Testing Messages for Black and Latino MSM

Generic Information Collection Request under 0920-0840

Supporting Statement
Part A

August 28, 2013

Contact

Technical Monitors: Gordon Mansergh, PhD
Centers for Disease Control and Prevention
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
Division of HIV/AIDS Prevention
Prevention Research Branch
1600 Clifton Rd, NE, Mailstop E-37
Atlanta, GA 30333

Telephone: 404-639-6135
Fax: 404-639-1950
E-mail: gcm2@cdc.gov

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. Attachment 1 Eligibility Screeners
35. 1a-Eligibility Screener (English)

1b-Eligibility Screener (Spanish)

Attachment 2- Focus group/Interview guides

2a-Focus group/Interview guide (English)

2b-Focus group/Interview guide (Spanish)

Attachment 3- Information for participants

3a-Information for participants (English)

3b-Information for participants (Spanish)

Attachment 4- Recruitment Materials

4a-Recruitment Flyers

4b-Recruitment Card

50. Testing Brief Messages for Black and Latino MSM: 51. Emerging HIV Prevention Information 52. 53. Supporting Statement 54.

55. A. JUSTIFICATION

56.

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

58.

59. Men who have sex with men (MSM) continue to experience the greatest incidence and prevalence of HIV and AIDS in the U.S., and black and Latino MSM are disproportionately impacted. New and emerging information about and approaches to reducing risk for HIV acquisition and transmission are needed for this population. As information continues to develop regarding HIV prevention approaches -- including new biomedical interventions such as antiretroviral treatment (ART) as prevention for people living with HIV/AIDS and pre-exposure prophylaxis (PrEP) using ART for HIV prevention among uninfected MSM, messages about these new and emerging information are needed for at-risk MSM. Testing of messages to determine potential impact on risk behavior is needed to prepare for information dissemination in the future.

60.

61. The primary aim of this project is to develop and assess the potential impact of practical messages about emerging HIV prevention information and approaches (e.g., PrEP, condom effectiveness, peer group HIV prevalence) for black and Latino MSM. The intent of the study is to determine how condoms and other HIV prevention approaches may be used in the future, given new and emerging information about and approaches to HIV prevention. This study is consistent with identified research priorities through the CDC’s Division of HIV/AIDS Prevention (DHAP) Strategic Plan and the National HIV/AIDS Strategy.

62.

63. The messages will be pilot tested using focus groups and individual interviews. Based on the findings, public health and HIV prevention specialists can better prepare for information delivery about emerging HIV prevention information. Qualitative pilot testing of test messages will be conducted using focus groups and interviews with 90 MSM (30 in each of three US cities). Potential participants will be recruited through online and print advertisements, referrals, and venue-based outreach. Local CBOs serving black and Latino MSM have been identified and partnered with in three cities, Chicago, IL (Center on Halsted), Fort Lauderdale, FL (Latinos Salud), and Kansas City, MO (Kansas City Care Clinic).

64.

65. The project is in alignment with several goals outlined in the National HIV/AIDS strategy:

66. •Goal 1- 1.2.1 Prevent HIV among gay and bisexual men and transgender individuals

67. •Goal 1- 1.2.2 Prevent HIV among Black men and women

68. •Goal 1- 1.2.3 Prevent HIV among Latino men and women

69. •Goal 1- 2.1 Design and evaluate innovative prevention strategies and combination approaches for preventing HIV in high risk communities

70. •Goal 1 – 2.4 Expand prevention with HIV-positive individuals

71.

72. A.1.2 Privacy Impact Assessment

73. The contractor will not collect information in identifiable form (IIF). All of the focus group and interview data from the pilot test will be collected through digital recordings and the detailed notes taken during each activity. Detailed notes, rather than verbatim transcripts, will be developed to summarize each group or interview. Data (notes and digital recording files) will be stored on the contractor's secure servers. All contractor servers and workstations are isolated from the Internet by means of a hardware firewall, and all devices (servers, workstations, routers, switches, etc.) require a valid user ID and password before they can be used.

74.

75. During recruiting and screening, aliases and telephone numbers of potential and actual participants will be collected via online scheduler to facilitate participation. These data will be maintained locally in the secure online scheduler of which only local research staff will have access. This system will not be linked to the screening, focus groups, or individual interviews in any way that could connect a participant's identity to his responses. Each site will keep the number of staff with access to this information to the minimum necessary. Contact information for study participants will be destroyed after recruitment is completed. This step is taken to prevent participants from being involved in the study more than once.

