

Request for Sub-collection under the Approved Generic ICR:
Formative Research and Tool Development
OMB No. 0920-0840, Expiration 02/28/2016

Supporting Statement B

Formative Research to Develop Social Marketing Campaigns: Prevention Is Care (PIC)

September 3, 2014

Contact Person:

Nancy Habarta, MPH

National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention

Centers for Disease Control and Prevention

1600 Clifton Rd. NE

Mailstop E-49

Atlanta, GA 30329

Telephone: (404) 639-2034

E-mail: eqq1@cdc.gov

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

B.1 Respondent Universe and Sampling Methods

The purpose of this study is to conduct in-depth interviews with health care providers (e.g. Infectious Disease Specialists and primary care physicians) and social service providers for the development of the social marketing campaign: *Prevention Is Care (PIC)*, an HIV social marketing campaign under the umbrella of the larger Act Against AIDS campaign. The yearlong study will consist of a series of in-depth interviews with 20 healthcare and social service providers in four cities. The sample will consist of a maximum of 80 respondents selected from professional recruiting facility databases. 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 the 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 (**Attachments 5.1-5.17**). Our discussion guide includes 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 (**Attachment 3**).

Before the qualitative interviews, the participants will be asked to review the materials independently and then participate in a brief 15-minute paper-and-pencil (PAPI) questionnaire (**Attachment 2**). Data collected by the brief PAPI will provide a source of quantitative data supplementing the qualitative data collected during the interviews. The PAPI will be administered to participants before each individual in-depth interview. The survey will collect basic background information about the participants' informational needs, use of electronics, patient population, and resources utilized, which will allow us to more fully describe the participants and to better determine the appropriate dissemination channels for campaign materials.

Our sample will be a nonprobability-based purposeful sample rather than a probability-based sample. Therefore, the results are not generalizable to the general population. We anticipate screening 160 individuals to obtain 80 individuals who will participate in in-depth

interviews, spend 15 minutes reviewing materials independently, and complete a 15-minute PAPI. All interviews will be conducted only one time.

Participants will be recruited from areas with high HIV/AIDS prevalence and incidence such as Houston, TX; Atlanta, GA; Miami, FL; and Boston, MA.

Statistical power is not applicable because this is a qualitative study. The quantitative data we collect from the PAPI will help to supplement the qualitative data but statistical power is not applicable because of low population size.

B.1.1 Study Population

The audience for this research will consist of health care providers (e.g. primary care physicians and Infectious Disease Specialists) and social service providers.

B.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. The professional recruitment firm will use a screener (**Attachment 4**) to identify eligible participants for the in-depth interviews.

As participants are recruited for the in-depth interviews, 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. 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 study's duration.

Recruitment will begin at least 4 weeks before the in-depth interviews 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 institutional review board (IRB) and Office of

Management and Budget (OMB) clearance is received. Typically, recruitment takes about 1 month and we will begin recruitment within a week of receiving clearance. Once we receive IRB and OMB clearance, we will assign dates to each activity on the timeline for tracking and monitoring purposes.

Personal information from the potential participants participating in the in-depth interviews will be maintained and protected to the extent allowable by law. At each facility, recruitment staff will sign a privacy agreement acknowledging the requirement to treat all data in a secure manner and to not disclose any data unless otherwise compelled by law (**Attachment 1**). At each facility and RTI, the screener forms will be kept in locked file cabinets. All identifying information (name, address, telephone number) will be recorded on the last page of the screener form, which will enable the facility and/or RTI to send reminder letters, e-mails, and phone calls. The last page of the screener form will be torn off and destroyed after the in-depth interviews are conducted. Local professional recruitment firms will send the screener forms (without the last page) to RTI. The screener forms will be stored in a locked file cabinet at RTI throughout the project's duration. Once the project ends, the screener forms 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.

Before data collection, we will send potential participants of the in-depth interviews a reminder letter or e-mails that also give directions to the study site (**Attachment 8**). We will also make confirmation calls 1 to 2 days before the interview to confirm all participants. Time permitting, , the materials that will be discussed during the interview will be mailed in advance to scheduled potential participants.

After checking in at the study site, participants will be given time to read a consent form (**Attachment 6**), and a trained RTI staff member will be available to answer any questions. If participants agree to be in the study, they will each sign a consent form and will be given a copy to keep for their records. Interviews will consist of pretesting draft materials (**Attachments 5.1-5.17**) for the Prevention Is Care campaign. We will ask participants to review draft materials independently before the interview (either off site, such as in their home or office, or on site at

the facility). Then we will ask participants quantitative and qualitative questions about the materials to determine their reaction to, comprehension of, and perceived usefulness of the materials (**Attachment 3**). Information will be gathered to inform the development and refinement of campaign messages and materials. Draft messages/concepts and materials will be pretested to obtain reactions regarding appropriateness, usability, and relevance to their practice. All individuals participating in the individual in-depth interviews will also take a 15-minute PAPI (**Attachment 2**).

We will remind all participants that they can refuse to answer any question and that they can withdraw from 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 project's duration. Once the project ends, all forms will be destroyed.

Each in-depth individual interview will last a total of 95 minutes. This includes time for the individual to review the draft materials independently (15 minutes), complete the PAPI (15 minutes), and time to consent to (5 minutes) and participate in the in-depth interview (60 minutes). 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) also may attend and observe the in-depth interviews (either in-person or via a live video stream). In addition, a note taker may be located behind a one-way mirror. All in-depth interviews will be audio recorded for the purpose of completing the final reports. RTI will retain audio files on secure servers; only project staff members will be able to access the servers via password-protected computers. All audio files will be destroyed three years after completion of the project.

B.3 Methods to Maximize Response Rates and Deal with Nonresponse

We will use the following procedures to maximize cooperation and to achieve the desired participation rates for the in-depth interviews:

- Recruitment through professional recruitment firms.

- Reminder letters and e-mails will be sent with directions to the research site and reminder phone calls placed 1 to 2 days prior to the scheduled data collection. Participants will not be contacted again after the in-depth interview is over.
- Provision of a token of appreciation to thank participants for their effort in the study (please see **Section A.9** for more information about the token of appreciation).

B.4 Test of Procedures or Methods To Be Undertaken

To estimate the burden for administering the screening questionnaires, we consulted two different project team members. 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, because almost all screening questions were presented in the interview. In addition, the project team members deliberately read each item slowly. The project team members estimated the maximum average burden for the screening instrument to be under 10 minutes. The screening instrument is shown in **Attachment 4**.

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

Jennifer D. Uhrig

RTI International

Center for Communication Science

3040 E. Cornwallis Rd.

Research Triangle Park, NC 27709-2194

uhrig@rti.org

(919) 316-3311

Julia Kish Doto

RTI International

Center for Communication Science

6110 Executive Boulevard, Suite 902

Rockville, Maryland 20852-3907

jkdoto@rti.org

(301) 230-4640

Brian Southwell
RTI International
Center for Communication Science
3040 E. Cornwallis Rd.
Research Triangle Park, NC 27709-2194
bsouthwell@rti.org
(919) 541-7384

Nancy Habarta
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
Centers for Disease Control and Prevention
1600 Clifton Rd, NE
Atlanta, GA 30333
eqq1@cdc.gov
(404) 639-2034

Jo Ellen Stryker
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
Centers for Disease Control and Prevention
1600 Clifton Rd, NE
Atlanta, GA 30333
gux6@cdc.gov
(404) 639-2071