Web-based Approaches to reach black or African American and Hispanic/Latino MSM for HIV Testing and Prevention Services

OMB# 0920-1284

Section A: Supporting Statement

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60.

- **Goal of the study**

  The goal of this study is to evaluate the effectiveness of mailing out rapid HIV home-testing kits and additional testing promotion components to increase HIV testing among black/African-American or Hispanic/Latino MSM.

- **Intended use of the resulting data**

  The findings from of this research will assist local and state health departments, and community based organizations in making decisions on how to improve HIV testing and linkage to HIV prevention services for black/African American and Hispanic/Latino men who have sex with men.

- **Methods to be used to collect**
  The research study is a randomized control trial.

- **The subpopulation to be studied**

  The subpopulation are individuals who: (1) identify as African-American/black or Hispanic/Latino; (2) report their HIV status as negative or report being unaware of their HIV status; (3) are not currently using PrEP or participating in other HIV testing prevention studies; (4) have had anal intercourse with another man in the past 12 months; (5) reside in one of the study states; (6) Are 18 years or older; (7)born male; and (8) identify as male.

- **How data will be analyzed (e.g., logistic regression)**

  The primary outcome analysis will be an intent-to-treat analysis comparing testing frequency and linkage to HIV services between study arms. In addition, we computed various summary statistics, including means, standard deviations (SDs), and frequencies for the study outcomes. For comparing frequencies, we will compute p-values using Fisher's exact test. For comparing means, we will perform t-tests using Satterthwaite's approximation for unequal variances.

82.

1. <u>Circumstances Making the Collection of Information Necessary</u>

83. The Centers for Disease Control and Prevention (CDC), National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Division of HIV/AIDS Prevention (DHAP) requests a 3-year approval for a Change Request to an existing data collection called "Web-based Approaches to reach black or African American and Hispanic/Latino MSM for HIV Testing and Prevention Services."

84. Among gay, bisexual, and other men who have sex with men (hereafter referred to as MSM) black or African American (hereafter referred to as black) and Hispanic/Latino MSM are more severely affected by HIV than any other racial and ethnic group in the US. In 2014, black MSM (BMSM) and Hispanic/Latino MSM (HLMSM) accounted for

38% and 26% of MSM diagnosed with HIV, respectively. Increasing rates of HIV have been observed among both BMSM and HLMSM. From 2005 to 2014, the number of BMSM diagnosed with HIV increased 22%, primarily before 2010. Among young BMSM aged 13 to 24, new diagnoses increased 87%, but this also has leveled off, with diagnoses declining 2% between 2010 and 2014. Recent modeling shows that these populations have the greatest risk for getting HIV in their lifetime. It is critical that MSM engage in preventative services, including HIV testing, to prevent HIV transmission.

85. Almost all Americans, including ethnic and racial minorities, are using the internet for a variety of purposes. Engaging BMSM and HLMSM through online venues could be a promising strategy for providing HIV testing and linking them to appropriate services. However, although BMSM and HLMSM have similar rates of social media and technology use compared to white MSM, their online participation in some HIV prevention studies and programs is low. Therefore, it is important to understand and overcome barriers that affect BMSM and HLMSM participation in web-based HIV prevention efforts so that prevention providers can develop and implement culturally-appropriate strategies for reaching these disproportionately affected populations online for HIV prevention services, including HIV testing.

86. CDC awarded a cooperative agreement to Emory University in September 2017 to conduct research that would increase testing among BMSM and HLMSM. The goal of the study is to conduct a comparative effectiveness trial of online recruitment strategies for increasing access to HIV at-home testing among 1,800 BMSM and 1,800 HLMSM recruited from traditional and innovative sources using culturally appropriate advertising materials developed by a marketing agency with experience in reaching BMSM and HLMSM with HIV testing campaigns. In addition to the primary aim of evaluating the cost-effectiveness of different recruiting strategies and venues, a co-primary aim is to determine whether testing promotion components, an app or a mobile optimized website, can increase linkage to HIV prevention or HIV care services (depending on HIV testing results) as well as return of home HIV tests. For this data collection we will follow the Public Health Service act (**Attachment 1**).

