

**Evaluation of Rapid HIV self-testing in MSM (eSTAMP): Field-
Performance study**

Generic Information Collection Request under 0920-0840

**Supporting Statement
Part A**

April 10, 2013

Contact

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54.

55. Supporting Statement

56.

57. A. JUSTIFICATION

58.

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

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61. The Centers for Disease Control and Prevention (CDC) requests a 1-year approval for a new data collection entitled, "Evaluation of Rapid HIV self-testing in MSM (eSTAMP): Qualitative and User Proficiency Assessments" to be conducted under the Generic Formative ICR 0920-0840, expiration date 02/29/2016. The proposed information collection is to conduct formative research to inform the development and implementation of a randomized-controlled trial that evaluates the use and effectiveness of self-test kits as a public health strategy for increasing testing among men who have sex with men (MSM).

62.

63. Innovative testing strategies are needed to reduce levels of undiagnosed HIV infection and increase early access to treatment. The availability of a HIV self-test may facilitate access to testing among individuals who have never been tested due to concerns about privacy and may increase compliance with current CDC HIV testing recommendations for those who require regular testing due to on-going risk behavior. Rapid HIV self-tests may play an important role in efforts to reduce both HIV morbidity and mortality. Self-test HIV kits may reduce HIV incidence by helping HIV-negative persons remain free from infection (primary prevention), as well as increase early diagnoses of those who are infected (secondary prevention). Policies that guide the public-health application and use of rapid HIV self-test kits, require data on whether persons at high risk for infection will use these tests, the effectiveness of the tests for primary and secondary prevention, and the utility of the tests in promoting additional testing and linkage to HIV services of persons with preliminary positive results. Given the unrelenting HIV crisis among MSM and the imminent release into the market of rapid HIV self-test kits, it is necessary to evaluate the impact of providing rapid HIV self-test kits on repeat HIV testing, linkage to care, partner testing, serosorting, and HIV sexual risk behaviors among MSM to determine the potential primary and secondary prevention effectiveness of Over-the-Counter (OTC)

rapid HIV self-tests. This information will assist the Division of HIV/AIDS Prevention (DHAP) in developing recommendations and future research and program needs concerning self-testing for MSM to aid in identifying undiagnosed cases of HIV infection and promoting linkage to care of persons with HIV.

64.

65. The purpose of this project is to assess the use and impact of rapid HIV self-testing among MSM located in high HIV prevalence cities in the United States. This study will be conducted in 4 parts. Each part will be independent and will provide information to develop and implement the next part of the study. Part 3 is a formative phase of the project and is the part for which we are submitting this generic information request.

66.

67. The final part of this project is a randomized prevention trial of HIV self-test kit distribution involving almost 4 times the number of participants in Part 3, with a purpose of evaluating the use and effectiveness of self-test kits as a public health strategy for increasing testing among MSM. Before moving forward with the larger trial (Part 4), Part 3 will provide assurance regarding the adequacy of the field performance of user-administered and interpreted tests by comparing participants' HIV self-test results to a laboratory-administered EIA performed on their dried blood spot (DBS) specimens. Part 3 is also a pilot test of the study referral support system and patterns of usage will inform us on how to improve its efficiency before the prevention trial. Further, Part 3 will help evaluate the adequacy of the amount of tokens of appreciation for collecting testing behavior data through online reporting and cell phone applications through multiple follow-up surveys in Part 4.

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69. A.1.2 Privacy Impact Assessment

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71. MANILA Consulting Group Inc., is the contractor for this study. MANILA has a subcontract with Emory University to complete study activities. Emory University, will collect information in identifiable form (IIF). Men who are determined by the screener to meet eligibility criteria will be asked to provide their contact information including email address, a cell phone number and a mailing address and will also be asked to provide a nickname or name of choice. Once a participant submits an email address as part of the registration process, an email containing a code will be immediately sent to that address. The purpose of this email

is to ensure that participants provide a valid email address. Also, a text message containing a code will be immediately sent to the cell phone number provided by the participant. The participant must then enter this code as part of the registration process in order to continue. The purpose of sending this code is to verify that the participant has provided a valid cell phone number. Men who successfully register will be provided with a link to the study web site where they will set up an account by selecting a user name, password and security questions, and complete the baseline survey.

