

**Evaluation of Rapid HIV Self-Testing: Qualitative and User
Proficiency Assessments**

Generic Information Collection Request under 0920-0840

**Supporting Statement
Part A**

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Contact

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Qualitative and User Proficiency Assessments**

53.

54. **Supporting Statement**

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56. **A. JUSTIFICATION**

57.

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

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60. The Centers for Disease Control and Prevention (CDC) is contracting with Emory University Rollins School of Public Health to conduct formative research to inform the development and implementation of the methods to conduct a randomized-controlled trial that evaluates the use and effectiveness of self-test kits as a public health strategy for increasing testing among men who have sex with men (MSM).

61.

62. Innovative testing strategies are needed to reduce levels of undiagnosed HIV infection and increase early access to treatment. The availability of a HIV self-test may facilitate access to testing among individuals who have never been tested due to concerns about privacy and may increase compliance with current CDC HIV testing recommendations for those who require regular testing due to on-going risk behavior. Rapid HIV self-tests may play an important role in efforts to reduce both HIV morbidity and mortality. Self-test HIV kits may reduce HIV incidence by helping HIV-negative persons remain free from infection (primary prevention), as well as increase early diagnoses of those who are infected (secondary prevention). Policies that guide the public-health application and use of rapid HIV self-test kits, require data on whether persons at high risk for infection will use these tests, the effectiveness of the tests for primary and secondary prevention, and the utility of the tests in promoting additional testing and linkage to HIV services of persons with preliminary positive results. Given the unrelenting HIV crisis among MSM and the imminent release into the market of rapid HIV self-test kits, it is necessary to evaluate the impact of providing rapid HIV self-test kits on repeat HIV testing, linkage to care, partner testing, serosorting, and HIV sexual risk behaviors among MSM to determine the potential primary and secondary prevention effectiveness of over-the-counter (OTC) rapid HIV self tests. This information will assist Division of HIV/AIDS Prevention (DHAP) at CDC in developing

recommendations and future research and program needs concerning self-testing for MSM to aid in identifying undiagnosed cases of HIV infection and promoting linkage to care of persons with HIV.

63.

64. The purpose of this project is to assess the use and impact of rapid HIV self-testing among MSM located in up to three high HIV prevalence cities in the United States. This project will be conducted in 4 parts. Each part will be conducted independently and will provide information to develop and implement the next part of the study. **Parts 1,2 are formative phases of the project and are the only parts for which we are submitting this generic information request.**

65.

66. Specifically, the types of information collection activities for formative parts 1 and 2 of this project are as follows:

- 1) Part 1 will include both focus group discussions and in-depth interviews. The focus group discussions will be conducted to identify issues related to recruitment, barriers to participation, perceptions of the accuracy and acceptability of HIV self-tests, and willingness to conduct self-tests and to provide test kits to others in their sexual and social networks. In-depth interviews will be conducted primarily to gather qualitative data that will be used to make the rapid testing and dried blood spot (DBS) specimen collection instructions clearer, but will also gather information regarding how to improve the packaging and marketing of test kits for later stages of the study. Information gained from Part 1 will inform Parts 2, 3, and 4 of the study.
- 2) Part 2 will consist of a user proficiency assessment to determine if potential users of rapid HIV test kits can successfully conduct the self-tests, accurately interpret the results, and prepare the DBS specimen. Results of the user proficiency assessment will be used to make the printed and video testing instructions clearer prior to Parts 3 and 4. Part 2 will be conducted using the same packaging and test kits to be used in Part 3: one oral fluid test (OraQuick), one finger-stick blood test (Sure Check), and one DBS specimen collection kit.

67.

68. These information collection activities fit under the Formative Research and Tool Development generic ICR because they involve qualitative interviewing to develop appropriate study methods and packaging for self-test kits as well as

field testing to evaluate the testing instructions, materials, and methods.

69. A.1.2 Privacy Impact Assessment

70.

