

**“Exploring HIV Prevention Communication Among Black Men Who Have
Sex with Men in New York City: Project BROTHA”**

0920-XXXX

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Date: June 16, 2010

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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 "Exploring HIV Prevention Communication Among Black Men Who Have Sex with Men in New York City: Project BROTHA" for 2 years. This project is not funded through ARRA funds or through the Health Reform Act.

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 new request is for "Exploring HIV Prevention Communication among Black Men who have Sex with Men in NYC (Project BROTHA)."

Data show that compared to their white and other minority counterparts in the United States, Black men who have sex with men (BMSM) experience higher and disproportionate HIV infection rates. BMSM in the United States are more than twice as likely to be HIV-positive as white and Latino MSM (CDC, 2005). Among young African American MSM in the United States(ages 15-22), 9 out of 10 HIV+ young African American MSM compared to 6 out of 10 HIV+ white MSM were unaware of their HIV infection. African American MSM are also much more likely to have sex with women than other MSM, and their female partners are usually unaware that these men are MSM because African American MSM may not

self-identify as gay or bisexual despite having sex with other men (Millett, 2005).

The objectives of the present study are to: 1) understand and describe communications among BMSM regarding HIV status and sexual identity and how this communication is affected by the stigma associated with both status and identity, 2) examine barriers as well as facilitators to HIV testing for BMSM, and 3) explore the role that one's social networks may play in the dissemination of information about HIV, HIV testing and HIV treatment.

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 the enrollment location—the Center for HIV Educational Studies and Training (CHEST), based in lower Manhattan, New York, in a locked file cabinet and on password protected files. Participants who enroll at the upper Manhattan location will have their files secured on a password-protected file, and the PI will retrieve these files weekly to be stored in his locked CHEST office. This information will not be transmitted to CDC. This project collects sensitive and personally identifiable data, such as names and contact information. Participants' names and contact information will be kept in a separate locked file. There will be a separate list that links the participant's name with their unique identifier in case a participant is ever needed to be contacted about information or results from the study. Other personal identifiable information collected includes age, sexual identity, educational background, race, and ethnicity. The grantee, Kingsborough Community College of the City University of New York, collects the data. The main purpose for collecting this information is to characterize the participants in the study. Knowledge of participant characteristics will assist with the design and targeting of future interventions for BMSM.

Overview of the data collection system

Men will be recruited to participate and visit either the CHEST location in lower Manhattan or the Gay Men of African Descent (GMAD) location in upper Manhattan, New York. After screening

for eligibility, a total of 300 BMSM and other MSM in their social networks will be enrolled in 2 phases with 100% electronic data collection: (1) 350 BMSM will be recruited and screened to find 100 eligible BMSM participants, and (2) the 100 first phase participants will then recruit 200 other MSM within their social networks to participate in the second phase. Quantitative surveys will be administered 100% by computers, and personal interviews will be conducted to collect qualitative data (at baseline and 3-month follow-up) with 100% digital recording/electronic data collection. Participants in both phases will be offered rapid HIV testing, and declining an HIV test will not negatively impact their study participation. Additional details about the study phases and data collection are in Supporting Statement, Part B.

Items of Information to be collected

If found to be eligible after screening, participants in both phases will be asked to complete a computer assisted survey which contains measures that ask for demographic information (e.g., age, sexual identity, educational background) and assess psychosocial and behavioral issues (i.e., drug use, unsafe sex, gay-related stigma, HIV-related stigma, gay community attachment, and ethnic community attachment, condom comfort) along with behavioral intention to test for HIV among BMSM. The survey will be administered in a private room through the Audio CASI system (ACASI) and should take 45 minutes to complete.

The interview will include items that request information on the participant's conversations about HIV prevention and testing, barriers and facilitators to testing (including preferred testing methods), contexts for and methods of exchanging information about HIV prevention and testing, as well as who the most important person is in his social network and why. After the participant completes the assessment, he will be asked if wants to receive an HIV test. If he answers "yes," he will be provided with the HIV counseling and testing (C&T) session based on New York State Guidance for HIV Counseling and Testing and state-approved HIV Testing Protocol (New York State Department of Health, 2006).