2. Purpose and Use of Information Collection

87. The goal of this study is to evaluate the effectiveness of mailing out rapid HIV home-testing kits and additional testing promotion components among BMSM and HLMSM. We will conduct a randomized control trial where BMSM and HLMSM are recruited to be tested for HIV from three venue types: general social networking sites, gay-themed websites (not for meeting partners), and geospatial networking apps. Study participants will be randomly assigned to one of three study arms. We will evaluate outcomes, including cost and yield of the recruitment sources and testing promotion strategies in linking MSM to HIV prevention and care cascades. These include, but are not limited to, costs per: HIV test, newly diagnosed MSM, newly diagnosed MSM linked to care, new linkages to PrEP for HIV-negative MSM and other measures.

88. This study has multiple primary aims. A first co-primary aim is to evaluate the cost-effectiveness of recruiting MSM or subgroups of MSM (e.g. newly HIV diagnosed, higher-risk, pre-exposure prophylaxis (PrEP)-eligible) from online venues such as Facebook, Instagram, gay.com, advocate.com, and MSM-oriented mobile apps or online dating websites. Additionally, a second co-primary aim is to determine whether the provision of additional testing promotion components, through a comprehensive HIV prevention mobile phone app, called HealthMindr, can result in a greater proportion of MSM accessing appropriate follow-up care following HIV testing.

89. The study will assess the effectiveness of HealthMindr as a strategy for increasing linkage to prevention or care services. The study will enroll men meeting the following criteria:

1) Identify as African-American/black or Hispanic/Latino
2) Report their HIV status as negative or report being unaware of their HIV status
3) Are not currently using PrEP or participating in other HIV testing prevention studies
4) Have had anal intercourse with another man in the past 12 months
5) Reside in one of the study States (Black MSM: NC, SC, GA, AL, MS, FL, LA; Hispanic MSM CA, NV, MS, LA, TX, NY, FL) and not planning on moving out of State in the next 4 months
6) Are 18 years or older
7) Born male
8) Identify as male.

90. Eligible men who consent to participate will be enrolled into a randomized controlled trial. They will be assigned to one of two groups:

1) A control/referent arm consisting of access to a mobile study participation management app (SMART, Emory University) or email communications and a mail-out self-testing kit
2) An intervention arm consisting of access to a mobile HIV prevention app (HealthMindr), a mobile study participation management app (SMART) or email communications, and a mail-out self-testing kit

91.

92. We expect to consent/screen approximately 10,000 potential participants to fully enroll 3,600 participants, defined as people who consent and screen eligible, register for the study by providing contact information (preferred name, email address, mobile phone number, and shipping address), complete the baseline survey, and are randomly allocated to one of the three groups.

93. All participants will be sent up to four rapid HIV test kits for their use and to give to their friends (hereafter referred to as “guests”) and they will report their results to the study. Participants will use the study app to complete study activities. All

participants and guests will have access to web-based HIV counseling upon request. All participants, regardless of study arm, will also complete a follow-up survey at the end of a 4-month follow-up period. At the end of the 4-month follow-up period, participants will be sent dried blood spot (DBS) and microtainer collection kits for research purposes and another rapid HIV self-test kit for their use. All participants in each of the arms will have access to videoconferencing delivered prevention counseling, and all participants, regardless of assigned arm, will be contacted if they report a positive test during the study period for active linkage to care. We estimate that approximately 2000 guests who receive a study HIV self-test kit will report the HIV self-test result online.

94. The purpose of the DBS collection is to verify reported information provided from participants on use of pre-exposure prophylaxis medications to prevent HIV acquisition, treatment for HIV infection and to identify infections missed by the HIV self-test. The oral fluid HIV self-test has a sensitivity of 91% when used by untrained users at home. The sensitivity and specificity of the Ag/Ab test to be conducted on the DBS sample is 100% and 99.6% respectively. Consequently, the laboratory testing may identify potential infections among participants who have a false negative HIV self-test.