71. CDC is sponsoring this data collection. The grantee, Emory University, will collect information in identifiable form (IIF). In each part, men who are determined by the screener to meet eligibility criteria will be asked to provide a nickname or name of choice, email address and telephone number so that they can be contacted by staff. Contact information will be destroyed following the appointment for participation in an interview, survey, or focus group. Audio and video recordings collected during all parts will be destroyed within 4 weeks after transcription, which will take place within 4 weeks of the data collection.

72.

73. No data will contain participant names. During the eligibility screening processes for parts 1 and 2, nicknames or name of choice, email addresses and phone numbers are collected to provide contact information to confirm participation, but names are not used during the focus group discussions, in-depth interviews, or proficiency assessment session. All personal data (i.e., phone numbers and email addresses) collected regarding study participants will be maintained in locked filing cabinets, separated from all other study data. Contact information used to confirm participation will be entered into a password-protected database accessible only by study staff. This contact information will be held separately from focus group, in-depth interview notes, and proficiency assessment data. Data stored in the locked filing cabinet will be destroyed after it is entered into the database. Information in the database will be destroyed before data collection begins, and will therefore never be associated with the study data collected. All participants in parts 1 and 2 will be assigned a unique identification number for the study. Consent forms and face sheets with names or nicknames will be separated from data, and a master list linking the identifiers and names will be developed. This data is only used to confirm participation and will be destroyed before the collection of any data begins. Electronic audio and video files will be stored on password protected computers accessed only by study staff transcribing the data. Access to study files is managed by the Principal Investigator and is limited to study staff directly involved in this research on a need-to-know basis. No study data will be permitted off

site, except when data are in transit from the focus group and interview sites to the research office.

74.

75. During part 2, HIV test results data will contain only participants' study identification number. If any test result is preliminarily positive, the individual will be offered HIV counseling and testing by trained Emory staff. This is a voluntary service that the participant can accept or not. Information will be collected by the Emory staff for HIV reporting purposes (name, mailing address and phone number). This information will be kept in a locked filing cabinet accessible only by Emory staff and kept only until the confirmatory results are received. If they are confirmed HIV-positive, this information will be reported by telephone to the Georgia Department of Public Health. Their information remains private when it is reported to the state health department. If the confirmatory testing is negative, this information will be destroyed.

76.

77. Identifying information will not be included with study data and will not be transmitted to CDC. CDC staff will not have access to any identifying information. De-identified data will be transmitted to CDC via a secure data network once data collection is complete. Deidentified study data will be maintained at CDC indefinitely.

78.

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

80.

81. Information for the focus groups and in-depth interviews in part 1 will be collected using focus group and interview guides (**Attachments 1b and 1c**). Focus groups will be audio recorded and interviews will be audio and video recorded. In part 2, participants will be audio and video recorded and observed by study staff while conducting the rapid HIV tests and the DBS collection. In addition, participants will complete a user proficiency assessment survey regarding the testing process (**Attachment 1d**) and interpret a panel of test result images (**Attachment 1e**).

82.

83. Specifically, the types of information collection activities for the formative parts of this project (parts 1-2) are as follows:

- 1) Part 1 will include both focus group discussions and in-depth interviews. The focus group discussions will be conducted to identify issues related to recruitment, barriers to participation, perceptions of the accuracy and acceptability of HIV self-tests, and willingness to conduct

self-tests and to provide test kits to others in their sexual and social networks. In-depth interviews will be conducted primarily to gather qualitative data that will be used to make the rapid testing and DBS specimen collection instructions clearer, but will also gather information regarding how to improve the packaging and marketing of test kits for later stages of the study. Information gained from Part 1 will inform Parts 2, 3, and 4 of the study.

