

Evaluation of Free Rapid HIV Home-Testing among MSM Trial

OMB No. 0920-New

SUPPORTING STATEMENT A

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Contact information

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Table of Contents

Section

A. Justification

1. Circumstances Making the Collection of Information Necessary
2. Purpose and Use of the Information Collection
3. Use of Improved Information Technology and Burden Reduction
4. Efforts to Identify Duplication and Use of Similar Information
5. Impact on Small Businesses or Other Small Entities
6. Consequences of Collecting the Information Less frequently
7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5
8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency
9. Explanation of Any Payment or Gift to Respondents
10. Assurance of Confidentiality Provided to Respondents
11. Justification for Sensitive Questions
12. Estimates of Annualized Burden Hours and Costs
13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers
14. Annualized Cost to the Government
15. Explanation for Program Changes or Adjustments
16. Plans for Tabulation and Publication and Project Time Schedule
17. Reason(s) Display of OMB Expiration Date is Inappropriate
18. Exceptions to Certification for Paperwork Reduction Act Submissions

19.

20. Exhibits

21. Exhibit 12.A Estimated Annualized Burden Hours
22. Exhibit 12.B Estimated Annualized Burden Costs
23. Exhibit 14.A Estimated Cost to the Government
24. Exhibit 16.A Project Time Schedule

25.

26. B. Collections of Information Employing Statistical Methods

27. 1. Respondent Universe and Sampling Methods
28. 2. Procedures for the Collection of Information
29. 3. Methods to Maximize Response Rates and Deal with Nonresponse
30. 4. Tests of Procedures or Methods to be Undertaken
31. 5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

32.

33. Attachments

34. 1 Authorizing Legislation – Public Health Service Act

- 35. 2 60 Day Federal Register Notice
- 36.
- 37. Attachment 3 Data Collection Forms
- 38. 3a. Eligibility Screener
- 39. 3b. Study Registration
- 40. 3c. Baseline Survey for RCT participants
- 41. 3d. Baseline Survey for HIV-positive participants
- 42. 3e. Reporting of Home-Test Results during the study
- 43. 3f. Follow-up Surveys for RCT participants
- 44. 3g. Follow-up Surveys for HIV-positive participants
- 45. 3h. Reporting of Home-Test Results at completion of study
- 46. 3i. Focus group discussion guide
- 47. 3j. Individual in-depth interview guide
- 48.
- 49. Attachment 4 Consent forms
- 50. 4a. RCT Informed Consent
- 51. 4b. Focus Group Discussion Consent
- 52. 4c. In-depth Interview Consent
- 53.
- 54. Attachment 5 Approvals
- 55. 5a. Local IRB approval-Emory University
- 56. 5b. NCHHSTP Project Determination
- 57.
- 58. Attachment 6 Screenshots
- 59.**

61. A. **JUSTIFICATION**

62.

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

64.

65. The Centers for Disease Control and Prevention (CDC) requests a 3-year approval for a new data collection entitled, "Evaluation of Free Rapid HIV Home-Testing among MSM Trial." The proposed information collection is to conduct a study that evaluates the use and effectiveness of free HIV home-test kits as a public health strategy for increasing testing among men who have sex with men (MSM). It is likely that community-based organizations (CBOs) and health departments will offer home-testing programs in the near future, where MSM enroll online and are provided free kits. This would be a cheaper option than having people come to testing sites because of reduced staff time and facility costs. This study will be used to inform future HIV testing programming provided by health departments and CBOs.

66.

67. The collected information will help determine whether the distribution of user-administered and interpreted HIV home-tests to HIV-negative or HIV status unknown MSM results in a higher frequency of MSM HIV testing at least 3 times in a 12 month period compared to a standard of referring MSM to testing locations. We are using a testing frequency of at least 3 times in a 12 month period as our main outcome because CDC has recommended at least annual testing for persons at risk of HIV infection and sexually active MSM may benefit from more frequent HIV testing; possibly every 3 to 6 months. Based on this guidance, the study's primary outcome is testing at least 3 times over twelve months, with an expectation of a baseline test, and follow-up testing at 6 and 12 months. This results in at least 3 tests in 12 months. As a secondary outcome we will be comparing the mean number of tests conducted between the two arms. This study will also evaluate the extent to which MSM (both HIV-negative and HIV-positive) distribute free HIV home-test kits to their social and sexual networks.