95. The purpose of the microtainer collection is to evaluate the feasibility of self-collection of microtainers among untrained MSM in the US and analyze samples for HIV infection and HIV (PrEP or ART) medications. This may serve as evidence for providing individuals a means to be clinically monitored from home which could alleviate the need for PrEP and VL monitoring clinic visits.

96. CDC recommends at least annual HIV testing for persons at risk of HIV infection and has suggested that MSM may benefit from more frequent HIV testing, e.g., every 3 to 6 months. In a previous CDC-funded HIV self-testing study, up to 4 HIV self-tests were provided every three months to participants. Over the 12-month period, participants who received the self-tests reported testing a mean number of 5.3 times during the study compared to 1.5 times among those who did not receive the self-tests. Additionally, 76% of all persons in the self-testing arm reported testing at least 3 times during the study. (See MacGowan RJ, Chavez PC, Borkowf CB, Owen SM, Purcell DW, Mermin JH, Sullivan PS, for the eSTAMP Study Group. Effect of internet-distributed HIV self-tests on HIV diagnosis and behavioral outcomes in men who have sex with men: a randomized clinical trial. *JAMA Intern Med.* Published online November 18, 2019. doi.org/10.1001/jamainternmed.2019.5222)

97. **Mail-Out Testing Kit Only Arm:** The estimated burden for participants depends on the condition they are randomized into and the activities in which they participate. For the mail-out testing kit arm, the estimated burden for participants is 2 hours and 25 minutes. In total, reading the consent form for eligibility screening (**Attachment 4a**), completing the online eligibility screener (**Attachment 3a**), completing the study registration process (**Attachment 3b**), consenting to participate in the study **(Attachment 4b)**, and completing the baseline assessment (**Attachment 3c**) is estimated to be 20 minutes. Completing the 4-month follow up assessment will take

approximately 30 minutes (**Attachment 3e**). Completion of the initial HIV self-testing kit is estimated to take 30 minutes (10 minutes to read the instructions and collect a sample and 20 minutes to wait for the test results to be processed). Estimated times for completion of the DBS sample collection is 15 minutes and the HIV self-testing is 30 minutes. Microtainer collection is estimated to take 10 minutes. Completion of the first test result survey **(Attachment 3d)** will take 5 minutes, and completion of the final test result survey will take 5 minutes **(Attachment 3f).**

98. **HealthMindr Arm:** The estimated burden for participants depends on the condition they are randomized in to and the activities in which they participate. For the HealthMindr arm, the estimated burden for participants is 2 hours and 45 minutes. In total, reading the consent form for eligibility screening (**Attachment 4a**), completing the online eligibility screener (**Attachment 3a**), completing the study registration process (**Attachment 3b**), consenting to participate in the study **(Attachment 4b)**, and completing the baseline assessment (**Attachment 3c**) is estimated to be 20 minutes. Completing the 4-month follow up assessment will take approximately 30 minutes (**Attachment 3e**). Completion of the initial HIV self-testing kit is estimated to take 30 minutes (10 minutes to read the instructions and collect a sample and 20 minutes to wait for the test results to be processed). Estimated times for completion of the DBS sample collection is 15 minutes and the HIV self-testing is 30 minutes. Microtainer collection is estimated to take 10 minutes. Completion of the first test result survey **(Attachment 3d)** will take 5 minutes, and completion of the final test result survey will take 5 minutes **(Attachment 3f).** Interaction with HealthMindr is estimated at 20 minutes over the 4 months, based on the HealthMindr pilot (Sullivan et al. Usability and acceptability of a mobile comprehensive HIV prevention app for men who have sex with men: A pilot study. *JMIR Mhealth Uhealth* 2017).

