Development of a Motion Comic for HIV/STI Prevention Among Young People – ages 15-24

Generic Information Collection request under 0920-0840

Section A: Supporting Statement

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62.
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64. A. JUSTIFICATION
65.
66. A.1 Circumstances Making the Collection of Information Necessary
67.

68. The Centers for Disease Control and Prevention proposes to conduct a formative research study to develop and pilot test a new health communication intervention tool, an HIV and STD themed motion comic designed to reduce HIV and STD among Black Men who have sex with men, Black heterosexuals, Latino Men who have sex with men, Latino heterosexuals and White Men who have sex with men between ages 15-24 who speak English and/or Spanish. Collecting this information, developing this intervention and pilot testing this tool will add to the CDC portfolio of effective interventions for at-risk populations. The proposed study will use focus groups and quantitative surveys to: a) develop content (storylines and messages), b) determine the presentation style of the content (visuals, sound effects, music) c) determine the feasibility and acceptability, d) determine the motion comics impact on knowledge, abilities, beliefs and intentions (KABI) related to HIV/STD prevention. The information gained from this study can benefit other researchers in several ways. First, this study will provide information feasibility, acceptability and therefore the viability of using the motion comic medium for health communication activities targeting young at-risk populations. Second, the information learned during the development process can aid other researchers who wish to design motion comics for other important health topics. Third, the findings can be used to better understand mental models about how to use new media to inform young people about HIV and STD. Finally, researchers can build on the results of this study to create new, youth-focused interventions which are low-cost, use new and emerging technologies and can be widely disseminated.

69.

70. In the US young people (ages 15-24) are significantly affected by human immunodeficiency virus (HIV) and other sexually transmitted diseases (STDs). The disease burden shouldered by young people may be due to deficits in HIV/STD knowledge, attitudes, beliefs and intentions (KABI) that may influence risk and protective behaviors for HIV/STD

transmission. It is imperative that interventions targeting this population address gaps in knowledge, instill attitudes and beliefs as well as impact behavioral intentions that are consistent with HIV/STD prevention.

71. Story telling is a useful method of HIV/STD prevention communication and capable of impacting KABI related to HIV/STD prevention. Comic books are pragmatic means of delivering HIV/STD prevention messages using storytelling. As traditional comic books have gained increased popularity, modern technological advances in computerized graphics have provided new ways of presenting comic books and their application for HIV/STD prevention. One promising approach is the “motion comic”, a technology that digitally animates traditional comics, making them more cinematic in tone and quality with voice actors and a musical score. While there are several examples of comics being used for HIV/STD prevention in national and international settings, to date there are no “motion comics” which focus on HIV/STD prevention. While there are a number of interventions in CDC’s portfolio designed to prevent HIV/STD in this age group, there are almost no technologically-advanced health communication interventions designed specifically for young people between the ages of 15-24.

72.

73. Given the current shortfall of health communication tools and methods focused on addressing HIV/STD prevention among youth, this study will produce a valuable and technologically timely tool and methodology for preventing HIV/STD among those between the ages of 15-24 that can be widely disseminated after further testing occurs with a larger sample.

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76. A.1.2 Privacy Impact Assessment

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78. The Centers for Disease Control and Prevention will collect information in identifiable form (IIF). IIF will be collected from participants using focus groups interviews and computer assisted self-interviews by local study staff. Research staff at CDC will collect phone numbers to contact participants to take part in the focus groups and/or survey, signatures on informed consent documents, voices and names on digital recordings, and transcripts of digital recordings. Other IIF collected include age, ethnicity, sexual orientation and gender. The main purpose of collecting this information is to characterize the participants in the study. Knowledge of participant characteristics will assist with the development of the proposed and future interventions.

Respondents' names will not be used in data collected. ID numbers will be used in place of names. This information will be kept in a locked file cabinet, password protected computers and will be accessible only by the project staff. ACASI survey data will be stored on secure USB drives and then transferred to a secure electronic database as a password protected file on a password protected computer in the PI's office. Only the Project staff will have access to the password for the master data file. The collected data is the property of The Centers for Disease Control and Prevention. After data analysis is completed, The Centers for Disease Control and Prevention will destroy all participant IIF and data. No IIF will be transmitted to the contractor for any aspect of the products development.

