Formative Research to Inform an HIV Testing Social Marketing Campaign for African American Men Who Have Sex with Men (MSM)", formally known as "Formative Research to Inform an HIV Testing Social Marketing Campaign for African American Heterosexual Men

Supporting Statement Section A

OMB control # 0920-0762

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A. Justification

The Centers for Disease Control and Prevention requests approval for revisions to a previously approved 3 year project 0920-0762 (expiration date January 31, 2011) called "Formative Research to Inform an HIV Testing Social Marketing Campaign for African American Heterosexual Men". Surveillance data from 2008 indicated that HIV incidence continued to increase only among African American Men who have Sex with Men (AAMSM). Therefore, CDC made a represent the majority of new infections. programmatic decision reallocating the funds for African American heterosexual men to AAMSM. The revised title for this collection will be "Formative Research to Inform an HIV Testing Social Marketing Campaign for African American Men Who Have Sex With Men (MSM)". No activities have taken place since the last approval. This request does not fall under the American Recovery and Reinvestment Act of 2009.

1. Circumstances Making the Collection of Information Necessary Background

In 2008, CDC released new estimates of HIV incidence. These estimates were derived by using new methodologies designed to more directly measure the number of new HIV infections in the United Sates. As a result, the estimates show that in 2006, 56,300 people were infected with HIV which is higher than CDC's previous estimates of 40,000 new cases of HIV annually. Also, according to these newly released data, by the end of 2006, over 1.1 million adults and adolescents in the United States were living with either diagnosed or undiagnosed HIV infection yielding a prevalence rate of 447.8 per 100,000 (CDC, 2008a). Moreover, the majority of those individuals living with HIV were nonwhite (65.4%) of which nearly half (48.1%) were MSM (CDC, 2008a). Research indicates that early knowledge of HIV status is important for linking those who are HIV-positive to medical care and services that can reduce morbidity and mortality and improve their quality of life (KFF, 2005). Knowledge of one's HIV serostatus can also help prevent the spread of the infection to others, because those who are aware they are infected with HIV are significantly more likely to protect their partners from infection (Wenger et al., 1994; Kilmarx et al., 1998). Estimated annual transmission rates have also been found to be lower among those who are aware of their HIV status than among those who are unaware of their status (Holtgrave and Anderson, 2004).

According to CDC's September 12, 2008 MMWR, "Subpopulation Estimates from the HIV Incidence Surveillance System-United States, 2006", MSM represent the majority of new infections in 2006 with young blacks aged 13-29 accounting for the majority of new HIV infections. The number of new infections among this subpopulation was approximately twice that of whites and Hispanics/Latinos (5,220 infections in blacks vs. 3,330 among whites and 2,300 among Hispanics/Latinos). With blacks comprising only13 percent of the US population, these statistics further emphasize the disproportionate impact of new HIV infections. Research from Adimora and Schoenbach (2005) show that contextual factors, such as poverty, discrimination, epidemiology of illicit drug use in the community, ratio of men to women, incarceration rates, and racial segregation also influence sexual behavior and sexual networks through a variety of mechanisms and these in turn impact the transmission risk factors for African American men.

One of the goals of CDC's HIV Prevention Strategic Plan through 2010 is to reduce the number of new HIV infections in the United States by 5% per year, or at least by 10%, focusing particularly on eliminating racial and ethnic disparities in new HIV infections. Two objectives related to accomplishing this goal are to (1) increase, through voluntary counseling and testing, the proportion of HIV-infected people in the United States who know they are infected from the current estimate of 75% to 80%; and (2) increase the proportion of HIV-infected people in the United States who are linked to appropriate prevention, care, and treatment services from the current estimate of 50% to 65% (CDC, 2007). Development the proposed HIV testing social marketing campaign for AAMSM is a direct initiative in response to these needs of this population and the goals and objectives of the CDC's HIV prevention strategic plan.

This study is authorized under U.S. Federal Code, 42 USC 241, Section 301 of the Public Health Service Act (see **Attachment 1**).

Privacy Impact Assessment

Overview of the Data Collection System

Research Triangle Institute (RTI) will implement all phases of this study. The respondents for this project will be 432 AAMSM across 12 cities over a 3 year period. Data will be collected in twelve of the following cities: Memphis, Tennessee; Baton Rouge, Louisiana; Detroit, Michigan; Philadelphia, Pennsylvania; Houston, Texas; Newark, New Jersey; Jacksonville or Miami, Florida; Cleveland, Ohio; Charlotte, North Carolina; Richmond, Virginia; Chicago, Illinois; Birmingham, Alabama; Oakland, California; Los Angeles, California; and Washington, D.C.

