Section A: Justification

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Formative Research to Inform an HIV Testing Social Marketing Campaign for African American Heterosexual Men

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TABLE OF CONTENTS

TABLES

Number **Page**

List of Attachments

1. Authorizing Legislation and Other Relevant Laws

2a. Data Collection Instruments with Interview Burden Statement

2b. Data Collection Instruments with Focus Group Burden Statement

3. Paper and Pencil Questionnaire

4. *Federal Register* Notices to the Public (60-day)

5. CDC and RTI Institutional Review Board Approval

6. Consent Forms

7. Study Screening Instruments

8. Confidentiality Agreement

Formative Research to Inform an HIV Testing Social Marketing Campaign for African American Heterosexual Men

The purpose of this study is to conduct formative research to inform the development of a CDC-sponsored social marketing campaign that will be aimed at increasing HIV testing rates among young, single, African American heterosexual men.

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

For the first two decades of the HIV/AIDS epidemic, the Centers for Disease Control and Prevention (CDC) prevention efforts emphasized helping persons at high risk for HIV infection change their risk behaviors and remain uninfected. Early in the new millennium, CDC expanded its prevention efforts to emphasize early detection of HIV through testing in clinical and nonclinical settings. This emphasis is reflected in CDC's initiative "Advancing HIV Prevention" (AHP) (CDC, 2003a). The initiative includes four strategies aimed at reducing barriers to diagnosis of HIV infection and access to and use of quality medical care, treatment, and ongoing prevention services for persons with HIV.

Although significant advances in HIV treatment and prevention have been made during the past decade, HIV infection rates have remained steady at an estimated 40,000 per year in the United States. One of the goals of CDC's HIV Prevention Strategic Plan is to reduce the number of new HIV infections in the United States to 20,000 per year, with particular focus on eliminating racial and ethnic disparities in new HIV infections. An estimated 25% of people living with HIV in the United States do not know they are infected (Fleming et al., 2002). 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).

In support of AHP, CDC is developing an HIV prevention social marketing campaign for African American heterosexual men, which will be aimed at increasing the

proportion of African American heterosexual men who get an HIV test and increasing the proportion of African American heterosexual men who are aware of their HIV serostatus.

According to CDC's March 2007 report *A Heightened National Response to the HIV/AIDS Crisis Among African Americans*,

> "African American men are more affected by HIV/AIDS than are women; in 2005, men made up about 64% of HIV/AIDS cases among African Americans in the 33 states with long-term, confidential name-based HIV infection reporting. African American males aged 13 and older accounted for 42% of HIV/AIDS diagnosis among all men. Of all African American men living with HIV/AIDS, almost half (48%) of the cases among African American men were related to male to male sexual contact, 23% were related to injection drug use, and 22% were linked to high-risk heterosexual contact. African American men who have sex with men (MSM), whether they identify themselves as gay, bisexual, or heterosexual, are most severely affected compared with other high risk groups such as injection drug users, high-risk heterosexuals and white and Latino MSM." (p.1).

Contextual factors, such as poverty, discrimination, epidemiology of illicit drug use in the community, ratio of men to women, incarceration rates, and racial segregation influence sexual behavior and sexual networks through a variety of mechanisms and these in turn impact the transmission risk factors for African American men (Adimora and Schoenbach 2005). Essien and colleagues (2005) conducted a focus group study of low income African American heterosexual men in Houston to determine whether they perceived HIV/AIDS to be a threat to the African American community and assess the men's personal risk behaviors. Participants perceived HIV/AIDS as a threat to their community and have placed themselves at risk for HIV infection through unsafe sex, substance abuse, and lack of knowledge. More specifically, participants reported having unprotected sex with female partners when under the influence of drugs or alcohol and having sex with men while incarcerated and then resuming unprotected sex with women upon release. Other studies report having multiple partners (Brunswick et al. 1998; Wolfe 2003), buying sex (Brunswick et al. 1998), having a stronger aversion to condoms (Wolfe 2003), and misperceptions about HIV/AIDS (Essien et al. 2002) are significant risk factors for African American heterosexual men compared with men from other racial/ethnic groups.

One of the goals of CDC's HIV Prevention Strategic Plan is to reduce the number of new HIV infections in the United States to 20,000 per year, with particular focus 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 70% to 95%; 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 80%. Development of an HIV prevention social marketing campaign for African American heterosexual men is a direct initiative in response to these needs.

The following section of the U.S. Federal Code (see **Attachment 1**) is relevant to this data collection: 42 USC 241, Section 301 of the Public Health Service Act authorizes conduct of "research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man."

