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

OMB No. 0920-0840, Expiration 02/29/2016

Pilot Test Study for the HIV Risk Reduction Educational Tool (HRRET)

Supporting Statement A

December 11, 2014

Contact Person:
Jocelyn Taylor
1600 Clifton Rd. NE
Mailstop E-49
Atlanta, GA 30329
Telephone: (404) 639-8815
Fax: (404) 639-2007
E-mail: uyy6@cdc.gov

TABLE OF CONTENTS

Section **Page**

EXHIBITS

ATTACHMENTS

A. Justification

A.1 Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) is requesting OMB approval for a new subcollection under the Generic Clearance Formative Research and Tool Development 0920-0840 exp. 02/29/2016 entitled, "Pilot Test Study for the HIV Risk Reduction Educational Tool (HRRET)" The project proposes to conduct a pilot study to examine user satisfaction with and potential efficacy of an online, HIV risk reduction tool [hereafter referred to as HRRET, **attachment 10**]. The HRRET includes tailored information on the risk of HIV transmission and acquisition and potential risk-reduction activities for men who have sex with men (MSM), heterosexual men and women, women who have sex with women (WSW), and transgender men and women. Over 1.1 million individuals are estimated to be living with HIV in the United States (CDC, 2013c). Estimates of HIV incidence in recent years indicate that about 50,000 individuals become infected with HIV each year (CDC, 2013c). MSM continue to be the risk group most severely affected by HIV. In 2010, even though MSM only represent 4% of the adult male U.S. population, they accounted for 63% of all new HIV infections and 78% of new infections among men (CDC, 2013c). Additionally, heterosexual transmission of HIV continues to be of concern in the United States, representing 25% of estimated new HIV infections in 2010. About two-thirds of those infected through heterosexual sex were women (CDC, 2012). Injection drug users are also at elevated risk for HIV infection if they share drug preparation (e.g., cookers, cotton, water) and injection (e.g., needles/syringes) equipment that can contain blood. Data from the 2009 National HIV Behavioral Surveillance System show that 8% of new infections were among injection drug users.

In recent years, newer behavioral and biomedical HIV prevention strategies have been introduced and are being studied. These strategies include serosorting; strategic positioning; circumcision; vaccines; and various antiretroviral (ARV)-related strategies, including microbicides, post-exposure prophylaxis (PEP), and pre-exposure prophylaxis (PrEP). Although there are some new guidelines and recommendations pertaining to the use of these newer strategies, and some MSM and heterosexuals are already using them, widespread awareness of available strategies is either unknown, as is the case for injection drug users, or thought to be low (Krakower et al., 2010). Thus, there is a need to communicate with the public about these newer strategies (as well as strategies that emerge in the future) and introduce them into the mix of current prevention messaging (e.g., condom use, monogamy) (Uhrig et al., 2011).

CDC developed the HRRET as a dynamic mechanism to deliver comprehensive, accurate, and timely information about HIV, its risk factors, and ways to prevent transmission and acquisition. This new technology is meant to address two of three goals of the National HIV/AIDS Strategy: (1) Reducing the number of people who become infected with HIV and (2) Increasing access to care and optimizing health outcomes for people living with HIV. The content of the tool was developed over a several year period and is based on the findings from two expert consultations (Uhrig et al., 2011; Lewis et al., 2011) and formative research with HIV positive and negative MSM and heterosexuals. The proposed pilot study is one component of the tool development process and is intended to determine the feasibility of various dissemination mechanisms for the HRRET content. The study will also assess user satisfaction with the tool and its potential efficacy with various audience segments (**attachment 10**). Findings will be used to determine if the HRRET should be broadcast on the web, narrowcast to only populations most at-risk for HIV, or if the content should be used in another form.

This request is authorized by Title III – General Powers and Duties of the Public Health Service, Section 301 (241.)a. Research and investigations generally (**Attachment 1**).