72.

73. Contact information used to confirm participation will be held in a password-protected database on a MANILA secure server (MANILA is the contractor for this study), accessible only by study staff. This contact information will be held separately from baseline survey data, follow-up survey data, and participants' HIV test results, which will contain only the participants' study identification number. The database will be backed-up to a hard drive housed in another location, also accessible only by study staff. The contact information (name, email address and phone number) in the database will be destroyed at the end of the study, and will never be associated with the study data collected. Emory study staff will notify MANILA when to destroy the information in the database; MANILA will use Norton CleanSweep software to delete the database file from the secure server and the back-up file(s) from the separate hard drive.

74.

75. All participants will be assigned a unique identification number for the study. Consent forms and files with contact information will be separated from the baseline survey, self-reported rapid test results, follow-up survey, and DBS specimen test results, and a master list linking the identifiers and names will be developed. Baseline survey data, participants' results from the HIV self-tests, and the follow-up survey data will be held in a separate password-protected database which will contain only the participants' study identification number. If a participant's HIV test result is positive, their contact information will be reported to their state health department as required by law. Their information remains private when it is reported to the state health department. This will have been previously explained to participants in the informed consent document.

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77. CDC will not receive any IIF. If there were a need to send data to CDC for review, all IIF collected by local partners would be unlinked or stripped from the data base that is submitted to CDC.

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80. A.1.3 Overview of the Data Collection System

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82. Information will be collected using an eligibility screener (**Attachment 1a**), study registration process (**Attachment 1b**), a baseline survey (**Attachment 1c**), HIV test results reporting system (**Attachment 1d**), and follow-up survey (**Attachment 1e**). Specifically, the eligibility screener will assess the age, race/ethnicity, gender, sexual risk, and HIV status of potential participants to determine eligibility. The baseline survey will collect information on demographic characteristics, prior laboratory training or experience, and HIV testing history.

83. Participants will log onto the study web site or download and access a secure cell phone application prior to starting the HIV testing process. This will enable participants to report their self-test results into the reporting system (**Attachment 1d**). They will take a follow-up survey (**Attachment 1e**) immediately after testing which will assess kit usage, experience with the study referral system, testing circumstances, experiences with using each HIV test kit (e.g. OraQuick, DBS, SureCheck), and token of appreciation information.

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86. A.1.4 Items of Information to be Collected

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88. Information will be collected to:

89.

1. To determine the field performance of user-administered and interpreted rapid HIV self-tests compared to a standard of a laboratory-administered Enzyme Immunoassays (EIA)
2. To implement and test the study referral support system for understanding how to improve its efficiency before the next phase of the study. The referral support system is a mechanism to support the immediate needs of participants who have difficulty with self-testing, who have concerns after testing, or who have a new preliminary positive test result.
3. To demonstrate the operations, feasibility and acceptability of home rapid HIV self-testing among MSM
4. To estimate the levels of yield of recruitment and the extent of MSM participation in HIV self-testing and returning DBS specimens in online prevention studies

5. To describe and evaluate token of appreciation strategies for collecting testing behavior data through online reporting and cell phone applications
6. To determine if the methods and operations of the pilot study are sufficient prior to launching the larger, randomized trial in the next phase (which is not covered by this generic information collection request)

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91.

92. **A.1.5 Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age**

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94. This information collection does not involve websites or website content directed at children under 13 years of age.

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

98.

99. Before moving forward with the larger trial (Part 4), Part 3 (a formative phase of the project and is the part for which we are submitting this generic information request) will provide assurance regarding the adequacy of the field performance of user-administered and interpreted tests by comparing participants' HIV self-test results to a laboratory-administered EIA performed on their DBS specimens. Part 4 is a randomized prevention trial of HIV self-test kit distribution involving almost 4 times the number of participants in Part 3, with a purpose of evaluating the use and effectiveness of self-test kits as a public health strategy for increasing testing among MSM. Part 3 is also a pilot test of the study referral support system and patterns of usage will inform us on how to improve its efficiency before the prevention trial. Further, Part 3 will help evaluate the adequacy of the amount of tokens of appreciation for collecting testing behavior data through online reporting and cell phone applications through multiple follow-up surveys in Part 4.

