

Testing Messages for Black and Latino MSM
Generic Information Collection request under 0920-0840

Supporting Statement
Part B

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B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

This information collection request does employ qualitative research methods. The following is a description of data collection procedures.

B.1. Respondent Universe and Sampling Methods

The study population will consist of black and Latino MSM who live or work in/near the metropolitan areas of the study sites (Chicago, IL; Ft. Lauderdale, FL; or Kansas City, MO). Recruitment targets will vary by site, based on local demographics. We expect that the Ft. Lauderdale site will recruit a predominantly Latino sample, Kansas City a predominantly black sample, and Chicago, a racially and ethnically mixed sample. Focus groups and/or individual interviews will be conducted with 90 MSM, of which 30 will be high-risk HIV negative, 30 will be low-risk HIV negative, and 30 will be HIV-positive.

To participate in the study, the men must:

- self-identify as black or Latino (mixed race/ethnicity is allowed, but primary self-identification must be black or Latino);
- be 18 years of age or older;
- self-identify as male (transgender excluded);
- live or work in the greater metropolitan area of each designated site;
- have had sex with a man in the past 12 months;
- not have tested HIV-positive for the first time within the past 6 months;
- not be currently enrolled in another HIV intervention study

The following criteria will be used to categorize participants:

- a. HIV-positive MSM: Self-report HIV-positive status, however not tested HIV-positive for the first time within the prior six months (recency effect)
- b. High-risk HIV-negative MSM: self-report HIV-negative status; engaged in unprotected anal sex with within the prior three months;
- c. Lower-risk HIV-negative MSM: Self-report HIV-negative status; no unprotected anal sex within the prior three months.

The target sample size for the focus groups and interviews is 90 MSM, including 45 black and 45 Latino MSM. Approximately 30 MSM

will participate in formative activities in each of the three cities.

B.2. Procedures for the Collection of Information

B.2.1. Recruitment

Working with each local site staff and its Community Advisory Board (CAB), the contractor will develop a "recruitment campaign plan" that will outline the specific methods and strategies to be used to identify eligible MSM at each site for the study. The exact mix of recruitment methods will vary depending on local factors, including acceptability of certain forms of advertisement (e.g., newspaper vs. online), availability of venues (e.g., public transportation, gay-identified clubs, etc.), and other sociocultural characteristics.

Recruitment for the focus groups and/or individual interviews will occur primarily through referrals and print advertisements (e.g., flyers). Given the relatively low number of participants (n=30) needed at each site, staff of the local partner agencies and members of the CAB will be used to help identify potential participants and refer them to the study staff for screening for eligibility (**Attachment 1a and b**). Flyers and palm cards will be posted or distributed at the agency, at local venues, and other events to solicit interest participants.

B.2.2. Screening and Scheduling Procedures

Potential focus group and individual interview participants will be screened for eligibility by phone, based on the inclusion criteria above. Recruitment materials will direct potential participants to call and reach a local study staff member who will conduct the screening over the phone. To facilitate routing of calls, the phone number (and/or extensions) provided will be for the local study staff (coordinator or outreach staff), and callers will be directed to mention a project "nickname" (TBD) in the event their call is misdirected or routed to the main line. Study staff will utilize a screening survey while on the phone with the potential participant, read the description and survey questions to the individual (with anonymity enabled by phone-based nature of interaction), determine eligibility, and schedule them for a focus group or key informant interview (**Attachment 1a and b**). Information collected for scheduling would be limited to an alias (e.g., name of their first pet) and either a phone number or email address.

Men interested in participating in the focus groups or individual interviews will have voluntarily called to screen for eligibility after seeing a flyer or being referred by local agency staff. The screener takes a few minutes at most, and the individual can refuse to participate in the screening process and/or the study immediately after screening. While the screening tool does ask some sensitive information (e.g., HIV status), no identifying information is collected in the screening survey. If an individual is eligible, a separate scheduling process is conducted. For the focus groups and individual interviews, local staff will access an online scheduler to set up an appointment. After screening is completed and participants are eligible, they will be told more about the study process, including information about informed consent, time involved and compensation for their time.

For phone-based screening, it is possible that a caller will be unable to reach a study staff member because he/she is on the line or is out of the office at the time of the call. For this situation, the voice mail message for these staff members will include the following script:

"If you are calling about [project nickname], please leave your alias only and phone number so that a member of our project team can call you back. If you do not want us to call you back, please try again later. We are available by phone [days/times]. You can also get more information on our website at [web address]. Thank you."

A "call back" database (Excel spreadsheet) will be kept by the study staff to record the alias and phone number from all voice mail messages, as well as to document call back attempts. Staff will attempt to call back individuals up to three times. If an individual is reached during a call back attempt, the study staff will first confirm whether the individual has already been screened. The staff member will administer the screener over the phone. The individual's phone number will be deleted from the "call back" database, and documentation of successful screening will be recorded. If an individual cannot be reached after three attempts, his phone number will be deleted from the call back database, and documentation of failed contact will be recorded.