A.1.1 Privacy Impact Assessment

Information will be collected electronically. CDC will not receive any personally identifiable information (IIF). CDC and RTI International (RTI), CDC's evaluation contractor, will receive data for analysis in aggregate form, and the randomly generated numbers assigned as participant ID numbers will not link data to individuals. The survey will be delivered via the Internet and will be accessible only to participants in the survey. All participants will be 18 years of age or older. All electronic files will be password controlled, accessible only to fully authorized personnel, and maintained and protected to the extent allowable by law.

A.1.2 Overview of the Data Collection System

CDC's contractor, RTI, will use Qualtrics survey software to implement this study. The respondents for the study will be a maximum of 1,500 members of the general public. Internet users who enter a keyword as a Google search term will be presented with a brief recruitment advertisement (**Attachment 6**). These paid Google search terms are called Google AdWords (**Attachment 7)**. The AdWords, predetermined by the study team, will include keywords such as "HIV," "HIV risk," "HIV prevention" and "condoms." The pre- and post-test survey will assess user satisfaction with and potential efficacy of a newly developed technology-based HIV prevention tool, HRRET, via the web (**Attachment 10; message topics attachment 8**).

A.1.3 Items of Information to be Collected

The screening questionnaire (**Attachment 2)** asks limited questions to assess participants' eligibility for the study (aged 18 or older) and describes the sample (e.g., sexual orientation, recency of sexual behavior, HIV status). The pretest survey (**Attachment 3a**) will collect information on additional sociodemographics (to augment information collected during screening), HIV knowledge, sexual and substance-use risk behaviors, HIV prevention and testing behavioral intentions, self-efficacy for HIV prevention and testing behaviors, and informed decision-making. The posttest survey **(Attachment 3b)** will reassess HIV knowledge, HIV prevention and testing behavioral intentions, and self-efficacy for HIV prevention and testing behaviors to examine the extent to which exposure to HRRET is associated with the outcomes of interest. In addition, the post-test will examine receptivity to and satisfaction with the tool and its impact on participants' capacity to make informed decisions about HIV prevention strategies.

A.1.4 Identification of Web Site(s) and Web Site 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 the Information Collection

The purpose of this study is to pilot test a new technology-based HIV prevention tool (HRRET) via the web to determine user satisfaction, and its potential efficacy for HIV prevention. The information gathered through this study will inform CDC's plans for dissemination to the public.

Participants will take a pretest to assess baseline characteristics including sociodemographics, HIV knowledge, sexual and substance-use risk behaviors, HIV prevention and testing behavioral intentions, self-efficacy for HIV prevention and testing behaviors, and informed decision-making. After the pre-test, participants will explore the tool for an average of 15 minutes. At the close of the of the exploration period (**Attachment 2a**), participants will take a posttest survey to examine (1) potential efficacy of the tool by reassessing HIV knowledge, HIV prevention and testing behavioral intentions, and self-efficacy

for HIV prevention and testing behaviors and (2) measure receptivity to and satisfaction with the tool and its impact on participants' capacity to make informed decisions about HIV prevention strategies.

The proposed study design will enable us to answer the following questions:

1) Was the information in the tool easy to understand?
2) Do participants like the layout and functionality of the tool?
3) Are the visuals in the tool appealing?
4) Do participants perceive the information in the tool as credible, persuasive, and actionable?
5) Is exposure to HRRET related to improved HIV knowledge?
6) Is exposure to HRRET related to participants' self-report of increased self-efficacy for HIV prevention?
7) Is exposure to HRRET related to increased intentions to take actions to prevent getting or transmitting HIV (e.g., using condoms, taking medications, communicating with partners about HIV and testing)?
8) Is exposure to HRRET related to participants' self-report of increased self-efficacy to find HIV-related information?
9) Is exposure to HRRET related to participants' self-report of increased ability to make informed decisions about HIV prevention?