All participants will be asked to return in 3 months to complete a follow-up assessment consisting of a shorter ACASI survey and interview, followed by HIV testing if desired.

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 prevention interventions for minority populations. Specifically, the information from this project will be used to develop health communication and behavioral interventions to reduce HIV/AIDS among Black Men who have sex with men (BMSM) in a large, urban area, such as NYC. The information collected in the proposed data collection is the minimum amount of information needed to complete the proposed study. The limits to generalizability of this study are that the findings of this study will apply to BMSM and other MSM living in or near urban centers.

The study will help toward (1) a better understanding of the underlying behavioral factors contributing to the high HIV/AIDS infection rates of BMSM, (2) increasing the number of HIV/AIDS behavioral intervention for BMSM and (3) increasing the number of BMSM in who are tested for HIV/AIDS.

The practical utility of this information collection is to generate knowledge about the content and context of messages being conveyed about HIV prevention and HIV testing among Black men who have sex with men and their social networks. Findings will provide information on how this type of interpersonal communication may relate to HIV testing opinions and behaviors. Results from the HIV testing component of this study will have significant implications for the public health of this population since new HIV testing rates will be determined in a new sample of BMSM and other MSM. Information from this study will help inform HIV prevention and testing efforts as well as social marketing and clinical interventions that are currently being developed at CDC. Without these data, CDC's campaigns for BMSM will be less culturally appropriate and likely have decreased success.

The results of this information collection will be analyzed and reported in scientific publications in peer-reviewed scientific and public health journals and presented in abstract form at scientific and public health meetings. To ensure study findings are disseminated to audiences who need the information, such as health professionals, HIV prevention program leaders and staff, and community members, study findings will also be announced in press releases and presented at local events such as town hall

meetings; “grand rounds” of local hospitals, medical schools, and research centers; and local professional conferences. In addition, we plan on using study findings to inform the development of a study to test the feasibility and efficacy of a motivational interviewing-based intervention to increase HIV prevention communication and HIV testing among BMSM as part of the CDC portfolio of interventions for BMSM.

Privacy Impact Assessment Information

This information is being collected in order to better understand the specific messages being conveyed about HIV prevention and HIV testing among Black men who have sex with men and their social networks. Findings will provide information on how this interpersonal communication may relate to HIV testing behaviors. This information will be used to inform HIV prevention and testing efforts as well as social marketing and clinical interventions.

The study will allow men to enroll at 2 sites (CHEST in lower Manhattan and GMAD in Harlem, New York) for convenience to the participants, and also to further protect participant’s privacy when participating in this study. Participants can choose to take part in the study at a location they believe is not frequented by anyone in their social or sexual network who is not already part of the study. To protect data security, ID numbers will be assigned to data. Information linking personal identifiers to ID numbers will exist only in a binder in a locked file drawer and only the Project Director for this study and the Director of Operations at CHEST will possess keys to this drawer. Further, de-identified data will be stored on the Project Director’s computer and will be password protected.

Individually identifiable information (IIF) will be collected by the research staff at CHEST and GMAD to conduct the study. It will be used by study staff to contact study participants about follow-up appointments.

No IIF will be available to or shared with the CDC. Analysis of the dataset will take place at CHEST. Summary data without identifiers will be made available to the CDC project officers at their request. If any data is shared with CDC it will be de-identified before being securely transferred to CDC.

3. Use of Improved Information Technology and Burden Reduction

One hundred percent of this data collection will be electronic. All self-report measures will be administered via the ACASI, using a computer and voice recordings so that the participant hears through headphones and sees on the screen each question and response list. Responses are entered directly into the computer. ACASI has been found to be an effective method for people of diverse educational backgrounds, and eliminates the effects that reading ability has on internal validity. This system has been demonstrated to provide reliable and valid data also reduces public burden by helping them through the survey process more quickly.