68.

69. Innovative testing strategies are needed to reduce levels of undiagnosed HIV infection and increase early access to treatment. The availability of a free home HIV 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 at home HIV tests may play an important role in efforts to reduce both HIV morbidity and mortality. Home-testing with free rapid HIV tests 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 home-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 positive results. Given the unrelenting HIV crisis among MSM and the release into the market of a rapid HIV test for at-home use, it is necessary to evaluate the impact of providing free rapid HIV home-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 home-tests. This information will assist the Division of HIV/AIDS Prevention (DHAP) in developing recommendations, future research and program needs concerning home-testing for MSM to aid in identifying undiagnosed cases of HIV infection and promoting linkage to care of persons with HIV.

70.

71. 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. Parts 1-3 are formative phases of the study and were submitted under the formative generic ICR (0920-0840, exp. 02/29/2016). Part 1 and 2 were submitted under the same GenIC titled "Evaluation of Rapid HIV Self-Testing: Qualitative and User Proficiency Assessments". The Part 3 GenIC is titled "Evaluation of Rapid HIV self-testing in MSM (eSTAMP): Field-Performance study."

72.

73. Part 1 was conducted from June 8th to July 18th and involved conducting 6 in-depth interviews with men who have sex with men (MSM) in Atlanta, and conducting 2 focus groups in Atlanta and 3 focus groups in Chicago. The focus group discussions were conducted to identify issues related to recruitment, barriers to participation, perceptions of the accuracy and acceptability of HIV self-tests, and willingness to conduct self-tests and to provide test kits

to others in their sexual and social networks. In-depth interviews were conducted primarily to gather qualitative data that was used to make the rapid testing and dried blood spot (DBS) specimen collection instructions clearer, and also gather information regarding how to improve the packaging and marketing of test kits for later stages of the study. Part 1 activities led to changes in the testing materials, including the outer boxes, the information provided to participants, DBS kit placemat and instructions, and the internal packaging of the DBS kit.

74.

75. Part 2 was conducted from September 4th to November 5th 2013. Part 2 consisted of a user proficiency assessment to determine if potential users of rapid HIV test kits could successfully conduct the self-tests, accurately interpret the results, and prepare the DBS specimen. Results of the user proficiency assessment were used to make the printed and video testing instructions clearer prior to starting Parts 3 and 4.

76.

77. Part 3 will begin in May 2014. 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.

78.

79. **Part 4 is the final phase of the project and is the part for which we are submitting this information collection request.** Part 4 is a randomized trial which aims to evaluate the use and effectiveness of free home-test kits as a public health strategy for increasing testing among MSM. A secondary aim of Part 4 is to evaluate the extent to which MSM (both HIV-negative and HIV-positive) distribute free HIV home-test kits to their social and sexual networks.

80.

81.

82. **A.1.2 Privacy Impact Assessment**

83.

84. The study will enroll men who report their HIV status as negative or report being unaware of their HIV status into

a randomized controlled trial. They will be assigned to either the intervention group or the comparison group (standard of care). We will enroll 3,200 participants who will be randomized to the intervention or comparison arm. All participants will take a baseline survey (**Attachment 3c**), and the intervention group will receive 4 free rapid HIV test kits (i.e., 2 oral fluid tests (OraQuick), and 2 finger-stick blood tests (Sure Check)). Men in the randomized controlled trial will complete short follow-up surveys (**Attachment 3f**) at 3-month intervals during the 12-month follow-up period, and men in the intervention arm will be allowed to order additional free test kits to replenish the ones they use or give away. At month 12, with the exception of those who tested positive during the study period and previously agreed to participate in the performance assessment, participants in the intervention arm and comparison arm will be sent a performance assessment kit containing 1 oral fluid test (OraQuick) and 1 finger-stick blood test (Sure Check) and a DBS specimen collection kit. Participants in the intervention arm or comparison arm who report a positive HIV rapid test result through results reporting or a follow-up survey will immediately be asked to complete the performance assessment. If the participant agrees, he will be sent a performance assessment kit (1 oral fluid test (OraQuick) and 1 finger-stick blood test (Sure Check) and a DBS specimen collection kit). Participants who report a positive test result before the end of the study and declined participation in the performance assessment, will be offered the performance assessment kit again at month 12. Participants will conduct the DBS collection and rapid HIV testing on themselves, and the DBS card will be returned to the study coordinators for laboratory testing using EIA.

