidence has demonstrated the ability of antiretroviral (ART) therapy to dramatically reduce the probability of HIV transmission, prompting increasing public health emphasis on treatment as prevention via early linkage to and retention in HIV care. The National HIV/AIDS Strategy lists increasing access to care as one of three strategic areas of national focus, and the Institute of Medicine (IOM) cites "delayed linkage to care for HIV [and] poor retention in care" as "among the primary challenges to optimal health outcomes for [People Living With HIV/AIDS]."

99.

100. MMP employs interviews and medical record abstraction to collect information about the ongoing care and treatment of HIV-infected persons. However, the current sampling method includes only HIV-diagnosed persons already receiving HIV medical care. Because it excludes persons not receiving HIV care, the current MMP sampling method has a limited ability to monitor delays in care entry and inform efforts to increase access to and utilization of care. Regarding MMP, the IOM recommended in a recent review of HIV data systems that "steps might be taken either to make the population more representative of the national population of people living with HIV or to include groups... who are less apt to be represented in other data systems." CSBS could potentially serve as a means for achieving this objective. However, the implementation challenges of CSBS sampling for MMP, and of recruitment of participants who are not receiving HIV medical care, who cannot be reached through a health care provider, must be worked out before

implementation across all MMP data collection sites is considered. Accordingly, the proposed formative research will explore solutions to implementation challenges associated with a new method to sample from among all HIV-diagnosed persons both receiving and not receiving care. Findings from the proposed project will guide a decision about whether to adopt CSBS sampling for MMP. This request is authorized by Title III - General Powers and Duties of the Public Health Service, Section 301 (241.)a. Research and investigations generally (**Attachment 1**).

101.

102. The current MMP study design relies on a national probability sample of persons with HIV infection, recruited from medical facilities where they are receiving HIV care, to generate nationally representative estimates of clinical outcomes and HIV-related behaviors. In 2004, comprehensive rosters of HIV-infected persons did not exist in all 50 states from which a sample could be drawn. However, it was possible to generate HIV patient lists from sampled medical facilities, so a facility-based sampling method was employed.

103.

104. The facility-based multistage cluster sampling approach employed by MMP has been successful in that it allows collection of interview and medical record data from the only national probability sample of persons living with HIV who are receiving HIV medical care. However, construction of a comprehensive list of HIV medical care facilities is expensive and time-intensive. Collecting data through facilities depends upon their voluntary participation, which has a large influence on response rates, because a facility that does not participate is, in effect, refusing participation for all of its patients. Most importantly, recruiting patients through medical facilities excludes HIV-infected persons not receiving care.

105.

106. HIV-diagnosed persons not receiving HIV medical care miss the substantial benefits of ART. Information that describes barriers to care is necessary for the development of strategies that maximize the impact of ART through improved care access and utilization. HIV-infected persons not receiving care are also more likely to transmit HIV infection than are those whose viral load is suppressed as a result of ART. Public health interventions designed to limit transmission from this subpopulation are a necessary

component of initiatives to prevent the spread of HIV. Information about care patterns is needed to guide intervention strategies and delivery of interventions where they are most needed. Changes to sampling methods for MMP that effectively include HIV-diagnosed persons receiving and not receiving care would allow for future MMP data collection that would meet these critical needs.

107.

108. As of April 2008, all 50 states, the District of Columbia, and 6 dependent areas have employed the same confidential name-based National HIV Surveillance System (NHSS; OMB Control No. 0920-0573, exp. 2/29/2016: The National HIV Surveillance System [NHSS]) to collect HIV case surveillance data. This system represents a national roster of HIV-infected persons both receiving and not receiving care, which might be used as a sampling frame for MMP.

109.

110. The experiences of two previous data collection efforts that sampled from NHSS are instructive in planning this formative research. The Never in Care (NIC) Project (OMB Control No. 0920-0748, expired 08/31/10) sampled HIV-diagnosed persons who had never received HIV care, from sampling frames derived from NHSS in five jurisdictions (Bertolli 2013), and the Not-In-Care Evaluation (NOTICE) Project, a county data collection effort, sampled HIV-diagnosed persons not receiving care from NHSS in King County, Washington (Buskin 2011, Dombrowski 2013). These projects encountered the following challenges related to sampling from NHSS that must be overcome for successful implementation:

111.

1. Misidentification of HIV-diagnosed persons as currently residing in the jurisdiction. NHSS is a data system designed to monitor HIV diagnoses, HIV disease, and mortality in funded jurisdictions. However, many HIV-diagnosed persons will subsequently migrate away from their residence at diagnosis.

112.

2. Difficulty making contact with HIV-diagnosed persons not receiving HIV medical care to recruit them. Making contact with individuals sampled from HIV case surveillance is problematic in that contact information in NHSS may be out-of-date.

113.

3. Difficulty recruiting HIV-diagnosed persons not receiving HIV medical care. Persons not receiving HIV care may be less

interested in participating in data collection activities than persons who are receiving care.

114.

