HIV Testing Factors Among Rural Black Men (HiTFARM)

Generic Information Collection request under 0920-0840

Section A: Supporting Statement

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Supporting Statement

A. Justification

A.1 Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention proposes to conduct a formative research study that will provide vital information about the factors associated with voluntary HIV testing and counseling among Heterosexual Black Men in rural areas. Collecting this information will aid the development of HIV counseling and testing interventions for heterosexual black men adding to CDC's portfolio of effective HIV prevention interventions for at-risk minority populations in rural areas. The proposed study will use Audio Computer Assisted Self-Interviews (ACASI) and focus groups completed by heterosexual black men living in rural areas to perform a psychometric evaluation of survey instruments and to uncover attitudes, barriers, facilitators, and feasibility and acceptability of various methods of HIV testing. The findings of this study can be used by researchers to improve future research in several ways. First, the psychometric evaluation will determine whether the survey items have been normalized for this population or if more research is required to do so. Second, this study will provide key information about the feasibility and acceptability of using ACASI surveys in rural settings with heterosexual black men. Third, the findings will aid researchers who wish to develop of culture based and culturally competent HIV counseling, testing and disclosure interventions for heterosexual black men in rural settings.

HIV/AIDS disproportionately affects the southeastern United States, and during 2006, non-Hispanic blacks in the state of Florida accounted for 52% of persons living with HIV. In addition, non-Hispanic blacks in northern rural areas in Florida accounted for over 65% of reported HIV cases. From 30% to 56% of these cases were acquired through heterosexual transmission, with non-Hispanic black males comprising from 38% to 58% of the cases (Florida Department of Health, 2008).

There is currently little information available about the factors that influence HIV testing and HIV positive status disclosure to sexual partners among rural/small city black men who identify as heterosexual. This data collection may lead to the development of HIV testing and HIV disclosure interventions that are specific to the cultural, gender and regional needs for this population.

These data will be used to develop a community-based HIV prevention intervention that will target rural, black men where they live, or socialize. Previous data suggests that this type of community-based intervention may have a greater impact among black males in rural areas than interventions which target traditional clinical venues. Without this information, CDC will not be prepared to adequately inform the development of targeted HIV testing and education programs to this population of rural, black men who are disproportionately at risk for HIV.

A.1.2 Privacy Impact Assessment

The awardee, CHARM Incorporated, will collect information in identifiable form (IIF). Research staff at CHARM will collect phone numbers to contact participants in order to contact them for participation in focus groups. Other IIF collected include age, gender, and race. The main purpose for collecting this information is to characterize the participants in the study. Knowledge of participant demographics will assist in the design and targeting of HIV prevention interventions. Steps will be taken to ensure privacy of data. ACASI Data will be stored on secure USB drives and then transferred to a secure password protected data file on a password-protected laptop kept in the PI's locked office. Only the PI and PD will have access to the password for the master data file. ID numbers only will be used to identify HIV tests performed as part of the randomized controlled trial. A list linking ID numbers to names will be kept separately in a locked location in the PI's office.

Audio recordings of focus groups will be transcribed by an outside contractor, transcripts will be stored on password-protected computers and in locked files. The audio tapes will be destroyed after transcription. A list linking ID numbers to participant names will be kept in a separate locked file cabinet in the PI's locked office. The collected data is the property of CHARM, Inc. After data analysis is completed, CHARM, Inc., will destroy all participant IIF and data.

CDC will not receive any IIF. If there were a need to send data to CDC for review, all IIF collected by local partners would be unlinked or stripped from the data base that is submitted to CDC.

A.1.3 Overview of the data collection system

The study will be completed in two phases. Phase I will consist of psychometric evaluation of several scales designed to explore

HIV risk and protective behaviors and HIV testing and disclosure barriers via ACASI. Phase II will qualitatively evaluate the ACASI survey, explore perspectives on barriers to testing and disclosure, strategies to improve HIV testing interventions and the testing process using focus groups.

The sample will consist of approximately 1072 Black/African American men who self-identify as heterosexual, are between the ages of 18 and 64, and reside in one of three rural counties (Columbia, Hamilton or Alachua) in North Florida.

In Phase I a cross-sectional survey will be administered to 1000 participants. The first 300 surveys completed will be used in the psychometric evaluation of the instruments. In Phase II of the study, approximately 8 focus groups with 6-9 participants each will be conducted, for a total of 48-72 participants. Participants will be recruited and screened by the Project Director (PD) or an outreach worker, who will collect contact information for those who meet the inclusion criteria. Once a focus group is scheduled, the participant will be contacted and notified of the specific date, time and location of the group. See Attachment 3a for a copy of a recruitment flyer, attachment 1 for contact and screening form (1a).