76.

77. Personally identifying information will not be included with study data and will not be transmitted to CDC or any other agency. CDC staff will not have access to any identifying information. All data will be transmitted to CDC via a secure data network. De-identified study data will be maintained at the site and at CDC indefinitely.

78.

79.

80.

81.

82. A.1.3 Overview of the Data Collection System

83.

84. The study will include a qualitative “pilot testing” of test messages using focus groups and individual interviews. All data will be collected and maintained by the contractor. The data collection system involves an eligibility screener, focus groups, and individual interviews.

85.

86. Participants will be screened over the phone. Study staff will access a screening survey **(Attachment 1a and b)** while on the phone with the potential participant, read the description and survey questions to the individual (with anonymity enabled by phone-based nature of interaction), determine eligibility, and schedule them for a focus group or key informant interview.

87.

88. After an individual is determined to be eligible, he will then be scheduled to visit the local site at a specific date and time to participate in the focus group or an interview. To schedule a study assessment appointment, each site will use its own online scheduling system (e.g., Bookfresh or Schedulicity) that will enable selection of a convenient appointment time and distribution of automated reminders to eligible participants. Each system will be configured to collect an “alias,” and a phone number or email address from potential participants. The online scheduling system will not be linked to the responses or the eligibility screener, and will be accessible only by staff at the local site. While the sites may all use the same online scheduler, they will have unique accounts and will not have access to the schedules of any other site. Upon arrival, participants will be checked in and escorted to the private space reserved for the focus groups and interviews. Following the informed consent procedures **(Attachment 3a and b)**, the facilitator will begin the focus group or interview. Focus groups and interviews will be conducted by members of the contractor’s research team who are trained in and experienced with conducting focus groups and interviews. Some focus groups and interviews may be conducted in Spanish, depending on the local population and/or the preference of eligible participants.

89.

90. A.1.4 Items of Information to be Collected

91.

92. During the focus groups and interviews, data will be collected to test the prevention messages. The purpose of these activities will be to assess comprehension and believability of the draft messages, explore how MSM obtain HIV information, and assess their use of technology to

access and receive HIV prevention information. The focus group/interview tool **(Attachment 2a and b)** will assess participant's thoughts about the message (e.g. meaning, believability, and reactions), Internet and phone use, and potentially recruitment strategies.

93.

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

95.

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

97.

98. A.2. <u>Purpose and Use of Information Collection</u>

99.

100. The primary purpose of this project is to develop and assess the potential impact of practical messages about emerging HIV prevention information and approaches (e.g., PrEP, condom effectiveness, peer group HIV prevalence) for black and Latino MSM. The intent of the study is to determine how condoms and other HIV prevention approaches may be used in the future, given new and emerging information about and approaches to HIV prevention.

101.

102. **A.3. <u>Use of Improved Information Technology and Burden Reduction</u>**

103.

104. Technology is used to reduce burden during the eligibility screening process. Potential focus group and individual interview participants will be screened for eligibility by phone based on certain inclusion criteria. Recruitment materials will direct potential participants to call and reach a local study staff member who will conduct the screening over the phone. To facilitate routing of calls, the phone number (and/or extensions) provided will be for the local study staff (coordinator or outreach staff), and callers will be directed to mention a project "nickname" in the event their call is misdirected or routed to the main line. Study staff will use an eligibility screening survey while on the phone with the potential participant, read the description and survey questions to the individual (with anonymity enabled by phone-based nature of interaction), determine eligibility, and schedule them for a focus group or individual interview. Focus group timeslots will be filled first, as participant availability allows.

105.

106. **A.4. <u>Efforts to Identify Duplication and Use of Similar Information</u>**

107.

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

109.

110. **A.5. <u>Impact on Small Businesses and Other Small Entities</u>**

111.

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

113.

114. **A.6. <u>Consequences of Collecting the Information Less Frequently</u>**

115.

116. This project is being conducted to gather information on the potential impact of practical messages regarding emerging information on HIV prevention and the HIV epidemic among men who have sex with men (MSM), including condoms and pre-exposure prophylaxis (PrEP) with anti-HIV medications. If this information were not collected, we would not be able to build the foundation for future messages in the prevention of HIV among black and Latino MSM, a population disproportionately affected by the HIV epidemic. It would therefore be impossible to inform further communication in the areas of HIV prevention without testing of new and emerging information.

