Informing the Development of Mobile Apps for HIV Prevention, Treatment, & Care

Generic Information Collection request under 0920-0840

Section A: Supporting Statement

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82.

83. **Supporting Statement**

84. **A. JUSTIFICATION**

85.

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

87.

88. Columbia University Medical Center proposes to conduct a formative research study underneath formative Generic 0920-0840, exp. 02/29/2016 (Formative Research and Tool Development) to explore the need for two different HIV prevention mobile phone applications (app): (1) an app for meeting the HIV prevention and health care needs for persons living with HIV, including adherence to HIV medications, retention in care, and treatment management, and (2) an app encouraging HIV testing by identifying testing sites and providing periodic reminders for testing among high risk men who have sex with men(MSM).

89. The proposed study will use qualitative ethnographic methods and user-centered human-computer interaction research methods to identify the mobile technology needs of users, mobile application (app) design preferences, as well as the barriers and facilitators that prohibit or encourage the uptake and sustained use of mobile apps for HIV prevention. Our sample will include 50 persons living with HIV (PLWH), 25 HIV healthcare providers and 50 high-risk MSM. At each phase of our study, we will use qualitative ethnographic methods and user-centered human-computer interaction research methods to ensure that the app meets end-user's goals. We will utilize the Information Science Research Framework in which various design processes are employed in order to create a design document. The design document will specify the functional requirements for two distinct apps for: 1) meeting the HIV prevention and health care needs of PLWH, including adherence to HIV medications, retention in care, and treatment management, and 2) encouraging HIV testing by identifying testing sites and providing periodic reminders for testing among high-risk MSM.

90. Findings from this study will inform future HIV prevention testing, treatment and care apps for Smartphones and other new media technologies for HIV prevention and will identify technology preferences and features, HIV-related content requirements, design specifications, and issues related to long-term appeal and maintenance of apps in at-risk or affected populations. Tools developed using this research have the potential to extend this impact and reach of HIV testing programs for high-risk MSM and HIV prevention and health care for PLWH.

91. The United States HIV epidemic continues to exact a huge toll, especially among racial and ethnic minorities, and MSM. New York City, the setting of the proposed study, has the largest HIV/AIDS epidemic in the nation, making it the ideal setting for the formative research study.

92. Mobile health technology shows potential as highly valuable tool in the management and prevention of chronic illness such as HIV. The ubiquitous nature of mobile technologies, namely smartphones, in daily life has created opportunities for applications that were not previously possible. Using mobile technologies to more rapidly and accurately assess and modify health-related behavior and biological states can transform patient decision making about their health.

93.

94. **A.1.2 Privacy Impact Assessment**

95.

96. Columbia University Medical Center will collect information in identifiable form (IIF). IIF will be collected from participants prior to the start of each focus group using paper survey forms administered by local study staff. Research staff at Columbia University Medical Center will collect phone numbers to contact participants to take part in the focus groups, signatures on informed consent documents, voices and names on digital recordings, and transcripts of digital recordings. Other IIF collected include age, ethnicity, race, 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. Data collected using paper survey forms will be entered in a statistical software package SPSS 20.0 (IBM). All paper surveys will be stored in a locked file cabinet in a locked office at the Columbia University School of Nursing. Once the data have been entered in an electronic database they will be stored on a password protected computer in the School of Nursing in a locked office. All of the data is saved on a secure server hosted by Columbia University Medical Center IT Department. All servers are located in a secure datacenter. The user community operates under a managed desktop solution which is locked down, including hard drive and thumb drive encryption. All updates are centrally managed and deployed. Currently the network can be accessed remotely via VPN. All servers have HIPAA compliant security. All data will be kept in a secure location in locked filing cabinets and on password protected computers. All data will be de-identified. All consent forms will be kept in a separate locked filing cabinet in a locked office. Only study PI and Project Coordinator will have access to locked files. Participant privacy will be further protected by the use of ID numbers on all data forms. Audio tapes will only be available to the Columbia study team and not shared with CDC. They will be given a study ID and stored in a password protected file and

computer. Participant names or any identifying information will not appear in transcripts or analyses. After analyses, all tapes will be erased. Demographic data will be destroyed 1 year after publication of the results.