115. MMP provides high-priority national indicators that must be monitored continuously for the National HIV/AIDS strategy, such as proportion of HIV-diagnosed persons receiving care for HIV and proportion of HIV-positive persons in care who are virally suppressed. Changing to a new sampling methodology before exploring how the identified challenges might be addressed could potentially interrupt monitoring of national indicators. Therefore, the objective of the proposed information collection is to test solutions to implementation challenges of CSBS in different settings with respect to sampling and recruitment. This information will be used to inform a decision about adopting CSBS methods in all MMP data collection sites.

116.

117. A.1.1 Privacy Impact Assessment

118. No information in identifiable form (IIF) will be collected for the proposed formative research. However, date of birth will be included as part of the sampling frame, which will be drawn from the NHSS database at CDC (OMB Control No. 0920-0573, exp. 2/29/2016: The National HIV Surveillance System [NHSS]). In addition, the NHSS coded identifier (STATENO) will be included in sampling frames drawn from CDC's NHSS database for the proposed formative research. Date of birth and the NHSS coded identifier are also present in the project areas' NHSS data, and will be stored, along with a survey identification number, with data collected for the proposed formative research both locally and at CDC.

119.

120. Although individuals cannot be directly or indirectly identified through the data stored at CDC, project areas do keep personal identifiers in project area NHSS databases, such as names and contact information. In the project areas, NHSS databases containing personal identifiers are maintained under strict access controls. Maintaining date of birth and the NHSS coded identifier in the sampling frames for the proposed project at CDC will allow CDC staff to inform project areas which persons have been selected to participate. Authorized project area staff will use the names and contact information in the project area NHSS database to contact and recruit sampled persons. In the project areas, data collected for the proposed research

will be stored separately from personal identifiers. Project areas will not transmit personal identifiers to CDC, nor will CDC staff have access to them.

121.

122. Retaining the NHSS coded identifier (STATENO) along with data collected for the proposed project will allow linkage between data collected for the formative research and data collected for NHSS, which is essential for accomplishing the purpose of the proposed data collection. The coded NHSS identifier will allow specified demographic and HIV-related laboratory information for sampled participants to be extracted from NHSS as is done for MMP. This minimum dataset (MDS) (**Attachments 4a-c**) will be used to compare persons recruited and not recruited for the proposed data collection and to adjust for participant nonresponse bias. As for MMP, one of the variables contained in the MDS for the proposed project is participant date of birth. Past experience with MMP has shown that date of birth is a strong predictor of non-response, and is thus essential information for non-response bias adjustment. In summary, retaining the NHSS coded identifier and date of birth with data collected for the proposed project will allow investigators to adjust for non-response bias and will allow comparisons of data collected using CSBS methods and current MMP methods. Such comparisons are necessary as part of a field test of new sampling methodology, and to inform decision-making about replacing current methods with CSBS.

123.

124. Security of data on the handheld, desktop, or laptop computers will be maintained through training, password protection, encryption, and controlling access to hardware. Data collectors will complete state-specific security and confidentiality training and sign a statement designed by each state indicating their understanding of security and confidentiality policies. Interviewers and abstractors will also receive training from CDC staff on how to protect the security and confidentiality of the information collected.

125.

126. As the information is collected, grantees will transmit data files to ICF International through the Data Coordinating Center (DCC) data portal, a secure web-based mechanism, or via the Secure Data Network (SDN) to CDC. These data transfer methodologies are compliant with the guidelines set forth in OMB memorandum M-0404 (E-Authentication Guidance for Federal Agencies) as well as

with OMB, HHS, and CDC Certification and Accreditation Guidelines outlined in NIST SP 800-37 (Guide for the Security Certification and Accreditation of Federal Information Systems). The DCC has received approval through the Information Technology Certification and Accreditation process (**Attachment 6b**).

127. A.1.1.1 Overview of the Data Collection System

128. The proposed formative research is designed to test solutions to three implementation challenges of replacing the current MMP sampling methodology with CSBS methodology. If approved, the proposed data collection will be conducted by state and local health departments. A total of five grantees (2 states and 3 separately funded metropolitan statistical areas) will be funded to conduct the formative research from among the 23 MMP grantees nationwide. Grantees will include: Los Angeles, CA; New York City, NY; San Francisco, CA; Mississippi and Washington State. The challenges and their potential solutions are as follows:

129.

1. Misidentification of HIV-diagnosed persons as currently residing in the jurisdiction. NHSS is a data system designed to monitor HIV diagnoses and HIV disease and mortality in funded jurisdictions. However, many HIV-diagnosed persons will subsequently migrate away from their residence at diagnosis. In the NOTICE project, 36% of the sample had moved out of the jurisdiction by the time that they were sampled (Buskin 2011). Such cases potentially make CSBS methods inefficient because they are ineligible for participation in data collection. For the proposed formative research project, we will explore two solutions to this problem. First, we will develop an algorithm to identify persons diagnosed in the five participating jurisdictions whose most recently recorded residential location indicates that they live in one of the five participating jurisdictions. Second, we will apply this algorithm to aggregated data from all 56 NHSS jurisdictions across the United States. Preliminary analyses suggest that constructing project area sampling frames with use of data aggregated from all NHSS jurisdictions, rather than using the individual project areas' surveillance data, would identify 10% of persons in project area datasets as ineligible because they had moved, reducing wasted effort.