100.

101. The study support system will be implemented and piloted in Part 3. It will support the immediate needs of participants who have difficulty with self-testing, who have concerns after testing, or who have a new preliminary positive test result. The study support system provides participants with a number to call in with any study-related concerns. The number will be attended by a voice-recognition system which will allow participants to: (1) get pre-recorded information about frequently asked questions; (2)

request to ask a question of study staff (answered during business hours, or transferred to voicemail after hours); and (3) request immediate consultation with a counselor for crisis support and triage. Immediate consultation will be available 24 hours a day, 7 days a week and will be provided by trained Emory study staff Monday through Friday from 8:00am to 5:00pm Eastern time, and by crisis hotline counselors at all other hours. Counselors at the crisis hotline and Emory study staff volunteers that will be part of the study referral support system will have completed training about the study procedures and in the fundamentals of HIV prevention counseling.

102.

103. For participants who have a new HIV preliminary positive test result as part of the study, we will arrange referral to supplemental testing and care at a local facility in the city where the participant lives using AIDSvu which is an online tool that allows users to visually explore the HIV epidemic alongside critical resources such as HIV testing center locations and NIH-Funded HIV Prevention and Vaccine Trials Sites, state and local health department contacts, and an existing database from Patrick Sullivan's (the Principal Investigator at Emory University) HIV Minority Health Initiative that was developed to link new preliminary HIV positive persons to services. In conversation with the participant, the counselor or study staff will help determine the type of setting (community-based, medical setting, university setting, etc.) and the neighborhood which will best suit the participant. Counselors or study staff will build on pre-established relationships with providers to develop a suitable referral to a health care provider for supplemental HIV testing and, if necessary, linkage to HIV care services.

104.

105. Counselors will also make an assessment to determine other resources that the participant may benefit from such as medical case management, mental health care, or comprehensive risk counseling and services. Newly preliminary positive persons will be directly linked to medical care by connecting them with a medical care contact, if necessary. Linkage managers will follow-up with them on the next business day to ensure that contact was made with a local facility in the city where the participant lives or with a medical care agency. The participant would be contacted at least three times: (1) to confirm an appointment was scheduled; (2) to confirm the appointment was attended; and (3) to report confirmatory results. Confirming appointment attendance from the participant will

be used to document a successful linkage to care. Documentation includes: (1) date of the visit to a local facility; (2) location of facility and/or name of provider; and (3) verification of visit using self-report. Persons who test preliminary positive will have the option to request a written document (via mail or email) with their preliminary positive test results that they can take to their own health care provider (**Attachment 4a**).

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

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110. This study employs many uses of technology. Recruitment will be conducted through banner advertisements displayed on social networking sites such as Facebook and dating and sex-seeking sites such as Manhunt and Adam4Adam (**Attachment 4b**). All participant consenting and data collection will be completed using an online reporting system (**Attachment 4d**). After clicking a banner advertisement, they will be taken to a page containing basic study information including a short description of study activities. If they express an interest in participation they will be taken to a consent form (**Attachment 2a**), and if they consent they will be directed to a short eligibility screener, which will confirm that they meet the eligibility criteria. Men who do not consent or do not meet the eligibility criteria will be taken to a screen thanking them for their interest and directing them to AIDSvu, an online tool that allows users to visually explore the HIV epidemic alongside critical resources such as HIV testing center locations and NIH-Funded HIV Prevention and Vaccine Trials Sites). Men who are eligible to participate will then be prompted to complete the online registration process (**Attachment 1b**). During the registration process they will provide their contact information including an email address, a cell phone number and a mailing address and will also be asked to provide a nickname or name of choice. Once a participant submits an email address as part of the registration process, an email containing a code will be immediately sent to that address. The purpose of this email is to ensure that participants provide a valid email address. Also, a text message containing a code will be immediately sent to the cell phone number provided by the participant. The participant must then enter this code as part of the registration process in order to continue. The purpose of sending this code is to verify that the participant has provided a valid cell phone number. Men who

successfully register will be provided with a link to the study web site where they will set up an account by selecting a user name, password and security questions, and complete the baseline survey.