97.

98. **A.1.3 Overview of the data collection system**

99.

100. The study will be completed in three cycles (Cycle 1: Rigor cycle, Cycle 2: Relevance cycle; Cycle 3; Design cycle) aimed at identifying acceptable and appropriate features for a mobile app for meeting the HIV prevention and healthcare needs of Persons Living with HIV (PLWH) and high-risk MSM. Cycle 1 will consist of the systematic review of existing theories and methods for designing and evaluating mobile apps and will NOT involve data collection from human subjects, Participants in cycles 2 and 3 will consist of:

101. 1-Persons living with HIV (PLWH)

102. 2-HIV Healthcare Providers*

103. 3-High-risk MSM

104. *Cycle 2 only

105.

106. HIV positive persons will be recruited at the Comprehensive HIV Program at Columbia University/New York Presbyterian Hospital (provides primary care and services to over 1400 people living with HIV), AIDS Service Center (CBO serves over 1800 HIV-positive persons and at-risk persons and conducts peer education and community outreach), and Project STAY (Services To Assist Youth - affiliated with Columbia University, provides services to high-risk and HIV-positive youth). HIV healthcare providers (i.e. doctors, nurses, and case managers) and patients will be recruited through personal contact and flyers in the patient care and case management sites. **(See Attachments 5a-f**) In order to ensure that the identified at-risk groups are enrolled we will screen potential participants using a screening form. (**See Attachments 2a, 2b, and 2c**) Based on similar research studies with the target populations approximately 300 people will be screened in order to reach our target enrollment. Informed consent for the participants will be obtained prior to beginning each data collection.

107.

108. Cycle 1 will consist of a systematic review of the literature to identify theories and methods related to technology based interventions including mobile apps for HIV treatment and prevention and apps relevant to HIV testing and prevention with high-risk MSM. Additionally, a meta-analysis of both peer-reviewed and grey literature will be conducted for existing apps that could meet the functional specifications and systems qualities drawn from the relevance cycle. Existing apps related to adherence, treatment,

disease management, HIV testing, and HIV prevention will be systematically reviewed.

109.

110. Cycle 2 will consist of 10 to 13 focus groups where participants will be asked about the features and content of an app they prefer and to identify barriers and facilitators to app use(**See Attachments 2d-h**). Separate focus groups will be conducted with each group (groups 1-3 listed above). Approximately 130 English and Spanish speaking participants will take part in the focus groups, (50 PLWH, 30 HIV Healthcare providers, 50 high-risk MSM) with 8-10 participants per focus group.

111.

112. Cycle 3 will consist of two design sessions incorporating findings from earlier cycles of the study. Each design session will build on knowledge gained during the previous session. Design sessions are an iterative process whereby study participants will be the experts and teachers, and the investigators the learners. Participants will provide feedback on effective interfaces, functions and tasks they find appealing (**See Attachments 2k**). Findings will be transformed into formal functional requirements and provide the foundation for the prototype for evaluation by human computer interaction experts and end-users.

113.

114. **A.1.4 Items of Information to be collected**

115.

116. The focus groups in cycle 2 will be comprised of approximately 8-10 participants each. Focus groups are expected to last 90 minutes, 60 minutes for the focus group guide and 30 minutes for the focus group assessment. The focus group moderator guides are included here as **Attachments 2d-h**. The focus groups assessments include questions about (**Attachments 2i and 2j**):

117.

1) Demographics
2) Mobile technology use and experience
3) Quality of Life
4) HIV health
5) Stigma
6) Information Privacy Concerns
7) Heuristics Principles
8) Education and Information
9) Care and Treatment Adherence
10) Factors affecting adoption
11) Personal health information management.

118.