99. **Guests of Trial Participants:** The estimated burden for guests depends on the rapid HIV self-test that they use. The estimated burden for guests is up to 37 minutes. Reviewing the consent form **(Attachment 4c**) will take 2 minutes, completing the survey **(Attachment 3h)** will take 5 minutes, conducting the rapid HIV self-test will take up to 30 minutes.

100. **Video Prevention Counseling:** All participants taking an at-home HIV test kit will be offered Video Prevention Counseling as an optional resource. This is a HIPAA-compliant videoconferencing platform that allows participants to interact with trained HIV counselors. As participants interact with the platform, data about length of sessions will be captured and stored in the administrative portal of the platform. These data will not contain any identifying information about the participant. Video counseling sessions will range depending on the participant and the results of an HIV test. Video counseling reduces burden as participants would not need to seek out a physical address for HIV counseling and can consult a counselor within the privacy of their own home.

3. Use of Improved Information Technology and Burden Reduction

101. As a web-based approach to distribution of HIV testing and information on linkage to prevention services, this study will reduce burden to both research and administration staff, and study participants, as nearly all activities will be conducted online including recruitment, data collection, and behavioral intervention. All information collection will be received electronically **(Attachment 6a)**. Participants may download a study management mobile app on their cellphones, SMART, or may be sent study information via email or text. The app will allow participants to see their progress in completing study milestones and link them to individualized study surveys located at SurveyGizmo.com. SurveyGizmo is currently being used for other CDC research projects and cooperative agreements approved by the Office of Budget Management (0920-1209).

4. Efforts to Identify Duplication and Use of Similar Information

102. The web-based approach to HIV testing for black and Hispanic/Latino MSM will collect key information that the Agency believes is not captured elsewhere. The Agency believes no other trial has been conducted or has been planned to collect similar information for these populations. CDC conducted a review of similar studies prior to the issuance of the contract, and determined that this study is collecting unique information from these populations. There is very little research on effective online venues for recruiting black and Latino/Hispanic MSM for HIV testing, and there are very few approaches that have been tested as effective means of linking black and Hispanic/Latino MSM who have tested for HIV into HIV treatment or PrEP services.

5. Impact on Small Businesses or Other Small Entities

103. This data collection will not involve small businesses.

104. **6. Consequences of Collecting the Information Less Frequently**

105. We have determined that the frequency of data collection provides enough data to conduct a rigorous evaluation of the comparative effectiveness trial without overburdening study participants or research staff. The consequences of collecting data less frequently would jeopardize the evaluation of the longer-term effects of the interventions and would jeopardize the scientific value of the evaluation we intend to conduct.

106. **7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**

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

108. 8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

109. A 60-day federal register notice to solicit public comments was published on 12/6/2018, pages 62864-62865, Volume 83, No. 234 (**Attachment 2**). One substantive public comment was received

(**attachment 2a**). Program staff responded in a written response (**attachment 2b**).

110. 9. Explanation of any Payment or Gift to Respondents

111. Participants will be provided with a token of appreciation for their completion of specific tasks during the study period. The values of these tokens are based on a CDC funded research study conducted in 2015-2016 with these populations by the Principal Investigator and Co-Investigators OMB #0920-1018: "Evaluation of Rapid HIV Home-Testing among MSM Trial". This previous study was similar to the current study in that they are both randomized control trials, men who have sex with men are recruited from the internet, and HIV testing and diagnoses are study outcomes. Previous research has demonstrated that high-risk population cannot be recruited and retained in HIV research studies, without the provision of a token of appreciation. Therefore, to ensure recruitment and retention of these stigmatized populations who are at high risk of acquiring HIV, a token of appreciation is required.