130.

131. To assess the effectiveness of this solution, we will estimate the proportion of persons included on sampling

frames drawn from project area surveillance databases who would have been excluded as ineligible (because of residence outside the jurisdiction) if the sampling frames had been drawn for the project areas from aggregated NHSS data. This evaluation will involve constructing sampling frames from individual project area surveillance databases for comparison with frames constructed for those areas from aggregated NHSS data.

132.

133.

134. 2. Difficulty making contact with HIV-diagnosed persons not receiving HIV medical care to recruit them. Making contact with individuals sampled from HIV case surveillance is problematic in that contact information in NHSS may be out-of-date. Investigators for the NIC project found that 68% of persons they attempted to contact could not be reached. For the proposed project, we will develop a search algorithm to query other databases to obtain contact information for persons sampled. Such databases include health department surveillance and intervention databases for other diseases such as tuberculosis or sexually-transmitted diseases, electronic medical record systems to which health departments have access, as well the Social Security Death Index. A model algorithm will be developed at CDC, and project areas will adapt the algorithm based on the local data sources they are authorized to consult. Data from other data sources consulted will not be transferred to CDC, nor will CDC staff have access to it.

135.

136. 3. Difficulty recruiting HIV-diagnosed persons not receiving HIV medical care. Persons not receiving HIV care may be less interested in participating in data collection activities than persons who are receiving care. In the NIC project, 29% of persons reached by study staff refused participation in the interview. In the proposed project, we will employ recruitment scripts developed in collaboration with our community advisory board, which is composed of persons living with HIV infection. We will also explore measures that maximize participant convenience such as evening and weekend availability as well as telephone in addition to in-person interviews.

137.

138. A central objective of the proposed formative research is to explore the feasibility of expanding the MMP target population to persons diagnosed with HIV who are not receiving care. In addition to maximizing the proportion of persons in

this group who agree to participate, we will explore increasing the effective sample size for this group by oversampling recently diagnosed persons. Oversampling the recently diagnosed has the potential to enrich the sample with persons not receiving medical care as the proportion of persons not receiving HIV care is higher among those diagnosed in the past 12 months than among those more remotely diagnosed. We will evaluate whether oversampling had an effect on the overall proportion of participants not receiving medical care by comparing the distribution of persons not receiving care among those diagnosed within 12 months of the sampling date with the distribution among those diagnosed more than 12 months from the sampling date.

139.

140. Because the project is intended to test solutions to implementation challenges of a new sampling method for MMP, so that a decision can be made about adopting the new method for future MMP cycles, data collection activities for the formative research must closely parallel the standard MMP data collection. Information from MMP is collected to inform care and prevention efforts by 1) providing information about the characteristics, behaviors, and needs of persons living with HIV, 2) providing information on the clinical status and medical care and treatment of persons with HIV, and 3) comparing the characteristics of persons who did and did not participate to facilitate non-response bias analysis and make inference to the population of persons living with HIV in the United States. Like MMP, the data collection for the proposed project will have three components: interview, medical record abstraction (**Attachments 2a, 2b, and 3a-3d**), and extraction of data from case records of the National HIV Surveillance System. Trained health department personnel will invite each selected person to participate in a 45-minute face-to-face or telephone interview. Additional clinical information will be abstracted from patient medical records.

141.

142. As for MMP, demographic and HIV-related laboratory information for sampled participants will also be extracted from an existing HIV case surveillance database, the National HIV Surveillance System (OMB Control No. 0920-0573, exp. 2/29/2016: The National HIV Surveillance System [NHSS]). This minimum dataset (MDS) (**Attachments 4a-c**) will be used to adjust for participant nonresponse bias and improve the ability to monitor ongoing care and treatment

of HIV-infected persons.

143.

144. Because the proposed project is intended to field test solutions to challenges for a new sampling method for MMP, information will also be collected regarding the performance of solutions tested. Data on the disposition of sampled persons are routinely collected for MMP through the Data Coordinating Center (DCC), which is contracted by CDC to facilitate secure data transfer from project areas to CDC. In order to assess the degree to which misidentification of HIV-diagnosed persons as currently residing in the jurisdiction is a problem we will calculate the proportion of sampled persons who are dispositioned as ineligible due to residence out of jurisdiction on the sampling date.

145.

146. In addition to data routinely collected from participants for MMP, two other types of process data will be collected in order to evaluate the effectiveness of solutions tested in the proposed formative research. First, a process documentation form will be used by project area staff to record whether or not sampled persons were successfully recruited and what methods were used to recruit them (**Attachment 5a**). The information will be used to identify the best means of obtaining usable contact information for sampled persons, and the most successful methods for contacting and recruiting participants. This process information will be used along with other data collected to assess the representativeness of participants compared with the sampling frame. Second, a contact attempt tracking database will be used by project area staff to log the time, date, method, and outcome of recruitment attempts (**Attachment 5b**). These data will be used to evaluate the most effective times and days of the week to recruit participants as well as the most effective methods (phone, letter, etc.). Neither of these forms of process data collection will involve collection of data from the public.