Each person will be recruited through local marketing research facilities that will be contracted RTI. Personal data will remain with the recruiters and destroyed at the end of each interview. The entire data collection system will be a one time in-depth individual interview and a one time paper and pencil survey per individual. RTI will take notes and audio tape each interview.

Items of Information to be Collected

Information to be collected through the interviews and surveys consist of participants': (1) knowledge, attitudes and beliefs about HIV and HIV testing; (2) opinions on motivating approaches, supporting data, and key messages for materials development; (3) opinions on creative concepts, messages, potential campaign themes, logos and names; and (4) opinions on creative materials. The local professional recruitment facility will collect the names, addresses, phone numbers and emails of the eligible individuals who have agreed to participate and have been given an interview appointment. The participant information will be used to provide appointment reminders. All identifying information will be kept in locked file cabinets at the local professional recruitment facilities and will be destroyed after the interviews are completed. No identifying information will be sent to CDC or RTI. All audio tapes will be destroyed after notes have been verified and no links will be maintained to any data collected. RTI will provide CDC with a report of the formative research results.

<u>Identification of Website(s) and Website Content Directed at</u> Children Under 13 Years of Age .

Websites are not used in this study

2. Purpose and Use of the Information Collection

The information gained through this project will inform the development of an HIV testing social marketing campaign for AAMSM. This project will contribute to CDC's mission by developing a campaign designed to increase: 1) HIV testing; 2) knowledge of HIV serostatus and; 3) increase appropriate linkage to care and treatment for individuals with a positive serostatus. Data collection under this request will serve as one component that CDC is implementing to address the HIV incidence estimates among AAMSM. Due to the qualitative study design, results generated from this project cannot be generalized to the general public.

Key research questions for this formative research are presented in **Exhibit A.2.1**. Interview guides and paper and pencil surveys are Attachment 3A and 3B, respectively.

Exhibit A.2.1. Research Questions

- 1. How knowledgeable are participants about HIV transmission, prevention, and treatment?
- 2. What is the participants' perception of self masculine identity?
- 3. What is participants' perceived level of risk for HIV infection?
- 4. What are participants' knowledge, attitudes and beliefs about HIV testing?
- 5. What are reasons why someone would want to get an HIV test? What are reasons why someone would not want to be tested?
- 6. How important is it to participants to know their HIV status?
- 7. How knowledgeable are participants about their access to getting an HIV test and what is their knowledge of HIV testing locations?
- 8. What are the testing behaviors of the participants? (why did they get tested, when did they get tested, where were they tested, who went with them when they got tested)
- 9. How could the participants' HIV testing experiences be improved?
- 10. What are motivators for getting tested for HIV?
- 11. What is participants' awareness of existing HIV/AIDS advertisements?
- 12. What are participants' preferred sources of information about health and specifically about HIV?
- 13. What are participants' perceptions of campaign messages, concepts, potential names, logos and materials? (likes/dislikes, strengths/weaknesses, relevance, importance, credibility, clarity, impact, etc.)
- 14. What campaign strategies may be effective in reaching the target audience?

- 15. To what extent does the participant feel that he is affirmed by his peers, community, or family?
- 16. To what extent and how does the participant feel stigma impacts decisions to get HIV testing?

Privacy Impact Assessment

This information is being collected in order to inform the development of a social marketing campaign aimed at increasing HIV testing among AAMSM. Without this information, the data needed to accurately develop the campaign messages, concepts, and materials would not be possible. Study results, in aggregate form, will be reviewed and approved by CDC prior to dissemination to the public through reports prepared for/by CDC and RTI, and peer-reviewed journal articles where appropriate.

Because the objective of the campaign is to increase HIV testing among AAMSM at risk for acquiring or transmitting HIV, some sensitive questions regarding HIV and HIV testing will be asked. However, the proposed data collection will have little or no effect on the respondent's privacy. The local recruitment facilities will maintain identifying information on individuals agreeing to participate. The identifying information will consist of names, addresses, phone numbers, and e-mail addresses for the purpose of sending reminder letters/e-mails and placing reminder calls about the study. All identifying information will be recorded on the last page of the screening instrument and will be torn off and destroyed after the interviews are conducted in each city. Local recruitment facilities will send the screeners (without the last page) to RTI. The screeners will be stored in a locked file cabinet at RTI throughout the duration of the project. Once the project ends, the screeners will be transferred into a locked RTI storage facility for three years. After three years, RTI staff will destroy the screeners. No identifying information about participants will be kept at any facilities after the interviews are completed and no identifying information will be sent to RTI or CDC.