119. The End User survey administered to the 16 (8 PLWH and 8 High-risk MSM) participants in cycle 3 are (**Attachment 2k**):

- Heuristic Evaluation Checklist

- Perceived Ease of Use and Usefulness

Exhibit A.1.4 Items of Information to be collected

Variables to be explored	**Data collection tool and citation**	**Study Related Procedures**
Age, ethnicity, race, computer experience, mobile technology use and experience	Demographic Survey	All Focus Groups
Quality of Life	SF-12	Focus Groups – PLWH and high-risk MSM
HIV health history		Focus Groups – PLWH
Stigma	HIV stigma	Focus Groups – PLWH and high-risk MSM
Engagement with Health Care Provider Scale	Engagement with Healthcare Provider Scale	Focus Groups – PLWH and high-risk MSM
Information Privacy Concerns	Information privacy concerns.	All Focus Groups
Heuristic Principles	Heuristic Evaluation Checklist.	Usability Testing
Usability	The Post Study System Usability Questionnaire (PSSUQ)	Usability Testing
Usability	Perceived Ease of Use and Usefulness Questionnaire.	Usability Testing
Education and Information		Focus Groups -PLWH, MSM and HIV healthcare

		providers
156. Identifying Resources	157.	158. Focus Group Guide – PLWH, MSM and HIV healthcare providers
159. Care and Treatment Adherence 160.	161.	162. Focus Groups – PLWH and HIV healthcare providers
163. Factors Affecting Adoption	164. Precede-Proceed Framework for Program Planning and Implementation	165. Focus Group Guide – PLWH and MSM
166. Personal Health Information Management	167.	168. Will be added to focus group guide - PLWH

169.

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

171.

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

173.

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

175.

176. The purpose of this information collection request is to conduct formative research 1) To identify acceptable and appropriate features for a mobile app for meeting the HIV prevention and healthcare needs of Persons Living with HIV (PLWH), including adherence to HIV medications, prevention with positives, retention in care and treatment management. 2) To explore the acceptable and appropriate features of a mobile app encouraging HIV testing by identifying testing sites and providing periodic reminders for testing among high-risk MSM. 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.

177.

178.

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

180.

Qualitative interviewing will be used with volunteer respondents between the ages of 13-64 (PLWH and high-risk MSM)to identify acceptable and appropriate features for a mobile app for meeting the HIV prevention and healthcare needs of Persons Living with HIV (PLWH), including adherence to HIV medications, prevention with positives, retention in care and treatment management, and to explore the acceptable and appropriate features of a mobile app encouraging HIV testing by identifying testing sites and providing periodic reminders for testing among high-risk MSM. Results from the focus groups will be used to develop and refine smartphone applications for use in future full-scale intervention trials with larger samples of PLWH and high-risk MSM.

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

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.

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

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

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

No small businesses will be involved in this data collection.

A.6. Consequences of Collecting the Information Less Frequently

The activities involve a one-time collection of data. There are no -consequences to collecting the information less frequently.

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

This request fully complies with the regulation 5 CFR 1320.5.

200.

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

202.

203. For sub-collection requests under a generic approval, Federal Register Notices are not required and none were published. A 30-Day Federal Register Notice for the generic clearance 0920-0840 was published on 12/4/2012, Vol. 77 No. 233, pages 71794-71795, exp. 02/29/2016.

204.

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

206.

207. HIV-positive persons and high-risk MSM participants will receive $25 as a token of appreciation for participation in focus groups, and HIV healthcare providers will receive $50 as a token of appreciation for participating in focus groups. In addition, food appropriate for the time of day will be served provided by the Columbia University team. Participants in the design sessions will receive $25 as a token of appreciation for each session. Each usability expert will be provided a $50 token of appreciation for participation in the Heuristic Evaluation. Participants in the end-user usability testing will receive a $25 token of appreciation. Study subjects can participate in multiple parts of the study.

- Focus group session = $25
- 2 design sessions = 2X $25 =$50
- Usability testing = $25
- Heuristic evaluators and HIV healthcare providers will only have one opportunity to earn $50.