A.3 Use of Improved Information Technology and Burden Reduction

The pilot test study will use Web-based information collections to be self-administered by participants on their personal computers or another computer of their choosing. The information collections are planned to collect the minimum amount of data necessary to accomplish the goals of the study. Using a Web-based data collection system reduces participant burden in several important ways. First, participants can take part in the study at a time and in a location of their choosing, including their home, which makes it more convenient to participate, reduces travel burden, and enhances privacy. Second, the Web interface allows for seamless transition between information collections which improves overall efficiency and thus, decreases participants' time burden. Third, Web-based data collection minimizes the possibility of participant error by electronically skipping questions that are not applicable to a particular participant, thus minimizing the time burden. Finally, the proposed Web-based information collections eliminates the potential for interviewer bias, minimizes the effects of social desirability, and eliminates the need to collect personally identifiable information which helps to preserve participants' privacy.

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

The National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) has verified that there are no other collections that duplicate the study types included in this request.

A.5 Impact on Small Businesses or Other Small Entities

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

A.6 Consequences of Collecting the Information Less Frequently

The study involves a one-time collection of data over a 3-month period. If these data are not collected, CDC will be unable to determine whether the materials should be made available to the general public.

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

This data collection 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 the Agency

The 60-Day federal register notice was published for the Generic umbrella collection (0920-0840) on August 2, 2012 (Vol. 77, No. 149, pp. 4604-46095). No comments were received.

Individuals consulted for this study are shown in **Exhibit A.8**.

Exhibit A.8 Individuals Consulted for HIV Risk Reduction Educational Tool

Dr. Isaac Lipkus Duke University DUMC 3322 School of Nursing Durham, NC 27710 Phone: (919) 668-2348 Fax: (919) 684-9350 E-mail: isaac.lipkus@duke.edu	Dr. Seth M. Noar Department of Communication University of Kentucky 248 Grehan Building Lexington, KY 40506-0042 Phone: (859) 257-7809 Fax: (859) 257-4103 E-mail: noar@uky.edu
Dr. Vicki Friemuth University of Georgia Center for Health and Risk Communication 501 D.W. Brooks Drive Athens, GA 30605 Phone: (706) 542-0586 Fax: (706) 683-0853 E-mail: freimuth@uga.edu	Dr. Joseph Cappella University of Pennsylvania Annenberg School of Communication 3620 Walnut Street Philadelphia, PA 19104 Phone: (215) 898-7059 Fax: 215-898-2024 E-mail: jcappella@asc.upenn.edu
Dr. Lisa Metsch Columbia University Mailman School of Public Health 722 West 168th Street New York, NY 10032 Phone: 212-305-3927 Fax: 212-305-1460 E-mail: LM2892@columbia.edu	Dr. Travis Sanchez Emory University Rollins School of Public Health 1518 Clifton Rd. Atlanta, Georgia 30322 Phone: (404) 727-8403 E-mail: Travis.Sanchez@emory.edu

A.9 Explanation of Any Payment or Gift to Respondents

Participants will receive a $25 Amazon gift card as a token of appreciation for completing the study (**Attachment 9**). A benefit of this token method is that it does not require the collection of IIF by CDC or RTI, as processing of the payment will be conducted by Qualtrics. The token amount was determined by reviewing our previous experiences conducting similar studies with the targeted populations. Numerous empirical studies have shown that honoraria can significantly increase response rates (e.g., Abreu & Winters, 1999; Shettle & Mooney, 1999). A smaller amount would not appear sufficiently attractive. We also believe that the small token of appreciation will result in higher data validity as participants become

more engaged in the data collection process. Participants will receive their token of appreciation after they complete the posttest survey.

A.10 Assurance of Confidentiality Provided to Respondents

Once potential participants read the full advertisement and proceed to screening, they will be presented with information on the private and voluntary nature of the screening process (**Attachment 2**). Potential participants will also be informed that CDC and RTI will not have access to IIF (participants' email and IP addresses) collected at the beginning of the pretest survey by Qualtrics. Email addresses will be collected in a separate Qualtrics system for two purposes: (1) reminding participants who break off from the survey to log back in to complete it if they have not done so in a specified time period (**Attachment 4**) and (2) distributing the Amazon gift card at the end of the study. Email addresses will not be contained in the data file accessible to CDC and RTI; thus, it is not possible to link individual data collections to specific participants. IP addresses will be tracked to help ensure that participants do not retake the survey. As participants enter the study website, their IP addresses will be compared to a running list of IP addresses; if a duplicate is identified, the participant will be informed that the survey is closed at the present time and asked to close their browser window. Email and IP addresses will be destroyed at the conclusion of the study.

