**Formative Research for the Web-Based HIV Behavioral Survey among Men who have Sex with Men**

Generic Information Collection request under 0920-0840

**April 21, 2011**

**Supporting Statement**

**Part A**

Contact

Kristina Bowles, MPH

Centers for Disease Control & Prevention

Division of HIV/AIDS Prevention

Program Evaluation Branch

Phone (404) 639-1815

Fax (404) 639-8640

KBowles@cdc.gov

**Table of Contents**

**Section**

**A. Justification**

1. Circumstances Making the Collection of Information Necessary
2. Purpose and Use of the Information Collection
3. Use of Improved Information Technology and Burden Reduction
4. Efforts to Identify Duplication and Use of Similar Information
5. Impact on Small Businesses or Other Small Entities
6. Consequences of Collecting the Information Less frequently
7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5
8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency
9. Explanation of Any Payment or Gift to Respondents
10. Assurance of Confidentiality Provided to Respondents
11. Justification for Sensitive Questions
12. Estimates of Annualized Burden Hours and Costs
13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers
14. Annualized Cost to the Government
15. Explanation for Program Changes or Adjustments
16. Plans for Tabulation and Publication and Project Time Schedule
17. Reason(s) Display of OMB Expiration Date is Inappropriate
18. Exceptions to Certification for Paperwork Reduction Act Submissions

**Exhibits**

Exhibit 12.A Estimated Annualized Burden Hours

Exhibit 12.B Estimated Annualized Burden Costs

Exhibit 14.A Estimated Cost to the Government

Exhibit 16.A Project Time Schedule

**B. Collection of Information Employing Statistical Methods**

1. Respondent Universe and Sampling Methods

2. Procedures for the Collection of Information

3. Methods to Maximize Response Rates and Deal with Nonresponse

4. Tests of Procedures or Methods to be Undertaken

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

**Attachments**

Attachment 1 Data Collection Forms

 1a. Eligibility Screener- Focus Group

 1b. Focus Group Interview

 1c. Eligibility Screener- Web-based Survey

 1d. Web-based Survey

 1e. Legislation: Public Health Service Act 301

1f. Legislation: Public Health Service Act 306

1g. Legislation: Public Health Service Act 308d

Attachment 2 Consent forms

 2a. Consent (in person Focus Group)

 2b. Consent (online Focus Group)

 2c. Consent (Web-based Survey)

Attachment 2 Emory University IRB Approval

Attachment 3 NCHHSTP Project Determination Approval

**A. JUSTIFICATION**

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

Men who have sex with men (MSM) account for the majority of new HIV infections in the U.S., comprising 53 percent of new infections (Hall, et al, 2008). CDC has received funding from the Affordable Care Act’s Prevention and Public Health Fund to conduct a web-based behavioral survey system annually in 65 U.S. jurisdictions to monitor HIV risk behavior and exposure to prevention services among internet-using MSM. This request is for sub-collection under a generic approval, for a one-year formative research project to identify optimal recruitment methods for the new web-based system before the system is launched nationally.

The internet is a rapidly evolving technology, which poses challenges to recruiting MSM via the internet. In order to develop an effective recruitment strategy for this national survey system, it is necessary to conduct formative research to gather the most recent information on such technologies and identify implications for recruiting men via the internet. For instance, the proliferation of social media sites and tools, such as mobile social media applications, must be considered to identify the optimal recruitment methods. Additionally, because recruitment for this project must compete with other web surveys, including consumer feedback surveys, it will be critical to collect information to understand the motivations and barriers of MSM for participating in this web-based HIV behavioral survey, and to adapt recruitment approaches accordingly.

The objectives of the formative research will be to: 1) identify recruitment methods that are expected to reach the population of interest, including important subgroups of MSM (those at highest risk of HIV, i.e., minority MSM) through the internet; and 2) test these methods to assess whether they do in fact reach the population of interest.

The findings from this formative research will be used to select recruitment methods for the national web-based survey.

**A.1.2 Privacy Impact Assessment**

CDC will not receive any personally identifiable information. Any individually identifiable information collected by the Contractor or Sub-contractor or their vendor during the formative research project will not be submitted to CDC.