85.

86. The study will also enroll 300 men who report being HIV-positive. They will be assigned to a one-arm descriptive cohort to assess test kit distribution by HIV-infected persons. Participants in the HIV-positive group will take a baseline survey (**Attachment 3d**) and will receive 4 free rapid HIV test kits (i.e., 2 oral fluid tests (OraQuick), and 2 finger-stick blood tests (Sure Check)) to distribute to persons in their social and sexual networks. Men in the HIV-positive group will complete short follow-up surveys (**Attachment 3g**) at 3 and 6 months and be allowed to order additional test kits at 3 months to replenish the ones they use or give away.

87.

88. After completing the randomized trial and test kit distribution evaluation, a final qualitative component will be conducted. For this component, a sample of participants from the intervention arm of the randomized controlled trial will be recruited to participate in focus group discussions (**Attachment 3i**) or individual in-depth interviews (**Attachment 3j**) (regardless of their HIV status) to obtain a greater understanding of their experiences in the study. Approximately 216 HIV-negative participants will take part in the FGDs and 30 HIV-positive participants in the IDIs, for a total of 246 participants for the qualitative data collection.

89.

90. Men for the randomized-controlled trial will be recruited from 12 cities known to have high HIV prevalence as of 2008: Atlanta, Baltimore, Chicago, Dallas, the District of Columbia, Houston, Los Angeles, Miami, New York City, Philadelphia, San Francisco, and San Juan. Recruitment will be conducted through banner advertisements displayed on a variety of social networking sites such as Facebook and dating and sex-seeking sites such as Manhunt and Adam4Adam. The contractor, MANILA Consulting Group, will collect information from participants in identifiable form (IIF). Men who click on the banner advertisements, 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 the study consent form, and if they consent they will be directed to a short eligibility screener (**Attachment 3a**), which will confirm that they meet the eligibility criteria for Part 4. 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 be prompted to complete the registration process (**Attachment 3b**). During the registration process they will provide their contact information including an email address, a cell phone number and a shipping 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 participant must then enter this code as part of the registration process in order to continue. The purpose of this email is to ensure that participants provide a valid

email address. Also, a text message containing a different 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. This study website will be used by participants to complete the baseline surveys (**Attachments 3c & 3d**), follow-up surveys (**Attachments 3f & 3g**) and to report their test results (**Attachments 3e & 3h**).

91.

92. As noted above, eligible men who consent to participate will provide their email address, phone number and shipping address as well as a nickname or name of choice. All participants will be assigned a unique identification number for the study. Identifying information will be held in a password-protected database accessible only by study staff. At the end of the study this information will be destroyed. Baseline survey data, follow-up survey data, participants' results from the HIV home-tests, and DBS specimen test results 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.

93.

94. For the qualitative component of the study, all participants will be assigned a unique identification number for the study. During the focus group discussions (FGD) and in-depth interviews (IDI) process nicknames or name of choice, email addresses and phone numbers previously collected will be used to provide contact information to confirm participation, but names are not used during data collection. This will be emphasized during the introduction to the FGD. Contact information used to confirm participation will be held in a password-protected database accessible only by study staff. This contact information will be held separately from focus group notes, and will never be associated with the study data collected. Electronic audio files will be stored on password protected computers accessed only by study staff transcribing the

data. Access to private 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 private data will be permitted off site, except when data are in transit from the focus group sites to the research office. Data will be protected in locked boxes when being transported from the research sites to the research office.

95.

96. All research personnel will have completed Collaborative Institutional Training Initiative (CITI) training before the research begins. In addition, all study personnel who will have access to study data will sign a confidentiality agreement before the study begins. Any other staff who request to analyze data after the study is completed will be required to complete CITI training, be added to the IRB protocol, and sign a confidentiality agreement before being allowed access to the data.

97.

98. 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. CDC will never have a link to the identifiable information.

99.

100. **A.1.3 Overview of the Data Collection System**

101.