111.

112. Men who consent to participate will take a short baseline survey (**Attachment 1c**). They will have the option of accessing the survey online or by downloading a secure cell phone application. They will also have the option of entering their rapid self-test results (**Attachment 1d**) and taking the follow-up survey (**Attachment 1e**) online or through a secure cell phone application.

113.

114. Online Surveys: Men who take the baseline survey online will enter responses to survey questions directly into their computer via a web interface. On completing this survey, they will be informed that a package containing: 1 oral fluid test (OraQuick), 1 DBS specimen collection kit, and 1 finger-stick blood test (Sure Check) is being sent to the mailing address they provided. They will be instructed on how they can log into the study web site to access the survey online or use the secure cell phone application to enter results of their rapid HIV self-tests that they conduct at home.

115.

116. Cell Phone Application Surveys: Men who take the baseline survey using their cell phone will interact with and enter responses to survey questions directly into the cell phone application. On completing this survey, they will be informed that a package containing: 1 oral fluid test (OraQuick), 1 DBS specimen collection kit, and 1 finger-stick blood test (Sure Check) is being sent to the mailing address they provided. They will be instructed on how they can log into the study web site to access the survey online or use the secure cell phone application to enter results of their rapid HIV self-tests that they conduct at home.

117.

118. Participants will follow the written instructions included with each individual kit to conduct DBS specimen collection and self-testing. They will be asked to log into the study web site or start the electronic application prior to starting the testing process so they can report their self-test results at the time of testing and take the follow-up survey immediately after testing. They will also have the option of viewing video instructions online or on a cell phone application, both of which will provide timers specific to each test. After conducting each rapid test they will report their results online or using the secure

cell phone application and select an image of the test kit device that most closely resembles their results. They will receive messages based on their results (positive, negative or invalid) that will direct them to the study referral support system or HIV testing services if they want or need supplemental HIV testing (Attachment 4c).

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

121.

122. NCHHSTP has verified that there are no other federal collections that duplicate the data collection tools and methods included in this request.

123.

124.

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

126.

127. No small businesses will be involved in this data collection.

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

129.

130. The activities involve a one-time collection of data. There are no legal obstacles to reducing the burden.

131.

132.

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

134.

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

136.

137.

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

139.

140. A Federal Register Notice for the generic clearance 0920-0840, exp. 02/29/2016 was published on 08/2/2012, Vol. 77, No. 149, pages 46094-46095 .

141.

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

143.

144. Men will receive tokens of appreciation for their time and participation upon completing specific tasks at four stages during Part 3. Upon completion of the baseline survey, men will be given \$20. They will be given an additional \$10 for reporting the results of both the oral and blood finger-stick self-administered and interpreted HIV

rapid tests, \$10 for completing the follow-up survey, and an additional \$20 for returning the DBS specimen. The tokens of appreciation will be provided by PayPal or by Amazon.com gift card, depending on participant preference. The amount of tokens of appreciation is based on the Principal Investigator's prior research experience with this population. A token of appreciation is necessary to ensure recruitment and retention of a stigmatized population who are at greatest risk of becoming infected with HIV. Without providing the tokens of appreciation, the contractor will not be able to recruit and retain the required number of individuals necessary to meet the goals of the study in the required timeframe. This will jeopardize the success of the government's contract.

145.

146.

147. **A.10. Assurances of Privacy Provided to Respondents**

148.

149. The Privacy Act does not apply to this data collection. All participants will be assigned a unique identification number for the study. Electronic consent forms and files with contact information will be separated from the baseline survey, self-reported rapid test results, follow-up survey, and DBS specimen test results, and a master list linking the identifiers and names will be developed. All data collected regarding study participants will be maintained on a password-protected network. Access to the files is managed by the Principal Investigator and is limited to study staff directly involved in this research on a need-to-know basis. No data will be permitted off site, except when data are in transit from the laboratory to the research office. Participant email addresses used to receive tokens of appreciation from secure web sites (Amazon and PayPal) will not be linked to participant survey or HIV testing results.