- 2) Part 2 will consist of a user proficiency assessment to determine if potential users of rapid HIV test kits can successfully conduct the self-tests, accurately interpret the results, and prepare the DBS specimen. Results of the user proficiency assessment will be used to make the printed and video testing instructions clearer prior to Parts 3 and 4. Part 2 will be conducted using the same packaging and test kits to be used in Part 3: one oral fluid test (OraQuick), one finger-stick blood test (Sure Check), and one DBS specimen collection kit.

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86. **A.1.4 Items of Information to be Collected**

87.

88. The focus groups and in-depth interviews conducted in part 1 will collect data to:

- Examine attitudes towards and perceptions among focus group participants regarding participation in a study of HIV self-testing among MSM
- Obtain feedback and reactions from participants about self-testing materials and packaging proposed for Parts 2, 3 and 4
- Understand what can be modified about the packaging of study materials to increase likelihood of kit use and distribution to network members
- Determine recruitment methods to be used in Parts 3 and 4
- Examine attitudes toward recruitment, participation, and retention in online studies, including establishing levels of comfort and trust of MSM to participate in an online survey in Parts 3 and 4 which will ask questions about high-risk sexual behavior
- Determine if instructions proposed for HIV self-testing are understood by typical users of rapid tests to be targeted in Parts 3 and 4

89.

90. Part 2 will assess user proficiency to:

- Determine the extent to which untrained users can proficiently conduct rapid HIV self-testing procedures and interpret the results, and conduct DBS specimen collection

procedures with the use of provided print and video instructions

- Demonstrate the operations, feasibility and acceptability of rapid HIV self-tests
- Compare the results of participants' self-administered and interpreted rapid HIV self-tests compared to laboratory-administered EIA

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

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

95.

96.

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

98.

99. The purpose of this information collection includes the following:

100.

101. Part 1

102. The focus group discussions will be conducted to identify issues related to recruitment, barriers to participation, perceptions of the accuracy and acceptability of HIV self-tests, and willingness to conduct self-tests and to provide test kits to others in their sexual and social networks. In-depth interviews will be conducted primarily to gather qualitative data that will be used to make the rapid testing and DBS specimen collection instructions clearer, but will also gather information regarding how to improve the packaging and marketing of test kits for later stages of the study. Information gained from Part 1 will inform Parts 2, 3, and 4 of the study.

103.

104. Part 2

105. The proficiency assessment will be conducted to determine if potential users of rapid HIV test kits can successfully conduct the self-tests, accurately interpret the results, and prepare the DBS specimen. Results of the user proficiency assessment will be used to make the printed and video testing instructions clearer prior to Parts 3 and 4. Part 2 will be conducted using the same packaging and test kits to be used in Part 3: one oral fluid test (OraQuick), one finger-stick blood test (Sure Check), and one DBS specimen collection kit.

106.

107.

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

109.

110. Focus groups will be digitally audio recorded and transcribed. Interviews will be digitally audio and video recorded and transcribed. In part 2, participants will complete the proficiency assessment survey (see Attachment 1d), electronically and use an electronic application (app) to review a panel of test result images for each rapid HIV test and will interpret the results.

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112.

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

114.

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

116.

117.

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

119.

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

121.

122.

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

124.

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

126.

127.

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

129.

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

131.

132.

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

134.

135. A Federal Register Notice for the generic clearance 0920-0000 was published on January 31, 2010.

136.

137.

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

139.

140. Focus group and in-depth interview participants in Part 1 will receive \$50 as a token of appreciation. Participants will also receive light refreshments during the focus group discussion. Proficiency assessment participants in Part 2 will receive \$75 as a token of appreciation. The amount of tokens of appreciation is based on both prior experience and for appropriate consideration of the potential burden in terms of travel and time commitment men will make to participate in the study. Investigators at the site drew upon their experience working with this population and community norms to come up with the token of appreciation plan.

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

143.

144. The Privacy Act applies to this data collection and information will be kept private under the Privacy Act. Only the research team members will have access to the audio and video recordings. Similarly, only the research team members will have access to the participants' and study staffs' interpretations of the user-administered rapid tests, participants' responses to the HIV test results panel interpretations, and participants' oral fluid test, finger-stick blood test and laboratory-tested EIA results.

