

SUPPORTING STATEMENT A

Testing Brief Messages for Black and Latino MSM

Generic Information Collection Request under 0920-0840

April 25, 2014

Contact information

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Table of Contents

Section

A. Justification

- A.1. Circumstances Making the Collection of Information Necessary
- A.2. Purposes and Use of Information Collection
- A.3. Use of Improved Information Technology and Burden Reduction
- A.4. Efforts to Identify Duplication and Use of Similar Information
- A.5. Impact on Small Businesses or Other Small Entities
- A.6. Consequences of Collecting the Information Less Frequently
- A.7. Special Circumstances
- A.8. Comments in Response to the FR Notice and Consultation
 - A.8.a. Federal Register Notice
 - A.8.b. Outside Consultation
- A.9. Explanation of Any Payment or Gift to Respondents
- A.10. Assurance of Confidentiality Provided to Respondents
- A.11. Justification for Sensitive Questions
- A.12. Estimates of Annualized Burden Hours and Cost
- A.13. Estimates of Annualized Respondent Capital and Maintenance Costs
- A.14. Estimates of Annualized Cost to the Federal Government
- A.15. Explanation for Program Changes or Adjustments
- A.16. Plans for Tabulation and Publication and Project Time Schedule
- A.17. Reason(s) Display of OMB Expiration Date is Inappropriate
- A.18. Exceptions to the Certification Statement

List of Tables

- Table A12A: Estimated Annualized Burden Hours
- Table A12B: Estimated Annualized Burden Costs

List of Attachments

- Attachment 1- Authorizing Legislation
- Attachment 2- Eligibility Screener in English
- Attachment 3-Eligibility Screener in English-**Screenshot**
- Attachment 4- Eligibility Screener in Spanish
- Attachment 5-Eligibility Screener in Spanish-**Screenshot**
- Attachment 6-Information for participants in English
- Attachment 7-Information for participants in English-**Screenshot**
- Attachment 8-Information for participants in Spanish
- Attachment 9-Information for participants in Spanish-**Screenshot**
- Attachment 10- Messages and Outcomes in English
- Attachment 11-Messages and Outcomes in English-**Screenshot**
- Attachment 12-Messages and Outcomes in Spanish
- Attachment 13-Messages and Outcomes in Spanish-**Screenshot**
- Attachment 14-Assessment in English

Attachment 15-Assessment in English-**Screenshot**
Attachment 16-Assessment in Spanish
Attachment 17-Assessment in Spanish-**Screenshot**
Attachment 18-Recruitment Materials

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

This request is for sub-collection under a generic approval (Formative Research and Tool Development, OMB Control No. 0920-0840, exp. 02/29/2016). The primary aim of this project is to develop and assess the potential impact of practical messages about emerging HIV prevention information and approaches (e.g., PrEP, condom effectiveness, peer group HIV prevalence) for black and Latino MSM. The intent of the study is to determine how condoms and other HIV prevention approaches may be used in the future, given new and emerging information about and approaches to HIV prevention. This study is consistent with identified research priorities through the DHAP Strategic Plan and the National HIV/AIDS Strategy (<http://www.whitehouse.gov/sites/default/files/uploads/NHAS.pdf>).

Men who have sex with men (MSM) continues to be the risk category experiencing the greatest incidence and prevalence of HIV and AIDS in the U.S., and black and Latino MSM are disproportionately impacted (CDC 2010). New and emerging information about and approaches to reducing risk for HIV transmission are needed for this population. As information continues to develop regarding HIV prevention approaches -- including new biomedical interventions such as pre-exposure prophylaxis (PrEP) using antiretroviral treatment (ART) for HIV prevention (Grant et al. 2010), messages about new and emerging information are needed for at-risk MSM. Testing of those messages to determine potential impact on risk behavior is needed to prepare for information dissemination in the future.

To assess the messages, a cross-sectional study approach will be used, with the primary outcome of behavioral intent to use the various prevention options presented in addition to condom use. Message understandability and believability will also be assessed. This approach is commonly used by HIV researchers (e.g., Koblin 2011, Marks 2000, Miller 2004, Sullivan 2011) and has been shown to be efficient in producing important public health information in the short term. The intent of this study is to test focused messages that are at the center of HIV prevention communications, and could be disseminated and expanded in a variety of ways -- from public health fact sheets to social marketing campaigns. Based on the findings, public health and HIV prevention specialists can better prepare for information delivery about emerging HIV prevention information.