Each participant will be given a written study consent form to review and sign (Attachment 4). Participants will be assured that their answers to screener and interview questions will not be shared with anyone outside the research team and that their names will not be reported with responses provided. Respondents will be told that the information obtained from all of the interviews will be combined into a summary report so that details of individual responses cannot be linked to a specific participant.

3. Use of Improved Information Technology and Burden Reduction

This project will collect only the minimum information necessary for purposes of this study. Our data collection methods require that RTI conduct interviews with participants to gather information needed to inform the development of an HIV testing social marketing campaign for AAMSM. Because the primary data collection method is qualitative in nature RTI will conduct one on one in person interviews. RTI will not utilize any automated, electronic respondent reporting.

4. Efforts to Identify Duplication and Use of Similar Information

In designing the proposed data collection activities, RTI have taken several steps to ensure that this effort does not duplicate ongoing efforts and that no existing data sets would address the proposed study questions. To ensure that this study is forging new ground, RTI conducted an extensive review of the literature by examining several large periodical journal databases. In addition to reviewing published information, RTI searched for "gray" literature by exploring the Internet. Searches were performed on several Internet search engines, including Google, Yahoo, AltaVista, Medline, and Science Direct. This is a new social marketing campaign for which campaign materials are being developed.

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 is an ad hoc data collection (i.e., a one-time study). There are no legal obstacles to reduce burden. The present study will provide the primary data needed to develop the materials for the HIV testing social marketing campaign for AAMSM. If this formative research were not conducted, it would not be possible to pre-test the campaign materials with the target audiences before they are widely distributed. It is important to incorporate the social marketing concept of consumer orientation when developing new health communication materials for AAMSM. Consumer orientation involves gaining an understanding of a target audience, including their perceptions and information needs, so that materials can be developed that respond to their needs (Maibach et al., 2002). Effective campaign materials need to reflect the target audience's concerns. If the target audience does not perceive the materials to be personally relevant, they are unlikely to use them (Kreps et al., 1992). Therefore, it is essential to conduct formative research to ensure that the materials are perceived as relevant by African American MSM. Our

formative research process includes gaining an understanding of a target audience's perceived needs, benefits sought, and barriers of concern. Subsequently, materials are developed that are responsive to the target audience's perspectives, needs, and concerns. RTI then test the materials with members of the target audience before they are widely disseminated (Slater, 1995). This project is critically important because it involves testing the materials that are being developed as part of the social marketing campaign described above.

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

There are no other special circumstances that require the data collection to be conducted in a manner inconsistent with 5 CRF 1320.5 (d)(2). This data collection request fully complies with the regulation.

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

- A. The original 60-Day Federal Register notice for OMB 0920-0762 was published on December 12, 2006 (Volume 71, Number 238, pages 74541-74542) to solicit comments from the public which none were received (Attachment 2). A revised 60-Day federal register notice for OMB 0920-0762 was published on February 20, 2009 (Volume 74, Number 33, page 7906-7907). Revisions in this 60-Day federal register notice were based on the revised content in this ICR and can be found as Attachment 2.
- **B.** On September 9, 2008, CDC hosted an external work group meeting with the following HIV/AIDS experts, researchers, and community leaders. The purpose of the work group meeting was to obtain suggestions, facts, and opinions regarding the proposed AAMSM HIV Testing campaign.

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9. Explanation of Any Payment or Gift to Respondents

All participants will be paid a \$75 honorarium to thank them for their time and effort in the study. The amounts were determined based upon the burden to the participants, taking into account the length of the interviews, the fact that participants may have to travel a considerable distance to the facility, and parking costs. The honoraria are intended to recognize the time burden placed on the participants, encourage their cooperation, and to convey appreciation for contributing to this important study. Numerous empirical studies have shown that honoraria can significantly increase response rates (e.g., Abreu & Winters, 1999; Shettle & Mooney, 1999; Greenbaum, 2000). A smaller honorarium would not appear sufficiently attractive to adults. We also believe that the honoraria will result in higher data validity as participants become more engaged in the interview process.

10. Assurance of Confidentiality Provided to Respondents Privacy Impact Assessment Information

The Privacy Act does not apply for this request. Local recruitment facilities will obtain and temporarily maintain names and contact information of the respondents for the purpose of providing appointment reminders. All identifying information will be kept secured in locked file cabinets at the recruitment facilities and will be destroyed upon completion of the interviews. No identifying information will be sent to CDC or

RTI. Audio tapes will be destroyed after notes have been verified, and no links will be maintained to any data collected.

