

**Development of CDC's Let's Stop HIV Together Social Marketing Campaign
for Consumers**

**Supporting Statement B
Reinstatement
OMB No. 0920-1169**

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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 and/or revise message, concepts, and materials focused on reducing stigma and promoting testing, prevention, and treatment across the HIV care continuum under the umbrella of the *Let's Stop HIV Together* campaign in support of the *Ending the HIV Epidemic* plan. The campaign focuses on consumers 18-64 years old and includes the following audiences: 1) general public; 2) MSM; 3) Blacks/African Americans; 4) Hispanics/Latinos; 5) Transgender individuals; 6) PWIDs; and 7) people with HIV (PWH).

Qualitative methods provide flexible in-depth exploration of the participants' perceptions and experience; and the data collection yields descriptions in the participants' own words. Qualitative methods also allow the interviewer/moderator 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 data collection 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 3b through 3o**).

Before the qualitative interviews/focus groups, the participants will take a brief 15-minute web-based survey (**Attachments 3p through 3s**). Data collected by the brief survey will provide a source of quantitative data supplementing the qualitative data collected during the interviews/focus groups. The survey will collect basic background information about the participants' knowledge, attitudes, and beliefs about HIV, HIV testing behaviors, risk behaviors, and sociodemographics 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 2,165 individuals in order to obtain 852 consumer participants for the in-depth interviews and focus groups annually; 352 individuals will participate in in-depth interviews and 500 will participate in focus groups annually. The individuals participating in the in-depth interviews and focus groups will also complete a 15-minute brief survey (852 participants annually). Each interview and focus group will be conducted only one time. A total of 657 individuals will participate in intercept interviews annually.

Participants will be recruited from locations (states, counties, and territories) identified as priorities in the *Ending the HIV Epidemic* plan.

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) general public; 2) MSM; 3) Blacks/African Americans; 4) Hispanics/Latinos; 5) Transgender individuals; 6) PWIDs; and 7) people with HIV (PWH).

2. Procedures for the Collection of Information

Contractor staff or professional recruitment firms, under the oversight of CDC, will recruit participants for the in-depth interviews and focus groups using a screener (**Attachment 3a**) to identify eligible participants.

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 sociodemographic 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 the contractor's worksite and at professional recruitment firms. The professional recruitment firms will destroy their copies of the recruitment grids after data collection is completed. The contractor 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 the contractor's worksite 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. The contractor will closely communicate with the professional recruitment firms to monitor the recruitment and troubleshoot any problems. The contractor 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 are received. Typically, recruitment takes about one 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. The recruitment and conduct of the intercept interviews will take place at the same time (i.e., a potential participant will be approached about participating in an interview, and if they agree, the interviewer will proceed with conducting the interview).

Personal information from in-depth interview and focus group participants will be maintained and protected to the extent allowable by law; no personal information will be collected from intercept interview participants. At each facility, recruitment staff will sign a Privacy Agreement acknowledging the requirement to treat all data in a secure manner and not disclose any data, unless otherwise compelled by law (**Attachment 5**). At each facility and at the contractor's worksite, the screeners will be kept in locked file cabinets or secure servers. All identifying information (name, address, telephone number) will be recorded on the last page of the screener, which will enable the facility and/or the contractor to send reminder letters/e-mails and make reminder phone calls. If hard copy, the last page of the screener will be torn off and destroyed after the in-depth interviews/focus groups are conducted. If electronic, the last page will be deleted. Recruitment firms will send the screeners (without the last page) to the contractor. The screeners will be stored in a locked file cabinet or on secure server at the contractor's worksite 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 the contractor 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 or emails will also be made 1 to 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 (**Attachment 4a and 4b**). The individual will be given time to read the consent form on his/her own and a trained contractor will be available to answer any questions. If the participant agrees to be in the study, he/she will provide consent. The participant will be offered a copy of the consent form to keep for his/her records, if they wish, and we will proceed with the interview/focus group. Questions in the interview and focus group discussion guides (**Attachments 3b through 3o**) 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 message, concept or material being developed; see **Attachments 3i through 3l**. Questions on the message, concept and materials testing guides will be the same across all individuals (**Attachments 3b through 3o**). 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 survey. The questions on the brief companion surveys will also vary and reflect the type of message, concept or material being developed, see **Attachments 3p through 3s**.

Participants for the intercept interviews will be recruited from venues where the public tend to gather. Once the intercept interview participant provides verbal consent (**Attachment 3t¹**), 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; see **Attachment 3t**. At the conclusion of the intercept interview, we will ask participants 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. Contractor staff will FedEx or personally take all forms back to the contractor's offices after the interviews/focus groups are completed in a particular location. The consent forms will be stored in a locked file cabinet or scanned and saved to a secure project share drive at the contractor's worksite for the duration of the project. Once the project ends, all forms will be destroyed.

On an annual basis, 352 individuals will participate in a one-hour in-depth interview and 500 individuals will participate in a two-hour focus group. The in-depth interview and focus

¹ Note that the consent script for the intercept interviews is embedded in the interview guide.

group participants will also complete a 15-minute survey. Six hundred sixty-one 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 interviewer/moderator. The location of the data collection will vary depending on the audience and may include professional focus group facilities, community-based organizations, contractor offices, or other locations convenient to participants. Flexibility in data collection location is particularly important when working with specialized respondents, rare groups, or minority populations at increased risk for HIV acquisition or transmission; they may lack transportation or feel uncomfortable attending data collection in a professional focus group 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 brief survey. In addition to the moderator, an additional contractor 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 identifying information. The intercept interviews will also be conducted in-person by a professionally trained interviewer. These 20-minute interviews will take place in venues where the general public tends to gather. The interviewer 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 staff.
- Reminder letters/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/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 at 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 two minutes. The screening instrument is shown in **Attachment 3a**.

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

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