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

OMB No. 0920-0840, Expiration 31 January 2013

Minority HIV/AIDS Research Initiative (MARI) Project: Sexual risk-taking among young black men who have sex with men: exploring the social and situational contexts of HIV risk, prevention, and treatment (BROTHERS CONNECT STUDY)

Supporting Statement
Part A

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

OMB No. 0920-0840, Expiration 31 January 2013

Minority HIV/AIDS Research Initiative (MARI) Project: Sexual risk-taking among young black men who have sex with men: exploring the social and situational contexts of HIV risk, prevention, and treatment (BROTHERS CONNECT STUDY)

Table of Contents

2. Procedures for the Collection of Information

3. Methods to Maximize Response Rates and Deal with Nonresponse

4. Tests of Procedures or Methods to be Undertaken

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Attachments

Attachment 1 Data Collection Forms

1a. Screener and Contact Forms

1b. ACASI Survey

1c. Web-based Sex Diaries and Final Debriefing Protocol

1d. In-depth Interviews

Attachment 2 Consent forms

Attachment 3 IRB Approvals

3a. Local IRB approval-Columbia University

3b. NCHHSTP Project Determination

Attachment 4 Recruitment Materials and Website Screenshots

Attachment 5 Certificate of confidentiality

50. Formative Research and Tool Development

51. Minority HIV/AIDS Research Initiative (MARI) Project:

52. Sexual risk-taking among young black men who have sex with men: exploring the social and situational contexts of HIV risk, prevention, and treatment (BROTHERS CONNECT STUDY)

53. Supporting Statement

54.

55. A. JUSTIFICATION

56.

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

58.

59. The National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) conducts formative research for developing new tools and methodologies that respond to the changing epidemiology of HIV/AIDS. Approval is requested for a formative research study that will provide vital information to facilitate HIV prevention efforts with young, black men who have sex with men (BMSM) in the United States.

60.

61. Young BMSM are disproportionately affected by HIV/AIDS in the United States. Few large-scale research projects have been conducted with young BMSM, and interventions have been limited in their reach and impact with this population. The objective of this project is to explore the contextual risk and protective factors linked to HIV risk among young BMSM to help inform effective HIV prevention interventions for young BMSM. This information will be used to ensure that culturally appropriate tools can be developed as part of the CDC portfolio of effective HIV prevention interventions for young BMSM.

62.

63. Data collection for this project is authorized under 42 U.S.C. 241 (OSCN 2007), CHAPTER 6A - PUBLIC HEALTH SERVICE; SUBCHAPTER II - GENERAL POWERS AND DUTIES Part A - Research and Investigations

64.

65. A.1.2 Privacy Impact Assessment

66. Information for the quantitative surveys will be collected 100% electronically using audio computer-assisted self-interview (ACASI) at the study enrollment sites. The local study staff will collect sensitive and personally identifiable data, such as names and contact information for possible later participation in a longitudinal web-based sex diary or in-depth interviews. Other personal identifiable data collected are age, race, and ethnicity. The grantee, Columbia University, collects the information. Contact

information will be destroyed at the end of data analysis (within 3 years, or earlier, if appropriate). All data will be identified by unique code numbers only. No quantitative surveys, web-based diaries or audio transcripts will contain participant names. Participants will be asked to provide private email addresses for reminders and sex diary communications. The only link to respondents' names will be consent forms, to be housed in a locked file cabinet separate from all contact info and data forms. Surveys will be labeled with a unique pre-assigned code to identify the computer-stored data. Interviews will be digitally recorded (100%). At the end of each interview, recordings will be transcribed and the transcripts will be stored in the password-protected Program Coordinator's computer. The computer with the stored data will be kept in a locked office, with the key accessible to only the Program Coordinator and PI. Any names used during interviews will be replaced during transcription by initials to prevent unintended disclosure. Transcripts will only be accessible to study investigators responsible for data analysis and the Program Coordinator.

67.

68. CDC will not receive any personally identifiable information. If there were a need to send data to CDC for review, all individually identifiable information collected by local partners would be unlinked or stripped from the data base that is submitted to CDC.

