Evaluating a HIV/AIDS Focused Video Game for Young People

Generic Information Collection request under 0920-0840

(exp. 2/29/2016)

Section A: Supporting Statement

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- The goal of the study is 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/AIDS among young people between the ages of 11-24.
- The intended use of the resulting data will benefit the federal government by (1) providing information feasibility, acceptability and therefore the viability of using video games as a medium for health communication activities targeting young at-risk populations, (2) aid other researchers who wish to design video games for other important health topics; and (3) produce a better understanding of the mental models about how to use new media to inform young people about HIV/AIDS. 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.
- The methods used to collect the information will use quantitative surveys to: a) determine the feasibility and acceptability, and b) determine the video game's impact on knowledge, abilities, beliefs and behavioral intentions and behaviors (KABIB) related to HIV/AIDS prevention.
- The subpopulation to be studied consists of young people from Georgia between the ages of 11-24 of any gender, race and ethnicity.
- The data will be analyzed using repeated measures t-tests for within group testing and repeated measures ANOVA's for testing between groups.

A. JUSTIFICATION

A.1 Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) requests a OMB approval to conduct a new information collection entitled, "Evaluating a HIV/AIDS Focused Video Game for Young People" under the OMB approved Generic Clearance, "Formative Research and Tool Development" (OMB #0920-0840 exp. 2/29/2016). Collecting this information, developing this intervention and pilot testing this tool will add to the CDC portfolio of effective interventions for at-risk populations.

CDC is authorized to collect the data described in this request by Section 301 of the Public Health Service Act (42 USC 241). A copy of this authorizing legislation is provided in **Attachment 1**.

Games have tremendous potential as a vehicle for health communication and education. According to the Entertainment Software Association, games are played by 58% of Americans—by both genders and by a wide age range. Health education games have been shown to increase knowledge, change behavioral intent, and improve adherence to medical treatment (healthgamesresearch.org).

. Interactive health education tools such as health education games and motion comics have demonstrated the ability to induce statistically significant changes in knowledge, abilities, beliefs and behavioral intentions and behaviors (KABIB) consistent with HIV prevention (Duncan et al. 2014, Fiellin, Hieftje and Duncan 2014, Kato et al. 2008, Willis et al. 2014a, Willis et al. 2014b).

After a careful review by a panel of experts across HHS, we have selected one of the games created at the 2014 Game Jam to test its potential impact on HIV/AIDS related KABIB among those who play it between the ages of 11-24.

In this request we are seeking to collect information to determine the impact of video game on the KABIB by comparing those who play it and to those who do not. By using the measures proposed we will be determining the impact, feasibility, and acceptability of the proposed health communication intervention tool among those aged 11-24.

A.2. Purpose and Use of Information Collection

The purpose of the project entitled “Evaluating a HIV/AIDS Focused Video Game for Young People” is to conduct pilot testing of a video game tool designed to impact the HIV/STD related knowledge, attitudes, beliefs, behavioral intentions and behaviors of young people (ages 11-24) in a manner that will lower their risk of contracting HIV. The types of data collection activities used are surveys.

A.2.5 Field Testing of New methodologies and Materials

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/AIDS focused video game.

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

All survey data will be collected as hard copies that will be entered into an electronic database.

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

NCHHSTP has verified that there are no other 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 legal obstacles to reducing the burden.

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

This request fully complies with the regulation 5 CFR 1320.5.

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

A 60 day notice to solicit public comments was published in the Federal Register on August 2, 2012, Vol. 77, No. 149. Page numbers 46094-46096. No public comments were received

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

This study seeks to recruit a specialized group, young people, and young people of color in order to conduct research on the effectiveness of an HIV-focused game designed to impact the HIV/AIDS related knowledge, attitudes, beliefs and behavioral intentions of young people in a manner that will lower their risk of contracting HIV/AIDS.

While there has been some debate on the necessity of offering incentives, numerous empirical studies have shown that incentives can significantly increase response rates (e.g., Abreu & Winters, 1999; Shettle & Mooney, 1999; Halpern et al,2004; Bentley and Thacker, 2004; Kalantar and Talley, 1999) and the use of modest incentives is expected to enhance survey response rates without biasing responses. In addition, HIV carries a social stigma which 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). This token is needed to facilitate the speedy, timely and adequate recruitment of participants which will improve the quality of the results. Participants in this study need to be recruited in a short time span. Specifically, this study needs to be begin before the end of the current school year and be completed early in the summer June 15th, 2015 to reduce the amount of study attrition that will likely occur due to due families traveling in the summer and not being in Atlanta metro area for follow-up data collections. Also, tokens of appreciation are also needed to recruit and retain the minimal sample size that is needed to detect effects of the intervention (n=200). These participants need to be recruited in a short amount of time in order for the project to be completed closer to its scheduled end date of April 30, 2015, since it is an HHS Ventures project, per the HHS IdeaLab mandate.

