Formative Research and Tool Development for the Medical Monitoring Project: Case-Surveillance-Based Sampling as an Alternate Sampling Method to Include HIV-Diagnosed People Both Receiving and Not Receiving HIV Care

Generic Information Collection Request under 0920-0840

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Supporting Statement
Part A

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A. JUSTIFICATION

A.1 Circumstances Making the Collection of Information Necessary

104.

105. This request is for sub-collection under a generic approval (Formative Research and Tool Development, OMB Control No. 0920-0840), for a one-year pilot project to identify the challenges of implementing 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]."

106.

107. MMP (OMB Control No. 0920-0740, expiration 5/31/2015), 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." Accordingly, the CSBS pilot will explore 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 1a**).

108.

109. 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.

110.

111. 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.

112.

113. 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.

114.

115. 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 (OMB Control No. 0920-0573, exp. 1/31/2013: Adult and Pediatric Confidential HIV/AIDS Case Reports) 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.

116.

117. However, the logistics of CSBS sampling for MMP, and of recruitment of participants who are not receiving HIV medical care—and therefore cannot be recruited through a medical facility—must be worked out before implementation across all MMP data collection sites is considered. 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 it is tested would potentially interrupt monitoring of national indicators. Therefore, it is necessary to evaluate CSBS through a pilot project. The objectives of the proposed project are to: 1) identify challenges of CSBS implementation in different settings with respect to sampling and recruitment; and 2) field test a new section of the MMP questionnaire that is applicable to persons not receiving care. This information will be used to determine whether replacing current MMP methods with CSBS pilot methods appears to be feasible for MMP, and if so, whether any additional formative research is needed before CSBS methods are implemented in all MMP data collection sites.

118.

119. A.1.1 Privacy Impact Assessment

120. The only information in identifiable form (IIF) collected for the CSBS pilot project is date of birth. Date of birth is being collected to determine eligibility for CSBS data collection, which is limited to persons over age 18 years. In addition, date of birth is collected for quality control purposes. Date of birth for sampled participants will be compared across CSBS interview, abstraction and minimum dataset to ensure that information is collected on the correct person and that duplicate information is not collected.

121.

122. 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. The data transfer methodology is compliant with the guidelines set forth in OMB memorandum M-0404 (E-Authentication Guidance for Federal Agencies) as well as with OMB, HHS, and

CDC 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**).

123. A.1.1.1 Overview of the Data Collection System

124. The proposed pilot project is designed to evaluate the challenges, in different settings, of replacing the current MMP sampling methodology with CSBS methodology. The CSBS pilot 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 pilot from among the 23 MMP grantees nationwide. CSBS pilot grantees include: Los Angeles, CA; New York City, NY; San Francisco, CA; Mississippi and Washington State. Because the pilot project is intended to assess the feasibility of changing MMP's sampling method and of recruiting subjects outside of medical facilities, data collection activities for the pilot must closely parallel the standard MMP data collection. Like MMP, the CSBS data collection will have three components: interview, medical record abstraction (**Attachments 2 and 3a-3d**), and extraction of data from case records of the National HIV Surveillance System. Trained health department personnel 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.

125.

126. As for MMP, demographic and HIV-related laboratory information on sampled participants will also be extracted from an existing HIV case surveillance database, the National HIV Surveillance System (OMB Control No. 0920-0573, Exp. 1/31/2013: Adult and Pediatric Confidential HIV/AIDS Case Reports for National HIV/AIDS Surveillance). This minimum dataset (MDS) (**Attachments 4a-c**) will be used to adjust for participant nonresponse bias and improve the ability of CSBS to monitor ongoing care and treatment of HIV-infected persons.

127.

128. In addition to data routinely collected for MMP from participants, 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 5**). The information will be used to identify the best means of obtaining usable contact information for sampling 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 in the pilot compared with the sampling frame.

129.

130. When collecting interview, medical record, and National HIV Surveillance System extracts, CSBS staff will collect the data 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 CSBS pilot project will be maintained indefinitely at CDC.

131.

132. A.1.1.2 Items of Information to be collected

133. The CSBS interview 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 (**Attachment 2**). 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, OMB Control No. 0920-0748, exp. 8/31/2010.

134.

135.

136. Like the medical record abstraction for MMP, the CSBS medical record abstraction 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**).

137.