69.

70. There will be no websites or internet content directed at children under the age of 13. Website screen shots are included as Attachment 4.

71.

72. A.1.3 Overview of the Data Collection System

73. The proposed formative study will consist of 3 components: cross-sectional surveys, a longitudinal, structured sex diary, and in-depth interviews (Attachment 1). For the cross-sectional surveys, data will be collected from young, black MSM who meet the screening criteria through ACASI. For the structured sex diaries, participants will be asked log on to the secure study website on a weekly basis to complete the structured sex diary, which will ask them about sexual behaviors they engaged in over the past week. For the in-depth interviews, young black MSM will be randomly selected to participate from those who complete the ACASI surveys.

74.

75. Specifically, the types of information collection activities included in this generic package are:

1) First, 250 young, black MSM will be surveyed by ACASI. Next, a sub-sample of sexually active ACASI survey participants (n=150) will be offered participation in an 8-week long web-based, structured sex diary. The usability of web-based diary data collection methodology will be explored as an effective HIV prevention approach with this population. The purpose of using this method for data collection is to develop new methods that can be used for HIV prevention with a segment of the population that is rapidly-evolving in their use of technology-based communications and interconnections. Additionally, exploring and using these technologies enhance CDC's projects and reduce the burden of future data collections.
2) Finally, a sub-sample of 30 young black MSM sex diary participants will be randomly invited to participate in qualitative interviewing. The information gathered from this study will be used to identify effective components of HIV prevention messages directed toward young BMSM in large, urban areas in the United States. This will inform the content of individual-, group-, and community-level interventions targeting young BMSM for the CDC HIV prevention portfolio as needed for national HIV prevention efforts.

76.

77. A.1.4 Items of Information to be Collected

78. The ACASI survey conducted among young, black MSM will collect data regarding:

- Acceptability of the computerized data collection process
- Demographic, psychosocial, family/peer group information
- Sexual behavior
- Substance use behavior
- Exposure to distal risk factors, including exposure to poverty, substance use, perceived discrimination, and violence and/or trauma
- Resiliency factors, such as social support, self-efficacy
- HIV transmission and testing knowledge, attitudes and beliefs

79.

80. The 8-week web-based sex diary will collect data regarding:

- Types of sexual behaviors,
- Sex partner characteristics

- Feelings toward sex partner
- Communication with sex partner
- Sexual urges
- Depression
- Any substance use by participant or sex partner

Qualitative, in-depth interviews will be used to collect information regarding:

- Salient experiences in childhood and adolescence,
- Sexual behaviors throughout lifetime
- Exposure to distal risk factors, including poverty, substance use, racism, and violence or trauma
- Barriers or facilitators HIV testing, prevention, and treatment.

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

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

A.2. Purpose and Use of Information Collection

The purpose of this information collection includes the following:

A.2.1 Qualitative interviewing for surveillance, research, and intervention methods and material development.

The purpose of this data collection is to use qualitative interviewing methods to explore the inter-relationships among proximal risk factors, distal risk factors, resiliency and sexual risk taking for young BMSM who are at increased risk for HIV infection. Qualitative interviews will be conducted individually with young BMSM, using standardized methods and an interview guide. Results of qualitative interviews will be used in conjunction with other formative information to develop appropriate HIV prevention interventions and data collection instruments for current and future projects to increase HIV prevention and testing efforts among young BMSM in large, urban areas nationally.

A.2.3a Methodological Research: Research on the effects of alternative instrument designs

To better understand and further evaluate the use of secure web-based sex diaries compared to one-time ACASI surveys for HIV prevention research, this data collection will also include detailed respondent diaries. For young BMSM, a group that increasingly uses technology for routine daily activities, exploring secure web-based data collections as an effective means

to do research will result in decreased burden for future public data collections and will enhance our HIV prevention efforts using this technology.