The project is in alignment with several goals outlined in the National HIV/AIDS strategy:

- Goal 1- 1.2.1 Prevent HIV among gay and bisexual men and transgender individuals
- Goal 1- 1.2.2 Prevent HIV among Black men and women
- Goal 1- 2.1 Design and evaluate innovative prevention strategies and combination approaches for preventing HIV in high risk communities
- Goal 1 – 2.4 Expand prevention with HIV-positive individuals

Privacy Impact Assessment

Overview of the Data Collection System

The data collection system includes eligibility screening, message testing, and a study assessment. Potential participants for the study assessment will be screened for eligibility based on the inclusion

criteria described in supporting statement B, using an online screening survey tool (**Attachments 2, 3, 4, & 5**). Depending on the method of recruitment, the online screening tool will either be self-administered by potential participants, or administered by research staff over the phone or in person to potential participants. After an individual is determined to be eligible for the study, he will then be scheduled to visit the local site at a specific date and time. Upon arrival, the participant will participate in a self-administered, online rescreening survey to confirm eligibility. This is the same set of screening questions used in the initial screening survey (**Attachment 2, 3, 4, & 5**). Following re-screening for eligibility, the online survey will present information to ensure informed consent (**Attachment 6, 7, 8, & 9**), including study procedures, risk, benefits, nature of privacy, study contact information, the nature of voluntary participation, information on the assessment, and token of appreciation. Participants will continue with a computer-based assessment. In a private room, participants will first be given a set of six HIV information messages, each followed by related outcome questions (**Attachment 10, 11, 12, & 13**). All HIV-negative participants will receive a set of six informational messages intended for HIV-negative men. All HIV-positive participants will receive a set of six informational messages intended for HIV-positive men. Following message testing, participants will complete a 60-minute online assessment survey about their socio-demographic characteristics, recent sexual and drug using behavior, substance use, psychosocial factors, and perceptions and attitudes about HIV and prevention options (**Attachment 14, 15, 16, & 17**). These items are critical in examining potential mediators and moderators of message effectiveness, and to eventually tailor and target messages for enhanced effect among MSM.

All assessment data will be collected via the online assessment tools, developed and administered using Qualtrics® online survey software. This includes the screening and rescreening tools, as well as the study assessment tool. Data will reside in the Qualtrics system, as part of JSI's account with the service provider. Qualtrics has SAS 70 Certification and meets the rigorous privacy standards imposed on health care records by the Health Insurance Portability and Accountability Act (HIPAA). All Qualtrics accounts are hidden behind passwords and all data are protected with real-time data replication. JSI has used Qualtrics for prior online surveys similar to the proposed study.

All study data will be downloaded from Qualtrics and stored on JSI's secure servers. Secure web servers using the latest SSL technology, state-of-the-art firewalls, mandatory scanning of all incoming e-mail, intrusion detection and monitoring systems are all utilized to ensure that JSI's network is safe and secure. All JSI servers and workstations are isolated from the Internet by means of a hardware firewall, and all devices (servers, workstations, routers, switches, etc.) require a valid user ID and password before they can be used.

Local partner sites will be responsible for data security. During recruiting and screening, names and telephone numbers of potential and actual participants will be collected via online scheduler to facilitate participation. These data will be kept in the secure online scheduler of which only research staff will have access. This system will not be linked to the screening or assessment surveys in any way that could connect a participant's identity to his responses. Each site will keep the number of staff with access to this information to the minimum necessary. Contact information for study participants will be destroyed (e.g. shredded, deleted) after recruitment is completed. This step is taken to prevent participants from being involved in the study more than once.

Personal identifying information will not be included with study data and will not be transmitted to CDC or any other agency. CDC staff will not have access to any identifying information. De-

identified data will be transmitted to CDC via a secure data network. De-identified study data will be maintained at the site and at CDC indefinitely.

Items of Information to be Collected

Data will be collected to assess whether and to what degree intended condom use, HIV testing, and other HIV protective approaches (e.g., PrEP, sero-adaptive behaviors, or use of ART by HIV-positive persons) may change given new information about HIV prevention approaches; and assess whether and to what degree perceived effectiveness of condom use and other HIV protective approaches (e.g., PrEP, sero-adaptive behaviors, or use of ART by HIV positive persons) may change given new information about HIV prevention approaches; assess overall message understanding and acceptability.

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 under 13 years of age.

