

**Minority HIV/AIDS Research Initiative (MARI) Research Project:
Promoting HIV Testing among Low Income Heterosexual Young Adult
Black Men (Brothers Encouraged to Access Testing Services: The
BEATS Project)**

Supporting Statement A

0920-09CJ

Contact Information

**CDC Mentor:
Samantha Williams, PhD
Research Psychologist
Division of STD Prevention**

**Project Officer:
Madeline Y. Sutton, MD, MPH
Team Lead, Minority HIV/AIDS Research Initiative
Division of HIV/AIDS Prevention**

**National Center for HIV/AIDS, Viral Hepatitis, STD, and TB
Prevention
Division of HIV/AIDS Prevention/Epidemiology Branch
Centers for Disease Control and Prevention
1600 Clifton Road NE, Mailstop E-45
Atlanta, GA 30333.**

**Voice: (404) 639-1814
Fax: (404) 639-6127
Email: msutton@cdc.gov**

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Title

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Supporting Statement

Section

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention requests approval for a new data collection called "Promoting HIV Testing among Low Income Heterosexual Young Adult Black Men" for 2 years. This project is not funded through ARRA funds.

Background

This project is one of the group of 8 studies within the Minority HIV/AIDS Research Initiative (MARI), which seeks to support junior investigators who are doing HIV/AIDS research in disproportionately impacted African American and Hispanic communities in the United States. The 8 MARI projects are: 1) "Evaluation of Pharmacy Syringe Access Linked to HIV Testing in Black and Hispanic IDU's", 2) "Preventing HIV Risk Behaviors in Hispanic Adolescents", 3) "Family and Cultural Impact on STD and HIV Risk Among Latino and African-American Youth", 4) "Exploring HIV Prevention Communication among Black Men who have Sex with Men in NYC", 5) Sexual Risk Taking Among Young Black Men who have Sex with Men: Exploring the Social and Situational Contexts of HIV Risk, Prevention and Treatment(Brothers Connect), 6) "Promoting HIV Testing among Low-Income Heterosexual Young Adult Black Men" (The Beats Project), 7) Empowering Latinas to Lash out Against AIDS (ELLAS), 8) HIV Testing Factors among Rural Black Men (HITFARM).

This request is for "Promoting HIV Testing among Low-Income Heterosexual Young Adult Black Men" (The Beats Project)." This study will be conducted by St. John's University and will focus on young adult Black men who have recently been arrested and/or released from jail/prison. Men with a history of arrest and/or jail/incarceration are at high risk for HIV infection. Prevalence rates of HIV are 8-10 times higher among those who are incarcerated than those in the general population (Hammett, Harmon and Maruschak, 1999). The rate of having ever gone to prison is six times higher for Black men (17%) compared to white men (3%) (Bureau of Justice Statistics, 2007a). Therefore, the BEATS project will collect data from young, non-Hispanic Black men who have been recently arrested/released from jail/prison.

The BEATS Project data collection will take place in Queens (St. John's location) and Brooklyn (Fortune Society location), New York and has two main objectives: 1) to identify attitudes toward HIV testing, socio-cultural norms, and behavioral factors which may influence participant willingness to take an HIV test in the next 6 months (intention) and history of HIV testing (behavior), and 2) to use the information gained through qualitative interviews, quantitative surveys, and focus groups to inform the development of tailored educational materials that promote HIV testing and are packaged to appeal specifically to Black (non-Hispanic), heterosexual men ages 18-25 who are recently arrested and/or released from jail/prison.

To be eligible for this study, the men should have been arrested and/or spent time in jail or prison. There is no time served requirement. The only requirement is that the arrest/incarceration should have been in the past year. Jail is defined as doing time in a city correctional facility. Prison is defined as doing time in a federal or state correctional facility.

This request is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241) (Attachment 1).