112. Participants in this trial will be provided with up to $80 over the study period if they complete all required activities. Men will be provided with $20 after they complete all modules of the baseline survey, and $30 after they complete all modules of the 4-month follow-up survey. Participants who return documentation of HIV testing during the study period will be provided with an additional $10 (limit one per participant) for providing an image of the HIV test device. Participants who return completed DBS cards will be provided an additional $10 upon receipt of the card. Participants who return completed microtainers will be provided an additional $10 upon receipt of the microtainer. All study tokens of appreciation will be provided in the form of a gift card. Our preferred methods are electronic gift cards or PayPal.

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

114. The Privacy Officer for CDC/ATSDR has assessed this package for applicability of 5 U.S.C. § 552a and determined that the Privacy Act does apply to the overall information collection as Personally identifiable information (PII) PII is being collected. PII is collected so that research staff can send study materials, including HIV test kits, to participants and reminders of scheduled study activities. Through Emory's participant management system and database, SMART, access to data is restricted to specific job tasks and individuals who perform those tasks. Access to PII will be limited to the study investigators and data manager. PII will not be transmitted to the CDC or retrievable by a personal identifier.

115. A privacy impact assessment (PIA) was conducted to ensure the protections of the collected information (**Attachment 5b**). Only Emory University and partners in this study, University of Michigan and the University of North Carolina, will have access and share PII. A memorandum of understanding (MOU) stipulating the sharing agreement is

attached to this request **(Attachment 5c).** CDC will receive a de-identified data set for review and analysis.

116. The Contractor will be responsible for collecting all data for this study. To ensure that respondents' health information is protected, we will take the following measures to separate personally identifiable information (PII) from study-related data: (1) all respondents will receive unique identification codes, which will be stored separately from PII on a password protected computer, a locked file cabinet, or both; (2) contact information collected for the purposes of recruiting (i.e., name and telephone number) will be collected and stored securely and separately from responses to screening and interview questions; and (3) we will train researchers who play a role in data collection and analysis in proper procedures for securing project data and protecting participant confidentiality. We will inform respondents that their responses will be kept private to the extent permitted by the law. All respondents interviewed will be informed that the information collected will not be attributable directly to the respondent and will only be discussed among members of the study team. Terms of the CDC contract authorizing data collection require the Contractor to maintain the privacy of all information collected.

117. Access to all data with respondents (name, phone number, email) will be limited to study staff with a data collection role in the project. Such data will be used only for scheduling study activities with respondents, and will not be used for analyses. In conjunction with the data policy, members of study staff are required to:

- Ensure project data are secured against improper disclosure or unauthorized use of information.
- Access information only on a need-to-know basis when necessary in the performance of assigned duties.
- Notify their supervisor, the Project Director, and the organizational Security Officer if information has either been disclosed to an unauthorized individual, used in an improper manner, or altered in an improper manner.
- Report immediately to both the Project Director and the organizational Security Officer all contacts and inquiries concerning information from unauthorized staff and non-research team personnel.

118.

119. The security procedures implemented by the study staff cover all aspects of data handling for hard copy and electronic data. SurveyGizmo was selected as the data collection platform for the quantitative behavioral assessment because of the anti-hacking measures, firewalls, and constant security scans, the parent company completes on behalf of subscribers. SurveyGizmo automatically encrypts all survey data, and requires unique passwords to access as well as decrypt collected data. Data will be stored on SurveyGizmo servers for

24 hours prior to download. All downloaded data will be eradicated from the SurveyGizmo servers.

120. The NCHHSTP IT Security Information System Security Officer (ISSO) consulted on the system security described in this section. The data system for this collection resides with the contractor at an external third party data center and underwent a Privacy Impact Assessment (PIA) **(Attachment 5b).**

121. This information is collected under the authority of the Public Health Service Act, Section 301, "Research and Investigation," (42 U.S.C. 241); and Sections 304, 306 and 308(d) which discuss authority to maintain data and provide assurances of confidentiality for health research and related activities (42 U.S.C. 242 b, k, and m(d)). This information is also being collected in conjunction with the provisions of the Government Paperwork Elimination Act and the Paperwork Reduction Act (PRA). This information will be used by Emory University, the Centers for Disease Control and Prevention (CDC), collaborators at the University of North Carolina and the University of Michigan. The purpose will be to evaluate the effectiveness of mailing out rapid HIV home-testing kits and additional testing promotion components to increase HIV testing among black/African-American or Hispanic/Latino MSM and improve health services and HIV prevention materials for these populations.