145.

146. All study participants will be assigned a unique identification number for the study. Consent forms and face sheets with names will be separated from interviews, and a master list linking the identifiers and names will be developed. All study data collected regarding study participants will be maintained in locked filing cabinets, separated from all other study data. Access to study files is managed by the Principal Investigator and is limited to study staff directly involved in this research on a need-to-know basis. No study data will be permitted off site, except when data are in transit from the focus group and interview sites to the research office.

147.

148. Respondents will be told that no information in identifiable form will be available to or shared with the CDC. If any data is shared with CDC it will be de-identified and transferred securely to CDC.

149.

150. Prior to participating in any part of the study participants will be required to give consent. Verbal informed consent will be obtained for the focus groups

(Attachment 2b) and in-depth interviews **(Attachment 2c)**. Men who report for participation in either a focus group or an in-depth interview will be given basic information about the purpose of the study, and provided with a written informed consent form for their records. For Part 1, we request a waiver of written documentation of informed consent. This is because the written consent document would be the only identifying document once voice and video recordings have been destroyed. Therefore, relying on verbal consent will reduce risk of loss of privacy for the participants. The consent process will take approximately 10 minutes per individual and will take place in a room at the research site that provides visual and audio privacy. The consent procedure will begin with welcoming remarks from the team member, who will then establish that the potential participants are aware of why they are at the research site. The team member will then explain the consent process to the potential participant, explaining (1) what is meant by consent; (2) why we need to take consent; and (3) the purpose of the consent form.

151.

152. Men who report for participation in Part 2 will be given basic information about the purpose of the study, and provided with a written informed consent form **(Attachment 2d)**. Upon arriving at the research site, potential participants will be taken through the consent process by one of the research team members. The consent process will take approximately 10 minutes per individual and will take place in a room at the research site that provides visual and audio privacy. The consent procedure will begin with welcoming remarks from the team member, who will then establish that the potential participants are aware of why they are at the research site. The team member will then explain the consent process to the potential participant, explaining (1) what is meant by consent; (2) why we need to take consent; and (3) the purpose of the consent form.

153.

154.

155. A.11. Justification for Sensitive Questions

156.

157. During screening for eligibility, participants are asked sensitive questions about race, ethnicity, gender, sexual risk behavior, HIV testing history, and HIV status. These sensitive questions are necessary to determine eligibility for the study, because it is necessary to evaluate the impact of providing rapid HIV self-test kits among MSM at risk for HIV to determine the potential primary

and secondary prevention effectiveness of OTC rapid HIV self-tests. Information on HIV status will be used to ensure a diverse population of MSM.

158.

159. **A.12. Estimates of Annualized Burden Hours and Costs**

160.

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

162.

163. Study staff will screen approximately 250 men for the part 1 and 2 study activities. The 250 men will take part in a 5-minute screening interview to assess study eligibility. For part 1, approximately 60 men are expected to participate in the focus groups, which will take 1.5 hours and up to twenty men will participate in the in-depth interviews, which will take 1 hour. Sixty men will participate in part 2, which includes, completing the user proficiency survey (10 minutes), and interpreting test result images (10 minutes).

164.

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

166. Type of Respondent	167. Form Name	168. No. of Respondents	171. No. of Responses per Respondent	175. Average Hours per Response	178. Total Response Burden (Hours)
182. Prospective Participant	183. Eligibility Screener	184. 250	185. 1	186. 5/60	187. 21
188. Enrolled participant	189. Focus Group	190. 60	191. 1	192. 1.5	193. 90
194. Enrolled	195. In-depth	198. 20	199. 1	200. 1	201. 20

166. Type of Respondent	167. Form Name	168. 169. No. of Respondents	171. 172. No. of Responses per Respondent	175. 176. Average Hours per Response	178. 179. Total Response Burden (Hours)
participant	197. interview				
202. Enrolled participant	203. Proficiency Assessment survey	204. 60	205. 1	206. 10/60	207. 10
208. Enrolled participant	209. Test result image interpretation	210. 60	211. 1	212. 10/60	213. 10
214. Total	215.	216.	217.	218.	219. 151

220.