Also, the use of modest incentives 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). Furthermore, it is considered unethical not to provide an incentive to research participants as doing so creates a perception of a researcher’s lack of respect for participants’ time and participation in the study. This is

also a practice which extends to many types of product development across business.

Moreover, there is a precedent in that has been set for providing tokens off appreciation to participants of research. CDC conducted two studies to develop a product for a similar of audience minors (15-24 years of age), an HIV/STD focused motion comic, a HHS Innovates awardee. These studies successfully used tokens of appreciation to successfully recruit participants and were approved by OMB (0840-0920-13JY & 0840-0920-13MK).

Project participants will receive tokens of appreciation for participation in the study in the form of a $10 gift card for completing the surveys on the day they begin the study and a $15 gift card for completing the 30 day follow up survey.

Not using tokens of appreciation will make it impossible to achieve the level recruitment and retention necessary to complete the study. Furthermore, intervention testing and product testing are unlike involuntary government data collections such as the census or surveillance data collection because participants choose whether or not they participate.

A.10. Assurance of Confidentiality Provided to Respondents

Survey data collected will be stored in 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 computer in the principal investigators office.

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 information in identifiable form (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.

CDC's collection and retention of IIF is covered under, Privacy Act System Notice 09-20-0136, System name, "Epidemiologic Studies and Surveillance of Disease Problems. HHS/CDC."

Prior to participating in the study adult participants and the parents of the participants who are minors will be required to give informed consent and assent respectively. The parent will provide consent prior to the child providing assent. Written consent and assent will be obtained when the participants arrive at the various focus group sites (e.g. Community Based Agencies, local Community Based Organizations).

The parent will be provided the opportunity to read the consent form and to ask the PI questions by calling a number provided on the parental consent form **(See Attachment 2a)**. The adolescent assent form will be read aloud if necessary (**Attachment 2b**). After they read the consent forms or the consent forms have been read for them, the minor participant 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. For adults, written consent will be obtained. Once the adults read the consent or have the consent forms read to them aloud, they will have the opportunity to ask questions in each of the phases (**Attachment 2c.**)

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.

10.1 Privacy Impact Assessment

The Centers for Disease Control and Prevention will collect information in identifiable form (IIF). IIF will be collected from participants using hard copy quantitative pre, immediate post, and 30 day post surveys by local study staff. Research staff will collect phone numbers to contact participants to get them to participate in the study by possibly playing the game and completing surveys and signatures on informed consent documents. 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.

Pre, immediate post and 30-day post evaluations will be collected in hard copy from participants on site. Upon conclusion of the event they will be entered electronically into a computer database that will reside on a secure CDC server. Compiled data will be backed up on a password-protected server. All records on active participants, such as study number, will be filed in locked file cabinets in the office of the Principle Investigator (PI), who will maintain strict privacy of these records. Study staff will file participant records numerically by case number, with no names attached to the database. Access to the database and data files will be limited to the data manager and the PI. Passwords are used to restrict entry into the database. To protect the privacy of the participants, all information will be coded so that it cannot be associated with any individual. A master sheet, with individual names and their respective code numbers, will be kept in a locked file in the locked PI's office and accessible only to study team members. All data entered into the computerized database will be identifiable by subject code number only. Participants will be told that no information in identifiable form will be available to or shared with anyone outside of the CDC.

After data analysis is completed, The Centers for Disease Control and Prevention will destroy all participant IIF and data.

Overview of the data collection system

We are proposing a 6-week study to pilot test an HIV/AIDS focused video game designed to impact HIV/AIDS related KABIB among young people between the ages of 11-24 years who speak English. A total of 200 participants will be recruited for the study. The participants in the study will be split into two groups: 1) an experimental and 2) a control group. Each group will consist of 100 participants. Participants in the experimental group will complete surveys before playing the game, immediately after playing the game (no longer than 30 minutes after finishing playing the game), and 30 days after playing the game. **(See Attachments 3b, 3c**

and 3d) Participants in the control group will complete a survey when they begin the study and then again 30 days afterward. **(See Attachment 3b and 3d)** Once data collection is completed, we will analyze the data to determine if there are changes in the experimental group based on pre/immediate posttests as well as a 30 day follow up survey. We will also compare the control group's pre and 30-day posttests with those from the experimental group to determine the games' impact on HIV/AIDS related KABIB.

All participants in all phases will be recruited and screened using convenience samples from different settings including, community based organizations, and civic organizations that serve youth in the target age range (11-24 years). Flyers will be posted and distributed to the parents of potential minor participants and potential participants who are over 18 years of age at the recruitment sites along with consent and assent forms **(see Attachment 4a)**. The flyer will have a phone number that the parents of participants and potential participants who are over 18 years of age can call for more information about the study and to answer any questions they might have. We will use a demographic form to screen potential participants to ensure that our participants are in the age range of the identified "at-risk" groups. We will obtain informed consent for the participants prior to beginning each data collection (**See Attachment 3a).**

Organizational staff will collect contact information (names and phone number) and consent and assent forms in hard copy form from those who have decided to participate. Additional demographic information that will be collected includes age, current, grade, sex, ethnicity, and race **(See Attachment 3a)**. Efforts will be made to obtain an equal number of study participants in the control and experimental group and will attempt to maintain proportions similar proportions of on age, race/ethnicity and gender.