208. All tokens of appreciation will be distributed as cash. This token is needed to facilitate the timely and adequate recruitment of participants which will improve the quality of the results. Although there has been some debate on the necessity of offering tokens of appreciation, numerous empirical studies have shown that tokens of appreciation can significantly increase response rates (e.g., Abreu & Winters, 1999; Shettle & Mooney, 1999) and the use of modest tokens of appreciation is expected to enhance survey response rates without biasing responses. In addition, HIV has a stigma that other health issues do not have, which makes it difficult to recruit participants for research when compared to other diseases, (e.g cancer, diabetes, obesity). One study on research participant recruitment in Hispanic communities, researchers noted that the stigma related to HIV/AIDS is a major

barrier in subject recruitment for HIV/AIDS behavioral research (Shedlin, Decena, Mangadu, & Martinez, 2011).

209. OMB offers justification which supports the use of tokens of appreciation, in this case “to improve coverage of specialized respondents, rare groups, or minority populations” (OMB, 2006).This study seeks to recruit minorities in order to conduct formative research for the development 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. Offering tokens of appreciation is necessary to recruit minorities and historically underrepresented groups in to research. Barriers cited related to recruitment of minorities included (1) lack of trust among minority communities towards the medical research process and research (Quinn, 1997; Wrobel & Shapiro, 1999; Gauthier& Clarke, 1999; Washington, 2006)(2) a lack of competence among researchers to use culturally competent approaches for recruitment and (Brown et al., 2000; Dilworth-Anderson & Williams, 2004)(3) reluctance to participate due to inconvenience and a lack of time (Brown et al., 2000; Brown et al., 2000; Schoenfeld et al., 2000). In a recent study of recruitment and retention of Black men who sleep with men by a Community Based Organization (CBO), recruiters found it difficult to retain information from the BMSM because many were reluctant to provide their names and contact information because of concerns about being seen giving these personal details to an HIV prevention program (Painter et al., 2010). Concern with potential social labeling and HIV-related stigma also may have contributed to their hesitation (Painter et al., 2010). Some of those who were screened provided incorrect contact information, making it difficult or impossible to locate them later (Painter et al., 2010). In this study, some agreed to participate in the evaluation because of the tokens of appreciation that were offered (Painter et al., 2010).

210.

211. **A.10.** **Assurance of Confidentiality Provided to Respondents**

212.

213. After the focus group or survey is completed, all contact information for 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.

214.

215. All data will be kept in a secure location in locked filing cabinets and on password protected computers. All data will be de-

identified. All consent forms will be kept in a separate locked filing cabinet in a locked office. Participant privacy will be further protected by the use of ID numbers on all data forms. Audio tapes will only be available to the Columbia study team and not shared with CDC. Participant names or any identifying information will not appear in transcripts or analyses. After analyses, all tapes will be erased. Original hardcopy forms of demographic data will be destroyed 1 year after publication of the results.

216.

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

218.

219. Prior to participating in any phase of the study adults, and participating minors will be required to give informed consent and/or assent. Written consent and assent will be obtained when the participants arrive at the focus group site.

220.

221. Written consent will be obtained after consent forms are read aloud to participants or once they read them and they have the opportunity to ask questions in each of the phases (**Attachments 3a, 3b, 3d, and 3e**). For participating minors, assent forms will be read aloud if necessary (**Attachments 3c and 3f**). After they read the consent forms or the consent forms have been read for them, the adolescents 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.

222.

223. According to the local Institutional Review Board, Columbia University met all of the conditions for a waiver of parental permission under 45 CFR 46.116(d). It was determined by their local IRB that this waiver will not adversely affect the rights and welfare of the subjects.

224.

225. All consent and assent forms with participant names and signatures will be kept in a separate locked filing cabinet in a locked office. They will be taken to this location promptly after they have been collected. Adult and adolescent participants will be provided with copies of their consent and assent forms.

226.

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

228.