122. 11. Institutional Review Board (IRB) and Justification for Sensitive Question

123. IRB Approval

124. The study protocol was approved by Emory University's Institutional Review Board on June 15, 2018 (**Attachment 5a**).

125. Sensitive Questions

126. This study will collect information on potentially sensitive behaviors related to HIV risk and prevention. We plan to ask the following questions that may be sensitive to some respondents:

1. Have you shot up or injected any drugs other than those prescribed for you in the last 12 months?
2. Have you ever been tested for HIV? An HIV test checks whether someone has the virus that causes AIDS?
3. What was the result of your most recent HIV test?

4. In the past 12 months, have you had anal sex with a man?

5. During the past 3 months, how many different men have you had anal sex with without using a condom?
6. Of the _X_ partners you had anal sex with without using a condom in the past 3 months, how many were HIV-positive?

7. Of the ___X_ partners you had anal sex with without using a condom in the past 3 months, how many had an HIV status you did not know?

8. Of the __X__ partners you had anal sex with without using a condom in the past 3 months, how many were HIV-negative?
9. Which of the following STIs were you told that you had?
10. During the course of the study did you pressure someone to use one of the study home HIV tests?

11. Are you taking HIV medicines prescribed by your doctor (also known as antiretrovirals, ART, or HAART) for your HIV infection?

127. There is a slight possibility that someone who uses the home HIV test will be anxious over the results, all staff who answer the study hotline, provide counseling, or remind participants of scheduled activities will be trained to provide respondents with city-specific hotlines for HIV and mental health care organizations. We will inform all respondents that they may skip any question or stop participation at any time.

128. 12. Estimates of Annualized Burden Hours and Costs

129. Information will be collected from approximately 3,600 study participants and 2,000 guests who received and used a rapid HIV self-test. OMB approval is requested for 3 years, thus the total annualized number of respondents is 1,867 and the annualized number of respondents in each assignment group is 622.

130. We expect to consent and screen approximately 10,000 potential participants so that we would fully enroll 3,600 participants. The estimated burden per response for the eligibility screener consent is 2 minutes (**Attachment 4a**). The estimated burden per response for the eligibility screener is 2 minutes (**Attachment 3a**). The estimated burden per response for the study consent is 4 minutes (**Attachment 4b**). The estimated burden per response for the registration is 2 minutes (**Attachment 3b**).

131. All enrolled participants will complete a baseline survey **(Attachment 3c).** The estimated burden per response for the baseline survey is 20 minutes.

132. Participants who complete a home HIV test will have the opportunity to complete the HIV Test Result Reporting Survey during the study **(Attachment 3d).** The estimated burden per response for the HIV test result survey is 5 minutes.

133. All participants will also complete a follow-up survey **(Attachment 3e)** at the end of a 4-month follow-up period. The estimated burden per response for the follow-up survey is 30 minutes.

134. Participants who complete a DBS card and home HIV test will have the opportunity to complete the HIV Test Result Reporting Survey at the completion of the study **(Attachment 3f).** The estimated burden per response for the HIV test result survey is 5 minutes.

135. Participants who order products will be able to request items through the Product Ordering systems **(Attachment 3g).** The estimated burden per response for the ordering products is 3 minutes.

136. Guests who use the study test kits will be able access the study website to read the Guest Consent. The estimated burden per response for the guest consent is 2 minutes (**Attachment 4c**).

137. We expect approximately 2000 guests will report the test result online through the URL provided on the outside of the HIV self-test kit. The estimated burden per response for the Guest HIV Test Result reporting survey is 5 minutes **(Attachment 3i)**.