**A.1.3 Overview of the Data Collection System**

To identify recruitment methods likely to reach the population of interest, information will be collected through audio recordings of online and in-person focus groups involving internet-using MSM in the demographic groups that the future web-based survey system will be designed to target. Internet-based recruitment methods, chosen based on the focus group findings, will be tested online in the 12 cities with the highest AIDS prevalence. The respondents will be volunteers who meet eligibility criteria, i.e., who are 18 years old or older, residents of the U.S. or Puerto Rico, and who report that they have ever had sex with men. The findings from the test of recruitment methods will be used to maximize the efficiency of the future web-based behavioral survey system, i.e., through the incorporation of proven methods into its design. The expected outcome is improvement in the quality of behavioral risk data, and a reduction in burden of future data collections.

**A.1.4 Items of Information to be Collected**

The screeners for both the focus groups and the test of recruitment methods will collect the following information: age, race/ethnicity, state of residence, gender identity, and whether the respondent ever had sex with a man. The focus group screener will also collect the first three digits of current zip code, which is used to identify city of residence (no additional information on residence can be ascertained through the use of the first three digits of zip code). For the test of the recruitment method, the screener will collect county of residence.

The discussion guide for the online and in-person focus groups is designed to collect data regarding:

* Previous experiences with online survey participation
* Recruitment approaches that enhance participation in online surveys
* Methods that enhance completion rates during online surveys
* Motivations for participating in online surveys
* Comfort level in answering questions related to sensitive topics, such as sex and drug behavior and HIV status
* Websites frequented by focus group members
* Means of assuring confidentiality and gaining participant trust
* Acceptability of recruitment advertisement mock-ups
* Acceptability and usability of survey web site design mock-ups

During the test of the selected recruitment methods, the survey will collect data regarding:

* Demographics
* Use of the internet to meet sex partners
* Recent sexual risk behaviors
* HIV testing history
* Recent testing for HIV and sexually transmitted infection
* Substance use behavior
* Distal risk factors, including perceived discrimination.

Information collected by the Contractor (through the Sub-contractor, Emory University) to schedule the focus groups will include personally identifiable information such as e-mail address, phone number and first name. This information will only be accessible to Sub-contractor staff, specifically, the Program Coordinator and study Investigators, and will be stored in a password-protected computer which the Program Coordinator will be responsible for securing. Participants’ contact information will be kept for no more than 1 month past the completion of the last focus group and will not be linked to any information collected from participants during the focus groups. When the focus groups are completed such information will be destroyed. Participants’ names will not be used during the focus groups. Any personally identifiable information collected by the Contractor through its Subcontractor will not be submitted to CDC. At no time will the Internet Protocol (IP) address of participants be collected by the Contractor or sub-Contractor.

For the online focus groups, screening will be conducted through a secure socket layer (SSL) connection similar to those used for banking and other secured transactions. The information collected for this project will be maintained or stored on a secure server under strict access controls, limiting access to the local Program Coordinator and relevant staff. The screening information will be backed up on a separate secure server subject to the same access controls. Project data will be stored separately from personally identifiable information. Under no circumstances will an individual be identified using a combination of variables such as age, race/ethnicity, or other descriptors.

Focus group audio recordings will be transcribed, and the transcripts will be stored in a secure password-protected computer, subject to the same access controls as the screening data. The recordings will be destroyed after transcription.

Data collected for the test of recruitment methods will be stored and accessed by a survey identification number. The sensitive information collected will not be linked to any other personally identifiable information and cannot be used to reveal the identity of any one person.

**A.1.5 Identification of Websites 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.2. Purpose and Use of Information Collection**

This sub-collection is intended to explore recruitment methods (methods that may result in increased enrollment of MSM into the survey, especially high-risk subgroups of MSM). Based on the findings, an optimal recruitment approach will be chosen, and this approach will be tested as part of this sub-collection. The findings from the test of the recruitment approach will be used to identify any changes necessary before implementation of the future behavioral survey system.

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

The use of online focus groups is intended to eliminate the requirement for respondents who have internet access to travel to participate in a focus group. The testing of online recruitment approaches will facilitate burden reduction by supporting the future web-based behavioral survey, which may reduce the burden on respondents by reducing the amount of time needed to complete the survey, as compared with a self-administered in-person survey. Web-based surveys also have advantages for ensuring respondent privacy and streamlining the data collection process.

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

NCHHSTP has verified that there are no other federal generic collections that duplicate the study types included in this request.

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

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

**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**

For sub-collection requests under a generic approval, Federal Register Notices are not required and none were published. A Federal Register Notice for the umbrella collection was published March 9, 2009, 0920-0840, expiration date 1/31/2013.