102. Information in part 4 will be collected using an eligibility screener (**Attachment 3a**), study registration process (**Attachment 3b**), baseline surveys (**Attachment 3c and 3d**), HIV test results reporting system to use during the study (**Attachment 3e**), follow-up surveys (**Attachment 3f and 3g**), HIV test results reporting system to use at the completion of the study (**Attachment 3h**), a focus group guide (**Attachment 3i**), and an individual in-depth interview guide (**Attachment 3j**). Specifically, the eligibility screener will assess the age, zip code, race/ethnicity, gender, sexual identity, sexual risk, bleeding disorder diagnoses, HIV testing history, use of antiretroviral medications, and vaccine trial participation to determine eligibility. The baseline survey will collect information on demographic characteristics, HIV testing history, and sexual risk behavior. Men will be asked to use the study web site or download a secure cell phone application to submit quantitative data. Focus group discussions and in-depth interviews will be used to examine experiences of participants in the study.

103.

104.

105. A.1.4 Items of Information to be Collected

106.

107. Part 4 will collect data to:

108.

1. To assess the acceptability and use of free rapid HIV home-tests among MSM residing in the US
2. To understand if the provision of free HIV home-test kits to MSM results in participants being tested at least 3 times in a 12 month period
3. To understand if the provision of free HIV home-test kits to HIV-negative or HIV status unknown and HIV-positive MSM results in the distribution to and use of test kits among persons in their social and sexual networks
4. To explore the likelihood of persons with a positive test result of requesting, being referred to and accessing follow-up supplemental HIV testing and care services
5. To examine if the provision of free HIV home-test kits results in sexual behavior change among study participants, including number of sex partners, unprotected anal intercourse, and serosorting
6. To assess perceptions of possible uses, benefits and disadvantages of HIV home-testing and participants' home-testing preferences regarding types of kits, and how to access kits, HIV information and support services

109.

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

111.

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

113.

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

115.

116. Part 4 will evaluate the use and effectiveness of free home-test kits as a public health strategy for increasing testing among MSM. A secondary purpose of Part 4 is to evaluate the extent to which MSM (both HIV-negative and HIV-positive) distribute HIV home-test kits to their social and sexual networks.

117.

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

119.

120. This study employs many uses of technology.

Approximately 90% of data collection will be performed using

technology. Study questionnaires will be administered using an online system. The use of computerized assessments has been found to reduce respondent burden and enhance respondent privacy during data collection. Computerized assessments have also been found to reduce interviewer bias in the collection of sensitive sexual behavior data. In addition to enhancing the validity of self-report data, computerized assessments can be programmed to customize question wording for individual respondent and prevent respondents from having to answer questions that are not applicable to them. All data collection instruments were designed to be as brief as possible.

121.

122. 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. All participant consenting and data collection will be completed using an online reporting system. 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.

123.

124. Men who consent 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 home-test results and taking the follow-up survey online or through a secure cell phone application.

125.

126. The toll-free study referral system will support the immediate needs of participants who have difficulty with home-testing, who have concerns after testing, or who have a new positive test result. It begins with a toll-free phone number which participants can use to call in with any study-related concern.

127.

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

129.

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

131.

132.

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

134.

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

136.

137.

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

139.

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

141.

142.

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

144.

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

146.

147.

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

149.

150. A 60-day Federal Register notice to solicit public comments was published in the Federal Register on 11/04/2013, Volume 78, Number 213, Page Numbers 66008-66009. A copy of this publication is attached (**Attachment 2**). One comment was received:

151.

152. From: bk1492 <bk1492@aol.com>
To: OM <OM@CDC.GOV>; PRESIDENT <PRESIDENT@WHITEHOUSE.GOV>;
SPEAKEBOEHNER <SPEAKEBOEHNER@MAIL.HOUSE.GOV>; AMERICANVOICES
<AMERICANVOICES@MAIL.HOUSE.GOV>; INFO <INFO@TAXPAYER.NET>; MEDIA
<MEDIA@CAGW.ORG>
Sent: Mon, Nov 4, 2013 3:51 pm
Subject: Fwd:PUBLIC COMMENT ON FEDERAL REGISTER noirmal taxpayers should not be paying for this abnormal behavior

