Submission 0920-13ABP under
0920-0840 Formative Research and Tool Development

Expiration 02/29/2016

Supporting Statement B

September 26, 2013

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B. STATISTICAL METHODS

1. Respondent Universe and Sampling Methods

The purpose of this study is to conduct formative research that will be used to develop materials for six specific HIV social marketing campaigns under the umbrella of the larger *Act Against AIDS* campaign. The campaigns target consumers 18-64 years old and include the following audiences:1) Latinos; 2) men who have sex with men; 3) HIV + individuals; and 4) African Americans. Some campaigns will target the general public as a whole and other campaigns will focus on specific subpopulations at greatest risk for HIV infection.

Qualitative methods provide flexible in-depth exploration of the participants' perceptions and experience; and the interviews yield descriptions in the participants' own words. Qualitative methods also allow the interviewer flexibility to pursue relevant and important issues as they arise during the discussion. Furthermore, a qualitative approach will allow us to capture subtle nuances in participants' attitudes, beliefs, and feelings related to the campaign materials. Our discussion guides (exploratory, concept, messages and materials testing) 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 (**Attachments 2b through 2o)**.

Before the qualitative interviews, the participants will also participate in a brief 15-minute paper and pencil survey (**Attachments 2p through 2s)**. Data collected by the brief paper and pencil survey will provide a source of quantitative data supplementing the qualitative data collected during the interviews. The paper and pencil survey will be administered to participants before the individual in-depth interview and focus group. The survey will collect basic background information about the participants' knowledge, attitudes and beliefs about HIV, HIV testing behaviors, risk behaviors and demographics to enable us to more fully describe the participants.

Our sample will be a non-probability based purposeful sample as opposed to probability based. Therefore, the results are not generalizable to the general population. We anticipate screening 2,338 individuals in order to obtain 1700 consumer respondents. Seven hundred individuals will participate in intercept interviews. There will be 500 respondents for in-depth interviews and 500

individuals participating in focus groups. The 1000 individuals participating in the in-depth individual interviews and focus groups will also complete a 15-minute paper and pencil survey. All interviews will be conducted only one time.

Participants will be recruited from areas with high HIV/AIDS prevalence and incidence such as New York, NY; Los Angeles, CA; Washington, DC; Chicago, IL; Atlanta, GA; Miami, FL; Philadelphia, PA; Houston, TX; San Francisco, CA; Baltimore, MD; Dallas, TX or other cities as appropriate.

Statistical power is not applicable because this is a qualitative study.

Study Population

The audience for this research will consist of the consumer groups, 18-64 years old and will include 1) Latinos; 2) men who have sex with men (MSM) of all races; 3) HIV + individuals; and 4) African Americans.

2. Procedures for the Collection of Information

RTI will select and reserve professional recruitment firms (with CDC's approval) in each city. The firms, under the oversight of RTI, or RTI staff will recruit study participants for the in-depth interviews and focus groups. RTI will conduct in person recruitment for the intercept interviews. RTI will use a screener (**Attachment 2a)** to identify eligible participants for both types of interviews.

As participants are recruited for the in-depth interviews and focus groups, recruitment grids will be prepared to keep track of recruitment. The recruitment grids will list the participants' first name and some demographic information obtained from the screener. The grids will not contain any identifying information. The recruitment grids will be stored in a locked file cabinet or on a password protected project share drive at RTI and at each professional recruitment firm. The professional recruitment firms 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 or on a password protected project share drive at RTI and CDC for the duration of the study.

Recruitment will begin at least four weeks before the in-depth interviews or focus groups are scheduled. RTI will closely communicate with each professional recruitment firm to monitor the recruitment and troubleshoot any problems. RTI will keep CDC apprised of the recruitment progress and will make any necessary adjustments during the recruitment process. Identification of recruitment facilities and recruitment will begin once IRB and OMB clearance is received. Typically, recruitment takes about 1 month and we will begin recruitment within a week of receiving clearance. Dates will be assigned to each activity on the timeline for tracking and monitoring purposes after receiving IRB and OMB clearance. The intercept interviews will take place in venues where the general public tend to gather and do not require recruitment grids as we will not collect personal identifying information. The screening and intercept interview will take place at the same time and we will obtain verbal consent rather than written consent.

Personal information from the potential participants participating in the in-depth interviews and focus groups will be maintained and protected to the extent allowable by law. At each facility, recruitment staff will sign a Data Management Agreement acknowledging the requirement to treat all data in a secure manner and not disclose any data, unless otherwise compelled by law (see **Attachment 4**). At each facility and at RTI, 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 and/or RTI to send reminder letters/e-mails and make reminder phone calls. The last page of the screener will be torn off and destroyed after the in-depth interviews/focus groups are conducted. Local professional recruitment firms 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 destroyed. No identifying information about participants will be kept at the professional recruitment firms after the interviews are completed and the professional recruitment firms will not send any identifying information to RTI or CDC. Again, we will not collect any personal identifying information from the intercept interview participants.