Interviews will be digitally recorded with participant consent. After transcription of the qualitative data, data from interviews will be entered immediately by the RA into a CASI system, so that data can be merged. Data will be downloaded from the CASI computers daily and merged in a centralized database coordinated by the PI. All digital data files will be password-protected and stored on CD-R discs and/or flash drives, which will also be password-protected. Paper and digital files (on CDs and/or flash drives) will be stored in locked cabinets with access for research study staff only.

As with all study data, project implementation data will be password-protected and stored in the Principal Investigator's and Project Coordinator's office computer. These data files will also be protected behind a computer network firewall.

4. Efforts to Identify Duplication and Use of Similar Information

This information collection does not duplicate any other federal effort. This is no similar data collection in progress for or about BSM and their networks in New York City. The PI is not funded by other sources to do similar projects.

5. Impact on Small Business or Other Small Entities

No small businesses will be involved in this data collection.

6. Consequences of Collecting the Information Less Frequently

BSM study participants and their MSM network associates will be asked to complete the 45 minute survey and 75 minute personal interview. All participants will be asked to return 3 months later for a 30 minute survey and 45 minute interview.

The 3 month follow-up is necessary to assess any changes to information provided during the baseline assessment, such as any changes in HIV prevention communication, reported risk behaviors and psychosocial factors. More importantly, the follow-up component will provide an opportunity to measure change in intention to test for HIV from baseline to follow-up. There are no legal obstacles to reduce the burden.

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 April 26, 2010, volume 75, page 21630 (Attachment 2).

No comments were received.

9. Explanation of Any Payment or Gift to Respondents

In order to facilitate adequate recruitment within the study timeline, each participant will be given \$60 as a token for the enrollment visit (2 hours total, or \$30 per hour for \$60 total). This token was determined by consulting with recruitment coordinators of other projects around NYC who explained that this is an appropriate amount for a 2 hour burden on participants' time, to reduce attrition at the 3 month-follow-up visit, and facilitate recruitment throughout the study.

The first 100 BMSM participants (seeds) will also receive a \$20 cash token for each time one of their referrals ("network associate" [NA]; maximum of 2 referrals per seed) qualifies, enrolls, and completes the study at either GMAD or CHEST. It is estimated that each time a seed tells a NA about the study for a referral, it will take about 30 minutes. So, the BMSM seeds have the potential to receive a total of \$100 (2 hour enrollment + 1 hour to facilitate 2 completed NA referrals) over the course of the study. The potential \$100 token for the 100 BMSM seeds is approximately \$33 per hour of time (3 hours total) for participating in the study. Each time an NA presents himself to participate in the study (after eligibility screening by phone),

presents a numerically-coded coupon, and completes the study, the initial seed will receive the \$20 token for encouraging the NA to participate. Each NA will receive the standard token of \$60 for completing the assessment and will not be eligible for the \$20 referral token.

There will not be a separate token for HIV testing occurring after the assessment. The token payments detailed above will be provided whether or not a participant decides to submit to HIV testing. By not incentivizing HIV testing, we will be able to truly measure the relationship between intent and actual testing behavior without the token acting as a mediator or moderator.

While tokens of appreciation will be utilized for 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

The privacy Act Assessment does not apply to these data, as no data are coming to CDC, and CDC is not engaged as part of this research.

This project collects sensitive or personally identifiable data. Individually identifiable information (IIF) will be collected by the research staff at CHEST and GMAD to conduct the study. Names and contact information will be used by study staff to contact study participants about follow-up appointments. The study will be conducted at both sites for convenience to the participants, and also to further protect participant's data security when participating in this study. Participants can choose to take part in the study at a location they believe is not frequented by anyone in their social or sexual network who is not already part of the study.