153. GENERAL TAXPAYERS HAVE BEEN GOUGED FOR 50 YEARS TO FUND INVESTIGATION OF THIS PERNICIOUS DISEASE CAUSED BY BEHAVIORAL ABERRATIONS. IT IS TIME THAT THIS POPULATION ASSUMES FULL COSTS OF THEIR BEHAVIOR WHICH BRINGS ON THIS HEALTH ISSUE. ALL HOME TESTING KITS SHOULD BE FULLY PAID FOR BY THOSE WITH WORRIES ABOUT THIS HEALTH ISSUE. ITS TIME TO STOP HAVING GENERAL TAXPAYERS BE GOUGED TO PAY FOR THE COSTS OF THIS BEHAVIOR. I DO NOT SUPPORT THIS PROJECT AT ALL. THE GOVT ENTITIES INVOLVED IN THIS DISEASE HAVE BEEN GETTING THE MAJOR SUMS OF MONEY FOR IT. ITS TIME THAT OTHER PRIORITIES FOR OUR KIDS LIKE AUTISM AND COLITIS GET THE MAJOR FUNDING, NOT THIS PROBLEM BROUGHT ON BY ABERRANT BEHAVIOR. THIS COMMENT IS FOR THE PUBILC RECORD. PLEASE ACKNOWLEDGE RECEIPT. JEAN PUBLIC

154.

155. [Federal Register Volume 78, Number 213 (Monday, November 4, 2013)]
156. [Notices]
157. [Pages 66008-66009]
158. From the Federal Register Online via the Government Printing Office
[www.gpo.gov]
159. [FR Doc No: 2013-26277]
160.

161. Efforts to consult outside the Agency

162.

163. There are several agencies outside of the CDC involved in this study. Manila Consulting group is the contractor for this study. They have subcontracts with Emory University, Northwestern University, and Public Health Solutions. There are also subcontracts with agencies leading the IT development (Cyclogram) as well as the study marketing (Creaxion).

164.

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

166.

167. Men will receive tokens of appreciation for completing specific tasks during Part 4. Men participating in the randomized control trial could be provided up to \$80 over the 12 months they are involved in the project, and men participating in the evaluation of home test kit distribution by HIV-positive MSM could be provided up to \$40 for the 6 months they are involved in the project. Upon completion of the baseline survey, men will be given \$20 as a token of appreciation. All men will be given a \$10 token of appreciation for completing each follow-up survey (men in the intervention and comparison arms at months 3, 6, 9 and 12, and men in the HIV-positive group at months 3 and 6), and men in the intervention and comparison arms will be given \$20 as a token of appreciation for reporting their rapid test results and returning the DBS specimen for the performance assessment conducted at the end of the study or when a participant reports a positive test result during the study. The token of appreciation is being provided for the performance assessment because these individuals have already been diagnosed with HIV and they are providing important data to this study. Their participation is both critical and voluntary, as is participation in any part of the study. Without providing a token of appreciation, we would expect a lower participation rate and this would seriously question the validity of the results. This design has also been approved by the Emory IRB.

168. The tokens of appreciation will be paid by PayPal or by Amazon.com gift card, depending on participant preference. Focus group and in-depth interview participants will receive

\$50 as a token of appreciation. Participants in the focus groups will also receive light refreshments during the discussion.

169.

170. 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..."

171.

172. The use of tokens of appreciation in the proposed study is appropriate according to this guidance. The primary goal of the project is to evaluate the use and effectiveness of home-test kits as a public health strategy for increasing testing among MSM by determining whether the distribution of user-administered and interpreted HIV home-tests to HIV-negative or HIV status unknown MSM results in a higher frequency of MSM HIV testing compared to a standard of referring MSM to testing locations. A secondary purpose of Part 4 is to evaluate the extent to which MSM (both HIV-negative and HIV-positive) distribute HIV home-test kits to their social and sexual networks. Many of the participants will have characteristics that make them more difficult to enroll such as unstable housing, substance abuse, and poverty. The survey instrument also contains highly sensitive questions regarding sexual history, experience of stigma and discrimination, and income. Providing incentives to respondents will be critical to achieving acceptable response rates in this hard-to-find, stigmatized population as demonstrated in the survey literature (Kulka 1995).

173.

