Section B: Statistical Methods

OMB control # 0920-07AD

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

August 31, 2007

PROJECT OFFICER:
Donata R. Green, Ph.D.
Centers for Disease Control and Prevention
Division of HIV/AIDS Prevention
8 Corporate Blvd.
Mail Stop E-49, Room 5020
Atlanta, GA 30329
(404) 639-3869 office
(404) 639-2007 fax
dqg7@CDC.GOV

B. STATISTICAL METHODS

1. Respondent Universe and Sampling Methods

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. Qualitative methods are well suited to this kind of research because they allow flexible, in-depth exploration of individual perceptions and experiences. In addition, both individual and group interviews yield descriptions in participants' own words. By design, qualitative interviews allow flexibility to pursue relevant and important issues as they arise during a discussion. Unlike quantitative survey methods, in which questions must be asked in the same way and the same order to ensure comparability of findings, qualitative methods allow researchers to tailor their approach and to be sensitive to the needs, interests, and concerns of each participant.

Furthermore, a qualitative approach will allow us to capture subtle nuances in participants' attitudes, beliefs, and feelings related to HIV and HIV testing that would not be practical through quantitative approaches. Our focus group and interview discussion guides include probes to ensure that we obtain input on specific items of interest, while open-ended questions ensure that participants' responses and perceptions are fully addressed and captured.

Our sample will be one of convenience as opposed to probability based. The total estimated sample size for this study is about 216 participants across all twelve cities. Statistical power is not applicable because this is a qualitative study.

2. Study Population

Our study will include a sample of African American heterosexual men, aged 18-44, with less than a 4 year college degree, who make less than $35,000 per year, report having more than one sexual partner in the past 12 months and report having unprotected sex with a woman in the past 12 months. Recruitment criteria for the study population were based on data obtained from the US Census and CDC's HIV/AIDS surveillance data. According to the August 2005 US Census report, "We The People: Blacks in the United States", approximately 85% African Americans 25 and older had less than a 4 years of college education. African Americans were also reported to have a median

income of $30,000 compared with $37,100 for all men. CDC's HIV/AIDS surveillance data (CDC MMWR, 2007) indicated that approximately 48% of the new HIV/AIDS diagnosis occurred among African Americans aged 25-44 years and approximately 44% of these new cases were African American men. By transmission category, most HIV/AIDS diagnoses of African American male adults and adolescents were classified as men who have sex with men, followed by high-risk heterosexual contact, IDU, MSM with IDU, and other. For purposes of this study, we are targeting African American men in the high-risk heterosexual category.

3. Procedures for the Collection of Information

RTI will select and reserve focus group facilities (with CDC's approval) in each of the twelve research cities. RTI will oversee the local focus group facilities' recruitment of participants. At each facility, recruitment staff will sign a confidentiality agreement (**Attachment 8**). In addition, the professional focus group facilities will use the IRB approved screening instrument (**Attachment 7**) to identify eligible participants.

Once initial contact is made with a potential participant, the individual will be told that we are conducting a research study about HIV. Participants will be told that we will need to ask them some personal questions, including questions about their sexual behavior and HIV to see if they qualify for the study. We will then obtain verbal consent from the potential participants to screen them for eligibility. If the potential participant agrees to be asked the verbal screener questions and meets the eligibility requirements, he will be invited to participate in the study, and told the location, time and date of the focus group or interview.

As participants are recruited, recruitment grids will be prepared. The recruitment grids will list the participants' first name and some demographic information obtained from the screener (age, marital status, income, education, and whether or not the person has tested for HIV). The recruitment grids will allow RTI and the focus group facilities to keep track of recruitment. The recruitment grids will be stored in a locked file cabinet at RTI and at each focus group facility. The focus group facilities will destroy their copies of the recruitment grids after data collection is completed in that city. RTI and CDC will have copies of the recruitment grids in order to describe the study sample. These copies

of the recruitment grids will be kept in locked file cabinets at RTI and CDC for the duration of the study.

Recruitment will begin at least four weeks before the focus groups and interviews are scheduled. Once recruitment has begun, RTI will closely monitor the recruitment, helping to troubleshoot as problems arise, and identifying potential problems and/or issues before they arise. RTI will keep CDC apprised of the recruitment progress. If there is a problem with recruiting participants, RTI will work with the facilities and with CDC to make any necessary adjustments.