Privacy Impact Assessment

The Principal Investigator and Project Coordinator will be the only staff members with access to participant information. Participant information and other contact information will be kept in a secure location at St. John's University, based in Queens, New York, in a locked file cabinet and in password protected files. This information will not be transmitted to CDC. This project collects sensitive and personally identifiable data. Names and contact information will be collected by local study staff to contact participants about study appointments. Other personal identifiable data collected are age, gender, race, and ethnicity. The grantee, St. John's University collects the information. Contact information will be destroyed following the appointment for participation in an interview, survey, or focus group. All data will be identified by code numbers. No quantitative surveys, demographic surveys, or audio transcripts will contain participant names. The only link to respondents' names will be consent forms, to be housed in a locked file cabinet separate from all data forms. Surveys will be labeled with a unique pre-assigned code to identify the computer-stored data. All computers will be stored in a locked file cabinet separate from any information linking the respondents to the

data. All electronic databases will be password protected, and access will be limited to key study staff.

Overview of the data collection system

The study will be conducted in three phases: qualitative interviews, quantitative surveys, and focus groups. In Phase 1, local investigators will conduct qualitative interviews with 20 non-Hispanic black, heterosexual men, ages 18-25, who are recently arrested and/or released from jail/prison and meet screening criteria. In Phase 2, 250 non-Hispanic black heterosexual men, ages 18-25, who meet screening criteria will be administered computer-assisted surveys. Each survey will last approximately 30 minutes. During Phase 3, educational materials promoting HIV testing will be developed and pilot tested in focus groups (3 groups of 8 each) of young black men who meet screening criteria to evaluate the acceptability of the materials. Additional details about the study phases and data collection are in Supporting Statement, Part B.

Items of Information to be collected

Though St. John's study team members for these evaluations may temporarily have access to individually identifiable information (IIF), none of this information will be shared with or accessible to CDC investigators. In Phase 1, the data elements for the qualitative interviews will include questions related to: experiences being a Black man, experiences in jail/prison, sexual experiences, health care experiences, HIV knowledge and HIV testing. In Phase 2, the data elements will include questions related demographics and behavioral information for the men who do the computer survey. In Phase 3, the data elements will include feedback from the men regarding HIV prevention and testing tools that may be developed for use with other young, Black men recently arrested/released from jail/prison. Attachment 3a-3i provides details of data elements to be collected.

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.

2. Purpose of Use of the Information Collection

This information contributes to CDC's Mission to support the development of effective, scientifically based HIV prevention interventions for minority populations. The information collected

in the proposed data collection is the minimum amount of information needed to complete the proposed study.

The practical utility of this information collection is to generate knowledge about factors that may influence HIV testing attitudes and behavior among heterosexual young adult Black (non-Hispanic) men who have been recently arrested and/or released from jail/prison. In addition, the culturally-tailored and gender-specific HIV testing educational materials developed through this study may have utility in increasing the number of men in this population who are HIV tested and become aware of their HIV status.

The study will help toward (1) increasing the number of behavior prevention interventions proven effective for young, non-Hispanic Black men who have been recently incarcerated, (2) increasing the number of young, non-Hispanic Black men who consider HIV testing upon release in an effort to potentially decrease the community impact of unknown status and possible ongoing HIV transmission.

Privacy Impact Assessment Information

This information is being collected in order to inform further development and implementation of tailored HIV prevention interventions for young, Black men who are recently arrested and/or released from jail. These programs will be focused on reducing disparities in HIV infection between non-Hispanic Black and non-Hispanic white populations.

Results from the proposed study will be disseminated through journal publications and scientific presentations. In addition, the investigator will present findings from the study to community agencies in New York City that serve Black men who are recently arrested and/or released from jail/prison. This forum will serve as a platform for informing service workers and community stakeholders about the results of our research and to receive feedback on the implications and future direction of the research. In addition, the finalized tailored educational materials will be sent to agencies that provide services to young adult Black men who are recently arrested and/or released from jail/prison. Future research will be developed based on findings from the proposed study to test the efficacy of the tailored HIV educational materials, including collection of HIV testing rates pre and post introduction of the tailored educational materials.