147.

148. Project staff will collect interview, medical record, and National HIV Surveillance System extracts using a software application loaded onto laptop, tablet, or desktop computers. All data will be encrypted and computers used for data collection will be password protected so that unauthorized users will be unable to view, export or modify collected data. Electronic data collected for the proposed formative research will be maintained indefinitely at CDC.

149.

150. A.1.1.2 Items of Information to be collected

151. As for MMP, the interview for the proposed formative research will collect data from sampled HIV-infected adults on demographic characteristics, access to and utilization of health care, stigma and discrimination, adherence to antiretroviral therapy, HIV testing, sexual behavior, drug and alcohol use, unmet needs for services, depression and anxiety, access to HIV prevention services, gynecological and reproductive history, health conditions and preventive therapy, and acculturation (**Attachments 2a and 2b**). A section was added to the approved MMP standard questionnaire, to be used to interview respondents who are not in care. Most questions in this section were taken from the standard questionnaire and modified to make them appropriate for respondents who are not in care; some new questions were added, many of which were adapted from a previously approved data collection, Surveillance of HIV-Related Events Among Persons Not Receiving HIV Care, OMB Control No. 0920-0748, exp. 8/31/2010.

152.

153. Like the medical record abstraction for MMP, the medical record abstraction for the proposed formative research will collect data from medical records on demographic characteristics, opportunistic illnesses, antiretroviral and other prescribed medications, laboratory test results, receipt of risk reduction counseling and referral, and other clinical diagnoses (**Attachments 3a, 3b, 3c, and 3d**).

154.

155. The Minimum Dataset for the proposed project will consist of data extracted from the HIV/AIDS Reporting System [HARS] (OMB Control No. 0920-0573, exp. 2/29/2016: The National HIV Surveillance System [NHSS]) including demographics, HIV diagnosis date, and HIV-related laboratory tests (**Attachments 4a-c**) on all sampled persons (both responders and non-responders). It is important to determine the characteristics of persons who did not participate in order to assess non-response bias. Past experience with MMP has shown that date of birth is a strong predictor of non-response, making date of birth necessary for non-response bias adjustment. Date of birth, extracted from the NHSS database, is the only information in identifiable form that will be maintained with data collected for the proposed formative research. Indirect

identification of individuals through the data will not be possible.

156.

157. A process documentation form will be used by project staff to record how they went about locating and recruiting sampled persons. Items include the sources of information used to locate sampled persons and whether or not those sources were useful (**Attachment 5a**). These data will be collected from project staff about their work process and not from the public.

158.

159. The NHSS coded identifier (STATENO) will also be collected. This identifier will be used to communicate to project areas which people have been sampled from the NHSS dataset maintained at CDC as CDC does not and will not have access to any personally identifying information associated with these persons. Project areas will then access the names and contact information for sampled persons, which are collected in their local NHSS databases under strict access controls, and use this information to contact and recruit sampled persons.

160.

161. Data collected through the proposed project will be stored and accessed by the NHSS coded identifier and a survey identification number, both locally and at CDC. Data will not be collected on paper forms.

162.

163. A.1.5 Identification of Websites and Website Content Directed at Children Under 13 Years of Age

164.

165. This information collection does not involve websites or website content directed at children less than 13 years of age.

166.

167. A.2. Purpose and Use of Information Collection

168.

169. The purpose of this sub-collection is to test solutions to implementation challenges associated with a new sampling method for a currently approved data collection, MMP, to assess their feasibility as a replacement for current MMP sampling methods. This information will be used to determine whether replacing current MMP methods with CSBS methods is feasible.

170.

171. Replacing current MMP methods with CSBS methods has the potential to expand the covered population of MMP from

HIV-diagnosed persons in care to all HIV-diagnosed persons. However, implementing the proposed sampling methodology will also require development of new procedures for contacting and recruiting HIV-diagnosed persons not receiving care. Standard MMP selects participants through medical facilities and often relies upon the patient-provider relationship to facilitate enrollment. In contrast, the proposed data collection will require project area staff to directly contact sampled persons.

172.

173. A.3. Use of Improved Information Technology and Burden Reduction

174.

175. Interview and medical record abstraction data will be collected on password-protected encrypted handheld and laptop computers using the Questionnaire Development Software (QDS), NOVA Research Company, Bethesda, Maryland for interviews and CDC-developed software for abstractions. Provision of electronic data collection software will help to reduce the burden of data collection on grantees conducting the proposed data collection. The use of an electronic questionnaire may reduce the burden on respondents by improving comprehension and reducing the amount of time needed to complete the survey, as compared with a paper-administered survey.

176.

177. Provision of electronic data collection hardware and software, training and technical assistance will help to reduce the burden on grantees implementing the proposed formative research. Transfer of data collected electronically will eliminate the need for data entry at the state/local sites. An evaluation of supplemental surveillance data using electronic data collection has shown the following: a reduction in the duration of the interview by up to 20%; a decrease in the average number of interviewer errors per interview such as skip patterns, out of range answers and missing data from an average of 2.5 per interview to .3 per interview; and the elimination of the need for data cleaning associated with data entry and the errors listed above, resulting in a reduction in the time between the last interview and the production of a final analysis dataset from approximately 6 months to only 1 month.

