

**Improving Surveillance Data Collection among Persons Not Receiving
HIV Care: A Qualitative Project to Enhance the Medical Monitoring
Project (MMP)**

Generic Information Collection Request under 0920-0840

April 18, 2018

Supporting Statement A

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A.46.

A.47.

- **Goals of the study:** The project goal is to collect qualitative data from people living with HIV who are not receiving routine HIV medical care to inform the Medical Monitoring Project's (MMP) recruitment and data collection activities, and the interpretation of the findings from MMP.
- **Intended use:** This project seeks to improve recruitment activities, the design of the MMP questionnaire and the interpretation of the findings from MMP.
- **Methods to be used to collect data:** This 1-year project will collect data from people living with HIV who are not receiving routine HIV medical care through qualitative semi-structured in-depth interviews. The semi-structured in-depth interview will be administered by telephone by a trained interviewer.
- **The subpopulation to be studied:** 40 people living with HIV who participated in the MMP 2018 cycle and have never received HIV care or have not received HIV care for at least 12 months prior to MMP participation. Respondents will live in one of MMP's 23 project areas.
- **How data will be analyzed:** Qualitative thematic analysis of 40 interview transcripts using NVivo.

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A.49. **A.1. Circumstances Making the Collection of Information Necessary**

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A.51. This request is for sub-collection under a generic approval (Formative Research and Tool Development, OMB Control No. 0920-0840, expires 01/31/2019) to collect formative qualitative data from people living with HIV who are not receiving routine HIV medical care in order to inform the methods and findings of the Medical Monitoring Project (MMP).

A.52.

A.53. The purpose of umbrella generic 0920-0840 is for NCHHSTP to conduct formative research for developing new tools and methodologies related to research on HIV/AIDS, STD, TB, and viral hepatitis. This includes cognitive research techniques to develop scientifically valid and population-appropriate methods, interventions, and instruments and field testing of new methodologies and materials.

A.54.

A.55. This project seeks to improve our understanding of a) how to recruit people who are out of care to participate in MMP, b) how to measure the receipt of routine HIV medical care, c) how to capture data on barriers, facilitators and motivations for obtaining routine HIV medical care, d) implications of not receiving routine HIV medical care. This 1-year project will improve surveillance, recruitment, and data collection methods among persons not receiving HIV care.

A.56.

A.57. MMP is a national surveillance system that captures behavioral and clinical data via structured interviews and medical record abstractions among adults living with diagnosed HIV in the United States. The CDC estimates that 72.5% of persons diagnosed with HIV received medical care during 2014, while fewer (56.9%) were retained in care [1]. Being without care compromises the benefits of HIV medication at the individual and population levels, as receipt of, and retention in, care are prerequisite for accessing treatment. A person living with HIV who takes HIV medication is likely to achieve durable viral suppression of HIV replication leading to immune system reconstitution and prolonged survival [2-5]. People living with HIV who take HIV medications daily as prescribed can achieve and maintain an undetectable viral load and have effectively no risk of sexually transmitting the virus to an HIV-negative partner [6-13]. Despite the benefits of HIV care engagement, maintaining routine medical care is difficult for many, as even those who have received care before may cycle in and out of care throughout their lifetimes [14-17].-

A.58.

A.59. In 2015, MMP expanded its population of inference to all adults with diagnosed HIV regardless of their care status. It is important to ensure that people who are not in care are identified and recruited, and participate in MMP. It has been difficult for MMP to recruit people who are not engaged in care. Unweighted data from the 2015 MMP data collection cycle indicate that less than 1% of respondents (n=48) were confirmed to have not received HIV care in the 12 months prior to their MMP interview based on self-report and medical record review. This number is low compared to data from the CDC's 2014 diagnosed-based HIV care continuum that indicate 27.5% of people diagnosed with HIV have not received care in the past 12 months and 43.1% are not retained in care [1]. MMP staff have made concentrated efforts to locate and recruit persons presumed to be out of care in recent cycles, and information collected from qualitative semi-structured interviews with MMP respondents who were out of care will inform future recruitment practices.

A.60.