Participants will be advised that the information will not be shared beyond what was revealed to them in their consent form. Research project staff will ensure that there will not be any perception of coercion. Participants will be informed that this project voluntarily and will know that they can choose to discontinue at any time even after enrollment.

3. Use of Improved Information Technology and Burden Reduction

Interviews and focus groups will be digitally recorded and transcribed, and written notes will be taken by study facilitators. The use of an A-CASI system will reduce the time need to complete the surveys and will thereby reduce the burden on the public. Electronic reporting has advantages for ensuring respondent privacy and streamlining the data collection process.

Other steps will be used to reduce the burden on respondents. The computer programs will allow participants to select for an audio assistant to read the questions and answer options. To ensure appropriate targeting of our methods to our study population, and further reduce burden, the methods have been developed with feedback from a Community Advisory Board composed of HIV prevention workers in the NYC area, individuals experienced with re-entry populations, and Black men with a history of incarceration.

4. Efforts to Identify Duplication and Use of Similar Information

This information collection does not duplicate any other effort. This is no similar data collection in progress for or about young, non-Hispanic Black men who have been recently arrested or released from jail or prison in New York City. St. John's University is not funded by other sources to do similar projects.

5. Impact on Small Business or Other Small Entities

This information collection will not have an impact on small businesses or other small entities.

6. Consequences of Collecting the Information Less Frequently

Each phase of the proposed study is a different one time data collection. Each participant will complete one interview, survey, or focus group meeting. Each phase collects different information and will be used to inform later parts of the study and development of HIV education materials.

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

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

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

A 60 day notice to solicit public comments was published in the Federal Register on September 1, 2009(Attachment 2).

No comments were received.

9. Explanation of Any Payment or Gift to Respondents

Participants will be given a gift card as a token for being part of the study: \$40 for interviews, \$25 for surveys, and \$50 for focus groups (focus groups will take 2 hours to complete, so focus group token is \$25 per hour). Tokens are intended to address the burden on the respondent for coming to the study site and completing the study. The different amounts are reflective of the varying burdens on the respondent for participating in different phases of the study. The tokens are being offered to justify the hours spent completing assessments and to maximize retention to ensure overall quality for the study and results. Tokens will also encourage participation among the target population of heterosexual, young adult Black men who have recently been arrested and/or released from jail/prison. High participation is important for adequate and timely recruitment and will improve the quality of the results.

While tokens of appreciation will be utilized for the phases of this study, there is no intention to continue their use once the study is proven to be effective and widely adopted, disseminated and continually evaluated.

10. Assurance of Confidentiality Provided to Respondents

Privacy Impact Assessment Information

A. The Privacy Act does not apply to this request.

The protocol titled "Promoting HIV Testing among Low Income Heterosexual Young Adult Black Men", has been approved by the St. John's University IRB on May 19, 2009 and will expire on May 19, 2010. This project also received an NCHSTP Project

Determination confirming CDC as non-engaged on June 4, 2009 (Attachments 6a and 6b).

This project collects sensitive or personally identifiable data. Individually identifiable information (IIF) will be collected by the research staff at St. John's University to conduct the study. Names and contact information will be used by study staff to contact participants about interview, survey, or focus group appointments.

Other personal identifiable data collected are age, gender, race, and ethnicity. The grantee, St. John's University, collects the information. This information is not transmitted to CDC. 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 future interventions.

Analysis of the dataset will take place at St. John's University. If any data are shared with CDC it will be de-identified and transferred securely to CDC on a disk.