178.

179. CDC Division of HIV/AIDS Prevention, (DHAP) has implemented the use of handheld and laptop devices for

other national surveillance systems. All state and local health departments participating in the proposed data collection are licensed to use the software and have extensive experience with implementing interview projects using electronic data collection in the field.

180.

181. The purpose of the Data Coordinating Center (DCC), managed by ICF International through a contract with CDC, is to implement a data management system (DMS) to provide participating project areas with a secure web-based data portal system through which project areas can easily submit data to CDC, revise submitted data sets, and receive final data from CDC. The system also allows the project areas and CDC staff to track critical respondent and medical record abstraction (MRA) activities. The system incorporates a secure web-based interface that allows CDC and project area staff to easily submit data, track project area activities, retrieve data sets and reports. This will help reduce project management burden at the project area and streamline the data collection and management process.

182.

183. A.4. Efforts to Identify Duplication and Use of Similar Information

184.

185. The proposed sub-collection is designed for a very specific purpose, i.e. to test solutions to implementation challenges associated with a new sampling method for a currently approved data collection, MMP, to assess their feasibility as a replacement for current MMP sampling methods. There are no other federal information collections that duplicate the specific formative research described in this request.

186.

187. A.5. Impact on Small Businesses and Other Small Entities

188.

189. Patients who attend small medical facilities that provide HIV care have a chance of being selected for the proposed project, and in those cases, small medical facilities may be asked to provide medical records. In some cases, facilities may be asked to look up contact information for patients or, less commonly, to make the first contact with patients. These types of facility participation are voluntary. On average, it is estimated that looking up contact information will take 2 minutes per patient and making first contact with patients will take an

average of 5 minutes per patient. Project staff will request the medical records of sampled patients who give their permission to have medical records reviewed. It is estimated to take an average of 3 minutes to pull each medical record for data abstraction.

190.

191. A.6. Consequences of Collecting the Information Less Frequently

192.

193. The proposed project involves a one-time data collection. There are no legal obstacles to reducing burden.

194.

195. A.7. Special Circumstances Relating to Guidelines of 5 CFR 1320.5

196.

197. This request fully complies with the regulation 5 CFR 1320.5.

198.

199. A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agencies

200.

201. For sub-collection requests under a generic approval, Federal Register Notices are not required and none were published.

202.

203. A.9. Explanation of Any Payment or Gift to Respondents

204.

205. Participants will be given approximately \$25 in cash as a token of appreciation for participation; the specific amount will be determined by grantees based on local standards. If local regulations prohibit cash tokens of appreciation, equivalent tokens of appreciation may be offered in the form of gift certificates, cash cards, or bus or subway tokens.

206.

207. In his memorandum for the president's management council dated January 20, 2006, the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget wrote, "Incentives are most appropriately used in Federal statistical surveys with hard-to-find populations or respondents whose failure to participate would jeopardize the quality of the survey data (e.g., in panel surveys experiencing high attrition), or in studies that impose exceptional burden on respondents, such as those asking highly sensitive questions..."

208.

209. The use of tokens of appreciation in the proposed formative research is appropriate according to this guidance. The primary goal of the project is to investigate solutions to challenges associated with a new method of sampling and enrolling a hard-to-find population, i.e. HIV-positive persons who have either never been linked to HIV care or who have fallen out of care. Many of these people will have characteristics that make them more difficult to enroll such as unstable housing, substance abuse, and poverty. The survey instrument also contains highly sensitive questions regarding sexual history, experience of stigma and discrimination, and income. Providing incentives to respondents will be critical to achieving acceptable response rates in this hard-to-find population as demonstrated in the survey literature (Kulka 1995). A central objective of the proposed data collection is to explore the recruitment implications of solutions for recruitment challenges associated with a new sampling method for MMP. Tokens of appreciation are currently offered for participation in MMP--therefore, not offering tokens of appreciation for participation in the proposed project would bias the comparison of response rates achieved with the methods tested through the proposed formative research against response rates with current MMP methods.

210.

211. The need for and amount of the remuneration is based, in part, on the fact that other, similar research projects that ask HIV risk behavior questions in many of the participating areas offer similar tokens of appreciation. Thus, the proposed project would be competing with local researchers who do offer remuneration. Persons at risk for HIV infection have frequently been the focus of health-related data collections, in which remuneration is the norm (Thiede 2009; MacKellar 2005). Research has shown that financial incentives are effective at increasing response rates among female residents in minority zip codes (Whiteman 2003). A meta-analysis of 95 studies published between January 1999 and April 2005 describing methods of increasing minority enrollment and retention in research studies found that incentives enhanced retention among this group (Yancey 2006). Data from MMP's 2007 cycle indicate that 65% of respondents reported a race or ethnicity other than non-Hispanic white. Providing remuneration to respondents is critical to achieve acceptable response

rates.

212.