117.

118. **A.7. <u>Special Circumstances Relating to Guidelines of 5 CFR 1320.5</u>**

119.

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

121.

122. **A.8. <u>Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agencies</u>**

123.

124. 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.

125.

126. **A.9. <u>Explanation of Any Payment or Gift to Respondents</u>**

127.

128. Participants will be given a $50 gift card as a token of appreciation for participation. 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…"

129.

130. The use of tokens of appreciation in the proposed formative research is appropriate according to this guidance. The primary goal of the project is to develop and assess the potential impact of practical messages about emerging HIV prevention information and approaches (e.g., PrEP, condom effectiveness, peer group HIV prevalence) for black and Latino MSM. The intent of the study is to determine how condoms and other HIV prevention approaches may be used in the future, given new and emerging information about and approaches to HIV prevention. Focus groups and individual interviews will be conducted with 90 MSM, of which 30 will be high-risk HIV negative, 30 will be lower-risk HIV negative, and 30 will be HIV positive. Thus, this study seeks to recruit, enroll, and follow a hard-to-reach and possibly hidden population, while also asking highly sensitive questions about issues such as sexual behavior, HIV and status.

131.

132. Providing incentives to respondents will be critical to achieving acceptable response rates in this hard-to-find population as demonstrated in the survey literature (Kulka 1995). 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 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 tokens of appreciation are effective at increasing response rates among female residents living in zip codes of predominantly minority populations (Whiteman 2003). A meta-analysis of 95 studies published between January 1999 and April 2005 describing methods of increasing minority persons' enrollment and retention in research studies found that remuneration enhanced retention among this group (Yancey 2006). Based on these scientific research studies, providing remuneration to hard-to-find racial/ethnic minority respondents is critical to achieve acceptable response rates.

133.

134. 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 formative research and have a similar length of time for completing the client interview. 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).

135.

136.

137. **A.10. <u>Assurances of Privacy Provided to Respondents</u>**

138.

139. All of the qualitative focus group and interview data will be collected through digital recordings and the detailed notes taken during each activity. These items will be stored on the contractor's secure servers. Summary notes will be used for standard qualitative data analysis to identify themes. The analysis will be a joint effort between contractor staff and CDC staff. A final written set of themes and recommendations will be shared with the CDC when the analysis is complete, as well as the anonymous/de-identified notes and digital recordings.

140.

141. As a requirement of the contract with CDC, the contractor must ensure that its information systems meet CDC certification and accreditation standards. This project will be assigned a security category and the contractor is required to develop a System Security Plan (SSP) to ensure protocols are in place to meet this designation. The contractor has recently received preliminary approval of an SSP for a low security categorization for another CDC-funded project, and if the proposed project receives a similar designation, the contractor will meet these standards for the proposed project. An SSP for the proposed project will be developed and submitted in early 2013, and approval must be received before data collection can begin.

142.

143. All focus group and individual interview data (notes and digital recording files) will be stored on the contractor's secure servers. Secure web servers using the latest SSL technology, state-of-the-art firewalls, mandatory scanning of all incoming e-mail, intrusion detection and monitoring systems are all utilized to ensure that the contractor's network is safe and secure. All contractor servers and workstations are isolated from the Internet by means of a hardware firewall, and all devices

(servers, workstations, routers, switches, etc.) require a valid user ID and password before they can be used.

144.

145. Local partner sites will also be responsible for data security. During recruiting and screening, contact information of potential and actual participants will be collected.. These data will be kept in the secure online scheduler to which only research staff will have access. This system will not be linked to the screening or data in any way that could connect a participant’s identity to his responses. Each site will keep the number of people with access to this information to the minimum necessary. Contact information for study participants will be destroyed after recruitment is completed. This step is taken to prevent participants from being involved in the study more than once.

146.

147. This study has been designed to minimize the collection of personal identifying information, and to eliminate any connection between that information and the research assessment data. Potential participants who are screened eligible over the phone will be scheduled by phone by local staff. Local staff will access the online scheduling system, set up an appointment, and collect alias information (e.g., name of their first pet)from potential participants (alias, and phone number or email address). This information will be kept in a separate, computerized spreadsheet or database, accessible only by local research staff and protected by password.