Risks will be minimized by notifying potential participants of the nature of the subject matter during recruitment and the informed consent process. It will be stressed that their participation is completely voluntary and in no way will affect their participation at the community agencies which support recently arrested/released men from jail/prison and/or their probation/parole. They will be told of their right to withdraw at any time or refuse to answer any questions. In addition, participants will be assured that their answers will be kept private. The interview/focus group facilitators will have been trained by the PI to use appropriate methods of interviewing skills, such as building rapport with participants and answering questions. Confidentiality, participants rights to refuse to answer questions and withdraw, the nature of the questions to be asked, informed consent, and handling adverse situations will also be covered during the training. Interviews and focus groups will take place in private rooms at a community agency which supports recently arrested/incarcerated men in Brooklyn, New York or study site at St. John's University in Queens, New York.

In order to guard against the loss of confidentiality, names and other identifying information will be deleted from the qualitative transcripts.

B. How the information will be secured.

All interview/focus group audio and notes will be labeled with a unique code number that is pre-assigned by the PI. This unique code will be used throughout the study to identify the data. The labeled notes and audio will be stored in a locked file cabinet. No information linking the respondent to the data (e.g., consents) will be housed together. Computer data will be stored in a password-protected file and accessible only to key project staff.

Interview/focus group session audio will be downloaded to a secure site and sent to an independent contractor for transcription. All transcripts will be labeled with the same identifier as the audio. Once transcriptions have been completed, they will be reviewed and cleaned, removing any information identifying the respondent by name or situations that compromise the integrity of the interviewee privacy. Once data collection is complete, all demographic information will be input into an SPSS file.

Electronic databases containing demographic data, survey responses, field notes, and analytic constructs (e.g., codes) will be kept in a password-protected file in a locked office at the study site. Access to these databases will be password protected and limited to the PI and key study personnel.

C. Opportunities for obtaining respondent consent.

Informed consent will be obtained before participants are enrolled in the individual interviews, surveys, and focus groups. At the beginning of each interview, survey, or focus group session, study staff will be available to distribute and read consent forms individually to the participant(s) to ensure uniformity in delivery (Attachment 4).

D. Indicate whether respondents are informed about the voluntary or mandatory nature of their response.

Participants provide written informed consent to participate in the study (Attachments 4). The consent forms indicate that the participant is voluntarily joining the study, and not taking part in the study will not have any effect on any community-based services they receive or their probation/parole status. They are also free to skip any questions they do not wish to answer or to leave the study at any time.

11. Justification for Sensitive Questions

During screening for eligibility, potential participants will be asked if they have been arrested or released from jail/prison within the past year (yes/no), if they identify as Black (yes/no), if they have been sexually active with a woman in the past 6 months (yes/no), and where they currently reside (list). Individuals will also be asked to respond to the following sequence of questions by providing a yes/no statement in response to all four items (1- are they of Hispanic origin (yes/no), 2- are they HIV negative 3- do they consider themselves heterosexual and 4- have they been arrested for a sexual offense).

These sensitive screening questions are necessary to determine eligibility for the study, since the study's purpose is to study attitudes and behaviors about HIV testing unique to young adult, heterosexual, non-Hispanic Black men who have recently been arrested or released from jail/prison. Selecting Black men who are HIV negative or unaware of their HIV status is integral to the study purpose. Sex offenders are excluded because they must register in their county as a sex offender. Such information is made available to the public and could compromise our ability to keep the offenders' reported behaviors confidential.

During the interview, participants will be asked about sexual experiences, racial identity, and experiences with jail/incarceration. These questions are important for describing factors that influence HIV testing attitudes and behavior. All participants will also be asked to complete an anonymous demographic survey, which includes questions about racial and ethnic background, jail/prison history, and sexual behavior. This information is necessary to characterize the study population, and knowledge of respondent characteristics will help in the development of prevention materials.

12. Estimates of Annualized Burden Hours and Costs (#14-16)

A.

St. John's University research staff will screen 30 young, non-Hispanic Black men to participate in the Phase 1 in-depth interviews during the first year. The 30 men will take part in a 10-minute screening interview to assess study eligibility. Of the total number screened for eligibility, approximately 20 men are expected to participate in the Phase 1 interviews, which are expected to take 1.5 hours to complete.