A.2.4 Usability testing of technology-based instruments and materials

Using web-based internet sex diaries with young BMSM will allow exploration of how this novel approach to HIV prevention affects the ability of users to effectively utilize these instruments for future effective interventions within this population. Also, this formative research will explore the acceptability of using web-based diaries for tool development with this population of young BMSM. In addition, the ACASI computer surveys will allow exploration of the appropriate HIV prevention language for appropriate tool development for this population.

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

The use of an ACASI system and web-based diaries will reduce the time need to complete the surveys and will thereby reduce the burden on the public. Electronic reporting has advantages for ensuring respondent privacy and streamlining the data collection process. The computer programs will allow participants to select for an audio assistant to read the questions and answer options in English. Interviews will be digitally recorded and transcribed.

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

NCHHSTP has verified that there are no other federal generic collections that duplicate the six study types included in this request.

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

This collection request does not involve burden to small business or other small entities.

A.6. Consequences of Collecting the Information Less Frequently

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

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

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

113.

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

115. For sub-collection requests under a generic approval, federal register notices are not required and none were published.

116.

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

118. BMSM (n=250) who participate in the 90-minute ACASI survey will receive a $30 token of appreciation for their time. BMSM who complete 15-minute structured, web-based sex diaries over the 8-week period will receive $10 for each completed diary session and an additional $20 for completing all 8 weeks of diary entries. BMSM (n=30) who participate in the 90-minute in-depth interviews will receive a $40 token for their time. It is possible that 30 out of 250 (12%) of total BMSM who participate in each part of the data collection can receive a total of $170 for a total of 5 hours of providing formative data, or a total of $34 per hour for 5 hours of data collection within the year if they complete 100% of the requested tasks.

119.

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

121. This project collects sensitive or personally identifiable data. Individually identifiable information (IIF) will be collected by the research staff at Columbia University to conduct the study. Names and contact information will be used by study staff to contact participants about interview or survey appointments. Email reminders for web-based sex diary entries will only be sent to private email addresses identified by the study participants.

122.

123. Other personal identifiable data collected are age, gender, race, and ethnicity. The grantee, Columbia University, collects the information. This information is not transmitted to CDC. The main purpose for collecting this information is to characterize the participants in the study. Knowledge of participant demographics will assist in the design and targeting of future HIV prevention interventions for young BMSM for CDC’s portfolio.

124.

125. To ensure confidentiality, this contact information database will be kept separate from other data collected and in a password-protected file in the PI’s locked office. All

codes that link participants' name with ID numbers will only be available to the PI and Program Coordinator and kept in a locked cabinet. ACASI data will be downloaded weekly and stored on a secure, password protected computer. Procedures to ensure quality control in the collection, verification, and documentation of data have been established and will be conducted by a Data Analyst/Programmer on the study staff in consultation with CDC Data Managers.

126.

127. Analysis of the dataset will take place at Columbia University. If any data are shared with CDC it will be de-identified and transferred securely to CDC.

128.

129. Prior to participating in any study activity, participants will be required to give consent. The consent forms are included as Attachment 2. Study purpose, risks and benefits will be explained to the participants, and they will have the opportunity to ask questions prior to signing. Participants and study staff will be asked to sign two identical consent forms. One of the signed consent forms will be kept in a locked cabinet separate from other databases in the locked PI's office and the other will be given to the participant.

130.

131. In addition, this study has obtained a "Certificate of Confidentiality" from CDC to provide legal protection of participant's information (Attachment 5). Contact information forms will be destroyed (via shredding) within three years after completion of the data analysis, or sooner if appropriate.

132.

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

134. During screening for eligibility, participants are asked sensitive questions about race, ethnicity and sexual activities. These sensitive questions are necessary to determine eligibility for the study, since the study's purpose is to understand more about the context of HIV prevention and testing for young BMSM and also to determine if using computer-based technology is an appropriate method to gather information that can lead to the development of appropriate HIV prevention materials for this population.

135.

136. During the surveys, sensitive questions include information about perceived racism and discrimination, substance use, exposure to violence or trauma, feelings about sex partners, sexual urges and depression. These questions are important to help us understand the context of

HIV prevention for young BMSM. This information is necessary to characterize the study population, and knowledge of respondent characteristics will help in the development of culturally appropriate HIV prevention materials for young BMSM as part of CDC's portfolio of effective HIV prevention tools.