Other personal identifiable data collected are age, gender, race, ethnicity, and sexual identity. The grantee, City University of New York, collects the information. The information is not transmitted to CDC. The main purpose for collecting this information is to characterize the participants in the study. Knowledge of participant characteristics will assist in the design and targeting of future interventions.

No sensitive or personal information will be available to or shared with the CDC. Analysis of the dataset will take place at CHEST. If any data are shared with CDC, it will be de-identified and transferred securely to CDC on a disk.

The protocol titled "Exploring HIV Prevention Communication Among Black Men Who Have Sex with Men in New York City: Project BROTHA", has been approved initially by the Kingsborough Community College IRB on October 20, 2009. The PI has a joint academic appointment at both Kingsborough Community College and Hunter College; this protocol is being covered by Kingsborough Community College only. This protocol was renewed on May 18, 2010 for the maximum allowable period of one year and it will expire on May 17, 2011 (Kingsborough Community College) (Attachment 6a). This project also received an NCHHSTP Project Determination confirming CDC as non-engaged on July 24, 2009 (Attachment 6b).

A. How the information will be secured.

Once participants enter the study, they will be assigned an identification (ID) number that contains no personally identifying information. The ID number will be used in place of the participant's name for all data collection. The participant's name will not appear on any forms (unique ID numbers only), audio recordings or computer data. Information that links the participant's name to their study identification will be kept in a double password protected electronic file on the project director's computer within a locked office. Information linking personal identifiers to ID numbers will exist only in a binder in a locked file drawer and only the Project Director for this study and the Director of Operations at CHEST will possess keys to this drawer. De-identified data will be stored on the Project Director's computer and will be password protected.

Interview tapes will be compiled and then shipped through a reliable service (e.g., Federal Express) to an outside service, ANP Transcription Services. ANP subscribes to all rules and regulations documented under HIPAA, medical privacy. All sensitive materials are kept private throughout the entire transcription process as each ANP employee is required to agree to ANP's rules of data security. Tapes will be promptly returned to CHEST through a reliable source (e.g. Federal Express). All transcripts will be uploaded by ANP to a secure FTP server as a Word document for retrieval by CHEST. Upon quality assurance

verification by CHEST staff, document files will be loaded into NVIVO software located on the Project Director's computer for analyses. At the end of the study period the audio tapes will be destroyed.

B. Opportunities for obtaining respondent consent.

After eligibility screening, a participant is further screened for mental health status in order to determine ability to provide proper informed consent.

Participants who are confirmed to be eligible and interested in study participation will be taken through the informed consent process and will be provided with a consent form to review as the project staff person reads it to him (Attachment 4a). A separate consent page for allowing audiotape recordings to be used after transcription will be presented along with original consent form (Attachment 4b). Any questions a potential participant has related to the consent forms will be answered by the project staff person. Upon signing the consent forms, a participant is enrolled in the project.

The HIV testing phase of the study occurs after the enrollment assessment. If the participant decides to receive HIV testing after the assessment phase of the study (including quantitative and qualitative data collection), the project staff member will review a separate consent form for HIV testing (as required by the New York State Department of Health) with the participant, which includes risk-reduction counseling. If the participant decides not to test immediately after assessment, he will be told that he will have another opportunity to receive HIV testing in the 3-month follow up. HIV testing consent will then be reviewed with the participant at follow-up.

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

Participants provide written informed consent to participate in the study (Attachment 4a and 4b). The consent forms indicate that the participant is voluntarily joining the study and there are no mandatory requirements that they join the study. They are also free to leave the study at any time.

11. Justification for Sensitive Questions

The study asks participants questions of a sensitive nature, regarding race and ethnicity, age, education level, and sexual

identity. These are needed to accurately describe the underlying characteristics of the participants. Future prevention programs and studies will need this information to best design and target interventions. Other questions asked or topics raised during the assessments and interviews may also be of sensitive nature, such as experiences with HIV-related stigma, perceiving one's own sexual risk, revealing any past HIV testing experiences, sexual identity and related stigma, and drug use. These questions are necessary to determine how these psychosocial and behavioral issues affect HIV prevention and testing communication. Information about past testing experiences is necessary to understand HIV testing intents and behaviors.