Personal information from the potential participants will be maintained and protected in a secure manner. At each facility, the screeners will be kept in locked file cabinets. All identifying information (name, address, telephone number) will be recorded on the last page of the screener, which will enable the facility to send reminder letters/emails and make reminder phone calls. The last page of the screener will be torn off and destroyed after the focus groups and interviews are conducted. Local focus group facilities will send the screeners (without the last page) to RTI. The screeners will be stored in a locked file cabinet at RTI throughout the duration of the project. Once the project ends, the screeners will be transferred into a locked RTI storage facility for three years. After three years, RTI staff will destroy the screeners. No identifying information about participants will be kept at the focus group facilities after the groups/interviews are completed and no identifying information will be sent to RTI or CDC.

Reminder letters/e-mails will be sent to potential participants prior to the focus group/interview giving them directions to the facility**.** Confirmation calls will also be made 1–2 days prior to the group/interview to assure that all recruits are confirmed.

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.

For this formative research project, RTI will conduct 12 focus groups and 108 individual interviews with African American heterosexual men. The data collection with be conducted in four rounds (exploratory, message testing, concept testing, and final materials testing) in twelve cities over the course of a one year period. The focus groups and interviews will be conducted in-person at focus group facilities by a professionally trained moderator. Each focus group will be scheduled for two hours and each interview for one hour. In addition to the moderator/interviewer, an additional RTI staff member will attend the focus groups and interviews to take notes on a laptop computer from behind a one-way mirror and to coordinate logistics of checking in participants and obtaining informed consent. CDC staff member(s) may also attend and observe the focus groups and interviews from behind a one-way mirror. All focus groups and interviews will be audiotaped and professionally transcribed. The audiotapes and transcribed documents will be stored in a locked file cabinet at RTI accessible only by select project staff for the duration of the project. At the end of the project, the tapes will be destroyed.

4. Methods to Maximize Response Rates and Deal with Nonresponse

The following procedures will be used to maximize cooperation and to achieve the desired participation rates:

- Recruitment through professional focus group facility recruitment firms.
- Reminder letters/e-mails will be sent with directions to the research site and reminder phone calls placed 1-2 days prior to the scheduled group/interview.
- Provision of honoraria to thank participants for their time and effort in the study.

5. Test of Procedures or Methods to Be Undertaken

To estimate the burden for administering the screening questionnaire, two different project team members were consulted. The project team members conducted mock screening interviews and provided affirmative responses to most or all questions that branched to further follow-up questions. In this way, the burden estimate most closely resembles a maximum average burden, since almost all screening questions were presented in the interview. In addition, the project team members deliberately read each item at a slow rate of speed. The project team members estimated the maximum average

burden to be 10 minutes for the screening instrument. The screening instrument is shown in **Attachment 7**.

6. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Jennifer D. Uhrig
RTI Task Leader
RTI International
3040 Cornwallis Rd.
Research Triangle Park, NC 27709
uhrig@rti.org
919-316-3311

Julia Kish Doto
RTI Deputy Task Leader
701 13th Street, NW, Suite 750
Washington, DC 20005-3967
jkdoto@rti.org
(202) 974-7850

References

Abreu, D.A., & Winters, F. (1999). Using monetary incentives to reduce attrition in the survey of income and program participation. *Proceedings of the Survey Research Methods Section of the American Statistical Association*.

Adimora AA and Schoenbach VJ. 2005. Social context, sexual networks, and racial disparities in rates of sexually transmitted infections. *J Infect Dis, 191 Supplement 1*: S115-22.

Brunswick AF and Flory MJ. 1998. Changing HIV infection rates and risk in an African-American community cohort. *AIDS Care, 10*(3): 267-81.

Centers for Disease Control and Prevention (CDC). 2003a. Advancing HIV Prevention: The Science Behind the New Initiative." http://www.cdc.gov/hiv/partners/AHP/AdvancingFS.pdf. As obtained on November 11, 2005.

Centers for Disease Control and Prevention (CDC). 2005. Cases of HIV Infection and AIDS in the United States. *HIV/AIDS Surveillance Report, 17*: 1-54.