138. The CSBS Minimum Dataset will consist of data extracted from the HIV/AIDS Reporting System [HARS] (OMB Control No. 0920-0573, Exp. 1/31/2013: Adult and Pediatric Confidential HIV/AIDS Case Reports for National HIV/AIDS Surveillance)

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 and make inference to the national population of HIV-diagnosed persons.

139.

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

141.

142.

143. The only information in identifiable form collected is date of birth, which is collected through interview, medical record abstraction, and minimum dataset. Date of birth is collected by CSBS for two reasons. First, it is used to ensure that participants meet the age eligibility criteria for participation in the survey. Second, it is used to identify potential duplicate records or participants who have participated more than once per cycle. Date of birth is sent to CDC, but is not shared beyond the CDC team conducting the data collection (i.e., it is not included in analysis datasets). No other information in identifiable form (IIF) will be collected during the CSBS interview. Individuals cannot be indirectly identified through CSBS data.

144.

145. Data collected through CSBS will be stored and accessed by a survey identification number, both locally and at CDC. Data will not be collected on paper forms.

146.

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

148.

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

150.

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

152.

153. The purpose of this sub-collection is to pilot new methods for a currently approved data collection, MMP, to

assess feasibility and identify associated challenges, and to field test new questionnaire items related to targeting a new subpopulation. This information will be used to determine whether replacing current MMP methods with CSBS pilot methods is feasible, and if so, whether any additional formative research is needed before CSBS methods are implemented in all MMP data collection sites.

154.

155. 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, this pilot will require project area staff to directly contact sampled persons.

156. The HIV/AIDS epidemic in the United States is more than three decades old and life expectancies for HIV patients on anti-retroviral therapy are approaching those in the general population. As a result, the current MMP sampling methodology results in the preponderance of sampled individuals having lived with HIV ≥ 5 years. However, in order to better understand the process of linkage to HIV care, it is desirable to have a sample of more recently diagnosed persons. Therefore, this pilot will also test a stratified sampling methodology that oversamples the recently diagnosed population. Lessons learned from this pilot will inform the future direction of MMP.

157.

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

159.

160. 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 CSBS. 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.

161.

Provision of electronic data collection hardware and software, training and technical assistance will help to reduce the burden on grantees conducting CSBS. 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.

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 CSBS are licensed to use the software and have extensive experience with implementing interview projects using electronic data collection in the field.

The purpose of the Data Coordinating Center (DCC), managed by ICF International through a contract with CDC, is to implement a data management system (DMS) to provide CSBS 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 also 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 streamlines the data collection and management process.

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

The proposed sub-collection is designed for a very specific purpose, i.e. to pilot new methods for a currently approved data collection, MMP, to assess their feasibility and identify associated challenges, and to field test new

questionnaire items related to targeting a new subpopulation. There are no other federal information collections that duplicate the specific formative research described in this request.

171.

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

173.

174. Patients who attend small medical facilities that provide HIV care have a chance of being selected for CSBS, 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. CSBS 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.

175.

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

177.

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

179.

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

181.

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

183.

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

185.

186. For sub-collection requests under a generic approval, Federal Register Notices are not required and none were published. A Federal Register Notice for the umbrella collection was published January 13, 2012, Vol 77, No. 9, pages 2066-20667, 0920-0740, expiration date 1/31/2013.

187.

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

189.

190. 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.
191.
192. 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…"
193.
194. The use of incentives in CSBS is appropriate according to this guidance. The primary goal of CSBS is to investigate methods of 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 CSBS respondents is critical to achieving acceptable response rates in this hard-to-find population as demonstrated in the survey literature (Kulka,1995). A central objective of CSBS is to explore the recruitment implications of a new sampling method for MMP. Incentives are currently offered for participation in MMP--therefore, not offering incentives for participation in CSBS would bias the comparison of response rates achieved with the methods tested through CSBS against response rates with current MMP methods.
195.
196. 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 incentives. Thus, CSBS 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 (Yancy 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 CSBS respondents is critical to achieve acceptable response rates.

197.

198. 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 in CSBS and have a similar length of time for completing the patient interview. In both of these other projects incentives were used to help increase participation rates; participants were offered approximately $25 as compensation for their time. Other studies have also found that incentives modestly improve response rates (Shaw et al. 2001).

199.

200.

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

202.

