Request for Sub-collection Under the
Approved Generic ICR: Formative Research and Tool Development

OMB No. 0920-0840, Expiration January 29, 2016

Title:

CBO Needs Assessment for Preparedness and Resources for Support of Biomedical HIV Prevention

Supporting Statement A

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61. A. JUSTIFICATION

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

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65. The Centers for Disease Control and Prevention (CDC), requests approval for a new data collection entitled, "*CBO Needs Assessment for Preparedness and Resources for Support of Biomedical HIV Prevention*" under the umbrella clearance 0920-0840, "Formative Research and Tool Development", exp. 02/29/2016. The proposed information collection is to conduct formative research to assess the interest and current capacity of community-based organizations (CBOs) to implement biomedical interventions. The knowledge gained will be used to develop training and educational resources and tools for use by CDC/DHAP-funded, and other CBOs. The results of this needs assessment may be shared by presentation at CBO grantee meetings, distribution to technical assistance providers for CBOs, and publication of a report on a CDC website or in a journal.

66.

67. The Division of HIV/AIDS Prevention (DHAP) funds CBOs to deliver HIV prevention services; some are directly funded and some indirectly through state and local health departments. Most are funded to provide non-clinical prevention services (e.g., counseling, HIV testing, HIV education). Some are clinical care sites funded to provide HIV testing and services to increase linkage to, and retention in, HIV treatment.

68.

69. Antiretroviral (ARV) medications can be effectively used to reduce the number of new HIV infections. In persons without HIV infection, ARVs can be given either: 1) for 28 days following a potential HIV exposure through sexual or injection behaviors as nonoccupational postexposure prophylaxis (nPEP) or 2) begun before potential sexual HIV exposures and taken daily for months to years as preexposure prophylaxis (PrEP). In persons with HIV infection, beginning treating with ARVs early in their infection (e.g., with high CD4 cell counts) can greatly lower their risk of transmitting infection to uninfected sexual partners; this is also called treatment as prevention or TasP.

70.

Because these prevention methods all involve prescribing ARVs to people and monitoring for side effects and safety, they can only be done by clinicians licensed to prescribe medication. Non-clinical CBOs are critical to educating communities about these biomedical prevention methods and working with men and women to provide support for the use of ARVs for prevention. This can include identifying clients who might benefit from biomedical interventions and referring/linking them to clinical care sites, supporting medication adherence, and supporting behavioral risk reduction activities. In addition, some non-clinical CBOs may want to add clinical staff or formally collaborate with clinical providers for the delivery of biomedical HIV prevention services.

With the expansion of effective clinically-delivered HIV prevention methods (PrEP, nPEP, and TasP), CDC/DHAP needs to assess the interest, current capacity, and anticipated needs of community-based organizations for engagement with these interventions as part of their HIV prevention services.

A.1.2 Privacy Impact Assessment

This is an organizational assessment and does not involve confidentiality issues for respondents. CDC will contact CBOs by telephone, from a list maintained by CDC, to elicit interest in participating in the online survey. If interested, two respondents will be identified per CBO, one executive level staff member and one line staff client service provider. Names and e-mail addresses will be collected for each respondent. CDC will collect data via web survey using “Survey Monkey”. An email with the survey link will be sent to each of these respondents for completion. In the survey database, individuals responding for organizations will only be entered by codes. Contact information for organizational respondents will be destroyed when the sample is complete and any data queries have been addressed.

A.1.3 Overview of the Data Collection System

The data collection process will use a combination of cognitive interviewing and an online survey. The Cognitive Interviewing techniques will be used in the pre-testing of the survey with a small number of participants to ensure

that the survey is clear and easy to complete. Cognitive interviews are commonly used for development and testing of specific data collection instruments and frequently involve several rounds of cognitive interviews with each iteration of the product. Results of cognitive interviews will be used to make instrument design decisions that minimize response error and reduce burden to the public.

