

**Community Context Matters Study**

Supporting Statement A

OMB No. 0920-1038

May 12, 2016

**Project Officer:**

Dawn K. Smith, MD, MS, MPH

National Center for HIV/AIDS, Viral Hepatitis, STD, and TB  
Prevention

Division of HIV/AIDS Prevention/Epidemiology Branch

Centers for Disease Control and Prevention

1600 Clifton Road NE, Mailstop E-45

Atlanta, GA 30333.

Voice: (404) 639-5166

Fax: (404) 639-6127

Email: [dsmith1@cdc.gov](mailto:dsmith1@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. Collection 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.**

- 35. 36. Authorizing Legislation  
1
  - 37. 38. 60-Day FRN  
2
  - 39. 40. Neighborhood Interview Recruitment Script and  
3 Informed Consent
  - 41. 42. Key Stakeholder Telephone Recruitment Script  
4
  - 43. 44. Key Stakeholder Informed Consent  
5
  - 45. 46. Neighborhood Interview (street-recruited  
6 participants)
  - 47. 48. Key Stakeholder Interview  
7
  - 49. 52. NORC-University of Chicago IRB Letter  
8
  - 50. 53. CDC IRB Letter  
9
  - 51. 54. Philadelphia Health Dept. IRB Letter  
1
  
  - 55. 56.
  - 57. 58.
- 59.**

**60.**

**61.**

62. **A. JUSTIFICATION**

63.

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

65.

66. The Centers for Disease Control and Prevention (CDC), requests a 3-year approval for a new data collection entitled, "*Community Context Matters Study*".

67.

68. The daily use of specific antiretroviral medications by persons without HIV infection, but at high risk of sexual or injection exposure to HIV, has been shown to be a safe and effective HIV prevention method. The Food and Drug Administration approved the use of Truvada® for preexposure prophylaxis (PrEP) in July 2012 and CDC has issued interim guidance for its use. With approximately 50,000 new HIV infections each year, increasing rates of infection for young MSM, and continuing severe disparities in HIV infection among African-American men and women, incorporation of PrEP into HIV prevention is important. However, as a new prevention tool in very early stages of introduction and use, there is much we need to learn about how to implement PrEP in a real world setting and the need to develop and validate new measurement tools to capture this information.

69.

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

71.

72. The goal of the proposed information collection is to learn about knowledge, misinformation, attitudes, hopes and fears as well as the extent of unsafe community practices (e.g., informal medication purchase) related to a new intervention (PrEP) over the period of its initial introduction. Because PrEP is new, and highly effective, additional efforts to inform key stakeholder and potential users, and to design programs to support its use are critical. The knowledge gained will be used to refine measurement instruments and methods, develop training and educational resources and tools for use by CDC/DHAP (Division of HIV/AIDS Prevention)-funded partners, and other clinical and non-clinical community based organizations. The results of this survey may be shared by presentation at grantee meetings, distribution to technical assistance providers for HIV prevention partners, and publication of a report on a CDC website or in a journal.

73.

74.

75.

76. **A.3 Overview of the Data Collection System**

77.

78. Surveys will be conducted with two categories of participants:

79.

80. 240 interviews per year will be conducted (40 Neighborhood Survey interviews X 5 clinic neighborhoods plus 10 Key Stakeholder interviews in each of 4 cities 240 interviews per year).

81.

82. 1) Neighborhood Interviews (street-recruited): persons approached in public venues in the catchment areas of the clinics for the interviews. Interviewers will use an Audio-computer assisted interview (ACASI) device to conduct the interview. Participants will be approached and screened by using "*Neighborhood Interview Recruitment Script and Informed Consent*" (**Attachment 3**). This screener will provide a brief description of the survey and will determine whether or not the person is eligible to participate in the survey. Eligibility criteria include age 18 years or older, conversationally fluent in English, and willingness to consent to survey participation. If the participant is eligible and gives consent, they will then proceed with the survey, "*Neighborhood Interview (street-recruited participants)*" (**Attachment 6**). Use of ACASI will allow confidential data collection to take place in public spaces (e.g., park, bus stop, fast-food shop) near the initial site of respondent contact. The survey will take about 20 minutes to complete. No personal identifiers will be collected in interview data.

