"Formative Research to Inform an HIV Testing Social Marketing Campaign for African American Men Who Have Sex with Men (MSM)", formerly known as

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

Supporting Statement
Part B: Statistical Methods

OMB control # 0920-0762

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B. STATISTICAL METHODS

1. Respondent Universe and Sampling Methods

The respondents providing the information for the proposed project are AAMSM; age 18-44; self-identify as gay; and report having sex with primarily a male(s). Recruitment criteria for the study population were based on CDC's HIV/AIDS surveillance data. Our sample will be a purposeful, homogenous, non-probability based as opposed to probability based sample (Carey and Gelaude 2008). The total estimated sample size for this study is about 432 participants across all twelve cities over a three year period (144 per year). Statistical power is not applicable because this is a qualitative study.

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 AAMSM. Qualitative methods are well suited to this kind of research because they allow flexible, in-depth exploration of individual perceptions and experiences. In addition, individual 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 capture of subtle nuances in participants' attitudes, beliefs, and feelings related to HIV and HIV testing that would not be practical through quantitative approaches. The interview guides include adequate probes to ensure participant response to specific items of interest. Open-ended questions ensure that participants' responses and perceptions are fully addressed and captured.

2. Procedures for the Collection of Information

RTI will select and reserve local recruitment facilities (with CDC's approval) in each of the twelve research cities. RTI will oversee the local recruitment facilities' recruitment of participants. The local recruitment facilities will use the IRB approved screening instrument (**Attachment 3C**) to identify eligible participants.

Once initial contact is made with a potential participant, the individual will be told that CDC is conducting a research study about HIV. Participants will be told that they will be asked some personal questions, to see if they qualify for the study. The questions will include sexual behavior and HIV-associated risk behaviors and testing practices. Participants will provide verbal consent prior to screening for eligibility. If the potential participant consents to 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 interview.

As participants are recruited, recruitment grids will be prepared. The recruitment grids will list the participants' first name only and some demographic information obtained from the screener (age and whether or not the person has tested for HIV). The recruitment grids will allow RTI and the recruitment facilities to keep track of recruitment. The recruitment grids will be stored in a locked file cabinet at RTI and at each recruitment facility. The recruitment 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 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 for a limited time 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 interviews are conducted. Local recruitment 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 any facilities after the 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 interview giving them directions to the facility. Confirmation calls will also be made 1–2 days prior to the 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 4**). 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 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 432 individual interviews with AAMSM. 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 three year period. The interviews will be conducted in-person at recruitment facilities by a professionally trained moderator. Each interview will be scheduled for one hour. In addition to the interviewer, an additional RTI staff member will attend the 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 interviews from behind a one-way mirror. All 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.

3. 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 a professional recruitment firm.
- 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 interview.
- Participants will receive $75 as a token of our appreciation to thank them for their participation and to cover any direct expenses they might incur.

4. 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 3C**.

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

The CDC technical monitor and contractor participated in the instrument development. The CDC technical monitor is also responsible for receiving and approving the contract deliverables for this data collection. The contractor awarded to work on this data collection is RTI International and they will collect and analyze the data.

CDC Contract Technical Monitor and Instrument Development
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