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80. A.1.3 Overview of the data collection system

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82. The study will be completed in three phases aimed at developing a HIV/STD themed motion comic designed to deliver health communication messages that will impact the knowledge, attitudes, beliefs, and intentions about HIV/STD of young people ages 15-24 in a manner that reduces their HIV/STD risk behavior. Participants in each of the three phases will consist of members of the following at-risk groups, who are most at risk for contracting HIV and STDs based on CDC surveillance data:

83. 1-Black Men who have sex with men

84. 2-Black Heterosexuals

85. 3-Latino Men who have sex with men

86. 4-Latino Heterosexuals

87. 5-White Men who have sex with men

88.

89. All participants in all phases will be recruited and screened using convenience samples from different settings including universities, community based organizations, schools, and civic organizations that serve youth in the target age range. (S**ee Attachments 4a and 4b**) In order to ensure that the identified at-risk groups are enrolled we will screen potential participants using a screening form. (**See Attachment 1a**) Based on similar research studies with the target populations approximately 300 people will need to be screened in order to reach our target enrollment. We will obtain informed consent for the participants prior to beginning each data collection.

90.

91. Phase 1 will consist of a round of 4 to 6 focus groups, which will focus of the feasibility, acceptability and the content development (storyline ideas, characters

designs) for the motion comic. (**See Attachment 1b**) Separate focus groups will be conducted with each at-risk group (groups 1-5 listed above). Approximately 60 participants will take part in the focus groups (10 to 12 Black Men who have sex with men, 10-12 Black Heterosexuals, 10 to 12 Latino Men who have sex with men, 10 to 12 Latino Heterosexuals, 10 to 12 White Men who have sex with men).

92.

93. Phase 2 will consist of a round of 4 to 6 focus groups, which will focus on testing the materials (story boards, scripts) created from the information provided in the phase 1 focus groups. (**See Attachment 1c**) Identical to the phase 1 groups, phase 2 focus groups will be conducted with each at-risk group. As in Phase 1, approximately 60 participants will take part in these focus groups, stratified by at-risk category.

94.

95. Phase 3 will consist of a round of 4 to 6 focus groups, which will focus on obtaining feedback on the motion comic tool that will be created using the feedback from the phases 1 and 2 focus groups. (**See Attachment 1d**) For this phase, 2 separate focus groups will be conducted with each at-risk group. Approximately 120 participants will take part in these focus groups (2 focus groups each): 10 to 12 Black Men who have sex with men, 10 to 12 Black Heterosexuals, 10 to 12 Latino Men who have sex with men, 10 to 12 Latino Heterosexuals, 10 to 12 White Men who have sex with men). In phase 3, participants will receive pre- and post-viewing ACASI surveys assessing their KABI about HIV/STD before and after viewing the three motion comic episodes. Subsequent data analysis will determine if the tool had any impact on KABI related to HIV/STD.

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97. A.1.4 Items of Information to be collected

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99. The focus groups for phases 1, 2, and 3 will be comprised of approximately 10-12 participants each. Focus groups are expected to last between 90 and 120 minutes. The focus group moderator guides are included here as **Attachments 1b, 1c, and 1d**. The focus groups include questions about:

100.

1) HIV/STD Knowledge
2) Condom Use
3) HIV Testing
4) Health Information Seeking
5) Feasibility and acceptability of a motion comic tool for HIV/STD Prevention
6) Content development for the motion comic tool

a. Proper look and tone
b. Story & character development

7) Future distribution methods of motion comic tool.

101.

102. The pre-and post-test surveys which will be administered to the 120 participants in phase 3 will assess:

- Demographics
- HIV/STD knowledge
- HIV/STD attitudes (Including HIV/STD testing and safe sex practices)
- HIV/STD beliefs (Including stigma and myths)
- HIV Related intentions to engage in behaviors that will reduce the risk of contracting HIV/STD. The questionnaire will include items about condom use, abstinence, negotiating safe sex and HIV/STD testing.