138. The total estimated annualized burden is 4,804 hours.

139. **Table A12A.**		**Estimate of Annualized Burden Hours**			
140. Type of Respondent	141. Form Name	142. Number of 143. Respondents	144. Number of 145. Responses per 146. Respondent	147. Average Burden 148. Per Response (in Hrs)	149. Total 150. Burden 151. Hours
152. Potential participant	153. Eligibility Consent **(Attachment 4a)**	154. 3,333	155. 1	156. 2/60	157. 111
158. Potential participant	159. Eligibility Screener **(Attachment 3a)**	160. 3,333	161. 1	162. 2/60	163. 111
164. Potential participant	165. Study Consent **(Attachment 4b)**	166. 1,333	167. 1	168. 4/60	169. 89
170. Potential participant	171. Registration contact informa	172. 1,267	173. 1	174. 2/60	175. 42

139. **Table A12A. Estimate of Annualized Burden Hours**					
140. Type of Respondent	141. Form Name	142. Number of 143. Respondents	144. Number of 145. Responses per 146. Respondent	147. Average Burden 148. Per Response (in Hrs)	149. Total 150. Burden 151. Hours
	tion **(Attachment 3b)**				
176. Enrolled participant	177. Baseline Survey **(Attachment 3c)**	178. 1,200	179. 1	180. 20/60	181. 400
182. Enrolled participant	183. Initial HIV Test Result Survey **(Attachment 3d)**	184. 1,000	185. 1	186. 5/60	187. 83
188. Enrolled participant	189. Follow-up Survey **(Attachment 3e)**	190. 1,000	191. 1	192. 30/60	193. 500
194. Enrolled participant	195. Final HIV Test Result Survey (completion) **(Attachment 3f)**	196. 1,000	197. 1	198. 5/60	199. 83
200. Enrolled participant	201. Product ordering **(Attach**	202. 400	203. 1	204. 3/60	205. 20

139. **Table A12A.**		**Estimate of Annualized Burden Hours**			
140. Type of Respondent	141. Form Name	142. Number of 143. Respondents	144. Number of 145. Responses per 146. Respondent	147. Average Burden 148. Per Response (in Hrs)	149. Total 150. Burden 151. Hours
	ment 3g)				
206. Guest	207. Guest Consent **(Attachment 4c)**	208. 667	209. 1	210. 2/60	211. 22
212. Guest	213. Guest HIV Test Result Survey **(Attachment 3h)**	214. 667	215. 1	216. 5/60	217. 56
218. **Total**	219.	220.	221.	222.	223. 1,517

224.

225. The annualized cost to respondents for the burden hours is estimated to be $33,571; details are provided in Table A12.B. The estimates of hourly wages were obtained from the U.S. Department of labor (Bureau of Labor Statistics Wage Data (http://www.bls.gov/news.release/pdf/ecec.pdf). **http://www.bls.gov/oes/current/oes434111.htm**

226.

227.

228. Table A12B.					**229.**
230. Type of Respondent	**231. Form Name**	**232. Average Burden per**	**233. Hourly wag**	**234. Total Burden Hours**	**235. Total Cost to respondents**

		response (in hours)	erate		
236. Potential participant	237. Eligibility Consent **(Attachment 4a)**	238. 2/60	239. $22.13	240. 111	241. $2,456
242. Potential participant	243. Eligibility Screener **(Attachment 3a)**	244. 2/60	245. $22.13	246. 111	247. $2,456
248. Potential participant	249. Study consent **(Attachment 4b)**	250. 4/60	251. $22.13	252. 89	253. $1,970
254. Potential participant	255. Registration contact information **(Attachment 3b)**	256. 2/60	257. $22.13	258. 42	259. $929
260. Enrolled participant	261. Baseline Survey **(Attachment 3c)**	262. 20/60	263. $22.13	264. 400	265. $8,852
266. Enrolled participant	267. Initial HIV Test Result Survey **(Attachment 3d)**	268. 5/60	269. $22.13	270. 83	271. $1,837
272. Enrolled participant	273. Follow-up Survey **(Attachment 3e)**	274. 30/60	275. $22.13	276. 500	277. $11,065
278. Enrolled participant	279. Final HIV Test Result Survey **(Attachment 3f)**	280. 5/60	281. $22.13	282. 83	283. $1,837
284. Enrolled partic	285. Product ordering **(Attachment 3g)**	286. 3/60	287. $22.1	288. 20	289. $443