213. Remuneration has been used in other HIV-related CDC data collection efforts such as for National HIV Behavioral Surveillance (OMB 0920-0770, exp. 5/31/2014) and the Transgender HIV Behavioral Survey (OMB 0920-0794, exp. 12/31/2010), both of which ask questions similar to those included in the proposed formative research and have a similar length of time for completing the patient interview. In both of these other projects tokens of appreciation were used to help increase participation rates; participants were offered approximately \$25 as a token of appreciation. Other studies have also found that incentives modestly improve response rates (Shaw et al. 2001).

214.

215.

216. A.10.Assurances of Confidentiality Provided to Respondents

217.

218. The proposed data collection will be anonymous (neither names nor social security numbers are collected). As is done for MMP (OMB Control No. 0920-0740, expiration 5/31/2015), previously collected date of birth will be extracted from NHSS (OMB Control No. 0920-0573, exp. 2/29/2016: The National HIV Surveillance System [NHSS]) as part of the minimum dataset (MDS) for the proposed project. Date of birth has been shown in MMP to be a strong predictor of non-response, and it will be used to adjust for non-response bias as is done for MMP.

219.

220. The NHSS coded identifier (STATENO) will be extracted from NHSS and maintained with data collected for the proposed project. This identifier can be used by authorized project area staff to link to locally maintained NHSS data containing personal identifiers, which will be used to recruit participants. CDC will not receive or have access to personal identifiers. Data collected in the project areas for the proposed formative research will be stored separately from personal identifiers.

221.

222. Sensitive information collected through the proposed formative research will not be linked to any other personally identifiable information and cannot be used to reveal the identity of any one person. The proposed data collection will have little or no effect on the

respondent's privacy. No information that could directly identify an individual will be collected as part of the interview, medical record abstraction, or minimum dataset.

223.

224. The proposed data collection is covered by an Assurance of Confidentiality for HIV/AIDS surveillance data (**Attachment 6a**). The Assurance provides the highest level of legal confidentiality protection to the individual persons who are the subjects of this data collection, and to the individuals and organizations responsible for data collection. The terms of the Assurance of Confidentiality reflect the collective experience of CDC, health departments, and the Council of State and Territorial Epidemiologists with respect to the collection, electronic transmission, and dissemination of HIV/AIDS surveillance data. The Assurance includes established policies and procedures governing all aspects of data collection and de-identification, physical security for paper forms and records, electronic data storage and transmission, and the release of aggregate data in forms that cannot be linked back to individual respondents. The protections afforded by the Assurance of Confidentiality last forever, and endure even after the respondent's death.

225.

226. Privacy Impact Assessment

227.

228. The interview will be conducted by trained staff in a private location where the questions and responses cannot be overheard by others. Interview and abstraction data will be transmitted to CDC via the secure system described above known as the Data Coordinating Center (DCC) or the CDC Secure Data Network (SDN). Encryption security for all project data must meet the current National Institute of Standards and Technology (NIST) Federal Information Processing Standards (FIPS), which meet or exceed Advanced Encryption Standards (AES). See the document "Technical Guidance for HIV/AIDS surveillance Programs, Volume III: Security and Confidentiality Guidelines" for further information (www.cdc.gov/hiv/surveillance.htm).

229.

230. A number of required protections ensure the security of the data on the data collection computers. The tablet computers and laptop computers will be solely used for the proposed data collection activities. The data will be encrypted when stored on a tablet device or laptop. Computers will be protected by using a coded password only

known by authorized project staff. The data will be deleted from the laptop computers after they are uploaded to the main secured database. The tablet and laptop computers must be kept with the staff at all times in the field; the computers will be collected and secured by the field supervisor after return to the local project office. When not in use in the field, the computers are to be locked in a drawer or an office.

231.

232. The Assurance of Confidentiality will be enforced with appropriate training and contractual agreements which clarify the responsibilities of all participants in HIV/AIDS surveillance activities who have access to directly identifiable data or to data that are potentially identifiable through indirect means. State and local health department personnel who conduct HIV/AIDS surveillance will be subject to the confidentiality obligations described in the CDC guidelines for the security and confidentiality of National HIV Surveillance System data (<http://www.cdc.gov/hiv/topics/surveillance/index.htm>) and will be required to undergo security and confidentiality training.

233.

234. Data collectors and data managers will undergo annual security and confidentiality training consistent with the guidelines set forth in the document "Technical Guidance for HIV/AIDS surveillance Programs, Volume III: Security and Confidentiality Guidelines" (www.cdc.gov/hiv/surveillance.htm). CDC's Procurement and Grants Office will require the inclusion of 308(d) clauses in any HIV/AIDS support services work done by contractors (e.g., data analysis, computer programming, LAN support). All CDC permanent employees and their contractors will be required to attend annual confidentiality training, to sign a Nondisclosure Agreement (**Attachment 8**), and to update their confidentiality agreements on an annual basis. Contractors must sign a "Contractor's Pledge of Confidentiality." Access to HIV/AIDS surveillance data maintained at CDC is restricted to authorized personnel who have signed the "Agreement to Abide by Restrictions on Release of Data." CDC-funded cooperative agreements with state and local health departments reference the Assurance of Confidentiality as a condition of award. Any project data maintained at CDC that are released to persons other than project staff will not include full date of birth.