The 587 participants consist of the 153 Directly Funded Community Based Organizations (CBOs), 26 Community Health Centers funded by DHAP as CBOs, and 408 unfunded CBOs. Both CDC funded and unfunded CBOs are included for a variety of reasons. Many of the currently unfunded CBOs have previously been funded by CDC. So, although they may not be funded currently, they might have been funded by CDC in the past and there is the potential for them to be funded by CDC in the future. Also, this assessment aims to understand the capacity of all CBOs to deliver biomedical prevention services to the community. Since we want to understand how these services are being delivered to the community, we need to include all of the CBOs that have the potential to deliver these services regardless of whether they are funded by CDC or not. Also, by including both funded and unfunded CBOs, the tools and trainings we develop as a result of this study will be more helpful to a wider range of CBOs.

"The Biomedical HIV Prevention Organizational Assessment" (**Attachment 9**) is a web-based survey that will be administered to participants via Survey Monkey. An email *("Survey Email Recruitment Script"* **Attachment 7**) will be sent to participants with a link to the web-based survey. The survey will include both open and closed ended questions.

A.1.4 Items of Information to be Collected

"The Biomedical HIV Prevention Organizational Assessment" (**Attachment 9a**) lists the survey questions that will comprise the online survey (**Attachment 9b**).

This is an organizational assessment and does not involve confidentiality issues for respondents. CDC will collect data via web survey using Survey Monkey. Phone calls will be made to each selected CBO to elicit interest in participating in the survey. If interested, two respondents will be identified per CBO, one executive level staff member

and one line staff client service provider. Names and e-mail addresses will be collected for each respondent. An email *("Survey Email Recruitment Script"* **Attachment 7**) with the survey link will be sent to each of these respondents for completion. In the survey database, individuals responding for organizations will only be entered by codes. Contact information for organizational respondents will be destroyed when the sample is complete and any data queries have been addressed.

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96. A.1.5 Identification of Websites and Website Content Directed at Children Under 13 Years of Age

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98. This information collection does not involve websites or website content directed at children less than 13 years of age.

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

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103. The Division of HIV/AIDS Prevention (DHAP) funds community-based organizations (CBOs) to deliver HIV prevention services; some are directly funded and some indirectly through state and local health departments. Most are funded to provide non-clinical prevention services (e.g., counseling, HIV testing, HIV education). Some are clinical care sites funded to provide HIV testing and services to increase linkage to, and retention in, HIV treatment.

104.

105. Antiretroviral (ARV) medications can be effectively used to reduce the number of new HIV infections. In persons without HIV infection, ARVs can be given either: 1) for 28 days following a potential HIV exposure through sexual or injection behaviors as nonoccupational postexposure prophylaxis (nPEP) or 2) begun before potential sexual HIV exposures and taken daily for months to years as preexposure prophylaxis (PrEP). In persons with HIV infection, beginning treating with ARVs early in their infection (e.g., with high CD4 cell counts) can greatly lower their risk of transmitting infection to uninfected sexual partners; this is also called treatment as prevention or TasP.

106.

107. Because these prevention methods all involve prescribing ARVs to people and monitoring for side effects and safety, they can only be done by clinicians licensed to

prescribe medication. Non-clinical CBOs are critical to educating communities about these biomedical prevention methods and working with men and women to provide support for the use of ARVs for prevention. This can include identifying clients who might benefit from biomedical interventions and referring/linking them to clinical care sites, supporting medication adherence, and supporting behavioral risk reduction activities. In addition, some non-clinical CBOs may want to add clinical staff or formally collaborate with clinical providers for the delivery of biomedical HIV prevention services.

108.

109. With the expansion of effective clinically-delivered HIV prevention methods (PrEP, nPEP, and TasP), CDC Division of HIV/AIDS Prevention needs to assess the interest, current capacity, and anticipated needs of community-based organizations for engagement with these interventions as part of their HIV prevention services.

110.

111. The primary use for this data collection is to plan training and educational resources for use by CDC-funded CBOs. The results of this needs assessment may be shared by presentation at CBO grantee meetings, distribution to technical assistance providers for CBOs, publication of a report on a CDC website or in a journal.

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

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116. The survey will be created using a Survey Monkey platform, which is extremely user friendly. Participants will be sent a link to the web based survey via email (*"Survey Email Recruitment Script"* **Attachment 7**). Users will be able to move quickly through the survey on their computer. Most of the questions are closed ended questions and require little effort to answer- often just a simple mouse click. When participants are finished with the survey, they simply click "submit" and they are finished. Since it is electronic, they do not have to mail in a hard copy of their survey.