ipant			3		
290. Guest	291. Guest Consent **(Attachment 4c)**	292. 2/60	293. $22.13	294. 22	295. $487
296. Guest	297. Guest HIV Test Result Survey **(Attachment 3h)**	298. 5/60	299. $22.13	300. 56	301. $1,239
302. Total	303.	304.	305.	306.	307. $33,571

308.

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

310. There are no other costs to participants for being a part of this study.

311. 14. Annualized cost to the government

312. The annualized cost to the government is $948,200. This activity will involve participation of CDC Project Officer and Co-Project Officer who will assist with project design, obtaining IRB and OMB approvals, and providing project oversight. 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. Additional costs to the government include costs associated with conducting the study incurred by Emory University and subcontractors.

313. The annualized cost to the government is $948,200.

314. Expense Type 315. (Based on FY17 dollars)	**316. Expense Explanation**	**317. Annual Costs (dollars)**
318. Direct Costs	**319.**	320.

to the Federal Government		
321.	322. **CDC study Personnel**	323.
324.	325. Research Officer (O-6) 50%	326. $56,000
327.	328. Research Officer (O-4) 10%	329. $7,200
330.	331. Epidemiologist (GS-13) 10%	332. $9,000
333.	334. Project Coordinator (contractor) (1) 30%	335. $22,000
336.	337. Biostatistician (GS-14) 5%	338. $6,000
339.	340.	341.
342.	**343. Total direct costs to federal government**	**344. $100,200**
345.	346.	347.
348. Contractor and Other Expenses*	349. Cooperative Agreement#RFA-PS-17-003.	350.
351.	352. Salary and Wages	353. $155,000
354.	355. Travel	356. $12,000
357.	358. Materials/Supplies	359. $295,000
360.	361. Consultants	362. $12,000
363.	364. Subawards	365. $180,000
366.	367. Shipping/postage	368. $6,000
369.	370. Miscellaneous	371. $10,000
372.	373. Indirect	374. $33,000
375.	376. Total contractor and other expenses	377. $145,000
378.	379.	380.
381.	**382. TOTAL COST TO THE GOVERNMENT**	**383. $948,200**

384.

385. 15. Explanation for Program Changes or Adjustments

386. We are requesting non-substantive modifications to this previously approved ICR. The changes requested are non-substantive modifications to include: 1) an additional method for HIV testing to be added to at-home HIV testing kits; and 2) the removal of one of the

study arms. No changes are requested to survey/data collection instruments and there are no changes to the burden hours calculated for the study. Please see attachment titled “Summary of Proposed Changes in the ICR for Web” for a full list of changes.

387.

388.

389. 16. Plans for Tabulation and Publication and Project Time Schedule

390. Data collection will be conducted during the 3 year period after OMB approval. Data analyses will occur from month 18 through month 24 which is within 6 months of final data collection. The following is a brief overview of the intervention trial timeline.

391.

392. Table16.A Project Time Schedule

393. Activity	**394. Time Schedule**
395. Initiate recruitment	396. Immediately after OMB approval
397. Conduct the study (12-month period)	398. 1 month through 1.5 years after OMB approval
399. Analyze data	400. 6 months through 2.5 years after OMB approval
401. Disseminate findings	402. Within 24 months of completing information collection through 4 years after OMB approval

403.

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

405. OMB Expiration Date will be displayed.

406.

407. 18. Exceptions to Certification for Paperwork Reduction Act Submissions

408. There are no exceptions to the certification.

409.