229. This study asks adult and adolescent participants certain questions that are sensitive in nature. Specifically, it asks questions concerning an individuals' HIV status. This measurement of a sensitive HIV-related question is necessary to identify PLWH to participate in the study. Since this study will not conduct HIV testing of potential participants to determine HIV status, proof of HIV status from potential participants is needed to confirm the validity of their participation in the study as a PLWH. Proof of HIV status one of the following items; a filled prescription bottle of HIV medication with participant's name on it; a letter from participant's physician, provider, or an agency (including a case manager) that states participant's name and positive HIV status; AIDS Drug Assistance Program [ADAP] documentation; or a positive test result with participant name. Proof of HIV status along with any personal information contained within will not be retained, stored, or shared by any study staff.

230. This method for determining HIV status is demonstrated in the following studies; Kalichman (2001) and Joseph et al (2011). While formal participation rates are not calculated for focus groups In Joseph et al (2011) (OMB# 0920-0774), study staff reported that the study was successful in "filling" participants for all planned focus groups. Despite having a complex set of inclusion criteria for each of the study's groups (based on demographics and experiences with HIV testing), the Project Officer reported that the participant group with the least challenges with recruitment were among HIV-positive persons. To the question of requiring proof, the PO also stated that study staff never encountered a situation where someone was eligible and willing to participate but was unable to because he or she did not have proof of status. Lastly, study staff was unable to recount an instance where a study participant was eligible to participate but was unwilling or declined because they were not comfortable providing verification of HIV status.

231. The study screener, **Attachment 2a,** will include a question to assess whether individuals have ever tested positive for HIV. Questions regarding HIV status will only be asked to identify and determine eligibility of PLWH for study participation.

232.

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

234.

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

236.

237. In order to ensure the proper number of participants in each of the cycles a 1-minute study screener will be administered to approximately 300 adults and adolescents in the target age range. There are several types of respondents who will participate in

the study they include PLWH, High-risk MSM, and HIV healthcare providers (**Attachments 2a, 2b, 2c**). A total of 130 participants will participate in the 60 minute focus groups in cycle 2. Focus groups conducted with English and Spanish speaking PLWH will include Adults (18-64 years old) and adolescents (13-17 years old) using Focus group guides PLWH or Focus group guide PLWH Spanish (**Attachments 2d, 2e**). The focus groups are followed by a 30 minute assessment using Focus group assessment #1 for English speaking participants or Focus group assessment #2 for Spanish speaking participants (**Attachments 2i, 2j**). Focus groups conducted with high-risk MSM will include English and Spanish speaking Adults (18-64 years old) and adolescents (13-17 years old) using Focus group guide high-risk MSM or Focus group guide High-risk MSM Spanish (**Attachments 2f, 2g**). The focus groups are followed by a 30 minute assessment using Focus group assessment #1 for English speaking participants or Focus group assessment #2 for Spanish speaking participants (**Attachments 2i, 2j**). Focus groups conducted with HIV healthcare providers, will only include English speaking Adults (18-64 years old) using Focus group guide for HIV Providers (**Attachment 2h**). In cycle 3, 16 English speaking PLWH (n=8) and High-risk MSM participants (n=8) will participate in a design session and will complete the End user survey (**attachment 2k**) which is designed to be completed in 30 minutes per survey.

Exhibit A.12.A **<u>Estimated Annualized Burden Hours</u>**

249. Type of Respondent	250. Form Name	251. Number of Respondents	252. Number of Responses Per Respondent	253. Average Burden Per Response (in Hours)	254. Total 255. Burden 256. Hours
257. General Public - Adults and Adolescents	258. Study Screener-PLWH	259. 120	260. 1	261. 1/60	262. 2
263. General Public - Adults and Adolescents	264. Study Screener-High-risk MSM	265. 120	266. 1	267. 1/60	268. 2
269. HIV Healthcare Providers	270. Study Screener	271. 60	272. 1	273. 1/60	274. 1
275. General Public - Adults and Adolescents	276. Focus Group Guide - PLWH	277. 25	278. 1	279. 1	280. 25