A.61. An additional issue is the current MMP structured interview questionnaire may not adequately capture the complexities of receiving and being retained in HIV care. For example, the structured interview questionnaire includes a series of questions aimed at capturing barriers to linkage and engagement in HIV care for persons living with HIV; however, interviewer observations and preliminary data collected in 2015 suggest that the questions do not align with respondents' perceptions of barriers to HIV care. The 35-question series includes stem questions that capture high-level structural, financial, and personal barriers [18] to linkage and engagement in care and, if applicable, probing questions that elicit details about specific barriers. Yet, more than 30% of

respondents endorsed the "other specify" response option, indicating a need to revise these questions. Because access to and utilization of care is typically determined by complex and often overlapping social, cultural, personal, economic, and biomedical influences, complementary qualitative exploratory methods are needed to adequately inform the collection of this information.

A.62.

A.63. Although there have been qualitative studies on care linkage and engagement [19-21], only a few have captured perspectives about HIV care engagement from people who are not currently engaged in care. Therefore, it is important that this perspective be captured in order to best understand how the MMP structured interview can address the complexities of HIV care engagement for all persons living with diagnosed HIV. The findings from the proposed qualitative formative research component of MMP will improve and streamline ongoing structured surveillance questions about HIV care and inform the interpretation of responses that are collected from MMP. This project presents a unique opportunity to link qualitative findings to comprehensive behavioral and clinical data from structured interviews and medical records, because the same people will participate in qualitative and structured interviews. This will allow for a more in-depth understanding of potential barriers and facilitators to care. Findings will also inform strategies to increase access to care and improve health outcomes for people living with HIV, which is a national prevention goal.

A.64.

A.65. **A.2. Purpose and Use of Information Collection**

A.66.

A.67. The goal of this 1-year formative project is to inform the design of MMP (OMB No. 0920-0740 exp. 06/30/2018) and the interpretation of the findings from MMP. Recruitment for this project will be done by 23 project areas where MMP operates: California; Chicago, IL; Delaware; Florida; Georgia; Houston, TX; Illinois; Indiana; Los Angeles County, CA; Michigan; Mississippi; New Jersey; New York City, NY; New York; North Carolina; Oregon; Pennsylvania; Philadelphia, PA; Puerto Rico; San Francisco, CA; Texas; Virginia; and Washington. However, data will be collected by the CDC.

A.68.

A.69. MMP's aim is to facilitate understanding of health-related behaviors, experiences, and needs of people diagnosed with HIV infection across the U.S. and in specific jurisdictions. MMP provides information about care patterns of all HIV-diagnosed persons in the U.S. to whom care services are directed, not just persons already in care, which is needed to guide strategies to improve care access and utilization, and to maximize the impact of antiretroviral therapy. This project aims to improve MMP through the following objectives:

A.70.

1. Evaluate existing measurement of engagement and retention in care based on how people living with HIV who are not in care describe conceptions of engagement and retention in care to inform questionnaire design and interpretation of findings from the Medical Monitoring Project.
2. Describe barriers and facilitators to, and motivations for, obtaining HIV care for people living with HIV who are not in care to inform the design of the MMP questionnaire.
3. Describe implications of not receiving HIV care to inform the design of the MMP questionnaire.
4. Improve MMP recruitment methods by increasing our understanding of best approaches for locating and recruiting people living with HIV who are not in care.

A.71.

A.72. The information for this project will be collected through qualitative semi-structured in-depth interviews (**Attachment 1**). The needs this project addresses are the ability to accurately measure engagement in routine HIV medical care and improve recruitment activities for MMP. Accurately measuring engagement in routine HIV medical care is crucial for the ability of MMP to monitor national progress towards improving HIV outcomes. Additionally, this project addresses the need for MMP to capture the broader implications of not receiving routine HIV medical care. Not collecting this data would adversely affect the ability of MMP to be nationally representative of all people living with HIV, especially persons who are not receiving routine HIV care. Without the 'information collected by this project the ability to understand programmatic needs for reengaging people into routine HIV care would be negatively affected.

A.73.