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

120. Literature searches were conducted to identify duplicate information collections. No similar information is

currently available for the purposes of this study. As far as we know, this information collection does not duplicate any existing efforts. With the expansion of effective clinically-delivered HIV prevention methods (PrEP, nPEP, and TasP), CDC Division of HIV/AIDS Prevention needs to assess the interest, current capacity, and anticipated needs of community-based organizations for engagement with these interventions as part of their HIV prevention services. Although clinical research exists on PrEP, nPEP and TasP, there is not any information on the willingness and capacity of CBOs to provide these or related services. There is also not any information on the potential obstacles that CBOs face in providing these services. Also, there is not any research on what tools and resources CBOs would need to help assist clients to effectively access and use these new HIV prevention methods.

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

Pilot Test

Phone calls will be made to select 4 CBOs to participate in the pilot test of the survey **(“***Pre-test Telephone Recruitment Script*” **Attachment 3)**. If interested, two respondents will be identified per CBO, one executive level staff member and one line staff client service provider. Emails will be sent out (“*Pre-test Recruitment Email*” **Attachment 4**) to these two individuals to invite them to participate in the telephone interviews. This initial call should take about 5 minutes. A telephone call will be scheduled so that the participants can “walk through” the survey to identify any potential problems with the survey **(“***Pre-test Telephone Interview Script*” **Attachment 5)**. This feedback will help improve clarity of the survey before sending out to the other CBOs. This call should take about 30 minutes.

Survey

Each organization (community health centers and other CBOs) will receive a telephone call to determine whether or not they are interested in participating in the survey **(“**Survey Telephone Recruitment Script” **Attachment 6)**. If they are interested, the investigator will ask for the names and emails addresses of two staff members (one executive level and one staff member involved in direct client

service). This initial call should take about 5 minutes. These two staff members will be emailed recruitment letters with links to the survey **(“***Survey Email Recruitment Script*” **Attachment 7).** The survey **(“***Biomedical HIV Prevention Organization Assessment*” **Attachment 9)** should take about 30 minutes to complete. The survey will be created using a Survey Monkey platform, which is extremely user friendly. Users will be able to move quickly through the survey on their computer. Most of the questions are closed ended questions and require little effort to answer- often just a simple mouse click. When participants are finished with the survey, they simply click “submit” and they are finished. Since it is electronic, they do not have to mail in a hard copy of their survey.

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

135. The activities involve a one-time collection of data. There are no legal obstacles to reducing the burden. Participants will complete the web-based survey one time.

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

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

139.

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

141. A 60 day notice to solicit public comments was published in the

142. Federal Register on August 2, 2012, Vol. 77, No. 149 (**Attachment 2**). No public comments were received

143.

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

145. Respondents will not be paid.

146.

147. **A.10.<u>Assurances of Confidentiality Provided to Respondents</u>**

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149. This is an organizational assessment and does not involve confidentiality issues for respondents. Prior to the survey, prospective respondents will be contacted via telephone from an existing list of CBOs maintained by CDC. Calls will be made to each selected CBO to elicit interest in participating in the survey **(“***Survey Telephone Recruitment Script*” **Attachment 6)**. If interested, two respondents will be identified per CBO, one executive level

staff member and one line staff client service provider. Names and e-mail addresses will be collected for each respondent. An email (“*Survey Email Recruitment Script*” **Attachment 7**) with the survey link will be sent to each of these respondents for completion. When the respondents click on the survey link, they will be taken to the consent form **(***“Consent Form”* **Attachment 8)**. In the database, individuals responding for organizations will only be entered by codes. Contact information for organizational respondents will be destroyed when the sample is complete and any data queries have been addressed.

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151. Since the focus of the survey is on the characteristics of the organizations, respondents will not be asked about their personal demographic variables (e.g., age, gender, race, ethnicity, etc.).

152.