174. The need for and amount of the remuneration is based, in part, on the fact that other, similar research projects that ask HIV risk behavior questions in many of the participating areas offer similar tokens of appreciation. Thus, the proposed project would be competing with local researchers who do offer remuneration. Persons at risk for HIV infection have frequently been the focus of health-related data collections, in which remuneration is the norm (Thiede 2009; MacKellar 2005). Research has shown that financial incentives are effective at increasing response rates among female residents in minority zip codes (Whiteman

2003). A meta-analysis of 95 studies published between January 1999 and April 2005 describing methods of increasing minority enrollment and retention in research studies found that incentives enhanced retention among this group (Yancey 2006). Data from MMP's 2007 cycle indicate that 65% of respondents reported a race or ethnicity other than non-Hispanic white. Providing remuneration to respondents is critical to achieve acceptable response rates.

175.

176. Remuneration has been used in other HIV-related CDC data collection efforts such as for National HIV Behavioral Surveillance (OMB 0920-0770, exp. 5/31/2014) and the Transgender HIV Behavioral Survey (OMB 0920-0794, exp. 12/31/2010), both of which ask questions similar to those included in the proposed project. In both of these other projects tokens of appreciation were used to help increase participation rates. Other studies have also found that incentives modestly improve response rates (Shaw et al. 2001).

177.

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

179.

180. As determined by our CIO, the Privacy Act applies 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, rapid test results, follow-up surveys, 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. This information collection is covered under a CDC Privacy System of Records Notice (SORN) entitled; "Epidemiologic Studies and Surveillance of Disease Problems-HHS/CDC"; #09-09-0136. The SORN was published in the Federal Register: December 31, 1992 (Volume 57, Number 252)] [Notices] [Page 62812-62813]

181.

182. 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 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. Study staff will notify the contractor when to destroy the information in the database; the contractor 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.

183.

184. Prior to participating in any part of the study, participants will be required to give consent. For Part 4, we will use documentation of informed consent obtained through electronic agreement to the informed consent form presented online. The informed consent document will explain: (1) what is meant by consent; (2) why we need to take consent; and (3) the purpose of the consent form. 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.

185.

186. 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.

187.

188. Study staff will be available 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 HIV positive on any of the home-

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, 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. Participants will be told through the informed consent document 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. The consent form has a Flesch-Kinkaid Reading Level of <8.0.

189.

190. For the qualitative component of part 4, the focus groups and in-depth interviews will be recorded. Focus groups will be recorded via tape recorder while the IDIs will be recorded via telephone recording equipment standard to telephone interviewing. All data will be transcribed verbatim, and the recordings will be destroyed within 4 weeks of the completion of the transcription. No identifying information other than city will be included in the transcripts.

191.

192. Verbal informed consent will be obtained for the both the focus group discussions (FGDs) and in-depth interviews (IDIs). Men who report for participation in either a FGD or IDI will be given basic information about the purpose of the study, and provided with a written informed consent form for their records. Men in the FGD will be given the informed consent to read in person, and will be allowed to keep a copy for their records. Men in the IDI will be emailed a consent form prior to the interview, and will be asked to ensure they have read it once the call begins. For Part 4, we obtained a waiver of written documentation of informed consent from the Institutional Review Board for the qualitative data collection. This is because the written consent document would be the only identifying document once voice recordings have been destroyed. Therefore, relying on verbal consent will reduce risk of loss of privacy for the participants. Upon arriving at the research site, potential FGD participants will be taken through the consent process by one of the research team members. The consent process will take approximately 10 minutes per individual and will

take place in a room at the research site that provides visual and audio privacy.

193.

194. Respondents will be told that no information in identifiable form will be shared with the CDC. All data provided to CDC will be de-identified and transferred securely to CDC.

195.

196. A.11. Justification for Sensitive Questions

197.

198. 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 home-test kits among MSM.

199.

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

201.

202. A.12.A. Estimated Annualized Burden Hours

203.