203. CSBS is anonymous (neither names nor social security numbers are collected). Full date of birth is collected by CSBS for two reasons: to ensure that participants meet the age eligibility criteria for participation in the survey, and for identifying potential duplicate records or participants who have participated more than once per cycle. Records that have exactly the same date of birth are compared on date of survey and other demographic information such as race/ethnicity, and education; determinations of whether a record is a duplicate or a participant who has already participated during the cycle (due to being sampled from another participating facility) are made based on how closely this information matches. Data collected through CSBS, both locally and at CDC, are stored and accessed by a survey identification number. Other data collected through CSBS, while sensitive, are not personally identifying; these data elements are described in **Attachments 2, 3a-3d, 4, and**

5.

Sensitive information collected through CSBS 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. Data collected for this project are protected under a Federal Assurance of Confidentiality (**Attachment 6a**).

CSBS 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.

Privacy Impact Assessment

The CSBS interview will be conducted by trained CSBS staff in a private location where the questions and responses cannot be overhead by others. CSBS 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 CSBS 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).

213. A number of required protections ensure the security of the data on the data collection computers. The tablet computers and laptop computers are solely used for CSBS data collection activities. CSBS data are encrypted when stored on a tablet device or laptop. Computers are protected by using a coded password only known by authorized CSBS project staff. CSBS data are 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 are collected and secured by the field supervisor after return to the local CSBS office. When not in use in the field, the computers are to be locked in a drawer or an office.

214.

215. The Assurance of Confidentiality is 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 are 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 are required to undergo security and confidentiality training.

216.

217. CSBS data collectors and data managers 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 10**), 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 CSBS data maintained at CDC that are released to persons other than project staff will not include full date of birth.

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. An example model consent document is included as **Attachments 7a-b**. Respondents will be informed that data collected from them for CSBS will be kept private and secure and that the data will be reported in aggregate format.

Project Determination for CSBS is currently underway. If CSBS is determined to be research, then the CSBS protocol will be reviewed by the CDC IRB. If CSBS is determined to be non-research, review by the CDC IRB will not be necessary. Each participating health department may obtain local IRB approval before data collection according to the needs of the jurisdiction.

A.11.Justification for Sensitive Questions

HIV can be transmitted from person to person through sexual contact and the sharing of HIV contaminated needles and syringes. In addition, HIV-infected persons with higher HIV viral loads may be at increased risk of transmitting the virus to others. These modes of transmission necessitate the collection of sensitive data regarding HIV/AIDS status, medical history, sexual orientation, sexual practices, and alcohol and drug use, which MMP has been approved to collect. Accordingly, CSBS will also collect these data. As with MMP's data collection, the CSBS 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 CSBS 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.

227.
228. The CSBS pilot project is intended to provide a realistic assessment of the challenges to performing MMP under different sampling conditions. Therefore, it is necessary for the interview to be largely unchanged from the standard version.
229.
230. The context in which questions are asked helps to overcome their potential sensitivity. There are several steps taken in CSBS to minimize sensitivity and reiterate to the respondent the legitimate need for the information:
231.
232. • Nearly all questions allow for responses of “don’t know” or “refuse to answer.”
233. • 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.
234. • Toll-free phone numbers are provided if the respondent has questions about the survey.
235. • 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.
236. • The use of encrypted, password-protected computers for data collection addresses concerns the respondent might have about privacy (that others can see their answers).
237. • The token of appreciation indicates clearly to the respondent that the information is important to the survey sponsors.
238.
239. All in-person interviews will be conducted by trained CSBS 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.
240.
241. Social security numbers will not be collected from respondents.
242.

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

244.

245. A.12.Estimates of Annualized Burden Hours and Costs

246.

247. **A.12.A. Estimated Annualized Burden Hours**

248.

249. The annualized response burden for this sub-collection is estimated to be 655 hours; details are provided in exhibit A.12.A. Pilot project areas will sample, locate, recruit, interview, and conduct medical chart abstraction. In some facilities, the sampled person's health care provider may inform the patient that he/she has been selected to participate in CSBS, and refer the selected patient to MMP staff for recruitment. Some facilities may be asked to look up patient's contact information. Model recruitment scripts are included (**Attachments 9a and 9b**). An estimated total of 1,000 persons will be sampled in the 5 participating project areas. CDC's current goal is to interview 80% or 800 persons. Interview participation is expected to take an average of 45 minutes. Thus, the total annual burden is 600 hours. Interviews of patients who engage in few risk behaviors or have no risk behaviors (sexual behavior, drug and alcohol use) or who take few HIV-related medications or no medications will take slightly less time. Interviews of patients who engage in many risk behaviors or are taking many HIV-related medications may take slightly longer.