150.

151. As noted above, eligible men who consent to participate will provide their email address, phone number and mailing address as well as a nickname or name of choice. Contact information used to confirm participation will be held in a password-protected database on a MANILA secure server, accessible only by study staff. This contact information will be held separately from baseline survey data, follow-up survey data, and participants' HIV test results, which will contain only the participants' study identification number. The database will be backed-up to a hard drive housed in another location, also accessible only by study staff. The contact information (name, email address and phone number) in the database will be destroyed at the end of the study,

and will never be associated with the study data collected. Emory study staff will notify MANILA when to destroy the information in the database; MANILA will use Norton CleanSweep software to delete the database file from the secure server and the back-up file(s) from the separate hard drive.

152.

153. Baseline survey data, participants' results from the HIV self-tests, and the follow-up survey data will be held in a separate password-protected database which will contain only the participants' study identification number. If a participant's HIV test result is positive, their contact information will be reported to their state health department as required by law. Their information remains secure and private when it is reported to the state health department. This will have been previously explained to participants in the informed consent document.

154.

155. Emory University and MANILA Consulting Group, Inc., are conducting this study, which is sponsored by the Centers for Disease Control and Prevention (CDC). Participants will be required to give consent prior to participating in any part of the study using an electronic online agreement to obtain and document informed consent. Emory will seek a waiver from IRB for signed consent, and use of electronic consent documentation. The written informed consent document will explain: (1) what is meant by consent; (2) why we need to obtain consent; (3) the purpose of the consent form, and (4) identify the study's sponsor and funding. Participants will be required to read the informed consent document before indicating whether or not they consent; this will be enforced by requiring participants to scroll through the entire consent before they can choose to consent to participate. Consent or lack thereof will be documented in the electronic database by the stored variable indicating consent or lack of consent. A button to allow participants to print the consent form for their records will be located at the end of the consent form document. The consent process will take approximately 5 minutes per individual (**See Attachment 2a**).

156.

157. Study staff will be available to participants during business hours by phone or by email to answer any questions that participants have prior to consenting. Participants will be informed that if they are found to be preliminarily HIV positive on any of the self-tests they are welcome to call the study referral support system and request immediate consultation with a counselor for crisis support and to

obtain referral information on where to get supplemental testing and care. If the laboratory-administered EIA tests are positive, Emory study staff will contact participants to provide them with referral information for supplemental testing and care in their respective cities of residence. Persons with a confirmed HIV-positive result will have the option to request a written document (via mail or email) with the test results that they can take to the own healthcare provider. The informed consent will notify participants that the contact information of persons with confirmed positive HIV test results will be reported to the relevant state health department as required by law.

158.

159. Respondents will be told that no information in identifiable form will be available to or shared with the CDC. If any data is shared with CDC it will be de-identified and transferred securely to CDC.

160.

161. A.11. Justification for Sensitive Questions

162.

163. During the study, participants are asked sensitive questions about race, ethnicity, gender, sexual risk behavior, HIV testing history, and HIV status. These sensitive questions are necessary to determine eligibility for the study and to evaluate the impact of providing rapid HIV self-test kits among MSM to determine the field-performance rapid HIV self-tests.

164.

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

166.

167. A.12.A. Estimated Annualized Burden Hours

168.

169. Study staff will screen approximately 7,000 men for the part 3 study activities identified in this ICR (attachment 1a). The 7,000 men will take part in a 3-minute screening interview to assess study eligibility; approximately 4,000 men are expected to participate in the study. The registration process will take approximately 15 minutes (attachment 1b). Completing the baseline survey will take approximately 10 minutes (attachment 1c). Entering the rapid self-test results will take approximately 5 minutes (attachment 1d). Completing the follow-up survey will take approximately 10 minutes (attachment 1e).