Items of Information to be collected

The surveys, (**Attachments 3b, 3c, and 3d)** will each take approximately 15 minutes to complete. The surveys will include questions in the following domains:

1) HIV/AIDS Knowledge
2) HIV Testing
3) HIV/AIDS Stigma
4) HIV/AIDS attitudes (including HIV/AIDS testing and safe sex practices)

5) HIV/STI beliefs (including stigma and myths)
6) HIV/STI related intentions to engage in behaviors that will reduce the risk of contracting HIV/STI.
7) HIV/AIDS related risk behaviors (initiation, abstinence, condom use, number of sex partners, #of times tested for HIV)

These seven domains will be included in the 1st survey the participants in the experimental and control groups will be asked to complete as well as in the 30 day follow up for both groups. Questions about the game itself will also be included in the second survey the experimental group will be asked to complete immediately after playing the game. Those questions are:

1. Did you like the game?
2. How many times did you play the game?
3. How likely would you be to play it again?
4. Would they share it with their friend?
5. Do you feel you learned something new from playing the game?
6. How much do you play games?
7. Do you think games can be used to educate people about health?

Identification of Website(s) 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.11. <u>Justification for Sensitive Questions</u>

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) (OMB # 0920-0493, exp. 9/31/2015 and the National HIV Behavioral Surveillance System (NHBS) (OMB # 0920-0770, exp. 03/31/2017), which are both conducted by the CDC, to 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.

A.12. Estimates of Annualized Burden Hours and Costs

A.12.A. Estimated Annualized Burden Hours

There are several types of respondents who will participate in the study. The study will include youth and young adults between of ages of 11-24. While we will include participants of any gender, race and ethnicity, our goal is to have our control and experimental groups with similar and equal demographic compositions In order to ensure the proper age of participants, a 1-minute participant demographic tool will be administered to 200 adults and adolescents in the target age range (attachment 3a). A total of 200 adolescents and adults will participate in study by completing the surveys: 1) pretest survey, 2) 30 day posttest (attachment 3d). 100 participants who are in the experimental group will complete the immediate post survey (attachment 3c). Each of these surveys is designed to take 15 minutes to complete.

Exhibit A.12.A Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses Per Respondent	Average Burden Per Response (in Hours)	Total Burden Hours
General Public-Adults and Youth	Participant Demographic Screener 3a	200	1	1/60	4
	Participant Enrollment Day Survey 3b	200	1	15/60	50

	Experimental Group Immediate Post-Survey 3c	100	1	15/60	25
	Participant 30-day post follow up survey 3d	200	1	15/60	50
				Total	**129**

A.12.B. Estimated Annualized Burden Costs

The annualized costs to the respondents are described in Exhibit A.12.B. The United States Department of Labor Statistics May, 2013. http://www.bls.gov/oes/current/oes_nat.htm#43-0000 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 $3,932.50.

Exhibit A.12.B: Estimated Annualized Burden Costs

Type of Respondent (Form Name)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
General Public-Adults and Adolescents (Participant Data Collection Tool)	4	$14.30	$57.20
General Public- Adults and Adolescents (Participant Enrollment Day Survey)	50	$14.30	$715.50
General Public-Adults and Adolescents (Experimental Group Immediate Post-Survey)	25	$14.30	$357.50
General Public- Adults and Adolescents (Participant 30-day post follow up survey)	50	$14.30	$715.50
Total	**129**		$1,845.70

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

There are no costs to respondents or record keepers.

A.14. Annualized Cost to the Government

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.

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

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government	CDC, Principal Investigator (GS-13,0.20 FTE)	$20,350
	CDC, Co-Principal Investigator (GS-15, 0.10 FTE)	$18,600
	Tokens of Appreciation	$43,950
	Subtotal, Direct Costs	**$43,950**
Cooperative Agreement or Contract Costs		$0
	Subtotal, Cooperative Agreement or Contract Costs	**$0**
	TOTAL COST TO THE GOVERNMENT	**$ 43,950**

A.15.Explanation for Program Changes or Adjustments

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

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

Data collection will be completed three months after OMB approval is granted. Data collection will begin 1 week after approval and completed within 2 months after OMB approval is granted. Data analysis will be completed 3 months after approval. Dissemination of results will begin 4 months after OMB approval.

Exhibit A.16: Project Time Schedule

Activity	Time Schedule
Recruit and begin data collection	1 week after IRB/OMB approval
End data collection and begin entry and analysis of data	1-2 months after IRB/OMB approval
Share findings with all stakeholders	3-4 months after IRB/OMB approval

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

OMB Expiration Date will be displayed.

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

There are no exceptions to the certification.