83.

84. 2) Key Stakeholder Interviews: Key Stakeholders in the neighborhood/community nominated by CBOs and community health clinics delivering PrEP in each of 4 cities (Chicago, Philadelphia, Washington, DC, and Jackson, MS) participating in this study. The Key Stakeholders will be contacted via telephone with the "*Key Stakeholder Telephone Recruitment Script*" (**Attachment 4**). If the Key Stakeholder is willing to participate, then the interviewer will schedule time in person for the Key Stakeholder to complete the survey via the Audio-computer assisted interview (ACASI) device or the Computer Assisted Personal Interviewing (CAPI) device. At the beginning of each key stakeholder interview, a consent script will be presented to the participant and verbal consent sought. Documentation of informed consent will be recorded on the ACASI/CAPI device by selection of a checkbox "*Key Stakeholder Informed Consent*" (**Attachment 5**). If the

participant is eligible and gives consent, they will then proceed with the survey, "Key Stakeholder Interview" (Attachment 7). The survey will take about 20 minutes to complete. No personal identifiers will be collected in interview data.

85.

86. If funding allows, the survey would be repeated two more years (3 years total), so the total number of interviews for the 3 years would equal 680 (200 for the first year and 240 for the next two years). For some descriptive analyses, information will be collapsed across the three years but for attitudinal and awareness measures, responses will be compared across the years for trend, using statistics appropriate to the small sample size. We do not anticipate significant changes in neighborhood demographics in the short-term (i.e. a 3-year period). Assessing attitudes over time is important as this new intervention becomes available in the community. A single year estimate would not provide information about changes in attitudes as community awareness, discussion, and familiarity with PrEP is changing.

87.

88. Data management will include the wireless transfer of encrypted survey data collected from the Audio-computer assisted interview (ACASI) or Computer Assisted Personal Interviewing (CAPI) at the completion of each interview to a secure server at NORC. There will be a daily review of data for completeness and data will be backed up and filed in secure offsite storage at regular intervals. All involved NORC data systems will be subjected to C&A review by CDC to ensure compliance with federal standards for data management, transfer, and storage.

89.

**90. A.3.1 Items of Information to be Collected**

91.

92. Surveys will be conducted with items of information in the following domains:

93.

94. 1) Neighborhood Interviews (street-recruited):

95. Demographics; basic HIV knowledge; HIV attitudes and beliefs; basic PrEP knowledge; PrEP attitudes, information, and experience; sexual and drug use behaviors.

96.

97. 2) Key Stakeholder Interviews:

98. Demographics; Organization type and role; basic PrEP knowledge, PrEP attitudes, information, and experience.

99.

100.

101. **A.3.2 Identification of Websites and Website Content Directed at Children Under 13 Years of Age**

102.

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

104. **A.4. Use of Improved Information Technology and Burden Reduction**

105.

106. The survey will be created using the Audio-computer assisted interview (ACASI) or Computer Assisted Personal Interviewing (CAPI) platforms, which are extremely user friendly. Most of the questions are closed ended questions and require little effort to answer- often just a simple click on the device. When participants are finished with the survey, they simply click "submit" and they are finished.

107.

108.

109. **A.5. Efforts to Identify Duplication and Use of Similar Information**

110.

111. 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. This study will provide us with an understanding of the knowledge, misinformation, attitudes, hopes and fears about Pre-Exposure Prophylaxis (PrEP) and its provision at local clinics as well as the extent of unsafe community practices (e.g., informal medication purchase) over time and an assessment of the utility of new measures developed or adapted to collect this information.

112.

113.

114. **A.6. Impact on Small Businesses and Other Small Entities**

115.

116. No impact on small business and other entities has been identified or is anticipated.

117.

118.

119. **A.7. Consequences of Collecting the Information Less Frequently**

120.