2. Purpose and Use of Information Collection

The goal of this project is to demonstrate effectiveness of brief informational messages regarding HIV prevention options. Messages will be tested for black and Latino MSM who are HIV-positive, high-risk HIV-negative (i.e., engage in unprotected anal sex with a non-primary partner in the past 6 months), and lower-risk HIV-negative (i.e., other MSM besides high-risk). A secondary goal is to determine whether message effects are moderated by race/ethnicity (i.e., black vs. Latino) and other demographic variables (e.g., age) for each of the three HIV-status groups. The specific messages to be tested are related to new and emerging HIV prevention information. Messages will be based on the scientific literature, and input from CDC subject matter experts (SMEs), CDC project advisory board, JSI SMEs, and local partner site staff and community advisory boards (CABs). Prevention message content will address oral PrEP with anti-HIV medications, condom effectiveness among MSM, HIV sero-adaptive behavior, and ART adherence. The intent of the study is to determine how condoms and other HIV prevention approaches may be used in the future by MSM, given new and emerging information about and approaches to HIV prevention.

3. Use of Improved Technology and Burden Reduction

Following Internet, phone, or in-person screening, eligible participants will complete computer-based message testing followed by an online, assessment survey (in English or Spanish) via computers at designated sites in each of the three cities. The message testing and assessment are completely computer-based and accessed via lap top computers provided by JSI at each site. Test messages will be pre-programmed on the lap-top computers, eliminating the need for messages to be coordinated and delivered to the device at a specific time. Messages will be accessed by the participant based on instructions provided at the appropriate point in the assessment.

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.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this study.

6. Consequences of Collecting the Information Less Frequently

This project is being conducted to test the potential impact of messages regarding emerging information on HIV prevention and the HIV epidemic among men who have sex with men (MSM), including condoms and pre-exposure prophylaxis (PrEP) with anti-HIV medications. If this information were not collected, we would not be able to build the foundation for future messages in the prevention of HIV among MSM. It would therefore be impossible to inform further communication in the areas of HIV prevention without testing of new and emerging information.

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

There are no special circumstances. The message testing activities fully comply with the regulations and guidelines in 5 CFR 1320.5.

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

A Federal Register Notice for the generic clearance 0920-0840, exp. 02/29/2016 was published on 08/2/2012, Vol. 77, No. 149, pages 46094-46095.

Throughout the process of message development and project design several individuals were brought on for their advice and expert opinions.

ROLE	Name
CDC Project Advisory Group	Susan Robinson
CDC Project Advisory Group	Gary Marks
CDC Project Advisory Group	Lamont Scales
CDC Project Advisory Group	Jocelyn Taylor
HHS	Miguel Gomez
CDC Subject Matter Expert	Jo Stryker
CDC Subject Matter Expert	Dawn Smith
CDC Subject Matter Expert	Alexa Oster
CDC Subject Matter Expert	Rich Wolitski
JSI Subject Matter Expert	Jeremy Holman
JSI Subject Matter Expert	Matthew Mimiaga

9. Explanation of Any Payment or Gift to Respondents

Participants will be given a \$40 gift card as a token of appreciation for participation. In his memorandum for the president's management council dated January 20, 2006, the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget wrote, "Incentives are most appropriately used in Federal statistical surveys with hard-to-find populations or respondents whose failure to participate would jeopardize the quality of the survey data (e.g., in panel surveys experiencing high attrition), or in studies that impose exceptional burden on respondents, such as those asking highly sensitive questions..."

The use of tokens of appreciation in the proposed research is appropriate according to this guidance. The primary goal of the project is to develop and assess the potential impact of practical messages about emerging HIV prevention information and approaches (e.g., PrEP, condom effectiveness, peer group HIV prevalence) for black and Latino MSM. The intent of the study is to determine how condoms and other HIV prevention approaches may be used in the future, given new and emerging information about and approaches to HIV prevention. This study seeks to recruit, enroll, and follow a hard-to-reach and possibly hidden population, while also asking highly sensitive questions about issues such as sexual behavior, HIV and status.

Providing tokens of appreciation to respondents will be critical to achieving acceptable response rates in this hard-to-find population as demonstrated in the survey literature (Kulka 1995). The need for and amount of the token of appreciation is based, in part, on the fact that other, similar research projects that ask HIV risk behavior questions offer similar tokens of appreciation. Thus, the proposed project would be competing with local researchers who do offer tokens of appreciation. Persons at risk for HIV infection have frequently been the focus of health-related data collections, in which tokens of appreciation is the norm (Thiede 2009; MacKellar 2005). Research has shown that financial tokens of appreciation are effective at increasing response rates among female residents living in zip codes of predominantly minority populations (Whiteman 2003). A meta-analysis of 95 studies published between January 1999 and April 2005 describing methods of increasing minority persons' enrollment and retention in research studies found that tokens of appreciation enhanced retention among this group (Yancey 2006). Based on these scientific research studies, providing tokens of appreciation to hard-to-find racial/ethnic minority respondents is critical to achieve acceptable response rates.