A.74. MMP collects data through structured interview and medical record abstraction. The information collected through the interview includes information to determine eligibility, demographic characteristics, stigma and discrimination, access to medical care, adherence to antiretroviral therapy, 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. The information collected through the medical record abstraction includes demographics and insurance status; the prevalence and incidence of AIDS-defining opportunistic illnesses and co-morbidities related to HIV disease; the receipt of prophylactic and antiretroviral medications; and whether patients are receiving screening and treatment according to U.S. Public Health Service guidelines. This project will combine the information collected through the qualitative semi-structured in-depth interview with the MMP structured interview and medical record abstraction in order to understand conceptions of HIV care and implications for being without HIV care among persons who are not receiving routine HIV

medical care. The MMP structured interview and medical record abstraction will be used for mixed methods analysis to triangulate the information collected in the qualitative semi-structured in-depth interview.

A.75.

A.76.

A.77. **A.3. Use of Improved Information Technology and Burden Reduction**

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A.79. An in-depth telephone interview (**attachment 1**) will be used to collect detailed information from respondents. The telephone interview data will be transcribed into an electronic document by the CDC. There will be no burden to the respondent to submit data. Additionally, the minimum amount of information will be collected to meet the project objectives. An electronic form of data collection (i.e. survey) would not provide the degree of detail necessary to achieve the project objectives. It is necessary to collect data through telephone in-depth interviews because we need detailed information that provides deep understanding through the free recounting of the respondent's experiences and perspectives.

A.80.

A.81. **A.4. Efforts to Identify Duplication and Use of Similar Information**

A.82.

A.83. We reviewed currently funded programs and did not identify potential areas of duplication. We are not aware of any department or agency that collects or maintains national data on people who are not receiving routine HIV medical care. National data on people who are not receiving routine HIV medical care is limited. Even if there are other projects that are collecting national qualitative data on people who are not receiving routine HIV medical care, no other data source specifically relates to evaluating and improving the on-going surveillance activities of MMP, such as the interview instrument and recruitment procedures.

A.84.

A.85. **A.5. Impact on Small Businesses and Other Small Entities**

A.86.

A.87. No small businesses will be involved in this data collection effort.

A.88.

A.89. **A.6. Consequences of Collecting the Information Less Frequently**

A.90.

A.91. The proposed project involves a one-time data collection. There are no legal obstacles to reducing burden.

A.92.

A.93. **A.7. Special Circumstances Relating to Guidelines of 5 CFR 1320.5**

A.94.

- A.95. This request fully complies with the regulation 5 CFR 1320.5.
- A.96.
- A.97. **A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency**
- A.98.
- A.99. 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 June 25, 2015, Vol. 80, No. 122, pages 36540-36542, 0920-0840, expiration date 1/31/2019.
- A.100.
- A.101. **A.9. Explanation of Any Payment or Gift to Respondents**
- A.102.
- A.103. The semi-structured in-depth interview takes approximately 60 minutes to complete. To increase response rates, eligible persons are offered a token of appreciation to participate. We require a sample size of 40 to thoroughly understand the complexities that prevent people living with HIV from obtaining routine HIV medical care. With this sample size, we hope to achieve data and contextual saturation. Respondents will be given a token of appreciation for participating in the qualitative interview of approximately \$50 in cash; the specific amount will be determined by project areas based on local standards. If local regulations prohibit cash tokens of appreciation, cash equivalent tokens of appreciation may be offered in the form of gift certificates, or bus or subway passes.
- A.104.
- A.105. 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 ... with hard-to-find populations or respondents whose failure to participate would jeopardize the quality of the ... data, or in studies that impose exceptional burden on respondents, such as those asking highly, sensitive questions..." Additionally, the memorandum states that: "Incentives are also often used in studies used to develop surveys. For example, research subjects who participate in cognitive research protocols and focus groups are typically paid an incentive for their participation." As this project was designed to recruit a hard-to-find population (people living with HIV who are not receiving routine HIV medical care) and ask some sensitive questions about their HIV in order to redesign the MMP structured interview survey, a token of appreciation is appropriate.
- A.106.
- A.107. The need for and amount of the tokens of appreciation is based, in part, on the fact that MMP (OMB 0920-0740, exp. 06/30/2018), which will be used as the sampling frame for this project, provides tokens of appreciation. In addition, similar