121. The survey will be conducted once a year for 3 years. If the survey were conducted less frequently, then we would



not be able to assess changes over time in the community. These changes over time are key to determine what types of resources need to be invested in assessing and addressing knowledge, misinformation, attitudes, hopes and fears about Pre-Exposure Prophylaxis (PrEP) and its provision at local clinics.

122.

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

124.

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

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

127.

128. A 60 day federal register notice (**attachment 2**) to solicit public comments was published in the Federal Register on 04/30/2014, Vol. 79, No. 83, Pages 24439-24440. There were no public comments received. No efforts to consult outside the agency were made.

129.

130.

131. **A.9. Explanation of Any Payment or Gift to Respondents**

132. Key Stakeholder survey respondents will not be paid.

133. Neighborhood survey respondents will be provided a \$20 gift card at the completion of their interview as a token of appreciation. Providing the token is a means to obtain higher response rates among persons intercepted on the street in the course of their daily activities to reduce participation bias and to reduce item nonresponse (Singer et al, Annal of Amer Acad Pol Soc Sci, 2013; Lynn, Int J Pub Opinion Res, 2001).

134.

135.

136. **A.10. Assurances of Confidentiality Provided to Respondents**

137.

138. The consent forms explains the privacy of information provided during the interviews.

139.

140. As described above (sections A.1.2 and A.1.3), precautions have been taken in design of the interview questions and data collection procedures to guard against any collection of PII, to ensure privacy of respondents when completing the surveys by ACASI, and the safeguard the interview data after collection. The PII collected on key stakeholders is business contact information only.

141.

142. For the neighborhood participant and key stakeholder surveys, responses will be entered onto password protected tablets that are provisioned with an automatic full disk encryption system (Win Magic) that meets FIPS 140-2 accreditation criteria. Encrypted files will be sent by secure wireless transmission to NORC servers specific to this study at the conclusion of each interview. No data are stored on the tablets. The receiving server is physically secure and data are backed up regularly to tape for secure off-site storage. These systems are currently being subjected to security review by ICSO to ensure they meet federal standards prior to its entry into the CDC Enterprise Systems Catalogue.

143.

144. IRB approvals have been received from NORC (**attachment 8**), CDC (**attachment 9**), and Philadelphia Health Department (**attachment 10**) IRBs. Four sites (Chicago (2 sites), Washington, DC, and Jackson, MS) have requested to be covered by the CDC IRB and are completing the required paperwork with the CDC IRB.

145.

#### 146. **A.11. Justification for Sensitive Questions**

147.

148. A few demographic questions may be considered sensitive (i.e., income, race, age, sexual orientation) but are essential for understanding the population surveyed.

149. Some behavioral questions on the neighborhood survey may be considered sensitive by some respondents (sexual and drug use behaviors) but are essential to understand which segments of the population have specific attitudes and knowledge about this new HIV prevention method and its potential relevance to them.

150.

#### 151. **A.12. Estimates of Annualized Burden Hours and Costs**

152.

153. This information collection will be collected once per year for three years. The survey, in aggregate response requires approximately 110 burden hours for the 600 respondents (see Table 12A below). For the Key Stakeholder Telephone Recruitment Script (**Attachment 4**), we estimate we will need to screen a total of 60 participants to achieve our goal of 40 respondents (**attachment 7**). Also, for the Neighborhood Interview Recruitment Script and Informed Consent (**Attachment 3**), we estimate we will need to screen a total of 300 participants to achieve our goal of 200 respondents (**attachment 6**). There is no cost to respondents other than their time.

154.

**155. Exhibit A.12.A Annualized Burden Hours**

156. Type of Respondent	157. Form Name	158. Number of Respondents	161. Number of Responses per Respondent	165. Average Hours Per Response	168. Total Response Burden (Hours)
Neighborhood Survey Street Interview Participant	Neighborhood Interview Recruitment Script and Informed Consent Att 3	172. 300	173. 1	174. 5/60	175. 25
176. Key Stakeholder Participant	177. Key Stakeholder Telephone Recruitment Script Att 4 and Informed consent Att 5	181. 60	182. 1	183. 5/60	184. 5
Street Interview Participant	Survey Att 6	185. 200	186. 1	187. 20/60	188. 67
Key Stakeholder Participant	Survey Att 7	190. 40	191. 1	192. 20/60	193. 13
<b>194. Total</b>	<b>195.</b>	196.	197.	198.	<b>199. 110</b>