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

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

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

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111. The purpose of the project entitled “Development of a Motion Comic for HIV/STI Prevention Among Young People – ages 15-24” is to conduct formative research for development and pilot testing of a motion comic tool designed to impact the HIV/STD related knowledge, attitudes, beliefs and behavioral intentions of young people (ages 15-24) in a manner that will lower their risk of contracting HIV/STD. The information collected from this study will be used to develop and pilot test an innovative health communication tool that can be an addition to CDC’s portfolio of HIV prevention materials. The types of data collection activities used are the following:

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113.

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

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116. Qualitative interviewing will be used with volunteer respondents between the ages of 15-24 (Black Men

who have sex with men, Black Heterosexuals, Latino Men who have sex with men, Latino Heterosexuals, White Men who have sex with men) to test the acceptability and feasibility of this motion comic health communication tool, to develop the intervention content, and to test its' impact of HIV/STD related KABI among young people. Results from the three phases of focus groups will be used to develop and refine the intervention content for use in future full-scale intervention trials with larger samples of young people.

117.

118. A.2.5 Field Testing of New methodologies and Materials

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120. The purpose of this data collection is to conduct field tests of new methods and interventions. The objective of such testing is to evaluate the feasibility of the "new" strategies in CDC-funded projects. Specifically, this project is new and innovative because it is the first attempt to develop and test a new youth-focused technological intervention, an HIV/STD focused motion comic.

121.

122. A.2.6 Testing of Communication Mental Models

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124. The purpose of this data collection is to develop and test mental modeling methodologies. The information that will be collected in the focus groups and the quantitative surveys will be used to develop, revise, augment and finalize a pilot health communication campaign in the form of three serial HIV/STD prevention motion comic vignettes.

125.

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

127.

128. All of the focus groups will be recorded on digital recorders. Upon completion of each group, the digital recording will be downloaded to a computer. Each focus group will be transcribed professionally from the digital recording into a word processing file. In the phase 3 pre- and post-test surveys, data will be collected using audio-computer assisted self interview (ACASI) that will be entered into an electronic database.

129.

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

131.

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

133.

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

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

136. A.6. Consequences of Collecting the Information Less Frequently

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

138.

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

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

141.

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

143.

144. A Federal Register Notice for the generic clearance 0920-0840 was published on January 15, 2010.

145.

146. A.9. Explanation of Any Payment or Gift to Respondents

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148. Project participants will receive tokens of appreciation for participation in the study, $25 per participant for the focus groups and $10 for the individual phase 3 surveys. This token is needed to facilitate the timely and adequate recruitment of participants which will improve the quality of the results.

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150. A.10. Assurance of Confidentiality Provided to Respondents

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152. After the focus group or survey is completed, all contact information of the participants will be destroyed. After the audio tapes have been transcribed, they will be deleted from the computer and erased from the recorder. Each name on the audio tapes will be changed to a general name, such as participant #1, #2, etc… in the typed transcripts.

153.

154. Survey data collected will be stored in a locked file box and transported to the CDC for data entry. After each data survey is entered into an electronic database it will be compiled with data that has already been collected. Compiled data will be backed up on a password-protected server.

155.

156. Respondents will be told that no information in identifiable form will be available to or shared with anyone outside of the CDC. Analysis of the dataset will take place at the CDC. The information collected in this project will be owned by the CDC. CDC will be the only entity with access to the IIF and information collected. If any data is shared with anyone outside of the CDC, it will be de-identified and transferred securely to CDC on an encrypted SFTP site or on an encrypted, password protected flash drive.

157.

158. Prior to participating in any phase of the study adults, the parents of teens and teens will be required to give informed consent and assent. Written consent and assent will be obtained when the participants arrive at the various focus group sites (e.g. CDC campus, local CBO).

159.