After an individual is determined to be eligible, he will then be scheduled to visit the local site at a specific date and time to participate in the focus group or the individual interview. Scheduling for the focus groups and interviews will be completed by local study staff, using an online scheduler (e.g., Schedulicity® or Bookfresh®). Project staff members will access

the online scheduling system to schedule appointments and set up reminders (unless the participants opt out of this service). This scheduling system will not be linked to the screener in any way that would enable information in the screener to be connected to an individual.

B.2.3. Data Collection Methods

Focus group procedures

Upon arrival, participants will be checked in and escorted to the private space reserved for the focus groups. Focus groups will be conducted by members of the contractor's research team who are trained in and experienced with conducting focus groups. Two senior members of the research team will attend each focus group, as well as one note taker. One of the senior members will be the primary facilitator, and the second will provide support as needed. The facilitators will proceed through the following steps:

- Informed Consent. Before the focus group begins, the facilitator will read the study consent form (**Attachment 3a and b**), including focus group procedures (including recording and note taking), risk, benefits, nature of confidentiality, study contact information, the nature of voluntary participation, and token of appreciation. Participants will be asked to acknowledge verbally that they consent to participation. No hard copy with signature will be required or collected, although a copy of the study information sheet (in English and Spanish) will be provided to each participant upon check in. If an individual declines to participate, he will be ineligible for completing the focus group and for receiving the token of appreciation.
- Discussion. Following the informed consent procedures, the facilitator will begin the focus group discussion with introductions and a short ice breaker. After this is complete, the digital recorder will be turned on, and the facilitator will guide participants through a presentation of several draft prevention messages and a series of questions and probes about message believability, comprehension, potential impact on behavior, and other items (**see Attachment 2a and b**). The note taker will take notes using a lap top computer; individual names will not be recorded in the notes so that information shared cannot be linked to a particular individual. At the conclusion of the allotted time, the facilitator will end the focus group, and distribute the \$50 token of appreciation gift cards to each participant.

Interview Procedures

Upon arrival, participants will be checked in and escorted to the private space reserved for the interview. Interviews will be conducted by members of the contractor's research team who are trained in and experienced with conducting interviews. Two members of the research team will attend each interview, including a senior member and a note taker. The interviewer will proceed through the following steps:

- Informed Consent. Before the interview, the interviewer will read the study information form, including interview procedures (including recording and note taking), risk, benefits, nature of confidentiality, study contact information, the nature of voluntary participation, and token of appreciation. Participants will be asked to acknowledge verbally that they consent to participation. No hard copy with signature will be required or collected, although a copy of the study information sheet (in English and Spanish) will be provided to each participant. If an individual declines to participate, he will be ineligible for completing the interview and for receiving the token of appreciation.
- Discussion. Following the informed consent procedures, the facilitator will begin the interview. The digital recorder will be turned on, and the facilitator will proceed through a presentation of several draft prevention messages and a series of questions and probes about message believability, comprehension, potential impact on behavior, and other items. The note taker will take notes using a lap top computer. At the conclusion of the allotted time, the interviewer will end the individual interview, and distribute the \$50 token of appreciation gift card to the interviewee.

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

All participants will receive a token of appreciation for their time and travel. Individual tokens of appreciation will be a \$50 gift card. Because each person may participate only once, the maximum token of appreciation that can be received by an individual is one, \$50 gift card. The types of gift cards will vary by location, based on input from the local CAB and project staff, but will include local retail stores (e.g., clothing, groceries, drug stores), or online sites like Amazon.com or iTunes. Individuals who decline to participate at any point before completing the assessment will be ineligible for the token of appreciation. See Supporting Statement A section A.9 for explanation of token of appreciation.

B.4. Tests of Procedures or Methods to be Undertaken

This submission is a request for authorization to conduct tests of procedures and methodologies typical in studies.

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

The CDC staff and the contractor—John Snow, Inc (JSI)—were involved in designing the study and will implement study procedures. The persons involved at JSI are:

- Jeremy Holman, PhD, Co-Principal Investigator, Project Director
- Matthew Mimiaga, ScD, MPH, Co-Principal Investigator
- Stewart Landers, JD, Technical Advisor
- Michele Clark, MPH, Site Coordinator
- Jodi Sperber, MSW, MPH, Site Coordinator
- Naima Cozier, MSPH, Site Coordinator
- Karen Schneider, PhD, Data Specialist
- Michelle Samplin-Salgado, MPH, Recruitment Specialist
- Arman Lorz, BA, Communications Specialist
- Mihaly Imre, MD, Survey Programmer
- William Felling, SB, IT Security Official
- Bekim Shala, MS, IT Security Specialist
- Sang Yoon, BS, Website Developer
- Melina Ward, BA, Research Associate
- David Landy, BA, Research Associate
- Nicolette Strauss, Research Associate

The federal (CDC) staff members who are involved with the various aspects of designing and implementing the study are listed below.

- Gordon Mansergh, PhD, Project Officer/Contracting Officer Representative
- Jeffrey H. Herbst, PhD, Consultant
- Arin Freeman, MPH, Project Coordinator
- Nicole Pitts, BS, Project Coordinator
- Simone Grey, PhD, Statistician Consultant