**200.**

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

202. The annualized costs to the respondents are described in Exhibit A.12.B. To estimate the Key Stakeholder participant costs, the hourly wage rate (\$21.27) for the Community and Social Service Occupations was used from the United States Department of Labor Statistics May, 2014 ([http://www.bls.gov/oes/current/oes\\_nat.htm](http://www.bls.gov/oes/current/oes_nat.htm)). For the Street Interview Participants, we used the "All Occupations" category at \$16.71. Since we do not know the occupations of the participants and since the participants vary according to age and region, we decided this was the best estimate. Thus, the total anticipated annual cost to participants for collection of information in this project will be \$1920.20.

203.

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

205. Respondent	206. Form Name	207. Total Burden Hours	208. Hourly Wage Rate	209. Total Respondent Cost
Neighborhood Survey Street Interview Participant	Neighborhood Interview Recruitment Script and Informed Consent Att 3	210. 25	211. \$16.71	212. \$417.75
213. Key Stakeholder Participant	214. Key Stakeholder Telephone Recruitment Script 215. Att 4 216. and Informed consent 217. Att 5	218. 5	219. \$21.27	220. \$106.37
Street	Survey	221. 67	222. \$	223. \$.1

Interview Participant	Att 6		16.71	119.57
Key Stakeholder Participant	Survey Att 7	224. 13	225. \$ 21.27	226. \$27 6.51
<b>227. Tot</b>	<b>228.</b>	<b>229.</b>	<b>230.</b>	<b>231. \$19</b>
<b>al</b>				<b>20.20</b>

232.

233.

**234. A.13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers**

235.

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

**237.**

**238. A.14. Annualized Costs to the Federal Government**

239.

The annualized cost to the government is estimated to be \$234,700 per year and will be used to hire a contractor to conduct the bulk of the study (\$200,000) and \$34,700 per year is estimated for percentage of FTE time spent on the study. The total cost to the federal government for 3 years planned is \$704,100.

240.

241.

242. Expense Type	243. Expense Explanation	244. Total Costs per year (dollars)
246. Contractor	247. Contractor to conduct the bulk of the study (program survey, recruit participants, conduct interviews etc.)	248. \$ 200,000
249. Project Officer	250. CDC Project Officer to monitor progress, review reports, etc. (GS-13 0.20 FTE)	251. \$ 20,000
252. Statistician	253. CDC Statistician (GS 13 0.05)	254. \$ 4,700
255. Data Manager	256. CDC Data Manager (GS 13 .10)	257. \$ 10,000
258.	259. Subtotal, Direct costs	260. \$ 234,700
261. Total Costs to Government	262.	263. \$ 234,700

264.

265.

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

267. A nonsubstantial change is requested in the number of street intercept interview respondents due to the addition of a second study clinic in a different part of Chicago to increase the racial/ethnic diversity of the clinic population. This results in 5 clinics rather than the original 4. Therefore the total annual number of street intercept interviews in the communities around each clinic increases from 160 to 200.

268. A nonsubstantial change is requested in the study sites because 2 of the original clinics (in Newark and Houston) did not provide PrEP (the clinical intervention being studied) and they were replaced by clinics in 2 new cities (Washington DC and Jackson MS).

269. A minor change in exit language after completing the key stakeholder survey is requested to indicate the next steps for

the respondent.

270.

271.

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

273.

274.	275. Activity	276.	277. Time Schedule
278.	Pretest survey	280.	1 month after OMB approval
279.			
281.	Refine survey based on interview responses	282.	1 month after OMB approval
283.	Administer survey	284.	2-4 months after OMB approval
285.	Data analysis	286.	5-6 months after OMB approval

287.

288.

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

290.

291. OMB Expiration Date will be displayed.

292.

293.

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

295. There are no exceptions requested.

296.