St. John's will then screen 300 young, non-Hispanic Black men to participate in the quantitative ACASI survey for Phase 2. The

screeners will take 10 minutes to complete to assess eligibility. Two hundred-fifty participants will spend approximately 30 minutes completing the ACASI survey in Phase 2. For Phase 3, 40 young, non-Hispanic Black men will be screened to participate in focus groups to review tools developed specifically for young, Black men, recently incarcerated or released. The screener will take 10 minutes per persons. Twenty-four men who participate in the focus groups will participate in a discussion moderated by a researcher using the focus group script. The estimated time for the focus groups is 2 hours.

Type of Respondents	Form name	Number of Respondents	Number of Responses per Respondents	Average Burden per Responses (hours)	Hours
General public	Screener for one-on-one interviews	30	1	10/60	5
General public	One-on-one interviews	20	1	1.5	30
General public	Screener for surveys	300	1	10/60	50
General public	Surveys	250	1	30/60	125
General public	Screener for focus groups	40	1	10/60	7
General public	Focus groups	24	1	2	48
Total					265

B.

Annualized cost to respondents for the burden hours is provided in Exhibit A.12.B. The estimates of hourly wages were obtained from the Department of labor.

Exhibit A.12. B: Estimated Annualized Burden Costs

Type of Respondent	Total	Hourly Wage	Total
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	Burden hours	Rate	Respondent Cost
General public-Screener for one-on-one interviews	5	\$20.23	\$101
General public-one-on-one interviews	30	\$20.23	\$607
General public-screener for surveys	50	\$20.23	\$1012
General public-surveys	125	\$20.23	\$2529
General public-screener for focus groups	7	\$20.23	\$142
General public-focus groups	48	\$20.23	\$971
Total	265	\$20.23	\$5,362

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

There are no costs to respondents other than their time.

14. Annualized Cost to the Federal Government

Government costs are estimated based on staff hours worked in an effort to prepare and revise the OMB package.

Exhibit A.14: Estimates of Annualized Costs to the Federal Government.

The cost of the project for the 2 years is estimated to be \$599,652 The annual cost is summarized in Exhibit A.14.

Expense Type	Expense Explanation	Annual Costs (dollars)
(Funding agency name)	Interagency agreement with CDC	\$247,000 (These are the total costs)
Direct Costs to the Federal Government	CDC Project Officer/Co-Principal Investigator (GS-14, .25 FTE)	\$35,326

	CDC -MARI Team Lead (Commissioned Corps Officer, T-05, .10 FTE)	\$13,000
	CDC Research Assistant (50%)	\$2,000
Operational	Equipment, travel, support staff, printing, etc	\$2,500 for travel
	Subtotal, Direct Costs to the Government	\$210,826 (Only direct costs)
	TOTAL COST TO THE GOVERNMENT	\$299,826 (includes direct and indirect costs)

Salary estimates were obtained from OPM salary scale (include web address).

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Exhibit A.16: Project Time Schedule

Activity	Time Schedule
Hire and train interview staff	1 month after OMB approval
Participant recruitment	1 month after OMB approval
Data collection and quality assurance	1 month after OMB approval
Transcribe interviews	2 months after OMB approval
Review interviews for themes to inform survey development	2 months after OMB approval
Edit survey instrument	2-3 months after OMB approval
Cognitive interviews to finalize survey	3 months after OMB approval
Submit IRB amendment to protocol	3-4 months after OMB approval
Complete formal qualitative analyses of interviews	3-4 months after OMB approval
Manuscript preparation of qualitative data	5-6 months after OMB approval
Hire and train survey research staff	6 months after OMB approval
Participant recruitment	6 months after OMB approval

Data collection and quality assurance	6-20 months after OMB approval
End of data collection; Report drafting	24 months after OMB approval

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

No exception is requested.

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

No exception is requested.