projects that ask HIV risk behavior questions in the participating areas offer similar tokens of appreciation. Tokens of appreciation have been used in other HIV-related CDC data collection efforts such as for National HIV Behavioral Surveillance (OMB 0920-0770, exp. 5/31/2020) and the Feasibility of HIV Behavioral Surveillance for Young MSM (OMB 0920-0840, exp. 1/31/2019), both of which ask questions sensitive to people living with HIV. In these other projects, tokens of appreciation were used to help increase participation rates. Previous CDC studies with people living with HIV who never received HIV care (OMB No. 0920-0748 exp. 08/31/2010) offered tokens of appreciation for participation. Tokens of appreciation have been found to increase willingness to participate in qualitative research [22]. Providing tokens of appreciation to respondents is critical to achieving acceptable response rates.

A.108.

A.109. A.10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

A.110.

A.111. There are no PII collected as part of this formative qualitative project. However, data will be linked to MMP interview and medical record data (OMB #0920-0740, Exp. 6/30/2018). The CDC Privacy Officer has assessed this (parent MMP) package for applicability of 5 U.S.C. § 552a, and determined that the Privacy Act does apply to the overall information collection. This activity is covered under the Privacy Act System of Records Notice (SORN) #09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems. HHS/CDC", which enables the Centers for Disease Control and Prevention (CDC) officials to collect information to better understand disease patterns in the United States, develop programs for prevention and control of health problems, and communicate new knowledge to the health community.

A.112. MMP is anonymous (neither names nor social security numbers are collected). Previously collected month and year of birth will be extracted from the National HIV Surveillance System (NHSS, OMB No. 0920-0573, exp. 6/30/2019) as part of the minimum dataset (MDS). Age has been shown to be a strong predictor of non-response in MMP, and it will be used to adjust for non-response bias.

A.113.

A.114. The NHSS coded identifier (STATENO) will be extracted from NHSS and maintained with data collected for MMP. This identifier can be used by authorized project area staff to link to locally maintained NHSS data containing personal identifiers, which will be used by the project areas staff to recruit participants. Data collected in the project areas for MMP will be stored separately from personal identifiers. All patient information is labelled with a unique MMP coded participant identifier (STATENO) only. The MMP database maintained at CDC has received Data Security Assessment and Authorization (SA&A) from the CDC Information Technology Office.

A.115.

A.116. Medical record data are abstracted by MMP staff via a web-based application called Discovere™ (Cerner Corporation). This system is called MMP-MRA - Discovere (MMPMRAD). Data are automatically uploaded to a secure Cerner Corporation server when they are entered into the application and saved. Cerner will subsequently upload the MMPMRAD data to the DCC portal on a monthly basis using approved encryption software. Access to the web-based MMPMRAD application will be username- and password-protected, such that unauthorized users will not be able to view, export, or modify the collected data. The MMPMRAD data are housed on servers that have been configured with the current National Institute of Standards and Technology (NIST) Configuration baselines, which adhere to the most restricted security settings consistent with operational requirements. The servers are located within a facility that meets the stringent physical security requirements from NIST Special Publication (SP) 800-53 Current Edition, Recommended Security Controls for Federal Information Systems and Organizations. The data are protected by multiple layers of security that ensure confidentiality, integrity, and availability, with tools such as anti-virus protection, intrusion detection systems, and firewall rules strictly limiting access to the system.

A.117.

A.118. The NCHHSTP IT Security Information System Security Officer (ISSO), consulted on the system security described in this section. The data system for this collection underwent a Privacy Impact Assessment (PIA) (**Attachment 7**) when it was granted authority to operate in 2013 during the SA&A process (Enterprise Systems Catalog, IT Record ID: 2288).

A.119.

A.120. Sensitive information collected through MMP will not be linked to any other personally identifiable information and cannot be used to reveal the identity of any one person. No information that could directly identify an individual will be collected as part of the interview, medical record abstraction, or minimum dataset.

A.121.