160. For adults, written consent will be obtained after consent forms are read aloud to them or once they read them and they have the opportunity to ask questions in each of the phases. (**Attachment 2a**). The parent's form will consent their child into the study. In all phases, the parents of teens will sign the consent form first and send it with their child to the focus group (**Attachment 2b**). The parent will be provided with an opportunity to ask the PI questions by calling a number provided on the consent form. The adolescent assent form will be read aloud if necessary (**Attachment 2c**). After they read the consent forms or the consent forms have been read for them, the child will be allowed to ask as many questions as needed to ensure they understand what they will be asked to do as part of the study prior to signing the assent form.

161.

162. All consent and assent forms with participant names and signatures will be kept in a locked file cabinet in a locked room, separate from the data files. They will be taken to this location promptly after they have been collected. Adult, adolescent participants and their parents will be provided with copies of their consent and assent forms.

163.

164. A.11. Justification for Sensitive Questions

165.

166. The study asks adult and adolescent participants questions of a sensitive nature. Questions concerning sexual behavior and intentions will be asked of all participants. These questions are necessary to understand and assess levels of STD/HIV risk behaviors in order to develop the appropriate intervention content and health communication messages. The questions used in this project are similar to the Youth Risk Behavior Surveillance System (YRBSS) and the National HIV Behavioral Surveillance System (NHBS), which are both conducted by the CDC, measure the risk behaviors of adolescent and adults respectively. Similar to data collected in the YRBSS and NHBS, the questions refer to past behaviors rather than current behaviors so there are no questions that mandate parents' knowledge. The verbal consent process will inform parents that their children will be asked these questions and that the researcher does not plan to share the specific information with the parent. However, the overall findings of the study will be shared with parents if they ask for them. If this makes the parent uncomfortable, they have the option of refusing to participate in the study. In no instance will a member of the research staff obtain a participant's (adult or adolescent) social security number.

167.

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

169.

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

171. There are several types of respondents who will participate in the study. They include Black Men who have sex with men, Black Heterosexuals, Latino Men who have sex with men, Latino Heterosexuals and White Men who have sex with men. Focus groups conducted with these types of respondents will include Adults (18-24 years old) and adolescents (15-17 years old). In order to ensure the proper number of participants in each of the phases a 1-minute study screener will be administered to 300 adults and adolescents in the target age range. A total of 120 adolescents and adults will participate in the 2-hour focus groups in phases 1 and 2. A total of 120 adults and adolescents will participate in the 2-hour phase 3 focus groups and will complete pre-test and post-test surveys designed to be completed in 15 minutes per survey.

172.

173.

174. Exhibit A.12.A Estimated Annualized Burden Hours

175. Type of Respondent	176. Form Name	177. Number of Respondents	178. Number of Responses Per Respondent	179. Average Burden Per Response (in Hours)	180. Total 181. Burden 182. Hours
183. General Public - Adults and Adolescents	184. Study Screener	185. 300	186. 1	187. 1/60	188. 5
189. General Public - Adults and Adolescents	190. Focus Group Guide 1	191. 60	192. 1	193. 2	194. 120
195. General Public - Adults and Adolescents	196. Focus Group Guide 2	197. 60	198. 1	199. 2	200. 120
201. General Public - Adults and Adolescents	202. Focus Group Guide 3	203. 120	204. 1	205. 2	206. 240

207. General Public - Adults and Adolescents	208. Pre-test Survey	209. 120	210. 1	211. 15/60	212. 30
213. General Public - Adults and Adolescents	214. Post-test Survey	215. 120	216. 1	217. 15/60	218. 30
				219. Total	**220. 545**

221.

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

223. The annualized costs to the respondents are described in Exhibit A.12.B. The United States Department of Labor Statistics May, 2010. http://www.bls.gov/oes/current/oes_nat.htm was used to estimate the hourly wage rate for the general public for the purpose of this generic request. The figure of $21.35 per hour was used as an estimate of average hourly wage for adults and the figure of $7.25 is used as an estimate of average hourly wage for minors across the country. These two figures were averaged to arrive at an average wage of $14.30 per hour. Thus, the total anticipated annual cost to participants for collection of information in this project will be $7,793.50.

224.

225. **Exhibit A.12.B: Estimated Annualized Burden Costs**

226.