204. Study staff will screen approximately 24,000 men for the part 4 study activities. The 24,000 men will take part in a 3-minute screening interview to assess study eligibility (**attachment 3a**); approximately 3,200 men are expected to participate in the RCT (**attachment 3c**) and 300 HIV-positive men are expected to enroll in the one-arm descriptive cohort to assess test kit distribution by HIV-infected persons (**attachment 3d**). The consent will take 10 minutes (**attachment 4a**). The registration process will take approximately 5 minutes (**attachment 3b**). Completing the baseline surveys will take approximately 15 minutes. Entering the rapid home-test results during the study will take approximately 5 minutes (**attachment 3e**). Completing the follow-up surveys will take approximately 10 minutes each (**attachments 3f and 3g**). Entering the rapid home-test results at the completion of the study will take approximately 5 minutes (**attachment 3h**). The consents for the focus group discussions and in-depth interviews will be 10 minutes for each. The focus group discussions will be 90 minutes each (**attachment 3i**) and the in-depth interviews will be 75 minutes each (**attachment 3j**). The total estimated burden for this study is 7,085 hours.

205.

206. Exhibit A.12.A Annualized Burden Hours

207. Type of Respondent	208. Form Name	209. No. of Respondents	212. No. of Responses per Respondent	216. Average Hours per Response	219. Total Response Burden (Hours)
223. Prospective Participant	224. Eligibility Screener	225. 24,000	226. 1	227. 3/60	228. 1,200
229. Enrolled participant	230. Study Registration	231. 14,000	232. 1	233. 5/60	234. 1,167
235. Enrolled participant	236. Consent for RCT	237. 3,200	238. 1	239. 10/60	240. 533
241. Enrolled participant	242. Baseline Survey for RCT	244. 3,200	245. 1	246. 15/60	247. 800
248. Enrolled participant	249. Baseline Survey for HIV-positive group	250. 300	251. 1	252. 15/60	253. 75
254. Enrolled participant	255. Reporting of Home-test Results during study	256. 1,600	257. 3	258. 5/60	259. 400
260. Enrolled	261. Follow-up	262. 3,200	263. 4	264. 10/60	265. 2,133

207. Type of Respondent	208. Form Name	209. 210. No. of 211. Respondents	212. 213. No. of 214. Responses per 215. Respondent	216. 217. Average Hours 218. Per Response	219. 220. Total Response 221. Burden 222. (Hours)
participant	Surveys for RCT			0	3
266. Enrolled participant	267. Follow-up Surveys for HIV positive group	268. 300	269. 2	270. 10/60	271. 100
272. Enrolled 273. participants	274. Reporting of Home-test Results at completion of study	275. 3,200	276. 1	277. 5/60	278. 267
279. Enrolled participant	280. Focus group consent	281. 216	282. 1	283. 10/60	284. 36
285. Enrolled participant	286. Focus group discussion	287. 216	288. 1	289. 1.5	290. 324
291. Enrolled participant	292. Individual in-depth interview with guide consent	293. 30	294. 1	295. 10/60	296. 5
297. En	298. Ind	299. 30	300. 1	301. 1	302. 4

207. Type of Respondent	208. Form Name	209. 210. No. of 211. Respondents	212. 213. No. of 214. Responses per 215. Respondent	216. 217. Average Hours 218. Per Response	219. 220. Total Response 221. Burden 222. (Hours)
rolled participant	individual in-depth interview w guide			.5	5
303. Total	304.	305.	306.	307.	308. 7,085

309.

310.

311. **A.12.B.**

Estimated Annualized Costs

312.

313. 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/oes/current/oes_nat.htm#00-0000)). We expect our sample to comprise men with various occupations and some who are unemployed. We cannot predict the breakdown of the occupations held by our respondents; therefore, we calculated estimates using the hourly wage data from all occupations and the unemployment rates in each of the 12 cities included in this study--Atlanta, Baltimore, Chicago, Dallas, the District of Columbia, Houston, Los Angeles, Miami, New York City, Philadelphia, San Francisco, and San Juan (see table below). A 6.9% average unemployment rate was taken into account. Thus, the average hourly wage is \$23.12.

(<http://www.bls.gov/news.release/pdf/metro.pdf>) in these cities. The total anticipated annual cost to participants for collection of information in this project will be **\$161,308.21**.