249. Type of Respondent	250. Form Name	251. Number of Respondents	252. Number of Responses Per Respondent	253. Average Burden Per Response (in Hours)	254. Total 255. Burden 256. Hours
281. General Public - Adults and Adolescents	282. Focus Group Guide – PLWH Spanish	283. 25	284. 1	285. 1	286. 25
287. General Public - Adults and Adolescents	288. Focus Group Guide – High-risk MSM	289. 25	290. 1	291. 1	292. 25
293. General Public - Adults and Adolescents	294. Focus Group Guide – High-risk MSM Spanish	295. 25	296. 1	297. 1	298. 25
299. HIV Healthcare Providers	300. Focus Group Guide	301. 30	302. 1	303. 1	304. 30

249. Type of Respondent	250. Form Name	251. Number of Respondents	252. Number of Responses Per Respondent	253. Average Burden Per Response (in Hours)	254. Total 255. Burden 256. Hours
305. General Public - Adults and Adolescents	306. Focus Group Assessment #1 English	307. 50	308. 1	309. 30/60	310. 25
311. General Public - Adults and Adolescents	312. Focus Group Assessment #2 Spanish	313. 50	314. 1	315. 30/60	316. 25
317. General Public - Adults and Adolescents	318. End User Survey	319. 16	320. 1	321. 30/60	322. 8
323. General Public - Adults	324. Consent form(PLWH and High-Risk MSM) 325.	326. 25	327. 1	328. 5/60	329. 2

249. Type of Respondent	250. Form Name	251. Number of Respondents	252. Number of Responses Per Respondent	253. Average Burden Per Response (in Hours)	254. Total 255. Burden 256. Hours
330. General Public - Adults	331. Consent form (PLWH and High-Risk MSM-Spanish) 332.	333. 50	334. 1	335. 5/60	336. 4
337. General Public - Adolescents	338. Assent form(PLWH and High-risk MSM) 339.	340. 25	341. 1	342. 5/60	343. 2
344. HIV Healthcare Providers	345. Consent form 346.	347. 30	348. 1	349. 5/60	350. 3
351. General Public - Adults	352. Usability Consent form	353. 8	354. 1	355. 5/60	356. 1

249. Type of Respondent	250. Form Name	251. Number of Respondents	252. Number of Responses Per Respondent	253. Average Burden Per Response (in Hours)	254. Total 255. Burden 256. Hours
357. General Public - Adolescents	358. Usability Assent form	359. 8	360. 1	361. 5/60	362. 1
				363. **Total**	364. **206**

365.

366. **A.12.B.** **<u>Estimated Annualized Burden Costs</u>**

367.

368. The annualized costs to the respondents are described in Exhibit A.12.B. The United States Department of Labor Statistics May, 2011 http://www.bls.gov/oes/current/oes_nat.htm was used to estimate the hourly wage rate for the general public for the purpose of this GenIC request. The figure of $21.74 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 $14.50 per hour. The figure of $34.97 per hour was used as an estimate of average hourly wage for healthcare providers across the country. Thus, the total anticipated annual cost to participants for collection of information in this project will be $3682.98.

369.

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

371.

372. Type of Respondent 373.	374. Total Burden Hours	375. Hourly Wage Rate	376. Total Respondent Costs
377. General Public-Adults and Adolescents(Study	378. 2	379. $ 14.50	380. $29.00

Screener-PLWH)			
381. General Public-Adults and Adolescents(Study Screener-High-risk MSM)	382. 2	383. $ 14.50	384. $29.00
385. HIV Healthcare Providers (Study Screener)	386. 1	387. $ 34.97	388. $34.97
389. General Public- Adults and Adolescents (Focus Group Guide -PLWH)	390. 25	391. $ 14.50	392. $362.50
393. General Public- Adults and Adolescents (Focus Group Guide PLWH Spanish)	394. 25	395. $ 14.50	396. $362.50
397. General Public- Adults and Adolescents (Focus Group Guide High-risk MSM)	398. 25	399. $ 14.50	400. $362.50
401. General Public- Adults and Adolescents (Focus Group Guide High-risk MSM- Spanish	402. 25	403. $ 14.50	404. $362.50
405. HIV Healthcare Providers (Focus Group Guide)	406. 30	407. $ 34.97	408. $1049.10
409. General Public- Adults and Adolescents (Focus Group Assessment #1 English)	410. 25	411. $ 14.50	412. $362.50
413. General Public- Adults and Adolescents (Focus Group	414. 25	415. $ 14.50	416. $362.50

