

## **SUPPORTING STATEMENT B**

**Testing Brief Messages for Black and Latino MSM**

**Generic Information Collection Request under 0920-0840**

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### **Contact information**

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## **B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS**

This information collection request does employ statistical 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 in the study (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. The sites will screen an estimated 1,800 eligible black and Latino MSM to ensure effective enrollment and assessment of 900 final participants. Of the final sample of 900, 300 will be high-risk HIV negative MSM, 300 will be low-risk, HIV negative MSM, and 300 will be HIV positive MSM (see inclusion criteria and estimated sample data below for more details).

To participate in the study, the men must:

- self-identify as black or Latino (mixed race/ethnicity is allowed, but primary must 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 study is 900 MSM, including 450 black and 450 Latino MSM. Approximately 300 MSM will be enrolled in each of the three cities. See Table 1 for a break down of the participants.

**Table 1. Target Sample Sizes by Study Activity, Risk Category, and Race/Ethnicity**

HIV Risk Category	Study Assessment
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	<b>Black MSM</b>	<b>Latino MSM</b>	<b>Total</b>
HIV-negative, low risk	150	150	<b>300</b>
HIV-negative, high risk	150	150	<b>300</b>
HIV positive	150	150	<b>300</b>
<b>Total</b>	<b>450</b>	<b>450</b>	<b>900</b>

## **B.2. Procedures for the Collection of Information**

### **B.2.1. Recruitment**

Working with each local site staff and its CAB, JSI 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 (including 30 for the formative activities and 300 for the assessment). 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.

#### *Study Assessment*

Recruitment for the study will occur through a combination of the following methods:

- **Online advertisements:** JSI will develop and design culturally and linguistically appropriate online advertisements targeting black and Latino gay and bisexual men. This may include banner ads to display on websites that these populations may frequent (both national and local), ads targeted to Facebook users in the three metropolitan areas who are likely to fit the target populations, and/or ads on Craigslist or other bulletin board sites. Imagery and text will be developed in conjunction with the local staff, CABs, CDC, and JSI design staff. Online ads will link directly to the project website and guide interested participants to the online eligibility screener.
- **Traditional print advertisements:** To reach potential participants who may not be reached via online methods, JSI will develop and design culturally and linguistically appropriate print advertisements. This may include ads in newspapers (especially those that target gay men and/or Latino or Black populations), ads on public transportation (e.g., buses and subway cars), and other hard copy advertisements (e.g., posters, flyers, or palm cards). These ads will use similar imagery and language as the online ads (as appropriate), but will include a phone number, web address, smartphone-scannable quick response (QR) code, and/or a mobile text code that can be used to access more information and screen for eligibility (**see Attachment 18**).
- **Referrals:** It is anticipated that some potential participants will be referred to the study through service providers. Referrals may include internal referrals from existing HIV care and prevention services within each local organization, or external referrals from partner agencies in the community. External and internal referral processes will be established with each local site, depending on existing programs and partnerships. Referrals will be facilitated through the use of the print materials described above (e.g., palm cards or flyers). JSI may also train staff (other than research staff) at each local site

to describe the study and target audience, to help facilitate referrals of potential participants.

- **In-person outreach:** Some potential participants may be recruited through direct person-to-person contact with local study staff. This is likely to occur as part of existing, venue-based outreach activities or through participation in health fairs, gay pride activities, and/or other events where the target populations may be reached. Local project staff will distribute palm cards or flyers to potential participants and encourage them to go online and/or call to be screened and schedule an appointment. In some cases (depending on the success of the above and preferred recruitment methods), local staff may also screen interested candidates in person at health fairs or other small events using mobile devices that can access the online screener from any location. To avoid any privacy concerns, local outreach staff would hand the device to the potential participant to answer the questions, then retrieve the device after eligibility has been determined.
- **Drop-Ins:** It is possible that a few participants may learn about the study online, see an advertisement, or hear about the study by word-of-mouth, and show up at the local site to participate. In such cases, these potential participants would be referred to the local study staff, and screening would proceed as described above for in-person outreach. If eligible, potential participants would be scheduled for an appointment as described above, or if an opening is available, enabled to immediately begin the study.

### **B.2.2. Screening and Scheduling Procedures**

Potential participants for the study will be screened for eligibility based on the inclusion criteria described above, using an online screening survey tool. Depending on the method of recruitment, the online screening tool will either be self-administered by potential participants, or administered by research staff over the phone or in person to potential participants. Individuals will be screened in one of three ways, depending on the method of contact.

1. **Online:** Potential participants who “click through” an online advertisement, or who see any print advertisement and opt to visit the project’s web address, scan the QR code, or text a code via their smartphones, will have the option of being screened online. These participants will be directed to an online screening survey (accessible via smartphone, tablet, or computer and available in English and Spanish) that will be self-administered to gather the minimum information necessary to determine eligibility. At the completion of this online screening survey, those who are eligible can choose to (1) access an online scheduler for their local site and choose an appointment date/time to visit the site and complete the assessment, or (2) submit their contact information (via secure, online form) to the site for a follow up email or phone call to schedule. Information collected for scheduling would be limited to first name, first initial of last name, month and year of birth, and either a phone number or email address.
2. **Phone:** In addition to the web address and scannable QR code (or mobile text code), print advertisements or palm cards will also include a phone number for the local site. Potential participants can 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 access the same online, study assessment 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 an appointment with those who are eligible and interested. Information collected for scheduling would be limited to first name, first initial of last name, month and year of birth, and either a phone number or email address.