314. City	315. Avg. hourly wage (all	316. Unemployment rate (December 2013)

		occupations May 2012)			
317.	Atlanta	318.	\$22.80	319.	6.8%
320.	Baltimore	321.	\$24.64	322.	5.9%
323.	Chicago	324.	\$23.91	325.	8.3%
326.	Dallas	327.	\$22.81	328.	5.4%
329.	District of Columbia	330.	\$36.51	331.	4.6%
332.	Houston	333.	\$23.49	334.	5.3%
335.	Los Angeles	336.	\$25.06	337.	7.9%
338.	Miami	339.	\$20.53	340.	6.0%
341.	New York City	342.	\$28.63	343.	6.6%
344.	Philadelph ia	345.	\$24.38	346.	6.4%
347.	San Francisco	348.	\$31.77	349.	5.6%
350.	San Juan	351.	\$13.43	352.	14.0%
353.	Average	354.	\$24.83	355.	6.9%

356.

357.

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

359.

360. Type of Respondent (Form Name)	361. Total Burden Hours	362. Hourly Wage Rate	363. Total Respondent Costs
364. Eligibility Screener	365. 1,200	366. \$23.12	367. \$27,744.00
368. Study Registration	369. 1,167	370. \$23.12	371. \$26,981.01
372. Consent for RCT	373. 533	374. \$23.12	375. \$12,322.96
376. Baseline Survey for RCT	377. 800	378. \$23.12	379. \$18,496.00

380. Baseline Survey for HIV-positive group	381. 7 5	382. \$ 23.12	383. \$1,734.00
384. Reporting of Home-test Results during study	385. 4 00	386. \$ 23.12	387. \$9,248.00
388. Follow-up Surveys	389. 2 ,1 33	390. \$ 23.12	391. \$49,314.96
392. Follow-up Surveys for HIV positive group	393. 1 00	394. \$ 23.12	395. \$2,312.00
396. Reporting of Home-test Results at completion of study	397. 2 67	398. \$ 23.12	399. \$6,173.04
400. Focus group Consent	401. 3 6	402. \$ 23.12	403. \$832.32
404. Focus group discussion	405. 2 16	406. \$ 23.12	407. \$4,993.92
408. Individual in-depth interviews consent	409. 5	410. \$ 23.12	411. \$115.60
412. Individual in-depth interviews	413. 4 5	414. \$ 23.12	415. \$1,040.40
416. Total	417.	418.	419. \$161,308.21

420.

421.

422.

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

424.

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

426.

427.

428. **A.14. Annualized Costs to the Government**

429.

430. 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. CDC project officers will conduct an estimated total of 6 site visits to the study sites and/or contractor office. During site visits, CDC project officers will meet with study staff to get updates on their progress and to address any challenges. This is also an opportunity to evaluate data security and storage procedures. CDC project officers will not be directly involved in any study activities or interact with study participants during site visits. 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.

431.

432.

433.

434. Expense Type	435. Expense Explanation	436. 437. Annual Costs (dollars)
438. Direct Costs to the Federal Government	439. CDC Project Officer (Commissioned Corps, 0-5, 0.50 FTE)	440. \$ 51,000
441.	442. CDC Co-Project Officer (Visiting Scientist, GS-13, 0.75 FTE)	443. \$ 64,125
444.	445. CDC Project Manager (GS-12,	446. \$

	0.25 FTE)	17,975
447.	448. CDC Project Consultants (GS-13, 0.20 FTE)	449. \$ 17,100
450.	451. CDC Site Visit Travel (6 trips)	452. \$ 7,000
453.	454. Subtotal, direct costs to the government	455. \$ 157,200
456. Contract Costs	457. Contract to the Manila Consulting Group, Inc.	458. \$ 388,550
459.	460.	461.
462.	463. Subtotal, contract costs	464. \$ 388,550
465.	466. TOTAL COST TO THE GOVERNMENT	467. \$ 545,750

468.

469.

470.

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

472.

473. This is a new information collection.

474.

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

476.

477. Data collection will be completed during the first two years after OMB approval is granted. Part 4 data collection, data analysis, and report of findings will be completed by 36 months after approval.

478.

479.

480. Exhibit 16.A. Project Time Schedule

481.

482. 483. Activity	484. 485. Time Schedule
486. Part 4 Data Collection	487. Months 1-30 after OMB approval
488. Part 4 Data analysis and Report of Findings	489. 30 to 36 months after OMB approval

490.

491.

492.

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

494.

495. OMB Expiration Date will be displayed.

496.

497.

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

499.

500. There are no exceptions to the certification.