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

Tokens of appreciation in the amount of $40 will be provided to in person focus group participants and $25 to the online focus group participants. The in-person focus group amount is greater due to compensating participants for travel to the focus group site. Tokens of appreciation will be in the form of a gift card, or free music downloads of similar value. For online participants, electronic gift card numbers will be sent to the email address provided by the participant. Email addresses will be destroyed once the focus group is completed; the responses and personally identifying information of participants will not be connected. For in-person focus groups, gift cards will be given to participants after the focus group has taken place. No tokens of appreciation will be provided to MSM participating in the test of the recruitment methods.

**A.10.Assurances of Confidentiality Provided to Respondents**

CDC’s Assurance of Confidentiality for HIV surveillance applies to this sub-collection. Respondents will be told that all personally identifiable information collected to schedule the focus groups will not be submitted to CDC, will be destroyed after the focus group has taken place, that names will not be used during the focus groups and that names or other personal identifiers will not be linked to their focus group responses. Further, respondents will be told that that voice recordings from the focus groups will be destroyed by the Contractor after transcription, within 3 months of the data collection. CDC will not receive any voice recordings or transcripts from the focus group interviews.

Participation in this project is strictly voluntary. Consent will be obtained before data are collected **(Attachment 2)**. During the in-person focus groups, study purpose, risks and benefits, as well as privacy protections will be explained to the participants, and they will have the opportunity to ask questions prior to signing.

For the online focus group interviews and the web-based test of the recruitment strategies, participants will be asked to read the consent form before indicating whether they consent. As for the in-person focus groups, study purpose, risks and benefits will be explained to the participants, as well as privacy protections. No personally identifiable information will be associated with the consent forms for the in-person or online focus groups, nor for the online test of the recruitment approach.

Analysis of the data will be the responsibility of the Contractor and Sub-contractor. No datasets will contain potential identifiers since none will be collected. Data will be password-protected and accessible only to the Program Coordinator and Investigators. Analysis datasets will be deleted and overwritten by the Contractor when the analysis is concluded. An analysis dataset from the test of the recruitment strategy will be transmitted to CDC through CDC’s Secure Data Network (SDN). This dataset will not contain personally identifying information. Any reports generated from this dataset will be released in the form of aggregate data that cannot be linked back to individual respondents.

Data collected from the focus group interviews will be provided to the CDC in the form of a written report summarizing key findings; neither focus group screener data nor focus group transcripts will be transmitted to CDC.

**A.11.Justification for Sensitive Questions**

During screening for eligibility (focus groups and online test of recruitment approach), participants are asked sensitive questions about race, ethnicity and sexual activities. These sensitive questions are necessary to determine eligibility for the data collection, as the purpose of this formative research is to develop optimal recruitment methods for a web-based behavioral survey of MSM.

The test of the recruitment approach involves collecting information on the respondents’ sexual or drug use behaviors that increase the risk for acquisition or transmission of HIV and patterns of HIV testing. Although the information requested is sensitive, this information is necessary to characterize MSM recruited with the approach being tested to assess whether the approach reaches the targeted sub-groups of high-risk MSM, i.e. men who engage in sexual or drug use behaviors that pertain to HIV acquisition or transmission.

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

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

The annualized response burden for this sub-collection is estimated to be 1,874 hours. For the focus groups, study staff will screen approximately 500 MSM to assess study eligibility (screening is expected to take 1 minute); 400 MSM are expected to participate in either the online and in person focus groups, which are expected to take 90 minutes. For the test of the recruitment approach, it is anticipated that a total of 8,736 persons will complete a 1-minute screening questionnaire and that 4,800 MSM determined to be eligible will participate in a 14 minute web-based survey.

Exhibit A.12.A Annualized Burden Hours

| Type of Respondent | Form Name | Number ofRespondents | Number ofResponses perRespondent | Average HoursPer Response | Total ResponseBurden(Hours) |
| --- | --- | --- | --- | --- | --- |
| General public  | Eligibility Screener – Focus Group | 500 | 1 | 1/60 | 8 |
| General public  | Focus group interview | 400 | 1 | 90/60 | 600 |
| General public  | Eligibility screener- Web-based Survey | 8736 | 1 | 1/60 | 146 |
| General public  | Web-based Survey | 4800 | 1 | 14/60 | 1120 |
| **Total** |  |  |  |  | **1874** |

 **A.12.B. Estimated Annualized Costs**

The annualized cost to respondents for the burden hours is estimated to be $**35,681**; details are provided in Exhibit A.12.B. The estimates of hourly wages were obtained from the Department of labor (Bureau of Labor Statistics Wage Data (http://www.bls.gov/bls/wages.htm).