3. In-person: To supplement the online and print advertisement, some in-person recruitment may be conducted at health fairs, gay pride events, clubs, and/or other venues where gay/bisexual men may be located. This method will be used only if online and phone recruitment does not produce adequate interest to reach the 300 person sample size in each location. Depending on the venue and event, in-person recruitment will consist of local study staff either (1) providing potential participants with a palm card, and directing them to go online or call to be screened, or (2) conducting “in the field” screening using a wifi-enabled tablet or smartphone to access the online screener, and permit potential participants to complete the screener.

Online, phone, and in-person screening will use the same online screening tool and script.

Men interested in the study will have either voluntarily accessed the online screener or called the researchers to screen for study participation after seeing an advertisement, or after being referred by internal or external partners. Screening in the field will be done only if other recruitment efforts are not adequate in enrolling men into the study (i.e., the intent is to screen all men online or by phone), and potential participants will be given the opportunity to decline to be screened. 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. If an individual is eligible, a separate scheduling process is conducted. For the study assessment, eligible participants will be directed to a separate process for scheduling, either an online scheduler (as a separate tool) or to the phone or email address. Screening is not easily completed if staff must verbally and/or in written form cover all required criteria of informed consent prior to screening. Such a consent process requires much more time than screening itself, and potential respondents could grow weary and discontinue the conversation, especially when screening over the phone. After screening is completed and participants are eligible, they will be told more about the assessment process, including information about informed consent, time involved and tokens of appreciation.

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 first name 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 first name 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 (e.g., by going online after failed phone attempt). If the individual has already screened online, the staff member will answer any questions the individual may have, and then end the call. If the individual has not screened online, the staff member will then administer the screener over the phone (using the same online screening tool). In both cases, 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.

## **Scheduling**

After an individual is determined to be eligible for the study, he will then be scheduled to visit the local site at a specific date and time to be rescreened and complete the assessment process. Scheduling will either be done using a self-administered, online scheduler or through a staff-assisted process. Each is described below.

- Online scheduling. Individuals who self-administer the online screener (which includes those who clicked through an online ad, or those who saw an ad and visited the project website) and are determined to be eligible, will be directed to a separate, online scheduling system (e.g., Schedulicity®). This system will enable eligible participant to select the location, date, and appointment time for the assessment and will have the option to opt out of receiving their choice of automatic reminders (e.g., email, text message, or phone call). Local research staff will have access to this scheduler, to establish appointment "slots" in advance and to monitor each day's appointments. This system will not be linked to the screener in a way that would enable information in the screener to be connected to an individual.
- Staff assisted scheduling. Individuals screened by phone or in-person, or that screened online but opted not to use the online scheduler, will be scheduled by research staff. The project staff members will access the same online scheduling system to schedule assessment appointments and set up reminders (unless the participants opt out of this service). This scheduling system will not be linked to the screener in a way that would enable information in the screener to be connected to an individual.

### **B.2.3. Data Collection Methods**

Upon arrival at the site, each individual will be checked in for the assessment by a research staff member, verifying the appointment in the online scheduler. The individual will be escorted to one of two private workstations available at each site that will contain a lap top computer (furnished by JSI). No more than two participants will be scheduled during any appointment period, ensuring adequate staff availability. The staff member will orient the participant to the equipment, explain the procedures, and answer any questions. The staff member will then open the web browser, initiate the appropriate survey (English or Spanish version), and leave the workstation. Using the online survey, the participant will then proceed through the following steps:

- Rescreen. The participant will participate in a self-administered, rescreening survey to confirm eligibility. This is the same set of screening questions used in the initial screening survey.
- Informed Consent. Once eligibility has been re-confirmed, the online survey will present information to ensure informed consent, including study procedures, risk, benefits, nature of privacy, study contact information, the nature of voluntary participation, information on the assessment, and token of appreciation. Participants will be instructed to read the information on the screen and then click “I agree” to indicate that they understand and consent to participate, or “I do not agree” to decline to participate. Both responses will be followed by a question to confirm the response (e.g., “You have indicated that you understand and have agreed to participate. Is this correct?”). 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 assessment and for receiving the token of appreciation.
- Test Messages. Following re-screening for eligibility and informed consent procedures, participants will continue with the online assessment. In a private room, participants will first be given a set of six HIV information messages, each followed by related outcome questions. All HIV-negative participants (high and lower risk) will receive a set of six informational messages intended for HIV-negative men. All HIV-positive participants will receive a set of six informational messages intended for HIV-positive men.
- Assessment. Following message testing, participants will complete a 60-minute online, assessment survey (range 40-70 minutes) about their socio-demographic characteristics, recent sexual and drug using behavior, substance use, psychosocial factors, and perceptions and attitudes about HIV and prevention options. These items are critical in examining potential mediators and moderators of message effectiveness, and to eventually tailor and target messages for enhanced effect among MSM. Throughout the assessment, research staff will be available to assist with any issues that may arise. At the completion of the assessment, the study staff will debrief with each participant, ask if they have any questions or concerns, and provide the \$40 gift card token of appreciation. In addition, the staff member will offer an HIV test and/or referral to services (described below).

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

At the end of each assessment, all participants will receive a token of appreciation for their time and travel. Receipt of the token of appreciation will not be contingent upon HIV testing, but rather for completing the assessment. Individual tokens of appreciation will be a \$40 gift card. Because each person may participate only once, the maximum token of appreciation that can be received by an individual is one, \$40 gift card. The types of gift cards will vary by location, based on input from the local community advisory group, 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.

#### **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