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 African American heterosexual men. Key research questions for are presented in **Table 1**. A copy of the data collection instruments is **Attachment 2a/b**.

Table 1. Research Questions

1. How knowledgeable are participants about HIV transmission, prevention, and treatment?
2. What is participants' perceived level of risk for HIV infection?
3. What are participants' knowledge, attitudes and beliefs about HIV testing?
4. What are reasons why someone would want to get an HIV test? What are reasons why someone would not want to be tested?
5. How important is it to participants to know their HIV status?
6. How knowledgeable are participants about their access to getting an HIV test and what is their knowledge of HIV testing locations?
7. 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)

8. How could the participants' HIV testing experiences be improved?
9. What are motivators for getting tested for HIV?
10. What is participants' awareness of existing HIV/AIDS advertisements?
11. What are participants' preferred sources of information about health and specifically about HIV?
12. What are participants' perceptions of campaign messages, concepts, potential names, logos and materials? (likes/dislikes, strengths/weaknesses, relevance, importance, credibility, clarity, impact, etc.)
13. What campaign strategies may be effective in reaching the target audience?

Study results will be disseminated to the public through reports prepared for/by CDC and RTI and peer-reviewed journal articles where appropriate. All releases of information will be reviewed and approved by CDC.

3. Use of Improved Information Technology and Burden Reduction

We will collect only the minimum information necessary for purposes of this study. Our data collection methods require that we conduct focus groups and interviews with participants to gather information needed to inform the development of an HIV testing social marketing campaign for African American heterosexual men. Because the data collected is qualitative in nature we will not utilize electronic respondent reporting.

4. Efforts to Identify Duplication and Use of Similar Information

In designing the proposed data collection activities, we 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, we conducted an extensive review of the literature by examining several large periodical journal databases. In addition to reviewing published information, we 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 African American heterosexual men. 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 African American heterosexual men. 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 heterosexual men. 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. We 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. A 60-Day *Federal Register* notice published on December 12, 2006 (Volume 71, Number 238, pages 74541-74542) solicited comments on Formative Research to Inform an HIV Testing Social Marketing Campaign for African American Heterosexual Men; no comments were received. A copy of the 60-day *Federal Register* notice can be found as **Attachment 3**.

B. CDC recognizes the importance of gaining valuable insights directly from members of the target audience and from organizations and individuals who work with them in the community. The purpose of this study is to conduct formative research with the intended target audience to gain insight about their knowledge, attitudes, and behaviors related to HIV, HIV testing, and HIV prevention and risk reduction (including their barriers and motivators to HIV testing). Information gathered from the formative research will inform the development of materials for an HIV testing social marketing campaign targeting African American heterosexual men. In addition to conducting a comprehensive literature review, the following individual was consulted at various times throughout 2006 to discuss the intended target audience and HIV prevalence and testing literature and data as related to the Formative Research to Inform an HIV Testing Social Marketing Campaign for African American Heterosexual Men. Consultation will continue as needed. There were no major problems that could not be resolved during consultations.

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After completion of the formative research, several social marketing, behavior change, and evaluation experts will be consulted for campaign development and evaluation, as needed.

9. Explanation of Any Payment or Gift to Respondents

All participants will be paid an honorarium to thank them for their time and effort in the study. Focus group participants will receive a $100 honorarium while interview participants will receive a $50 honorarium. The amounts were determined based upon the burden to the participants, taking into account the length of the focus groups and 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 focus group/interview process.

10. Assurance of Confidentiality Provided to Respondents

This submission has been reviewed for Privacy Act applicability and it has been determined that the Privacy Act does not apply. Individual focus group facilities will temporarily maintain names and contact information of the respondents for the purpose of reminders. All identifying information will be kept in locked file cabinets at the focus group facilities. No identifying information about participants will be kept at the focus group facilities after the groups/interviews are completed and 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.

This project was submitted to the Institutional Review Board (IRB) at CDC and received approval on July 23, 2007 (see **Attachment 5**). An electronic copy of the IRB approval letter has also been sent to the CDC OMB Clearance Office. This project was submitted to the IRB at RTI and received approval on July 13, 2007 (see **Attachment 5**). Once the potential participant comes to the study site and checks in, he will be given a consent form (see **Attachment 6**). 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 sign the consent form. 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 focus groups/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 focus group 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 and will be destroyed upon

the completion of the groups/interviews in each city. This information will never be linked to the qualitative data collected in the groups/interviews. CDC and RTI will never have access to any identifying information about participants.