235.

236. Informed consent will be obtained from all respondents prior to the interview. The informed consent process for respondents will be fulfilled by obtaining a consent document signed by the respondent, or by having the interviewer sign a consent document attesting to the respondent's verbal consent. All sites must obtain consent from respondents and store the consent forms in a secure location. Respondents will be informed that data collected from them for the proposed project will be kept private and secure and that the data will be reported in aggregate format.

237.

238.

239.

240. A.11. Justification for Sensitive Questions

241.

242. HIV can be transmitted from person to person through sexual contact and the sharing of HIV contaminated needles and syringes. In addition, HIV-infected persons with higher HIV viral loads may be at increased risk of transmitting the virus to others. These modes of transmission necessitate the collection of sensitive data regarding HIV/AIDS status, medical history, sexual orientation, sexual practices, and alcohol and drug use, which MMP has been approved to collect. Accordingly, the proposed project will also collect these data. As with MMP's data collection, this formative research data collection will request sensitive information relating to race/ethnicity, alcohol and drug use, mental health conditions such as depression and psychosis, history of suicide attempt, and history of arrest. Although the information requested is highly sensitive, the purposes of the project cannot be accomplished without their collection. Participants will be told that they may decline to participate without penalty or, if they agree to participate, they may refuse to answer any question. They will also be informed that only aggregated data may be released in published reports.

243.

244. The proposed formative research is intended to provide an evaluation of solutions to the challenges of implementing MMP under different sampling conditions. Therefore, it is necessary for the interview to be largely unchanged from the standard version.

245.

246. The context in which questions are asked helps to overcome their potential sensitivity. Steps taken in this

project to minimize sensitivity and reiterate to the respondent the legitimate need for the information will include:

247.

248. • Nearly all questions allow for responses of "don't know" or "refuse to answer."

249. • Consent scripts make it clear that the survey is sponsored by CDC and the local health department and that the information will be put to important uses.

250. • Toll-free phone numbers are provided if the respondent has questions about the survey.

251. • The questionnaire is carefully organized to lead smoothly from one topic to another. Transitions are made clear to respondents and the need for the information explained. Assurances about the privacy and confidentiality of the data are reiterated.

252. • The use of encrypted, password-protected computers for data collection addresses concerns the respondent might have about privacy (that others can see their answers).

253. • The token of appreciation indicates clearly to the respondent that the information is important to the survey sponsors.

254.

255. All in-person interviews will be conducted by trained staff in a private location, either as part of a routine visit to a medical facility or by an interview in the patient's home, in a hospital or clinic, or other mutually agreed-upon location. Telephone interviews will be administered in a private location that ensures the confidentiality of responses. Interviewers will be trained to administer the consent script and all interview questions by reading each item verbatim, thus ensuring that all respondents receive the same information from the consent process and are asked the same questions. No interviews will be conducted without the consent of the respondent.

256.

257. Social security numbers will not be collected from respondents.

258.

259. No data will be collected from agencies regarding their policies, performance data or other practices.

260.

261. **A.12.Estimates of Annualized Burden Hours and Costs**

262.

263. A.12.A. Estimated Annualized Burden Hours

264.

265. The annualized response burden for this sub-collection is estimated to be 983 hours; details are provided in exhibit A.12.A. An estimated total of 1,500 persons will be sampled in the 5 participating project areas. CDC's current goal is to interview 80% or 1200 persons. Interview participation is expected to take an average of 45 minutes (Attachments 2a and 2b). Thus, the total annual burden for the patient interview is 900 hours.

266.

267. Project areas will sample, locate, recruit, interview, and conduct medical chart abstraction. Some facilities may be asked to look up patients' contact information and contact selected patients. It is estimated that for 20% or 300 sampled persons a request will be made of facility staff to look up contact information for sampled persons; this process is estimated to take 2 minutes per patient, for a total of 10 hours. There is no data collection and therefore no form associated with this activity. It is estimated that 10% or 150 sampled persons will be approached by facility staff to participate in the project; this process is estimated to take 5 minutes per patient, for a total of 13 hours. There is no data collection and therefore no form associated with contacting patients. Facility staff will use the recruitment script included as Attachment 7 to approach sampled persons.

268.

269. Facility staff will pull each of 1200 medical records only once for each record abstraction. The estimated time to pull a medical record is 3 minutes, for a total of 60 hours. There is no form associated with pulling medical records. The forms included in **Attachments 3a, 3b, 3c, and 3d** are to be used to abstract data from medical records for the proposed formative research. Medical record abstraction will be conducted by CDC-funded staff and not by medical facility staff. No burden is associated with this task, therefore, it is not reflected in the burden table, nor has Worksheet 2 been completed for **Attachments 3a-3d**. The medical record abstraction process and burden documentation described for the proposed formative research are identical to those described in the approved ICR submission for MMP (OMB Control No. 0920-0740, expiration 5/31/2015).

270.