Assessment #2 Spanish)			
417. General Public- Adults and Adolescents (End User Survey)	418. 8	419. $ 14.50	420. $1 16.00
421. General Public- Adults (Consent form for PLWH and High-risk MSM) 422.	423. 2	424. 425. 426. $ 14.50	427. $2 9.00
428. General Public- Adults (Consent form for PLWH and High-Risk MSM 429. - Spanish)	430. 4	431. 432. 433. $ 14.50	434. $5 8.00
435. General Public- Adolescents (Assent form for PLWH and High-Risk MSM)	436. 2	437. 438. 439. $ 14.50	440. $2 9.00
441. HIV Healthcare Providers (Consent form)	442. 3	443. 444. $ 34.97	445. $1 04.91
446. General Public- Adults (Usability Consent form)	447. 1	448. 449. $ 14.50	450. $1 4.50
451. General Public- Adolescents (Usability Assent form)	452. 1	453. 454. $ 14.50	455. $1 4.50
456. **Total**	457.	458.	459. **$3 682.98**

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

461.

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

463. **A.14. <u>Annualized Cost to the Government</u>**

464.

465. The annualized cost to the government is $290,804. This activity will require the participation of CDC staff members. A project officer will be responsible for leading the team of researchers, preparing the IRB and OMB documents, and working with the designated PI, and providing project oversight. A Co-project officer will assist in the project design and work with the project officer to obtain OMB and IRB approvals. Finally, a project coordinator is necessary to manage the daily operations and logistics of the project.

466.

467.

468.

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

470.

471. **Expense Type**	472. **Expense Explanation**	473. 474. **Annual Costs (dollars)**
475. Direct Costs to the Federal Government	476. CDC, Project Officer (LCDR 0-4,0.25 FTE)	477. $ 12,825
478.	479. CDC, Co-Project Officer (GS-13, 0.10 FTE)	480. $ 9,975
481.	482. CDC, Project Coordinator (GS-12, .30 FTE)	483. $ 21,570
484.	485. **Subtotal, Direct Costs**	486. **$ 44,370**
487. Cooperative Agreement or Contract Costs	488. Cooperative Agreement Cost	489. $ 246,434
490.	491. **Subtotal, Cooperative Agreement or Contract Costs**	492. **$ 246,434**
493.	494. **TOTAL COST TO THE GOVERNMENT**	495. **$ 290,804**

496.	497.	498.

499.

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

501.

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

503.

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

505.

506. Data collection will be completed during the first year after OMB approval is granted. Focus group data collection will be completed by 2 months after approval. Collaborative user interface design sessions will be completed by 4 months after approval and prototype development will begin based on the focus group data and design sessions. Usability testing will be completed by 7 months after approval. Data analysis will be completed by 8 months after approval. Dissemination of results will begin 12 months after OMB approval.

507.

508. **Exhibit A.16: Project Time Schedule**

509.

510. 511. **Activity**	512. 513. **Time Schedule**
514.	515.
516. Recruit and conduct focus groups	517. 2-3 months after OMB approval
518. Analyze focus groups	519. 4-5 months after OMB approval
520. Conduct Interface Design Sessions	521. 5-6 months after OMB approval
522. Prototype Development	523. 7-8 months after OMB approval
524. Usability testing	525. 8-9 months after OMB approval
526. RE-AIM Framework Analysis	527. 9-10 months after OMB approval
528. Preparation of manuscripts	529. 10-11 months after OMB approval
530. Share findings with all stakeholders	531. 12 months after OMB approval

532.

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

534. OMB Expiration Date will be displayed.

535.

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

537. There are no exceptions to the certification.