148.

149. An alias will be used to avoid personal identifiers, and an email address or phone number (as preferred) will be used to send a text-based reminder or confirmation of the appointment. The alias has to be something that the individual can easily remember, that can be prompted by local staff, that others will not readily identify a particular participant with, and that is somewhat unique across the many study participants. Thus, we propose to ask for the name of the participant’s first pet as their alias. If the participant has not had a pet or prefers not to say, then the name of the first street they remember living on will be their alias.

150.

151. Local project staff will keep any personal information of participants confidential. Confidentiality and scientific ethics will be covered during staff training to emphasize the importance of this issue. Participants will be instructed that they do not have to share personal information with which they are uncomfortable sharing, consistent with the nature of voluntary involvement.

152.

153. **A.11.Justification for Sensitive Questions**

154.

155. The majority of questions asked during the focus groups and interviews will not be of a sensitive nature, they will be asked to assess comprehension and believability of the messages, explore how MSM obtain HIV information, and assess the use of Internet and mobile device technology by the target population to inform future message dissemination.

156.

157. To avoid fear of disclosure of sensitive information, no personally identifiable information will be collected and respondents will be told that all data provided by respondents will be treated in a secure manner and will not be disclosed.

158.

159. Also, access to servers, workstations and other equipment containing sensitive or valuable data is limited to those personnel required to use these systems as part of their jobs. For example, servers are kept in a locked room accessible only to the staff responsible for their operation. All sensitive data are stored on servers and not on individual workstations. Additionally, sensitive data are protected by complex passwords, which are changed on a regular basis. Full system backups are performed nightly and include secure off-site storage to assure data security.

160.

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

162.

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

164.

165. It is estimated that the screening questions will take 5 minutes. Each focus group and individual interview will take 90 minutes.

166. Exhibit A.12.A Annualized Burden Hours

167. Type of Respondent	168. Form Name	169. No. of Respondents	170. No. Responses Per Respondent	171. Average Burden Per Respondent (in hours)	172. Total Annual Burden in Hours
173. Prospective Participant	174. Eligibility Screener	175. 180	176. 1	177. 5/60	178. 15
179. Enrolled Participant	180. Focus Group/ Interview Guide	181. 90	182. 1	183. 1.5	184. 35
185. Total	186.	187.	188.	189.	190. 50

191.
192.
193. **A.12.B. Estimated Annualized Costs**
194. Table A12.B displays the annualized cost to Respondents for burden hours shown in Table 12.A. In order to estimate the cost to the Respondents, we used the seasonally adjusted average hourly wage earnings of total production and non-supervisory workers on private nonfarm payrolls proposed for January 2010 by the US Department of Labor.

195. Exhibit A12.B. Estimated Annualized Burden Costs

196. Type of Respondent	197. Total Annual Burden in Hours	198. Average Hourly Wage Rate	199. Total Annual Respondent Cost
200. Eligibility Screener	201. 15	202. $19.30	203. $289.50
204. Focus Group/Interview Guide	205. 135	206. $19.30	207. $2,605.50
208. Total	209.	210.	211. $2,895.00

212.

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

214.

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

216.

217.

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

219.

220. The average estimated annual cost to the Federal government for conducting the message testing activities proposed in Table A12B is $691,395. This total cost includes approximately $600,000 for contractual costs (e.g., test design, data collection, analysis, and reporting), and $91,395 for personnel costs for Federal employees involved in project oversight activities.

221.

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

223.

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

225.

226.

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

228.

229. Data collection will be completed during the first year after OMB approval is granted. Data collection, data

analysis, and report of findings will be completed by 4 months after approval.

230.

231. Exhibit A16. Project Time Schedule

232. Activities	**233. Time Schedule**
234. Begin recruitment	235. 1 month post OMB approval
236. Complete recruitment, intervention implementation, and data collection	237. 2 months post OMB approval
238. Analysis of key outcomes	239. 3 months post OMB approval
240. Refinement of messages based on results	241. 4 months post OMB approval

242.

243. **A.17.<u>Reason(s) Display of OMB Expiration Date is Inappropriate</u>**

244.

245. OMB Expiration Date will be displayed.

246.

247.

248. **A.18.<u>Exceptions to Certification for Paperwork Reduction Act Submissions</u>**

249.

250. There are no exceptions to the certification.