A.1.4 Items of Information to be collected

Each Participant will complete an ACASI questionnaire which will assess the following:

- Attitudes toward HIV testing
- HIV testing history
- Intention to disclose HIV+ test results
- AIDS stigma
- Barriers and facilitators of HIV testing
- HIV knowledge
- HIV Risk and protective behaviors

Focus Groups will be comprised of 6-9 participants each. Focus groups will be conducted and expected to last between 60-90 minutes. Focus groups will include questions about:

- attitudes toward HIV testing,
- perceptions of barriers and facilitators of HIV testing
- strategies to improve HIV testing
- comfort and skills needed to disclose HIV+ status.

A.1.5 Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

There will be no websites or internet content directed at children under the age of 13.

A.2. Purpose of Use of the Information Collection

The purpose of the Minority HIV/AIDS Research Initiative (MARI) research project, “HIV Testing Factors among Rural Black Men (HiTFARM)” is to conduct formative research for developing new tools and methodologies for exploring the factors related to voluntary HIV testing and counseling among self-identified heterosexual black males in rural areas. The goal of this study is to generate knowledge about barriers and facilitators that may influence HIV testing and disclosure of HIV positive status among rural/small city black males who self-identify as heterosexual. The information collected in this study will be used to develop innovative and culturally relevant interventions and materials promoting HIV testing and disclosure of HIV positive status to sexual partners that are culturally, gender, and regionally specific for rural/small city self-identified heterosexual black males.

A.2.1 Qualitative interviewing for surveillance, research, and intervention methods and material development

Qualitative interviewing will be used with volunteer respondents to identify the factors associated with voluntary HIV counseling and testing among heterosexual, black males who reside in rural areas. The results will be used to develop the gender and culturally appropriate data collection procedures and communication tools for future HIV prevention projects and interventions.

A.2.2 Cognitive interviewing for development of specific data collection instruments

Cognitive interviewing will be used with volunteer participants to refine data collection instruments related to identifying the factors associated with voluntary HIV counseling and testing among heterosexual, black males who reside in rural areas. The ACASI survey items have been normalized on other, non-rural populations and are being tested with this population in an attempt to determine if these questions resonate and function appropriately with rural/small city, heterosexual black men.

A.2.4 Usability testing of technology-based instruments and materials

The purpose of this data collection is to test the usability and acceptability of the ACASI data collection method with volunteer participants, heterosexual black Men who reside in rural areas. This is the first time this questionnaire will be used in the ACASI format with this target population. The investigator will evaluate whether the users can effectively navigate and complete the questionnaire in ACASI format. Participants will be asked questions about the design and layout of the questionnaire to enhance and refine the ACASI functionality (e.g. volume level of voice, positioning of the questions, font size, position of help buttons etc.)

A.2.5 Field Testing of New Methodologies and Materials

The purpose of this data collection is to conduct field test of new methods and data collection instruments. The objective of such testing is to evaluate the feasibility of the "new" strategies. Specifically, the investigator-developed ACASI method and questionnaire will be tested for the first time with heterosexual black men who reside in rural areas in northern Florida.

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

The use of an ACASI system will reduce the time needed to complete the surveys of individuals and will thereby reduce the burden on the public. Electronic reporting has advantages for ensuring respondent privacy and streamlining the data collection process. The computer programs will allow participants to select for an audio assistant to read the questions and answer options in English. Interviews and focus groups will be digitally recorded and transcribed, which also reduces burden and streamlines data collection.

A.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.

A.5. Impact on Small Business or Other Small Entities

No small businesses will be involved in this data collection.

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 the Guidelines of 5 CFR 1320.5

The request fully complies with the guidelines of 5 CFR 1320.5.

A.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 was published on March 11, 2009.

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

Participants will receive tokens of appreciation for their participation in the study: $25 for 90-minute focus groups and $10 for the 45 minutes for survey completion. No one in the study will receive more than $40 total in tokens of appreciation.

This token is being offered to show appreciation for the time spent completing assessments and for participating in focus group sessions. Through previously conducted research with this target population of rural, black men, the investigators have determined that this level of token is the most reasonable amount to ensure participation and meet the goals of this information collection.

While tokens of appreciation will be utilized for the assessments in this information collection, there is no intention to continue their use if these study materials are proven to be effective and widely adopted.

A.10. Assurance of Confidentiality Provided to Respondents

After the ACASI survey and focus groups are completed all contact information for participants will be destroyed. After the audio files from the focus groups are transcribed, they will be erased from the recorder and deleted from the computer. Each name on the audio files will be changed to a general name in the typed transcripts. Survey data collected with the ACASI survey will be initially stored to the laptop computers. In order to compile

data to a master file each interview will be stored on a secure USB drive for transfer to the master file. The password protected master file will be located on a secure password protected computer in the PI's locked office. Data will be routinely purged from the USB drives and laptop computers after transfer is complete to the master file.