A.122. Data that will be collected as part of this formative qualitative project, while sensitive, are not personally identifying. Personally identifiable information (PII) is NOT included in the data collection (**Attachment 1**). However, the unique identification code assigned to respondents by the project areas will link the interview data to the MMP interview and medical record abstraction data for analysis purposes. Contact lists that are used for standard MMP procedures will be maintained by project areas in accordance with the previously approved MMP data storage protocol. Potential respondents will be introduced to the project by the MMP interviewer according to procedures recommended by the CDC, using scripts developed from CDC templates (**Attachment 2**). The

recommended procedures address protection of privacy and confidentiality, and the templates for the scripts include assurance of confidentiality. The oral informed consent document will incorporate language that assures confidentiality (**Attachment 3**).

A.123.

A.124. This project is covered by an Assurance of Confidentiality for HIV/AIDS surveillance data (**Attachment 4**). 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. All project staff will have completed security and confidentiality training and signed a statement indicating their understanding of security and confidentiality policies.

A.125.

A.126. The Assurance of Confidentiality is enforced with appropriate training and contractual agreements which clarify the responsibilities of all respondents 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 document "Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs" available at (www.cdc.gov/nchhstp/programintegration/docs/PCSIDataSecurityGuidelines.pdf).

A.127.

A.128. The qualitative interview will be conducted by a trained CDC staff person in a private location where the questions and responses cannot be overheard by others. Transcripts and audio-recordings of qualitative interviews will be stored in a password-protected database on a secure server at the CDC. The CDC will destroy the digital audio files 5 years after data collection ends. The interviewer and data managers will undergo annual security and confidentiality training consistent with the guidelines set forth in the document ("Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and

Tuberculosis Programs" available at (www.cdc.gov/nchhstp/programintegration/docs/PCSIDataSecurityGuidelines.pdf). CDC's Office of Financial Resources will require the inclusion of 308(d) clauses in any HIV/AIDS support services work done by contractors (e.g., data analysis, computer programming, and LAN support). All CDC permanent employees and their contractors will be required to attend annual confidentiality training, to sign a Nondisclosure Agreement, 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" (**Attachment 6**) CDC-funded cooperative agreements with state and local health departments reference the Assurance of Confidentiality as a condition of award.

A.129.

A.130. **A.11. Institutional Review Board (IRB) and Justification for Sensitive Questions**

A.131.

A.132. IRB Approval

A.133.

A.134. Project Determination for this project (**Attachment 5**) was approved on February 20, 2018. The project was granted "non-research" status, as the primary intent is to inform routine disease surveillance in MMP. As the project determination for "non-research" status was approved, the protocol will not be reviewed by CDC's IRB. Each participating health department may be required to obtain local IRB approval before data collection, in accordance with their local guidelines.

A.135.

A.136. The informed consent process for respondents will be fulfilled by obtaining oral consent. Model consent forms are included as **Attachment 3**. These forms may be modified as required by a project area Institutional Review Board (IRB). Respondents will be informed that data collected from them will be kept private and secure and that the data will be reported in aggregate format.

A.137.

A.138. Sensitive Questions

A.139.

A.140. This project will collect some sensitive information related to HIV care and sexual behavior. Respondents will be asked a limited number of sensitive questions, however, their responses to questions posed in the semi-structured in-depth interview may include some sensitive information.

A.141.

A.142. Although the some information requested from respondents is sensitive, the objectives of this project cannot be accomplished without their collection. The context in which questions are asked helps to overcome their potential sensitivity. Several steps will

be taken to minimize sensitivity and reiterate to the respondent the legitimate need for the information:

A.143.

- Consent scripts make it clear that the interview is sponsored by CDC and the local health department and that the information will be put to important uses.
- The interview is carefully organized to lead smoothly from one topic to another. Transitions are made clear to respondents and the need for information is explained.
- All questions allow for responses of “don’t know” or “refuse to answer.”
- A phone number to call about concerns with the project will be included in the consent.
- Assurances about the anonymity, privacy, and confidentiality of the data will be reiterated.
- The provision of a token of appreciation indicates clearly to the respondent that the information is important to the study sponsors.

A.144. All interviews will be conducted by trained staff in a private location. Interviewers will be trained to administer the consent script verbatim, thus ensuring that all respondents receive the same information for the consent. No interviews will be conducted without the verbal consent of the respondent.

A.145.