Exhibit A.12.B. Annualized Cost to Respondents

|  |  |  |  |
| --- | --- | --- | --- |
| **Activity** | **Total Burden Hours** | **Hourly Wage Rate** | **Total Respondent Cost** |
| Eligibility Screener – Focus Group | 8 | $19.04 | $152 |
| Focus Group Interview | 600 | $19.04 | $11,424 |
| Eligibility screener- Web-based Survey | 146 | $19.04 | $2,780 |
| Web-based Survey | 1120 | $19.04 | $21,325 |
| **Total** | **1,874** |  | **$35,681** |

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

There are no other costs to respondents or record keepers.

**A.14**.**Annualized Costs to the Federal Government**

The estimated annualized costs to the federal government are estimated to be $971,096. These costs include a CDC project officer (0.75 FTE) to provide oversight, and a contract to recruit and collect the data from respondents.

|  |  |  |
| --- | --- | --- |
| **Expense Type** | **Expense Explanation** | **Annual Costs (dollars)** |
| Direct Costs to the Federal Government |  |  |
|  | CDC Project Officer (GS-13, 0.75 FTE) | $68,400 |
| Contract  | Contract deliverables: Formative Research | $902,696 |
|  |  Task 1 – Kick-off meeting | $12,777 |
|  |  Task 2- Web-based platform report | $142,944 |
|  |  Task 2a – Data security report | $78,167 |
|  |  Task 3- Program survey instrument | $108,993 |
|  |  Task 4- Market research report | $100,312 |
|  |  Task 5- Develop progress plan | $153,416 |
|  |  Task 5a- Programming routines  | $57,330 |
|  |  Task 6- Recruitment materials | $93,473 |
|  |  Task 7 – Test of recruitment strategy | $125,577 |
|  |  Task 8 – Programming monitoring reports | $29,707 |
|  | **TOTAL COST TO THE GOVERNMENT** | $971,096 |

**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**

All data collection will be completed during the 12 month period after OMB approval. Data analysis and revisions to the web survey system will occur within 12 months of OMB approval.

**Exhibit 16.A Project Time Schedule**

| **Activity** | **Time Schedule** |
| --- | --- |
| Focus group data collection begins | Immediately after OMB approval |
| Focus group data collection ends | 5 months after OMB approval |
| Report summarizing focus group findings sent to CDC | 7 months after OMB approval |
| Test of recruitment strategy data collection begins | 9 months after OMB approval |
| Test of recruitment strategy data collection ends | 10 months after OMB approval |
| Analysis dataset sent to CDC | 12 months after OMB approval |

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

The OMB Expiration Date will be displayed. No exception is requested.

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

There are no exceptions to the certification.

**B. Collection of Information Employing Statistical Methods**

This information collection request does not employ statistical methods. The following is a description of data collection procedures.

**B.1. Respondent Universe and Sampling Methods**

The respondent universe for this formative project will be men at least 18 years old who reside in the U.S. or Puerto Rico (focus groups) or in one of the 12 cities with highest AIDS prevalence (online test of recruitment approach), and report that they have ever had oral or anal sex with a man.

For the online and in-person focus groups, MSM will be recruited from internet sites such as social networking sites or sites with gay-focused consent or, for the in-person focus groups, MSM will be recruited from venues such as gay bars and clubs. Efforts will be made to recruit men across a variety of age groups, racial/ethnic identities, and geographic regions. A total of 400 MSM will be interviewed through the use of focus groups; 200 MSM for online focus groups and 200 men for in-person focus groups.

For the test of the recruitment approach, the goal is to recruit MSM from a diverse number of internet sites frequented by MSM, including social networking sites, dating sites and gay news sites, and include sites that attract African American and Hispanic MSM. A test of the recruitment strategy will be conducted for one month among 400 MSM in each of the 12 cities with the highest AIDS prevalence (New York Division; Los Angeles Division; Washington Division; Chicago Division; Miami Division; Philadelphia Division; Atlanta-Sandy Springs-Marietta, Georgia; Houston-Baytown-Sugar Land, Texas; San Francisco Division, Baltimore-Towson, Maryland; San Juan-Caguas-Guaynabo, Puerto Rico; Dallas Division).