After reading the informed consent for the screening survey (**Attachment 2**), each participant must check a box labeled "YES, I agree to be screened" or "NO, I do not wish to be screened." Only participants who select "YES" will enter the screener. Those who are eligible will be invited to participate in the study and will be routed to the consent form (**Attachment 5**). Those who are ineligible will be thanked for their time and asked to close their browser window.

Prior to the pretest survey, potential participants will be asked to click a button in their Web browser indicating if they agree ("I have read this consent form and agree to participate in the survey.") or decline ("I have read this consent form and do not want to participate in the survey.") to participate. Those who decline to participate will be thanked for their time and asked to close their browser window.

The consent form will advise participants that it is possible that others may see their survey responses should they participate in the study in a public location, which may threaten their privacy. Thus, the consent form will recommend to individuals that they participate in a private location, such as in their own homes and/or in a room with a door. Participants will be reminded to properly log out to avoid such threats to privacy and provided with instructions about how to do so. There will be a "button" for terminating participation should a participant feel his/her privacy is threatened (or if he/she chooses to discontinue the study for other reasons).

RTI maintains restricted access to all project data. All data files on multi-user systems will be under the control of a database manager, with access limited to project staff on a "need-to-know" basis only. As mentioned previously, neither CDC nor RTI will have access to IIF collected by Qualtrics. All survey responses will be SSL encrypted. The survey data will be archived for analysis and managed by project leadership in accordance with all of RTI's confidentiality procedures and IRB policies.

A.11 Justification for Sensitive Questions

The study entails sensitive questions about race/ethnicity, recent sexual behavior and substance use, sexual orientation, and HIV serostatus. It is necessary to ask these questions for two reasons. First, screening questions about race/ethnicity, sexual orientation, and HIV serostatus will be used to help describe the sample as well as those who ultimately participate in the study since these demographic

questions will not be re-asked in the pre- or posttest survey. Second, responses to sensitive questions will enable examination of the potential efficacy of technology-based HIV prevention materials among various segments of the general population.

There is a minimal risk that some questions may make respondents feel uncomfortable. The consent includes a statement about this risk and informs participants that they may choose not to answer a particular question if they wish and/or end the study at any time. Participants will also be provided with the contact information for CDC Info and AIDS.gov should they have questions about HIV or wish to locate an HIV testing site, health centers, or other service providers.

A.12 Estimates of Annualized Burden Hours and Costs

A.12.A Estimated Annualized Burden Hours

The total annualized response burden is estimated at 1,750 hours. **Exhibit A.12.A** provides details about how this estimate was calculated. Screening is expected to take about 5 minutes to complete. The study in its entirety will last approximately 45 minutes: 15 minutes for the pretest, 15 minutes for the exploration period, and 15 minutes for the posttest. We expect to screen a total of 7,500 individuals to complete 1,500 usability tests.

Exhibit A.12.A Annualized Burden Hours

Type of Respondent	Form Name	No. of Respon-dents	No. of Responses per Respondent	Average Burden Per Response (in Hours)	Total Response Burden Hours
General public	Screener	7,500	1	5/60	625
	Pretest survey	1,500	1	15/60	375
	Exploration period	1,500	1	15/60	375
	Posttest survey	1,500	1	15/60	375
Total					**1,750**

A.12.B Estimated Annualized Costs

We do not know what the wage rate category will be for the selected participants (or even whether they will be employed); thus, we used $22.33 per hour as an estimate of mean hourly wage across the country (Bureau of Labor Statistics, 2013). The estimated annual cost to participants for the hour burden for collections of information will be $39,077.50.

Exhibit A.12.B Annualized Cost to Respondents

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Screener	625	$22.33	$13,956
Pretest survey	375	$22.33	$8,374
Exploration period	375	$22.33	$8,374
Posttest survey	375	$22.33	$8,374
Total			**$39,078**

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

CDC does not anticipate providing start-up or other related costs to private entities. There are no costs to respondents or record keepers.