137.

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

139.

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

141. All respondents will be young BMSM between the ages of 18 and 30 years. Study staff will screen (5-minute screen) approximately 300 young BMSM during the first year to assess study eligibility; 250 young BMSM are expected to participate in this study.

142.

143. During the first year after OMB approval, all data collection will occur: 1) 250 young BMSM participants will be surveyed using ACASI once (90 minutes); 2) 150 young BMSM who complete the ACASI survey will be offered participation in web-based structured sex diaries (15 minutes weekly over 8 weeks; total of 2 hours), and 3) 30 young BMSM who participate in the first 2 components will be invited to participate in in-depth individual interviews (90 minutes).

144.

145. Exhibit A.12.A Annualized Burden Hours

146. Type of Respondent	147. Form Name	148. 149. Number of 150. Respondents	151. 152. Number of 153. Responses per 154. Respondent	155. 156. Average Hours 157. Per Response	158. 159. Total Response 160. Burden 161. (Hours)
162. General public	163. Screener	164. 300	165. 1	166. 5/60	167. 25
168. General public	169. 170. ACASI Survey	171. 250	172. 1	173. 1.5	174. 375

146. Type of Respondent	147. Form Name	148. 149. Number of 150. Respondents	151. 152. Number of 153. Responses per 154. Respondent	155. 156. Average Hours 157. Per Response	158. 159. Total Response 160. Burden 161. (Hours)
	ys				
175. General public	176. Web-based sex diaries	177. 150	178. 8	179. 15/60	180. 300
181. General public	182. In-depth interviews	183. 30	184. 1	185. 1.5	186. 45
187. Total	**188.**	**189.**	190.	191.	**192. 745**

193.

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

195. Annualized cost to respondents for the burden hours is provided 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).

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

197.

198. Activity	**199. Total Burden Hours**	**200. Hourly Wage Rate**	**201. Total Respondent Cost**
202. Screener	203. 25	204. $20.23	205. $506
206. ACASI Surveys	207. 375	208. $20.23	209. $7,586
210. Web-based sex diaries	211. 300	212. $20.23	213. $6,069

214. In-depth interviews	215. 45	216. $20.23	217. $910
218. Total	**219. Average annual burden= 745**	220.	**221. Average annual total=$15,071**

222.

223.

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

225. There are no costs to respondents or record keepers.

226.

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

228.

229. The estimated annualized costs to the federal government include a CDC project officer who spends about 0.25 FTE assisting with project design, obtaining IRB and OMB approvals, and providing project oversight. A student research assistant has spent 50% of her working hours assisting with literature reviews and editing documents. Travel expenses include site visits to ensure the site is ready to begin enrollment once approved.

230.

231.

232. Expense Type	**233. Expense Explanation**	**234. 235. Annual Costs (dollars)**
236. Direct Costs to the Federal Government	237.	238.
239.	240. CDC Project Officer (Commissioned Corps, 0-5, 0.25 FTE)	241. $ 37,000

242.	243. CDC Research Assistant (50%)	244. $ 3,000
245.	246. CDC Travel (6 trips)	247. $ 7,000
248. Cooperative Agreement	249. Cooperative Agreement costs to Columbia University	250. $ 272,845
251.	252. TOTAL COST TO THE GOVERNMENT	253. $ 319,845

254.

255.

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

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

258.

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

260. All data collection will be completed during the first year after OMB approval. Data analysis and review will begin during the first year after OMB approval. Presentations and revisions to CDC's portfolio of effective HIV interventions for young BMSM will continue for 18-24 months after OMB approval.

261.

262. Exhibit 16.A Project Time Schedule

263.

264.

265. 266. Activity	**267. 268. Time Schedule**
269. Data collection with general public	270. First 12 months after OMB approval
271. Data collection ends; data analysis and review begins	272. 12 months after OMB approval

273.

274.

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

276. OMB Expiration Date will be displayed. No exception is requested.

277.

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

279. There are no exceptions to the certification.

280.