**B.2. Procedures for the Collection of Information**

**B.2.1. Recruitment**

**B.2.1.1 Online and in-person focus group interviews**

For online focus group interviews, recruitment will be through advertisements on relevant websites. For the in-person focus group interviews, flyers advertising the project and detailing inclusion criteria, incentive amount and the aims of the project will be distributed in local venues within the areas where the formative research will be conducted. The flyers will also include an email address so that potential participants can email for more information.

MSM living in the 12 cities with the highest AIDS prevalence will be recruited for the in-person focus groups using multiple strategies, including recruitment through community-based organizations (CBOs), public placement of posters and through ads placed on websites for MSM, including those that attract African American and Hispanic MSM.

**B.2.1.2 Test of the selected recruitment methods**

Men will be recruited for the survey using an approach based on focus group findings. Recruitment will occur through websites (also identified through focus groups), such as general social networking sites, as well as gay-focused websites. Men who are interested in learning more about the survey will click on a link and be redirected to the vendor’s website to complete the survey.

**B.2.2. Screening and Scheduling Procedures**

1. **Online and in-person focus group interviews**

For the in-person focus groups, men interested in participating will contact study staff through an email address listed on the recruitment flyer. Interested men will then be contacted via e-mail by the research team and provided with a link to the screening questionnaire to determine eligibility **(Attachment 1a)**.

For online focus groups, potential participants will be shown a recruitment advertisement on websites they frequent and those who click on it will be directed to a screening questionnaire online that will be used to determine eligibility and will also collect e-mail address, phone and first name. The research team will then initiate email contact to provide date and time options for online focus groups, set an appointment for participation in a specific focus group, and then conduct a second eligibility screening (using the same screener). Those who meet eligibility requirements will be selected at random to participate.

1. **Test of the selected recruitment strategy**

When potential respondents click on the link in a banner ad, they will click through to a screening page. Potential participants will be self-administered the screening questionnaire, from which eligibility will be determined **(Attachment 1c)**, based on age, race/ethnicity, gender identity, county and state of residence and whether or not the participant has ever had oral or anal sex with a man. Eligible respondents will be routed to the consent form and, if they consent, re-directed to the survey, whereas respondents who are ineligible will be thanked for their interest. All screening and interview data will be written to a secure web server operated by the Contractor’s vendor.

**B.2.3. Data Collection Methods**

 **a)** **Online and in-person focus group**

The general procedures will be the same for the online and in person focus groups. Online focus groups will be conducted via a web conference setting with an audio link. The facilitator will begin by explaining the purpose of the focus group, and will ask permission from the participants to tape record the discussion. Participants will be told no names will be used in the discussion and that recordings will be destroyed after their content has been transcribed. The discussion will then proceed according to the question guide **(Attachment 1b)**.

 **b)** **Test of the selected recruitment strategy**

Eligible respondents who consent to participate in the survey are directed to complete a questionnaire that collects self-reported demographics, sex and substance use behaviors, HIV testing patterns, and exposure to and use of HIV prevention services **(Attachment 1d).**

**B.3. Methods to Maximize Response Rates and Deal with Nonresponse**

If focus group response rates are less than 80%, study staff will increase recruitment efforts at sites visited by MSM. The token of appreciation amount ($25 for online focus groups$40 for in-person focus groups) will help ensure that target enrollments are reached. Based on the sub-Contractor’s previous experience, the anticipated response rate is at least 80%. Screening data will also be assessed to characterize MSM who decline to participate to identify changes needed in the recruitment strategy for the focus groups.

For the test of the recruitment strategy, monitoring of response will occur at regular intervals throughout the one-month recruitment period. Based on previous market research, recruitment ads, user interfaces, and graphics, including animation, will be specifically tailored to appeal to and attract the target population. When user profile information is available from websites, banner ads specifically tailored to demographic characteristics of users will be used to further increase response rates. Population-specific themes will be developed and maintained throughout the interview to appeal to participants extant motivations (e.g. altruism) as identified during focus groups. Interviews will be short, easy to use, and visually attractive to increase interview completion rates.

**B.4. Tests of Procedures or Methods to be Undertaken**

This submission is a request for authorization to conduct tests of procedures and methodologies typical in methods and instrument development.

**B.5. Individuals Consulted on Statistical Aspects and Individuals and/or Analyzing Data**

No other individuals were consulted on the statistical aspects or analysis of data from this sub-collection.