Tokens of appreciation has been used in other HIV-related CDC data collection efforts such as for National HIV Behavioral Surveillance (OMB 0920-0770, exp. 5/31/2014) and the Transgender HIV Behavioral Survey (OMB 0920-0794, exp. 12/31/2010), both of which ask questions similar to those included in the proposed formative research and have a similar length of time for completing the client interview. In both of these other projects, tokens of appreciation were used to help increase participation rates. Other studies have also found that tokens of appreciation modestly improve response rates (Shaw et al. 2001).

10. Assurance of Confidentiality Provided to Respondents

Data Management

All assessment data will be collected via the online assessment tools, developed and administered using Qualtrics® online survey software. This includes the screening and rescreening tools, as well as the study assessment tool. Data will reside in the Qualtrics system, as part of JSI's account with the service provider. Qualtrics has SAS 70 Certification and meets the rigorous

privacy standards imposed on health care records by the Health Insurance Portability and Accountability Act (HIPAA). All Qualtrics accounts are hidden behind passwords and all data are protected with real-time data replication. JSI has used Qualtrics for prior online surveys similar to the proposed study.

JSI's survey programmer and data specialist will be responsible for monitoring the incoming data and downloading the data at least once per week. Downloaded data will be stored on JSI's secure servers, and will be accessible only by the project Data Specialist and the Project Director. At the completion of the project, JSI will not store and maintain a copy of the aggregate data as a component of the contract agreement after the contract is completed. Data cleaning will be completed and data frequencies will be provided by JSI to CDC at completion of the study. All data analyses will be conducted by CDC staff.

Information Security

As a requirement of the contract with CDC, JSI must ensure that its information systems meet CDC certification and accreditation standards. This project will be assigned a security category and JSI is required to develop a System Security Plan (SSP) to ensure protocols are in place to meet this designation. JSI has recently received preliminary approval of an SSP for a low security categorization for another CDC-funded project, and if the proposed project receives a similar designation, JSI will meet these standards for the proposed project. An SSP for the proposed project will be developed and submitted in early 2013, and approval must be received before data collection can begin.

All assessment data will be downloaded from Qualtrics and stored on JSI's secure servers. Secure web servers using the latest SSL technology, state-of-the-art firewalls, mandatory scanning of all incoming e-mail, intrusion detection and monitoring systems are all utilized to ensure that JSI's network is safe and secure. All JSI servers and workstations are isolated from the Internet by means of a hardware firewall, and all devices (servers, workstations, routers, switches, etc.) require a valid user ID and password before they can be used.

Access to servers, workstations and other equipment containing sensitive or valuable data is limited to those personnel required to use these systems as part of their jobs. For example, servers are kept in a locked room accessible only to the staff responsible for their operation. All sensitive data are stored on servers and not on individual workstations. Additionally, sensitive data are protected by complex passwords, which are changed on a regular basis. Full system backups are performed nightly and include secure off-site storage to assure data security.

Access to areas requiring additional security is accomplished by means of either traditional lock-and-key (storerooms, file cabinets) or by means of additional electronic locks accessible only to authorized staff. Hard copies of project data are stored in locked file cabinets. Data requiring additional security are secured within locked rooms that are not accessible by window. Access to locked rooms is limited to specific project and JSI management personnel and no unauthorized personnel are allowed in secure areas without an escort. Hard copy and electronic storage devices containing private information are destroyed upon completion of a project (or when instructed by the client) and when allowable by state regulations. Documents are shredded either in-house or by an authorized agent. Electronic storage devices are physically destroyed or sanitized before reuse or disposal.

Local partner sites will also be responsible for data security. During recruiting and screening, names and telephone numbers of potential and actual participants will be collected via online scheduler to facilitate participation. These data will be kept in the secure online scheduler to which

only research staff will have access. This system will not be linked to the screening or assessment tool in any way that could connect a participant's identity to responses. Each site will keep the number of people with access to this information to the minimum necessary. Contact information for study participants will be destroyed after recruitment is completed. This step is taken to prevent participants from being involved in the study more than once.