250.

251. MMP medical record abstractors and project coordinators at state and local health departments provided estimates of time required to pull patient medical records, look up contact information and/or approach patients for enrollment. It is estimated that for 20% or 200 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 7 hours. Each of 800 medical records will be pulled only once for each abstraction. The estimated time to pull a medical record is 3 minutes, for a total of 40 hours. As some sampled persons may never have been in care, this may take slightly less time. It is estimated that 10% or 100 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 8 hours.

252.

253.

254. Exhibit A.12.A Annualized Burden Hours

255. Type of Respondent	256. Form Name	257. 258. Number of 259. Respondents	260. 261. Number of 262. Responses per 263. Respondent	264. 265. Average Hours 266. Per Response	267. 268. Total Response 269. Burden 270. (Hours)
271. Sampled, Eligible HIV-Infected Patients	272. CSBS Interview	273. 800	274. 1	275. 45/60	276. 600
277. Facility office staff looking up contact information	278. N/A	279. 200	280. 1	281. 2/60	282. 7
283. Facility office staff pulling medical records	284. N/A	285. 800	286. 1	287. 3/60	288. 40
289. Facility office staff approaching sampled persons for enrollment	290. N/A	291. 100	292. 1	293. 5/60	294. 8
295. Total	**296.**	**297.**	298.	299.	**300. 655**

301.

302. A.12.B. Estimated Annualized Costs

303. The annualized cost to respondents for the burden hours is estimated to be $**13,285**; 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).

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

305.

306. Activity	**307. Total Burden Hours**	**308. Hourly Wage Rate**	**309. Total Respondent Cost**
310. Sampled persons completing CSBS interview	311. 600	312. $20.14	313. $12,084
314. Facility office staff looking up contact information	315. 7	316. $21.82	317. 153
318. Facility office staff pulling medical records	319. 40	320. $21.82	321. $873
322. Facility office staff approaching sampled patients for recruitment	323. 8	324. $21.82	325. $175
326. Total	**327. Average annual burden=655**	328.	**329. Average annual total=$13,28**

			5

330.

331.

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

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

334.

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

336.

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

338.

339.

340. Expense Type	**341. Expense Explanation**	**342. 343. Annual Costs (dollars)**
344. Direct Costs to the Federal Government	345. MMP – Personnel 346. Epidemiologist-14 1 80% $86,216 347. Epidemiologist-14 3 10% $32,331 348. Epidemiologist-13 1 10% $9,120 349. ORISE Fellows 2 100% $155,792 350. Data Managers 2 100% $160,000 351. 352.	353. $443,459
354.	355. Cooperative agreement funds to project areas	356. $969,374
357. Contractor and other Expenses	358. Contracted Questionnaire Programming (2) 0.25 FTE	359. $30,000
360.	361. Data Coordinating Center (CDC Contractor for data collection)10%	362. $110,000
363.	364. Travel	365. $7,500
366.	367. Meetings and	368. $1,000

	Trainings	
369.	370. Spanish Language Translation	371. $900
372.	373. Printing	374. $500
375.	**376. TOTAL COST TO THE GOVERNMENT**	377. $1,562,733

378.
379.
380. The personnel hired specifically to conduct the CSBS data collection consists of 2 ORISE Fellows and 2 data managers. Travel is related to providing technical assistance and conducting site visits.
381.
382. 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).
383.
384.
385. A.15.Explanation for Program Changes or Adjustments
386. Not applicable – request is for a sub-collection under a generic approval.
387.
388. A.16.Plans for Tabulation and Publication and Project Time Schedule
389. All data collection will be completed during the 12 month period after OMB approval. Data analysis will occur within 12 months of OMB approval. The following is a brief overview of the CSBS Timeline.
390.
391. Exhibit 16.A Project Time Schedule
392.

393. 394. Activity	**395. 396. Time Schedule**
397. Case-based sampling begins (2012 cycle)	398. Immediately after OMB approval
399. Sampled cases interviewed	400. 3-6 months after OMB approval
401. Abstract medical records of sampled cases	402. 3-6 months after OMB approval
403. Data management	404. 3-6 months after OMB approval
405. Evaluation	406. 7-8 months after OMB approval

393. **394. Activity**	**395.** **396. Time Schedule**
407. Analysis	408. 9-12 months after OMB approval
409. Publication	410. 12 months after OMB approval

411.

412.

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

414.

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

416.

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

418. There are no exceptions to the certification.

419.