Centers for Disease Control and Prevention (CDC). 2003b. Cases of HIV Infection and AIDS in the United States. *HIV/AIDS Surveillance Report, 15*: 1-46.

Centers for Disease Control and Prevention (CDC). 2007. Racial/ Ethnic disparities in diagnoses of HIV/AIDS--- 33 states, 2001-2005. Morbidity and Mortality Weekly Report (*MMWR), 56,* (9), 189- 192.

Essien EJ, Meshack AF, Peters RJ, Ogungbade GO and Osemene NI. 2005. Strategies to prevent HIV transmission among heterosexual African-American men. *BMC Public Health, 5*: 3.

Essien EJ, Meshack AF and Ross MW. 2002. Misperceptions about HIV transmission among heterosexual African-American and Latino men and women. *J Natl Med Assoc, 94*(5): 304-12.

Fleming, P., R.H. Byers, P.A. Sweeney, D. Daniels, J.M. Karon, and R.S. Janssen. 2002. HIV Prevalence in the United States, 2000 (Abstract). In *Program and Abstracts of the 9th Conference on Retroviruses and Opportunistic Infections*.

Greenbaum, T. L. (2000). *Moderating focus groups: A practical guide for group facilitation*. Thousand Oaks, CA: Sage Publications, Inc.

Holtgrave, D.R. and T. Anderson. 2004. Utilizing HIV Transmission Rates to Assist in Prioritizing HIV Prevention Services. *International Journal of STD and AIDS, 15*(12): 789-792.

Kaiser Family Foundation (KFF). 2005. HIV/AIDS Policy Fact Sheet: HIV Testing in the United States. http://www.kff.org/hivaids/upload/Updated-Fact-Sheet-HIV-Testing-in-the-United-States.pdf. As obtained on November 11, 2005.

Kaiser Family Foundation (KFF). 2006. HIV/AIDS Policy Fact Sheet: African Americans and HIV/AIDS. http://www.kff.org/hivaids/upload/6089-03.pdf. As obtained on December 5, 2006.

Kilmarx, P.H., F.F. Hamers, and T.A. Peterman. 1998. Living with HIV: Experiences and Perspectives of HIV-Infected Sexually Transmitted Disease Clinic Patients After Posttest Counseling. *Sexually Transmitted Diseases, 25*: 28-37.

Kreps, G.L., & Thornton, B.C. Health Communication Theory and Practice. 2nd ed. Prospect Heights, Illinois: Waveland Press; 1992.

Maibach, E.W., Rothschild, M.R., & Novelli, W.D. Social Marketing. In: Glanz, K., Rimer, B., & Marcus, Lewis F., eds., Health Behavior and Health Education, 3rd ed. San Francisco, CA: Jossey-Bass; 2002:437-461.

Miles, M.B., and A.M. Huberman. 1994. *Qualitative Data Analysis*. CA: Sage Publications.

Shettle, C., & Mooney, G. (1999). Monetary incentives in U.S. government surveys. *Journal of Official Statistics, 15*, 231-250.

Slater, M.D. Choosing audience segmentation strategies and methods for health communication. In: Maibach, E., & Parrott, R.L., eds., Designing Health Messages: Approaches from Communication Theory and Public Health Practice. Thousand Oaks, CA: Sage Publications; 1995:186–198.

US Census Bureau. The Black Population: 2000. August 2001.

Wenger, N.S., F.S. Kussling, K. Beck, and M.F. Shapiro. 1994. Sexual Behavior of Individuals Infected with the Human Immunodeficiency Virus: The Need for Intervention. *A.M.A. Archives of Internal Medicine, 154*: 1849-1854.

Wohl AR, Johnson DF, Lu S, Jordan W, Beall G, Currier J and Simon PA. 2002. HIV risk behaviors among African American men in Los Angeles County who self identify as heterosexual. *J Acquir Immune Defic Syndr, 31*(3): 354-60.

Wolfe WA. 2003. Overlooked role of African-American males' hypermasculinity in the epidemic of unintended pregnancies and HIV/AIDS cases with young African American women. *J Natl Med Assoc, 95*(9): 846-52.