170.

171. Exhibit A.12.A Annualized Burden Hours

172. Type of Respondent	173. Form Name	174. 175. No. of 176. Respondents	177. 178. No. of 179. Responses per 180. Respondent	181. 182. Average Hours 183. Per Response	184. 185. Total Response 186. Burden 187. (Hours)
188. Prospective Participant	189. Eligibility Screener	190. 7,000	191. 1	192. 3/60	193. 350
194. Enrolled participant	195. Study Registration	196. 4,000	197. 1	198. 15/60	199. 1,000
200. Enrolled participant	201. 202. Base line Survey	203. 1,500	204. 1	205. 10/60	206. 250
207. Enrolled participant	208. Reporting of Self-Test Results	209. 960	210. 1	211. 5/60	212. 80
213. Enrolled participant	214. Follow-up Survey	215. 900	216. 1	217. 10/60	218. 150
219. Total	220.	221.	222.	223.	224. 1,830

225.

226.

227. A.12.B. Estimated Annualized Costs

228. The annualized costs to respondents are described 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/bls/wages.htm>)). The total annual cost to

participants based on burden hours for collection of information in this project will be \$37,020.90.

229.

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

231. Type of Respondent (Form Name)	232. Total Burden Hours	233. Hourly Wage Rate	234. Total Respondent Costs
235. Eligibility Screener	236. 350	237. \$ 20.23	238. \$7,080.50
239. Study Registration	240. 1,000	241. \$ 20.23	242. \$20,230.00
243. Baseline Survey	244. 250	245. \$ 20.23	246. \$5,057.50
247. Reporting of Self-test Results	248. 80	249. \$ 20.23	250. \$1,618.40
251. Follow-up Survey	252. 150	253. \$ 20.23	254. \$3,034.50
255. Total	256.	257.	258. \$37,020.90

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261. A.13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

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

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266. A.14. Annualized Costs to the Government

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268. The annualized cost to the government is \$545,750. This activity will involve participation of CDC Project Officer who will assist with project design, obtaining IRB and OMB approvals, and

providing project oversight. A CDC Co-Project Officer who will assist with project design and obtaining required C&A approvals. A CDC Project Manager will assist with project coordination, obtaining IRB and OMB approvals. CDC consultants who assist with study design, sample size determinations, ethical considerations, and analytical plan design issues on an as-needed basis. Travel expenses include six site visits.

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270.

271.

272. Expense Type	273. Expense Explanation	274. 275. Annual Costs (dollars)
276. Direct Costs to the Federal Government	277. CDC Project Officer (Commissioned Corps, 0-5, 0.50 FTE)	278. \$ 51,000
279.	280. CDC Co-Project Officer (Visiting Scientist, GS-13, 0.75 FTE)	281. \$ 64,125
282.	283. CDC Project Manager (GS-12, 0.25 FTE)	284. \$ 17,975
285.	286. CDC Project Consultants (GS-13, 0.20 FTE)	287. \$ 17,100
288.	289. CDC Site Visit Travel (6 trips)	290. \$ 7,000
291.	292. Subtotal, direct costs to the government	293. \$ 157,200
294. Contract Costs	295. Contract to the Manila Consulting Group, Inc.	296. \$ 388,550
297.	298.	299.
300.	301. Subtotal, contract costs	302. \$ 388,550
303.	304. TOTAL COST TO THE GOVERNMENT	305. \$

		545,750
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308.

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

310.

311. Not applicable - This is a new request for a sub-collection under a generic approval.

312.

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

315.

316. Data collection will be completed during the first year after OMB approval is granted. Part 3 data collection, data analysis, and report of findings will be completed by 3 months after approval.

317.

318.

319. Exhibit 16.A. Project Time Schedule

320. 321. Activity	322. 323. Time Schedule
324. Conduct Part 3	325. 1 month after OMB approval
326. Part 3 Data analysis and Report of Findings	327. 2 months after OMB approval

328.

329.

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

331.

332. OMB Expiration Date will be displayed.

333.

334.

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

336.

337. There are no exceptions to the certification.