Assurance of confidentiality is addressed and provided in writing to participants in the Consent forms (**Attachment 6)**. Participants will be assured that their answers to screener and focus group/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 groups/interviews will be combined into a summary report so that details of individual responses cannot be linked to a specific participant.

11. Justification for Sensitive Questions

The HIV Testing Social Marketing Campaign for African American heterosexual men is a direct initiative in response to the need to decrease the estimated 25% of HIV positive individuals who are unaware that they are infected. According to the to 2000 US Census, African Americans accounted for approximately 13% of the total population. However, in 2005, African Americans accounted for 49% of the estimated new HIV/AIDS diagnoses in the United States. 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 heterosexual contact, our study will only target African American heterosexual men. 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 7**) 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 women, our pre-survey screening instrument includes two questions (13 and 14) that assess sexual behavior.

The discussion guides (see **Attachment 2a/b**) 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.

We plan to supplement the qualitative data collected during the focus groups and interviews with a brief paper and pencil questionnaire (see **Attachment 3**) that will be administered to participants either immediately before (while they are waiting to begin their group or interview) or at the end of the focus group or interview while the moderator is checking with observers about whether there are additional questions. 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 focus group or 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 focus group or interview discussion.

12. Estimates of Annualized Burden Hours and Costs

The annualized response burden is estimated at 152 hours. **Tables 2 and 3** provide details about how this estimate was calculated. Timings were conducted during our instrument development process to determine the overall burden per respondent. Administration of the screening instrument is estimated to take 10 minutes. A participant reading and signing the consent form is estimated to take 5 minutes. Participation in a focus group is estimated to take 2 hours while participation in an interview is estimated to take 1 hour. We will complete 153 screening questionnaires (26 hours), 72 men will complete the paper and pencil questionnaires (12 hours), 36 men will participate in a focus group (72 hours) and 36 men will participate in an interview (36 hours), totaling 146 hours.

Because it is not known what the wage rate category will be for these selected participants (or even whether they will be employed at all), 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 $876.00.

Table 2. Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses	Average Burden Per	Total Burden

			Per Respondent	Response (in hours)	Hours
African American Heterosexual Men	Screener	153	1	10/60	26
African American Heterosexual Men	Paper and Pencil Questionnaire	72	1	10/60	12
African American Heterosexual Men	Focus Group	36	1	2	72
African American Heterosexual Men	Interview	36	1	1	36
Total					146

Table 3. Annualized Cost to Respondents

Form Names	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in Hours)	Hourly Wage Rate	Total Burden Hours	Total Respondent Costs
Screener	153	1	10/60	$6.00	26	$ 156.00
Paper and Pencil Questionnaire	72	1	10/60	$6.00	12	$ 72.00
Focus Group	36	1	2	$6.00	72	$ 432.00
Interview	36	1	1	$6.00	36	$ 216.00
Total					146	$876.00

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

Respondents participate on a purely voluntary basis and, therefore, are subject to no direct costs other than their time to participate; there are no start-up or maintenance costs. We do not require any additional record keeping.

14. Annualized Cost 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 $197,514 (**Table 4**). This is the cost estimated by the contractor, RTI, and includes the estimated cost of coordination with the CDC, data collection, analysis, and reporting.

Table 4. 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
Recruitment and Data Collection (Contractor)	Labor hours and ODCs	$126,296
Analysis and Reporting (Contractor)	Labor hours and ODCs	$42,098
Total		$197,514

15. Explanation for Program Changes or Adjustments

There is no change in burden requested, as this is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Data from the focus groups and 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 focus group and 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 phase—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 5.**

Table 5. Project Time Schedule

Project Activity	Date
OMB clearance process begins	December, 2006
IRB clearance process begins	February, 2007
Reserve focus group facilities and begin recruitment	Upon receiving OMB clearance
Conduct focus groups and interviews for Phase 1	5 weeks after recruitment begins
Phase 1 topline report due	14 days after Phase 1 data collection is complete
Conduct focus groups and interviews for Phase 2	4 weeks after data collection for Phase 1 is complete
Phase 2 topline report due	14 days after Phase 2 data collection is complete
Conduct focus groups and 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 focus groups and 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 IRB and OMB clearance is received. Typically, recruitment takes about 1 month and we will begin recruitment 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. Dates will be assigned to each activity on the timeline for tracking and monitoring purposes after receiving IRB and OMB clearance.

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

We do not seek approval to eliminate the expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification statement.