Reminder letters/e-mails for the in-depth interviews and focus groups will be sent to potential participants prior to the data collection giving them directions to the study site**.**

Confirmation calls will also be made 1–2 days prior to the focus group/interview to assure that all recruits are confirmed.

Once the potential participant comes to the study site and checks in for the in-depth interview or focus group he/she will be given a consent form (see **Attachment 3a and 3b**). The individual will be given time to read the consent form on his/her own and a trained RTI staff member will be available to answer any questions. If the participant agrees to be in the study, he/she will sign the consent form. The participant will be given a copy of the consent form to keep for his/her records and we will proceed with the data collection. Questions on the data collection instruments (**Attachments 2b through 2o**) will be the same for the individual interviews and focus groups. However, because the focus group will have more than one person, it is likely that several conversations will be generated requiring more time for the moderator to cover all questions in the guide. The questions for the exploratory round of research will vary and reflect the type of campaign being developed (i.e. HIV testing, prevention, prevention with positives or communication and awareness), see **Attachments 2b through 2o.** Questions on the message, concept and materials testing guides will be the same across all individuals regardless of the type of campaign being developed (**Attachments 2b through 2o**). As with the exploratory guides, more time will be allotted for the focus groups. All individuals participating in the individual in-depth interviews and focus groups will also take a 15-minute paper and pencil survey. The questions on the paper and pencil survey will also vary and reflect the type of campaign being developed, see **Attachments 2p through 2s**.

Participants for the intercept interviews will be recruited from venues where the public tend to gather and we will obtain verbal consent rather than written consent. Once the intercept interview participant provides verbal consent (see **Attachment 3c**), we will proceed with the 20 minute intercept interview. The 20-minute intercept interview guide will only be used to test messages, concepts and materials and the questions will be the same for all participants regardless of the type of campaign being developed, see **Attachment 2t.** At the conclusion of the intercept interview, we will ask for them to initial a receipt form for their token of appreciation. The receipt form is for accounting purposes only and requires that the participant provide his/her initials.

All participants, regardless of data collection type, 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 all 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, all forms will be destroyed.

On an annual basis, 500 individuals will participate in a 1-hour in-depth interview and 500 individuals will participate in a 2-hour focus group. The in-depth interview and focus group participants will also complete a 15-minute survey. Seven hundred individuals will participate in a 20 minute intercept interviews annually. The in-depth interviews and focus groups for all campaigns will be conducted in-person by a professionally trained moderator. The location of the data collection will vary depending on the audience and may include professional focus group facilities, community-based organizations, RTI offices, or other locations convenient to participants. Flexibility in data collection location is particularly important when working with high-risk populations who may lack transportation or feel uncomfortable attending data collection in a professional facility.

Each data collection for the in-depth individual interview will last a total of 1 hour and 15 minutes, and each focus group will last a total of 2 hours and 15 minutes. The interview time for the individual in-depth interviews and focus groups includes the 15-minute paper and pencil survey. In addition to the moderator, an additional RTI staff member will attend the data collection to take notes on a laptop computer and to coordinate logistics of checking in participants and obtaining informed consent. CDC staff member(s) may also attend and observe the in-depth interviews/focus groups. All in-depth interviews and focus groups will be audio taped for the purpose of completing the final reports. All audio tapes will be destroyed after notes have been verified and no links will be maintained to any data collected. The intercept interviews will also be conducted in-person by a professionally trained moderator. These 20-minute interviews will take place in venues where the general public tends to gather. The interview will take notes for the purpose of completing the final reports.

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:

In-depth Individual Interviews and Focus Groups:

- Recruitment through professional 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 data collection. Participants will not be contacted again after the in-depth interview/focus group is over.
- Provision of a token of appreciation to thank participants for their time and effort in the study (please see Section A-9 for more information about the token of appreciation).

Intercept Interview:

- Recruitment will take place at venues where the general public tends to gather.
- Recruitment and screening will take place a the same time
- Provision a token of appreciation to thank participants for their time and effort in the study (please see Section A-9 for more information about the token of appreciation).

4. Test of Procedures or Methods to Be Undertaken

To estimate the burden for administering the screening questionnaires, 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 for the screening instrument to be 2 minutes. The screening instrument is shown in **Attachment 2a.**

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

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