A.146. **A.12. Estimates of Annualized Burden Hours and Costs**

A.147.

A.148. **A.12.A. Estimated Annualized Burden Hours**

A.149.

A.150. The estimate of annualized burden hours for this sub collection is 40 hours; details are provided in exhibit A.12.A. We expect 40 eligible and consenting individuals to participate, which is expected to take 1 hour per participant.

A.151.

A.152. Exhibit A.12.A Estimate of Annualized Burden Hours

A.153. Type of Respondent	A.154. Form Name	A.155. Number of Respondents	A.158. Number of Responses per Respondent	A.162. Average Hours per Response	A.165. Total Response Burden (Hours)
A.169. People	A.171. Attachment 1	A.173. 40	A.174. 1	A.175. 1	A.176. 40

A.153. Type of Respondent	A.154. Form Name	A.155. A.156. Number of A.157. Respondents	A.158. A.159. Number of A.160. Responses per A.161. Respondent	A.162. A.163. Average Hours A.164. Per Response	A.165. A.166. Total Response A.167. Burden A.168. (Hours)
living with HIV who are not receiving HIV care, >18 years old A.170.	Interview Guide A.172.				
A.177. Total	A.178.	A.179.	A.180.	A.181.	A.182. 40

A.183.

A.184. A.12.B. Estimated Annualized Costs

A.185.

A.186. The annualized cost to respondents for the burden hours is estimated to be \$973.20; 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- September 2017 <http://www.bls.gov/news.release/pdf/ecec.pdf>).

A.187. Exhibit A.12.B. Annualized Cost to Respondents

A.188.

A.189. Activity	A.190. Total Burden Hours	A.191. Hourly Wage Rate	A.192. Total Respondent Cost
A.193. Attachment 1 Interview Guide A.194.	A.195. 40	A.196. \$24.33	A.197. \$973.20
A.198. Total	A.199.	A.200.	A.201. \$973.20

A.202.

A.203.

A.204. **A.13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers**

A.205.

A.206. There are no other costs to respondents or record keepers with this proposed collection of information.

A.207.

A.208.

A.209. **A.14. Annualized Cost to the Federal Government**

A.210.

A.211. The annualized cost of this project is estimated to be \$84,738 to fund a data collector to conduct the interviews, code the qualitative data, and produce reports on the findings.

A.212.

A.213. **Exhibit 14.A. Estimated Cost to the Government**

A.214.

A.215. Expense Type	A.216. Expense Explanation	A.217. Annual Costs (dollars)
A.219. Contractor and Other Expenses	A.220. ORISE Fellow 1 @ 100%	A.221. \$84,738
	A.223. TOTAL COST TO THE GOVERNMENT	A.224. \$84,738 A.225. \$84,738 A.226.

A.227.

A.228.

A.229. **A.15. Explanation for Program Changes or Adjustments**

A.230.

A.231. Not applicable - request is for a sub-collection under a generic approval.

A.232.

A.233. **A.16. Plans for Tabulation and Publication and Project Time Schedule**

A.234.

A.235. All data collection will be completed during the 12-month period after OMB approval. The following is a brief overview of the timeline.

A.236.

A.237. **Exhibit 16.A. Project Time Schedule**

A.238.

A.239. Activity	A.241. Time Schedule
A.240. Data collection	A.242. June 2018 - May 2019
A.243. Data analysis	A.244. August 2018 - December 2019
A.245. Publication	A.246. June 2020

A.249.

A.250.

A.251.

A.252. **A.17. Reason(s) Display of OMB Expiration Date is Inappropriate**

A.253.

A.254. The OMB Expiration Date will be displayed. No exception is requested.

A.255.

A.256. **A.18. Exceptions to Certification for Paperwork Reduction Act Submissions**

A.257.

A.258. There are no exceptions to the certification.

A.259.

A.260.

A.261. **References**

A.262.

A.263. 1. Centers for Disease Control and Prevention, *Understanding the HIV Care Continuum*. 2017. p. 1-4.

A.264. 2. Andrade, H.B., et al., *Highly active antiretroviral therapy for critically ill HIV patients: A systematic review and meta-analysis*. PLoS One, 2017. **12**(10): p. e0186968.

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