271. Exhibit A.12.A Annualized Burden Hours

272. Type of Respondent	273. Form Name	274. Number of Respondents 275. Number of Respondents 276. Respondents	277. Number of Responses per Respondent 278. Number of Responses per Respondent 279. Responses per Respondent 280. Respondent	281. Average Hours per Response 282. Average Hours per Response 283. Per Response	284. Total Response Burden (Hours) 285. Total Response Burden (Hours) 286. Burden (Hours) 287. (Hours)
288. Sampled, Eligible HIV-Infected Patients	289. Interview Questionnaire 290.	291. 1200	292. 1	293. 45/60	294. 900
295. Facility office staff looking up contact information	296. N/A 297.	298. 300	299. 1	300. 2/60	301. 10
302. Facility office staff approaching sampled persons for enrollment	303. N/A 304.	305. 150	306. 1	307. 5/60	308. 13
309. Facility office staff pulling medical records	310. N/A	311. 1200	312. 1	313. 3/60	314. 60
315. Total	316.	317.	318.	319.	320. 983

321.

322. A.12.B. Estimated Annualized Costs

323. The annualized cost to respondents for the burden hours is estimated to be **\$19,937**; details are provided in Exhibit A.12.B. The estimates of hourly wages were obtained from the Department of labor (Bureau of Labor Statistics Wage Data (<http://www.bls.gov/news.release/pdf/ecec.pdf>)).

324. Exhibit A.12.B. Annualized Cost to Respondents

325.

326. Act ivity	327. To tal Burden Hours	328. Hourly Wage Rate	329. T otal Respon dent Cost
330. Sam pled persons completi ng intervie w	331. 900	332. \$20.14	333. \$ 18,126
334. Fac ility office staff looking up contact informat ion	335. 10	336. \$21.82	337. \$ 218
338. Fac ility office staff pulling medical records	339. 60	340. \$21.82	341. \$ 1309
342. Fac ility office staff approach ing sampled patients for recruitm ent	343. 13	344. \$21.82	345. \$ 284
346. Tot al	347. 983	348.	349. \$ 19,937

350.

351.

352. A.13.Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

353. There are no other costs to respondents or record keepers.

354.

355. A.14.Annualized Costs to the Federal Government

356.

357. The annualized cost of this project is estimated to be \$1,562,733.

358.

359.

360. Expense Type	361. Expense Explanation	362. 363. Annual Costs (dollars)
364. Direct Costs to the Federal Government	365. MMP - Personnel 366. Epidemiologist-14 1 80% \$86,216 367. Epidemiologist-14 3 10% \$32,331 368. Epidemiologist-13 1 10% \$9,120 369. ORISE Fellows 2 100% \$155,792 370. Data Managers 2 100% \$160,000 371. 372.	373. \$443,459
374.	375. Cooperative agreement funds to project areas	376. \$969,374
377. Contractor and other Expenses	378. Contracted Questionnaire Programming (2) 0.25 FTE	379. \$30,000
380.	381. Data Coordinating Center (CDC Contractor for data collection)10%	382. \$110,000
383.	384. Travel	385. \$7,500
386.	387. Meetings and Trainings	388. \$1,000

389.	390. Spanish Language Translation	391.	\$900
392.	393. Printing	394.	\$500
395.	396. TOTAL COST TO THE GOVERNMENT	397.	\$1,562,733

398.

399.

400. The personnel hired specifically to conduct the proposed data collection include 2 ORISE Fellows and 2 data managers. Travel is related to providing technical assistance and conducting site visits.

401.

402. The information collection described in this request will be funded through cooperative agreements with state and local health departments (CDC surveillance activities are routinely funded through cooperative agreements with state and local health departments).

403.

404.

405. A.15.Explanation for Program Changes or Adjustments

406. Not applicable - request is for a sub-collection under a generic approval.

407.

408. A.16.Plans for Tabulation and Publication and Project Time Schedule

409. All data collection will be completed during the 12 month period after OMB approval. Data analysis will occur within 18 months of OMB approval. The following is a brief overview of the project timeline.

410.

411. Exhibit 16.A Project Time Schedule

412.

413. 414. Activity	415. 416. Time Schedule
417. Case-based sampling begins (2013 cycle)	418. Immediately after OMB approval
419. Sampled cases interviewed	420. 1-11 months after OMB approval
421. Abstract medical records of sampled cases	422. 3-12 months after OMB approval
423. Data management	424. 1-12 months after OMB approval
425. Data collection ends	426. 12 months after OMB approval

413.		415.	
414. Activity		416. Time Schedule	
427. Evaluation of collected data		428. 13-14 months after OMB approval	
429. Analysis of collected data		430. 15-18 months after OMB approval	
431. Publication		432. 18 months after OMB approval	

433.

434.

435. A.17.Reason(s) Display of OMB Expiration Date is Inappropriate

436.

437. The OMB Expiration Date will be displayed. No exception is requested.

438.

439. A.18.Exceptions to Certification for Paperwork Reduction Act Submissions

440. There are no exceptions to the certification.

441.

442.

443.

444. References

445.

446.

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- 477.