Once the potential participant comes to the study site and checks in, he will be given a consent form (see Attachment 4). The individual will be given time to read the consent form on his own and a trained RTI staff member will be available to answer any questions. If the participant agrees to be in the study, he will be given the consent form to read and sign. The participant will be given a copy of the consent form to keep for his records. Participants will be reminded that they can refuse to answer any question and they can stop being in the study at any time, without penalty. RTI staff will FedEx or personally take these forms back to RTI after the interviews are completed in a particular city. The consent forms will be stored in a locked file cabinet at RTI for the duration of the project. Once the project ends, the forms will be transferred to a locked RTI storage facility for three years. After three years, RTI staff will destroy the forms.

The local recruitment facilities will maintain a list of participant names, addresses, phone numbers, and e-mail addresses for the purpose of sending reminder letters/e-mails and placing reminder calls about the study. This information will be kept in locked file cabinets or on password protected computers for a limited time and will be destroyed upon the completion of the interviews in each city. This information will never be linked to the qualitative or paper and pencil survey data collected in the interviews. CDC and RTI will never have access to any identifying information about participants.

Participants will be assured that their information will not be shared with third parties except as reports using aggregated data to CDC's program personnel or in publications which is based on statistically treated aggregated data.

The approved OMB 0920-0762 was first submitted to the Institutional Review Board (IRB) at CDC and received approval on July 23, 2007. The original project was submitted to the IRB at RTI and received approval on July 13, 2007. The amended IRB corresponding to the revised OMB 0920-0762 was approved by CDC's IRB on March 9, 2009 and approved by RTI's IRB on December 12, 2008 (see Attachment 5)

11. Justification for Sensitive Questions

The reported HIV/AIDS cases were highest among men who have sex with other men, followed by injection drug use and high-risk heterosexual contact. Due to the high HIV/AIDS prevalence rates among African Americans and high risk homosexual contact, our

study will only target AAMSM. As such, our study entails the measurement of some sensitive HIV-related questions.

Because HIV testing will be the primary behavioral outcome of this campaign, those who voluntarily admit they are HIV positive during the screening process will be excluded from the outset of the study. Our screening instrument (see Attachment 3C) includes a question (12) that assesses whether individuals have ever been tested for HIV. Furthermore, because our campaign materials are targeted at men who are at risk for HIV because they are having unprotected sex with men, our pre-survey screening instrument includes three questions (13 - 15) that assess sexual identity and behavior.

The interview guides and paper and pencil survey (see Attachment 3A and 3B) also include questions about HIV knowledge attitudes and beliefs, questions about HIV testing attitudes, beliefs and experience, as well as questions about perceptions of risk, normative beliefs, and behavioral beliefs related to HIV and HIV testing. These questions are necessary to inform the development of the campaign materials that will promote HIV testing.

Data collected by the paper and pencil survey (Attachment **3B**) will provide a source of quantitative data supplementing the qualitative data collected during the interviews. The paper and pencil survey will be administered to participants either immediately before (while they are waiting to begin their interview) or at the end of the interview while the moderator is checking with observers about whether there are additional questions. The paper and pencil survey was revised to expand the following sections: Knowledge, Attitudes, Beliefs about HIV; HIV Testing; Channel Research; Risk Behaviors; Theoretical Constructs; and Stigma. The actual questions for the will consist of a much smaller subset of items found in Attachment 3B. These items will be consistent across all participants. The brief questionnaire will collect basic background information about the participants' knowledge, attitudes and beliefs about HIV, HIV testing behaviors, risk behaviors and demographics to enable us to more fully describe the participants. Some of these questions could be asked as warm-up questions during the interview, but we feel that using the brief questionnaire provides the opportunity to ask these items consistently across all participants and will not take time away from the interview discussion.

12. Estimates of Annualized Burden Hours and Costs

The annualized response burden is estimated at 228 hours. Time required for the interviews were estimated by mock interviews among project staff at RTI and CDC. These trials

indicated that administration of the screening instrument would take 10 minutes; reading and signing the consent form 5 minutes, and the actual interview is estimated to take 1 hour. Two hundred and eighty eight screening questionnaires would require 48 hours. One hundred and forty four men completing the paper and pencil questionnaire would take 36 hours. The hour-long interview of 144 men will require 144 hours. The total estimated burden hours are 228.