Privacy and Voluntary Involvement

This study has been designed to minimize the collection of personal information, and to eliminate any connection between that information and the research assessment data. Personal information, such as first name, phone number, and/or email address will only be collected for scheduling purposes. This information will be kept in a separate, computerized spreadsheet or database, accessible only by local research staff and protected by password. This database will not be linked in any way to the online assessment tool, will not be provided to JSI or CDC research staff, and will be deleted from the local site computer or network upon completion of the study.

Local project staff will keep any personal information of participants secure. Privacy and scientific ethics will be covered during staff training to emphasize the importance of this issue. Participants will be instructed that they do not have to share personal information with which they are uncomfortable sharing, consistent with the nature of voluntary involvement.

11. Justification for Sensitive Questions

The majority of questions asked will not be of a sensitive nature, they will be asked to gauge an individual's knowledge on a particular topic of new emerging information. There will be no request for a respondent's Social Security Number (SSN) or other personal identifiers.

It will, at times, be necessary to ask questions considered to be of a sensitive nature in order to test messages about health-relevant behavior. Questions about messages concerning lifestyle (e.g., messages about HIV medication use, intimate partner issues), and questions about messages related to illnesses such as HIV could be considered sensitive. To avoid fear of disclosure of sensitive information, respondents will be told that all data provided by respondents will be treated in a secure manner and will not be disclosed, unless otherwise compelled by law.

To avoid negative reactions to these questions, several steps will be taken:

- Respondents will be informed that they need not answer any question that makes them feel uncomfortable or that they simply do not wish to answer.
- Where possible, use of touch-screen methodology or other self-directed techniques will provide privacy; not having to verbalize a response may increase comfort.
- When such numbers are available and appropriate, participants will be provided with specific agency hotline numbers to call in case they have a question or concern about the sensitive issue.

Most components of the study are self-administered and allow respondents to complete the information at their convenience and privacy.

12. Estimates of Annualized Burden Hours and Costs

A. Time

It is estimated that the screening questions will take 5 minutes. Reviewing the test messages will take 15 minutes. The study assessment survey will take 60 minutes.

Exhibit A12.A. Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. Responses Per Respondent	Average Burden Per Respondent (in hours)	Total Annual Burden in Hours
Prospective Participant	Eligibility Screener	1,980	2	5/60	330
Enrolled Participant	Messages and Outcomes	900	1	15/60	225
Enrolled Participant	Assessment Survey	900	1	1	900
Total					1,455

Table A12.B displays the annualized cost to Respondents for burden hours shown in Table 12.A. In order to estimate the cost to the Respondents, we used the seasonally adjusted average hourly wage earnings of total production and non-supervisory workers on private nonfarm payrolls proposed for January 2010 by the US Department of Labor.

Exhibit A12.B. Estimated Annualized Burden Costs

Type of Respondent	Total Annual Burden in Hours	Average Hourly Wage Rate	Total Annual Respondent Cost
Eligibility Screener	330	\$19.30	\$6,369.00
Messages and Outcomes	225	\$19.30	\$4,342.50
Assessment Survey	900	\$19.30	\$17,370.00
Total			\$28,081.50

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

There are no other costs to Respondents or record keepers associated with this study.

14. Annualized Cost to the Government

The average estimated annual cost to the Federal government for conducting the message testing activities proposed in Table A12B is \$691,395. This total cost includes approximately \$600,000 for contractual costs (e.g., test design, data collection, analysis, and reporting), and \$91,395 for personnel costs for Federal employees involved in project oversight activities.

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

D. Dissemination, Notification, and Reporting of Results

1) Notifying participants of individual results and study findings.

There will be no individual feedback about results provided on their assessment. Aggregate summary of results may be available upon request of the participants after the study is completed and analyses are conducted.

2) Dissemination of findings.

Findings from this study will be disseminated to the site CBOs and their CABs following completion of the analyses, which can then be disseminated to participants as requested. Findings will be presented at conferences, seminars, and through peer review publications.

Analysis Plan

Data cleaning will be completed and data frequencies will be provided by JSI to CDC at completion of the study. All data analyses will be conducted by CDC staff.

Timeline

Exhibit A16. Project Time Schedule

Activities	Time Schedule
Begin recruitment	1 month post OMB approval
Complete recruitment, intervention implementation, and data collection	9 months post OMB approval
Data management and validation	12 months post OMB approval
Analysis of key outcomes	15 months post OMB approval
Dissemination of results	18 months post OMB approval

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

CDC is not seeking approval to not display the expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification statement.

References

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