221.

222. **A.12.B. Estimated Annualized Costs**

223.

224. The annualized costs to respondents are described in Exhibit A.12.B. The estimates of hourly wages were obtained from the Department of labor (Bureau of Labor Statistics Wage Data (<http://www.bls.gov/bls/wages.htm>)). The total anticipated annual cost to participants for collection of information in this project will be \$2,346.68.

225.

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

227.

228. Type of Respondent	229. Total Burden	230. Hourly Wage Rate	231. Total Respondent Costs
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Form Name	Hours			
232. Eligibility Screener	233. 21	234. \$20.23	235. \$424.83	
236. Focus Group	237. 60	238. \$20.23	239. \$1,213.80	
240. 241. In-depth 242. interview	243. 20	244. \$20.23	245. \$404.60	
246. Proficiency Assessment survey	247. 10	248. \$20.23	249. \$202.30	
250. Test result image interpretation	251. 10	252. \$20.23	253. \$202.30	
254. Total	255.	256.	257. \$2,447.83	

258.

259.

260.

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

262.

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

264.

265.

266. A.14. Annualized Costs to the Government

267.

268. The annualized cost to the government is \$545,750. This activity will involve participation of CDC Project Officer who will assist with project design, obtaining IRB and OMB approvals, and providing project oversight. A CDC Co-Project Officer who will assist with project design and obtaining required certification and accreditation (C&A) approvals. A CDC

Project Manager who will assist with project coordination, obtaining IRB and OMB approvals. CDC consultants who assist with study design, sample size determinations, ethical considerations, and analytical plan design issues on an as-needed basis. Travel expenses include six site visits.

269.

270.

271.

272. Expense Type	273. Expense Explanation	274. 275. Annual Costs (dollars)
276. Direct Costs to the Federal Government	277. CDC Project Officer (Commissioned Corps, 0-5, 0.50 FTE)	278. \$ 51,000
279.	280. CDC Co-Project Officer (Visiting Scientist, GS-13, 0.75 FTE)	281. \$ 64,125
282.	283. CDC Project Manager (GS-12, 0.25 FTE)	284. \$ 17,975
285.	286. CDC Project Consultants (GS-13, 0.20 FTE)	287. \$ 17,100
288.	289. CDC Site Visit Travel (6 trips)	290. \$ 7,000
291.	292. Subtotal, direct costs to the government	293. \$ 157,200
294. Contract Costs	295. Contract to the Manila Consulting Group, Inc.	296. \$ 388,550
297.	298.	299.
300.	301. Subtotal, contract costs	302. \$ 388,550
303.	304. TOTAL COST TO THE GOVERNMENT	305. \$ 545,750

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307.

308.

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

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

312.

313.

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

315.

316. Data collection will be completed during the first year after OMB approval is granted. Part 1 data collection, data analysis, and report of findings will be completed by 3 months after approval. Part 2 data collection, data analysis, and report of findings will be completed by 6 months after approval. Part 3 data collection, data analysis, and report of findings will be completed by 9 months after approval.

317.

318.

319. **Exhibit 16.A. Project Time Schedule**

320.

321. 322. Activity	323. 324. Time Schedule
325. Conduct Part 1	326. 1 month after OMB approval
327. Part 1 Data analysis and Report of Findings	328. 2 months after OMB approval
329. Conduct Part 2	330. 3 months after OMB approval
331. Part 2 Data analysis and Report of Findings	332. 4 months after OMB approval

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334.

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

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338. OMB Expiration Date will be displayed.

339.

340.

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

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343. There are no exceptions to the certification.