Respondents will be told that no information in identifiable form will be shared with the CDC. Analysis of the data sets will take place at CHARM, Inc. The information collected in this project will be owned by CHARM, Inc. They will be the only entity with access to the IIF and information collected. If any data is shared with CDC, it will be de-identified and transferred securely to CDC via the Secure Data Network's (SDN) file transfer service.

Prior to participating in any part of the study participants will be required to give informed consent. Written consent will be obtained for the ACASI survey after participants are recruited before they are administered the ACASI at the various field study sites (Attachment 2a) and focus groups (Attachment 2b). All consent forms with participant names and signatures will be kept in a locked file cabinet in a locked room separate from the data files. They will be taken to this location as soon as possible after the data collection has been completed. Participants will be provided with copies of their consent forms.

A.11. Justification for Sensitive Questions

The survey instruments ask questions of a sensitive nature. Questions about sexual behavior are needed to assess HIV risk and protective behaviors and how these may relate to HIV testing and disclosure attitudes and behaviors. Participants are also asked about diagnosis of HIV/AIDS or STDs. These questions are needed to assess how these factors affect HIV status disclosure, as well as other risk or protective behaviors. Furthermore, these questions are needed to gain information and insight that will be used to strengthen CDC's prevention efforts for heterosexual black men who reside in rural areas. In no case will a participant's social security number be obtained by agency staff.

A.12. Estimates of Annualized Burden Hours and Costs

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

There will only be one type of respondent in this study: heterosexual, black men ages 18-64, who reside in rural areas. In order to ensure 1000 participants in phase 1, a 5-minute study screener to 1400 Black Men living in rural areas will be conducted. 1000 participants will participate in the 45-minute ACASI. For Phase 2, 72 participants will participate in 90 minute focus groups.

Exhibit A.12.A. Estimate of Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Respondent (in hours)	Total Burden (in hours)
General Public-Black Men	Screening and Contact Form	1400	1	5/60	117
General Public-Heterosexual Black Men	Survey Instrument	1000	1	45/60	750
General Public-Heterosexual Black Men	Focus Group Guide	72	1	90/60	108
Total					975

A.12.B. Estimated Annualized Burden Costs

The annualized costs to the respondents are described in Exhibit A.12.B. The United States Department of Labor Statistics May, 2009. (http://www.bls.gov/oes/current/oes_nat.htm was used to estimate the hourly wage rate for the general public for the purpose of this generic request. The figure of $20.90 per hour was used as an estimate of average hourly wage for adults. Thus, the total anticipated annual cost to participants for collection of information in this project will be $20,373.20.

Exhibit A.12.B: Estimated Annualized Burden Costs

Type of Respondent (Form Name)	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
General Public-Black Men (Screening and Contact Form)	117	$20.90	$2,436.00
General Public-Heterosexual Black Men (Survey Instrument)	750	$20.90	$15,680.00
General Public-Heterosexual Black Men (Focus Group Guide)	108	$20.90	$2,257.20
Total	975		$20,373.20

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 Cost to the Federal Government

This activity will involve participation of one CDC project officer and CDC mentor who will assist with project design, obtaining IRB and OMB approvals, and providing project oversight. A data manager is involved to provide support and maintenance for the ACASI QDS program that will be used during data collection and analysis. Travel expenses include two site visits.

Exhibit A.14: Estimates of Annualized Cost to the Government

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government	CDC Project Officer (GS-13,0.25 FTE)	$22,087
	CDC Mentor (USPHS Commissioned Corps Officer, 0-3, .05 FTE)	$7,250
	CDC Travel for Site Visits (2 trips)	$4,500
	Subtotal, Direct Costs	**$33,837**
Cooperative Agreement or Contract Costs	Cooperative Agreement to CHARM Inc.	$200,000
	Contractor CDC Data Manager/QDS Support (GS-9/10 equivalent; 0.25 FTE)	$13,500
	Subtotal, Cooperative Agreement or Contract Costs	**$213,500**
	TOTAL COST TO THE GOVERNMENT	**$247,337**

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

Data collection will be completed during the first year after OMB approval is granted.

Exhibit A.16: Project Time Schedule

Activity	Time Schedule
Recruit and Administer ACASI Survey	1-4 months after OMB approval
Conduct Psychometric Evaluation	5-6 months after OMB approval
Recruit for Focus Groups	6-7 months after OMB approval
Conduct Focus Groups	8-9 months after OMB approval
Focus Group Analysis	9-10 months after OMB approval
Manuscript Development Share Findings with Stakeholders	10-12 months after OMB approval

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

OMB Expiration Date will be displayed.

18. Exceptions to Certification for Paperwork Reduction Act (PRA) Submissions 5CFR 1320.3(h)(1)-(10)

There are no exceptions to the certification.