A.14 Annualized Costs to the Federal Government

The contractor's costs are based on estimates provided by the contractor who will carry out the data collection activities. With the expected period of performance, the annual cost to the federal government is estimated to be $402,015 (**Exhibit A.14**). This is the cost estimated by the contractor, RTI, and includes the estimated cost of coordination with CDC, data collection, analysis, and reporting.

Exhibit A.14 Estimates of Annualized Cost to the Government

Expense Type	Expense Explanation	Annual Costs
CDC oversight of contractor and project	20% of FTE: GS-13 Health Communication Specialist	$17,100
Recruitment, data collection, analysis, and reporting (contractor)	Labor hours and ODCs	$384,915
Total Cost		$402,015

CDC = Centers for Disease Control and Prevention; FTE = full-time equivalent; ODC = other direct cost

A.15 Explanation for Program Changes or Adjustments

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

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

Data analysis will be conducted to analyze the usability of new technology-based HIV prevention materials. Data will be analyzed overall, as well as by important sociodemographic characteristics (e.g., age, gender identity, race/ethnicity, sexual orientation, and HIV serostatus). Response rates for individual questions will be calculated. Data analysis will include basic summary statistics for the purposes of describing the sample and examining the distribution of the primary outcome variables (e.g., feasibility, understandability, and layout and graphics appeal, HIV knowledge, self-efficacy for making informed decisions).

A final report will provide background, results, and recommendations on the study's findings. This report of less than 50 pages will include an introductory overview of the data collection needs and challenges that led to this pilot test study; a summary of the pilot test study methods and activities; results; discussion of findings; strengths and limitations of the pilot study; recommendations for implementation of the new technology-based HIV prevention materials via the web; and appendices.

The key events and reports to be prepared are listed in **Exhibit A.16.**

Exhibit A.16 Project Time Schedule

Activity	Time Schedule
Begin recruitment	Months 1-4 after OMB approval
Conduct data collection	Months 1-4 after OMB approval
Analyze data and draft report	Months 5-7 after OMB approval

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

The OMB expiration date will be displayed.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

REFERENCES

Centers for Disease Control and Prevention. (2012). New HIV Infections in the United States. Retrieved August 13, 2014 from http://www.cdc.gov/nchhstp/newsroom/docs/2012/HIV-Infections-2007-2010.pdf
Centers for Disease Control and Prevention. (2013). HIV in the United States: At a Glance. Retrieved from http://www.cdc.gov/hiv/resources/factsheets/PDF/stats_basics_factsheet.pdf

Krakower DS, Mimiaga MJ, Rosenberger JG, Novak DS, Mitty JA, et al. (2012) Limited awareness and low immediate uptake of pre-exposure prophylaxis among men who have sex with men using an internet social networking site. *PLoS ONE, 7*(3), e33119. Retrieved from http://www.plosone.org/article/info%3Advertisementoi%2F10.1371%2Fjournal.pone.0033119

Lewis, M. A., Uhrig, J. D., Ayala, G., & Stryker, J. (2011). Reaching men who have sex with men for HIV prevention messaging with new media: Recommendations from an expert consultation. *Annals of the Forum for Collaborative HIV Research, 13*(3), 10–16.

Purcell, D. W., Johnson, C., Lansky, A., Prejean, J., Stein, R., Denning, P., et al. (2010). Calculating HIV and syphilis rates for risk groups: Estimating the national population size of men who have sex with men. Presented at the 2010 National STD Prevention Conference, Atlanta, GA.

Uhrig, J. D., Lewis, M. A., Ayala, G., & Stryker, J. E. (2011). Informing the next generation of HIV prevention messaging for men who have sex with men. *Annals of the Forum for Collaborative HIV Research, 13*(3), 1–9.

Bureau of Labor Statistics (2013). *May 2013 National Occupational Employment and Wage Estimates United States*. U.S. Department of Labor. Retrieved July 14, 2014, from http://www.bls.gov/oes/2013/may/oes_nat.htm#00-0000.