Table A.12.1. Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses Per Respondent	Average Burden per Response (in hours)	Total Burden Hours
African American MSM	Screener 3c	288	1	10/60	48
African American MSM	Paper and Pencil Questionnaire 3b	144	1	15/60	36
African American MSM	Interview 3a	144	1	1	144
<u>Total</u>		720		1	228

It is not known what the wage rate category will be for selected participants (or even whether they will be employed at all); therefore, the figure of \$6.00 per hour was used as an estimate of average minimum wage across the country. The estimated annual cost to participants for the hour burden for collections of information will be \$1368.00.

 Table A.12.2.
 Annualized Cost to Respondents

Type of Respondent	Form Name	No. of Respondents	Hourly Wage Rate	Total Respondent Costs
African	Screener	288	\$6.00	\$ 360.00

American MSM				
African American MSM	Paper and Pencil Questionnaire	144	\$6.00	\$ 216.00
African American MSM	Interview	144	\$6.00	\$ 864.00
<u>Total</u>		720		\$1368

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

There are no start-up or maintenance costs. We do not require any additional record keeping.

14. Annualized Cost to the Federal Government

The annualized estimate cost to the federal government is \$197,514 which is based on the contractor's costs for carrying out the data collection activities, analysis, and reporting and CDC's oversight of the contractor and project (**Table A.14.1**).

Table A.14.1 Government Costs

Item/Activity	Details	\$ Amount
CDC oversight of contractor and project	60% of FTE: GS-13 Health Communication Specialist and 15% of FTE GS-13 Health Communication Specialist	\$29,120
RTI Recruitment and Data Collection (Contractor)	Labor hours and ODCs	\$126,296
RTI Analysis and Reporting (Contractor)	Labor hours and ODCs	\$42,098
Total		\$197,514

15. Explanation for Program Changes or Adjustments

The rapidly changing epidemiology of HIV necessitated a programmatic change in the target audience from African American heterosexual men to AAMSM. The revised collection has deleted

focus groups and increased the sample size for individual interviews. These changes have increased the total number of annual burden hours to 228 from 151.56 and the total of respondents to 144 from 108 annually.

16. Plans for Tabulation and Publication and Project Time Schedule

Data from the interviews will be entered into an electronic data matrix by the RTI note taker during the data collection and stored on a password protected computer. Analysis of the interview data will start immediately after completion of data collection in each city and will be conducted under the supervision of a senior staff member with extensive experience in qualitative research. RTI will conduct thematic or ground theory analysis of the data to understand participants' reactions to the campaign messages in as rigorous and detailed manner as possible. RTI and CDC will review the preliminary data within one week after data collection is completed in each city via a debriefing conference call. RTI analysts will further analyze the data in the matrices and summarize results in three separate topline reports (one per round-exploratory, message testing, concept testing, and materials testing) and one summary report. Data from the paper and pencil questionnaires will be keyed into Microsoft Excel and be reported in descriptive data tables and with accompanying narrative in the topline and summary reports. The key events and reports to be prepared are listed in Table A.16.1.

Table A.16.1 Project Time Schedule

Project Activity	Date
Reserve recruitment facilities and begin recruitment	Upon receiving OMB approval
Conduct interviews for Phase 1	5 weeks after recruitment begins at each site
Phase 1 topline report due	14 days after Phase 1 data collection is complete
Conduct interviews for Phase 2	4 weeks after data collection for Phase 1 is complete
Phase 2 <i>topline</i> report due	14 days after Phase 2 data collection is complete
Conduct interviews for Phase 3	4 weeks after data collection for Phase 2 is complete
Phase 3 topline report due	14 days after data collection for Phase 3 is complete
Conduct interviews for Phase 4	4 weeks after data collection for Phase 3 is complete
Phase 4 topline report due	14 days after data collection for Phase 4 is complete
Summary report due	30 days after data collection for Phase 4 is complete

Identification of recruitment facilities and recruitment will begin once OMB has approved the collection. Study sites will be selected on the basis of the local HIV prevalence and incidence data for the most recent years. Typically, recruitment takes about 1 month and recruitment will begin for the first 3 cities within a week of receiving clearance. Recruitment for the first city in phase 2 (fourth city overall) will occur while conducting research in the last city of phase 1 (third city overall). This overlapping process will continue until all 4 phases (12 cities total) have been completed. Table A. 16. is a description of a 5 month cycle of events that include overlapping time lines across the 12 study sites as the study progresses from recruitment of participants to Phase 4 of the study.

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

 OMB expiration date will be displayed on paper data
 collection forms
- 18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification statement.

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