153. **A.11.<u>Justification for Sensitive Questions</u>**

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155. Since the questions focus on the characteristics of the organizations (CBOs) and not individual level data, there are no sensitive questions. Respondents will not be asked about their personal demographic variables (e.g., age, gender, race, ethnicity, etc.). An email (“*Survey Email Recruitment Script*” **Attachment 7**) with the survey link will be sent to each of the respondents for completion. In the database, individuals responding for organizations will only be entered by codes. Contact information for organizational respondents will be destroyed when the sample is complete and any data queries have been addressed.

156.

157. A.12.<u>Estimates of Annualized Burden Hours and Costs</u>

158.

159. This information collection is a one-time occurrence that will begin after OMB approval is granted. The needs assessment tool (**Attachment 9**) will be used to assess the capacity of 587 CBOs. In aggregate, CBO response requires approximately 323 burden hours for the 895 respondents (see Table 12A below). There is no cost to respondents other than their time.

160.

161. Exhibit A.12.A Annualized Burden Hours

162. Type of Respondent	163. Form Name	164. 165. Number of 166. Respondents	167. 168. Number of 169. Responses per 170. Respondent	171. 172. Average Hours 173. Per Response	174. 175. Total Response 176. Burden 177. (Hours)
178. HIV Community Based Organization Staff	179. Pre-test Telephone Interview 180. Att5	181. 8	182. 1	183. 30/60	184. 4
HIV Community Based Organization Staff	Survey Telephone Recruitment Script Att6	185. 300	186. 1	187. 5/60	188. 25
HIV Community Based Organization Staff	Biomedical HIV Prevention Organizational Assessment Att9a	189. 587	190. 1	191. 30/60	192. 294
193. Total	**194.**	195. 895	196.	197.	**198. 323**

199.

200.

201. A.12.B. Estimated Annualized Burden Costs

202. The annualized costs to the respondents are described in Exhibit A.12.B. The United States Department of Labor Statistics May, 2011. (http://www.bls.gov/oes/current/oes_nat.htm was used to estimate the hourly wage rate for the Community and Social Service Occupations for the purpose of this generic request. The figure of $21.07 per hour was used as an estimate of

average hourly wage for adults. Thus, the total anticipated annual cost to participants for collection of information in this project will be $6805.61.

203.

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

205. Activity	**206. Total Burden Hours**	**207. Hourly Wage Rate**	**208. Total Respondent Cost**
209. Pre-test Telephone Interview	210. 4	211. 21.07	212. 84.28
Survey Telephone Recruitment Screener	213. 25	214. 21.07	215. 526.75
Biomedical HIV Prevention Organizational Assessment	216. 294	217. 21.07	218. 6194.58
219. Total	220. 323	221. 21.07	**222. 6805.61**

223.

224.

225. **A.13.<u>Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers</u>**

226. There are no costs to respondents other than their time.

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229. A.14.<u>Annualized Costs to the Federal Government</u>

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231. The annualized cost to the government is estimated to be $14,100.00. The only expense to the government will be the percentage of FTE time spent on the study, which has been paid for out of the Epidemiology Branch budget at CDC. There will be no contractors working on this study. The only expense in creating the survey will be FTE time. The survey will be created by the CDC Project Officer by using SurveyMonkey software, which CDC already has a license to use. So, there will be cost associated with using the SurveyMonkey software. All activities regarding study recruitment will

be conducted by the CDC Project Officer. The survey data will be analyzed by a CDC Statistician.

232.

233. Expense Type	234. Expense Explanation	235. 236. Annual Costs (dollars)
237. Direct Costs to the Federal Government	238. CDC Project Officer (GS-13 0.10) FTE)	239. $ 9,400
240.	241. CDC Statistician (GS 13 0.05)	242. $ 4,700
243.	**244. Subtotal, Direct costs**	**245. $ 14,100**
246. Total Costs to Government	**247.**	**248. $ 14,100**

249.

250.

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

252. Not applicable – request is for a sub-collection under a generic approval.

253.

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

255.

256. 257. Activity	258. 259. Time Schedule
260. Interviews to pretest test survey 261.	262. 1-3 months after OMB approval
263. Refine survey based on interview responses	264. 1-3 months after OMB approval
265. Administer internet survey	266. 4-7 months after OMB approval
267. Data analysis	268. 8-9 months after OMB approval

269.

270.

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

OMB Expiration Date will be displayed.

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

There are no exceptions requested.