227. Type of Respondent 228. (Form Name)	229. Total Burden Hours	230. Hourly Wage Rate	231. Total Respondent Costs
232. General Public-Adults and Adolescents(Study Screener)	233. 5	234. $14.30	235. $71.50
236. General Public- Adults and Adolescents	237. 120	238. $14.30	239. $1,716.00

(Focus Group Guide 1)			
240. General Public- Adults and Adolescents (Focus Group Guide 2)	241. 120	242. $ 14.30	243. $1 ,716.00
244. General Public- Adults and Adolescents (Focus Group Guide 3)	245. 240	**246.** $ 14.30	247. $3 ,432.00
248. General Public- Adults and Adolescents (Pre-test Survey)	249. 30	250. $ 14.30	251. $4 29.00
252. General Public- Adults and Adolescents (Post-test Survey)	253. 30	254. $ 14.30	255. $4 29.00
256. Total	**257. 545**	**258.**	259. $7 ,793.50

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

261.

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

263. A.14. Annualized Cost to the Government

264.

265. This activity will require the participation of CDC staff members. A principal investigator will be responsible for designing the study, leading the team of researchers, preparing the IRB and OMB human subjects documents, working with the designated contractor, and providing project oversight. Also necessary is a Co-principal investigator who will assist in the project design and work with the principal investigator to obtain OMB and IRB approvals. Finally, a project manager is necessary to manage the operations of the project. Travel expenses include travel for data collection (4 round trips to domestic locations to conduct focus groups). Domestic focus group locations will be selected based on a number of criteria including being located in high incidence areas, ease of access for the target population.

266. **Exhibit A.14: Estimates of Annualized Cost to the Government**

267.

268. Expense Type	269. Expense Explanation	270. 271. Annual Costs (dollars)
272. Direct Costs to the Federal Government	273. CDC, Principal Investigator (GS-13,0.25 FTE)	274. $ 22,800
275.	276. CDC, Co-Principal Investigator (GS-12, 0.20 FTE)	277. $ 16,777
278.	279. CDC, Project Manager (GS-12, .30 FTE)	280. $ 25,884
281.	282. CDC Travel for focus groups/data collection (4 domestic trips)	283. $8,500
284.	285. **Subtotal, Direct Costs**	**286. $ 73,961**
287. Cooperative Agreement or Contract Costs	**288.** Contractor Costs, TBN	289. $ 81,500
290.	**291. Subtotal, Cooperative Agreement or Contract Costs**	**292. $ 81,500**
293.	**294. TOTAL COST TO THE GOVERNMENT**	**295. $ 155,461**

296.

297. A.15.<u>Explanation for Program Changes or Adjustments</u>

298.

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

300. A.16. <u>Plans for Tabulation and Publication and Project Time Schedule</u>

301.

302. Data collection will be completed during the first year after OMB approval is granted. Phase 1 data collection will be completed by 2 months after approval. Phase 2 of data collection will be completed by 5 months after approval, and the motion comics will be developed based on the focus group data from phases 1 & 2. Phase 3 of data collection will be completed by 9 months after approval. Data analysis will be completed by 11 months after approval. Dissemination of results will begin 12 months after OMB approval.

303.

304. Exhibit A.16: Project Time Schedule

305.

306. **307. Activity**	308. **309. Time Schedule**
310. Recruit and conduct 1st set of focus groups	311. 1-2 months after OMB approval
312. Analyze 1st set of focus groups	313. 2-3 months after OMB approval
314. Recruit and Conduct 2nd set of focus groups	315. 4-5 months after OMB approval
316. Analyze 2nd set of focus groups	317. 5-6 months after OMB approval
318. Contractor will create motion comics based on data from phase 1 and 2 focus groups	319. 7-8 months after OMB approval
320. Recruit and Conduct 3rd set of focus groups	321. 8-9 months after OMB approval
322. Analyze 3rd set of focus groups	323. 9-10 months after OMB approval
324. Analyze quantitative survey	325. 10-11 months after OMB approval
326. Share findings with all stakeholders	327. 12 months after OMB approval

328.

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

330. OMB Expiration Date will be displayed.

331.

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

333. There are no exceptions to the certification.

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336.