12. Estimates of Annualized Burden Hours and Costs

A.

There are 2 types of respondents, BMSM and other MSM from their social networks, but all respondents will participate in the same assessments. A total of 300 BMSM and other MSM in their social networks will be recruited in 2 different phases. For the first phase, we expect to recruit and screen 350 BMSM in order to find 100 who will be eligible for the study. These men will be recruited via active and passive recruitment methods at specific venues in-person and online and at special community events. The 100 BMSM eligible in the first phase will then recruit 200 other MSM from within their social networks to participate in the second phase of the study. We anticipate that the phase I BMSM will have to recruit 400 men in total in order to find 200 eligible for the study. In total, 750 men will be recruited and screened in order to finalize a sample of 300 eligible BMSM and other MSM.

Men will complete a 5-minute eligibility screening interview. For the baseline assessment, the computer-based survey will take approximately 45 minutes to complete for those who agree to participate in the study. The qualitative interview will take approximately 75 minutes to complete. We estimate that 2/3 of participants will consent to receive HIV testing at baseline. HIV counseling and rapid testing will take 45 minutes to complete.

Study participants will be requested to return for a follow-up survey and interview 3-months post-baseline. The follow-up survey will take approximately 30 minutes to complete; the follow-up qualitative interview will take approximately 45 minutes to complete. We again estimate 200 will consent to HIV testing, accounting for those who did not test at baseline and

those who do not consent to test at follow-up. As previously mentioned, HIV counseling and rapid testing will take 45 minutes to complete.

The total response burden for the 1-year data collection period is estimated to be 1338 hours.

Table 12.A Estimate of Annualized Burden Table

Estimated Burden Hours:					
Type of Respondents	Form Name	Number of respondents	Number of responses per respondent	Average burden per Response (Hours)	Total Burden (Hours)
BMSM/MSM volunteers	Screening	750	1	5/60	63
	A-CASI Baseline	300	1	45/60	225
	Interview Baseline	300	1	1.25	375
	HIV Testing & Counseling Baseline	200	1	45/60	150
	A-CASI 3 month Follow-up	300	1	30/60	150
	Interview 3 month Follow-up	300	1	45/60	225
	HIV Testing & Counseling 3 month Follow-up	200	1	45/60	150
	Total:				

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, year 2009 estimates at (<http://www.bls.gov/ncs/>) and represent the average hourly wages for adults across all walks of life.

Exhibit A.12. B: Estimated Annualized Burden Costs

Type of Respondent	Total Burden	Hourly Wage Rate	Total Respondent
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	hours		Cost
BMSM/MSM volunteers (who complete each component at baseline and 3-month follow-up, with 1 HIV test)	1338	\$20.23	\$24,033.20
Total	1338		\$27,067.74

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

There are no costs to respondents or record keepers.

14. Annualized Cost to the Federal Government

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

Expense Type	Expense Explanation	Annual Costs (dollars)
(Funding agency name)	Cooperative agreement with CDC	\$255,200
Direct Costs to the Federal Government	CDC Project Officer (GS-15, .10 FTE)	\$15,000
	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)	\$31,000
	Subtotal, Direct Costs to the Government	\$316,200 (only direct costs)
	TOTAL COST TO THE GOVERNMENT	\$366,000 (includes direct and indirect costs)

Salary estimates were obtained from OPM salary scale (<http://www.bls.gov/ncs/>).

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
Participant enrollment	1-12 months after OMB approval
Preliminary data analysis	12-16 months after OMB approval
Recruitment catch-up	16-18 months after OMB approval
Final data analyses	19 months after OMB approval
Dissemination of results	20 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

There are no exceptions to the certification.