Request for Sub-collection Under the
Approved Generic ICR: Formative Research and Tool Development
OMB No. 0920-0840, Expiration 31 January 2013

"Development of HIV Prevention Decision Support Messages for Men Who Have Sex with Men and Heterosexuals"

Supporting Statement A

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Submitted by:
RTI, International

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Development of HIV Prevention Decision Support Messages for Men Who Have Sex with Men and Heterosexuals

A. JUSTIFICATION

A.1 Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention proposes to conduct a formative research study using qualitative interviews and field testing via Web-based surveys and/or handheld devices and audio computer-assisted self-interview (ACASI) to test messages that will be used to develop two separate safer sex guides that include information on the risk of HIV transmission and acquisition, and potential risk reduction activities for men who have sex with men (MSM) and for heterosexuals. In the United States, MSM account for more than half of all new HIV infections every year (CDC, 2010), although they represent only 4% of the adult male population (Purcell et al., 2010). Additionally, heterosexual transmission of HIV continues to be of concern in the United States, representing nearly a third of new HIV infections. Injection drug users represent approximately 12 percent of annual new HIV infections and 19 percent of those living with HIV (CDC, 2010).

In recent years, newer behavioral and biomedical HIV prevention strategies have been introduced and are being studied. These include serosorting; circumcision; vaccines; and various antiretroviral (ARV)-related strategies, including microbicides, pre-exposure prophylaxis (PEP), pre-exposure prophylaxis (PrEP). Currently, there are limited recommendations or guidelines pertaining to the use of these newer strategies. Although some MSM and heterosexuals are already using some of these strategies, other strategies may soon be available as options for consideration. Therefore, it will become important to include messages and information about these newer strategies into the mix of current prevention messaging (e.g., condom use, monogamy) when communicating with MSM and heterosexuals about available HIV prevention or risk reduction options.

The messages and the way they are communicated need to be tested and verified to ensure their acceptability and effectiveness in MSM and heterosexuals populations. The messages could eventually be delivered via pamphlets, comprehensive guides, or Web-based

tools. The current study will pre-test these messages and draft separate materials for MSM and heterosexuals. The study will consist of conducting qualitative interviews with 60 MSM, 30 heterosexual males, and 30 heterosexual females (Phase 1) and field testing messages via Web-based surveys and/or handheld devices or ACASI with 200 MSM, 100 heterosexual males, and 100 heterosexual females (Phase 2). Further field testing of materials via Web-based surveys and/or handheld devices or ACASI will occur with 30 MSM, 15 heterosexual males, and 15 heterosexual females (Phase 3). A total of 580 individuals will participate over a 1-year period.

A.1.1 Privacy Impact Assessment

Information will be collected on paper (Phase 1) and electronically (Phases 1-3). CDC will not receive any personally identifiable information (IIF). All IIF collected by the contractor will be unlinked or stripped from data delivered to CDC. The use of Web-based surveys may involve the hosting of a Web site or subcontracting of the evaluation through a different vendor. No evaluation materials, surveys, Web sites or Internet content will be directed at children under 13 years of age. All personal identifiers needed to locate potential participants will be stored in separate locked file cabinets in locked offices in a secured facility. Each interview facility will destroy their copy of the recruitment grid after data collection has been completed. All electronic files will be password controlled, accessible only to fully authorized personnel, and maintained and protected to the extent allowable by law.

A.1.2 Overview of the Data Collection System

RTI International will implement all three phases of this study. The types of information collection activities included in this sub-collection request are

- qualitative interviews (Phase 1); and
- field testing of new materials via Web-based surveys, handheld devices, or ACASI (Phases 2 and 3).

The participants for this project will be 580 English speaking individuals (290 MSM and 290 heterosexuals) over a 1-year period. Data will be collected in up to six cities with high HIV and AIDS prevalence and incidence, such as Baton Rouge, Louisiana; Birmingham, Alabama; Charlotte, North Carolina; Chicago, Illinois; Cleveland, Ohio; Detroit, Michigan; Houston, Texas; Jacksonville, Florida; Los Angeles, California; Memphis, Tennessee; Miami, Florida; Newark, New Jersey; Oakland,

California; Philadelphia, Pennsylvania; Richmond, Virginia; and Washington, DC.

A.1.3 Items of Information to be Collected

The proposed study consisting of qualitative interviews (Phase 1) and field testing to be conducted via Web-based surveys (Phases 2-3) will collect information on the following: message comprehension, clarity, word choice, reactions, personal relevance, credibility, practicality, and motivational appeal, as well as information on sociodemographics, sexual identity, HIV testing behaviors and prevention strategies, risk behaviors, substance use, and knowledge, attitudes, behaviors, and perceived social norms around HIV/AIDS. A copy of the qualitative interview guide is provided in **Attachment 1.** A copy of the screening instrument is attached as **Attachment 2**. The survey will be delivered via the Web, handheld devices, or ACASI.

A.1.4 Identification of Web Site(s) and Web Site Content Directed at Children Under 13 Years of Age

This information collection does not involve Web sites or Web content directed at children under 13 years of age. The contractor will use a survey vendor to host the Web-based survey and the Web site hosting the survey will have controlled access.

A.2 Purpose and Use of the Information Collection

RTI will conduct qualitative interviews and field testing via Web-based surveys, handheld devices, or ACASI to qualitatively and quantitatively assess the acceptance of the messages to determine and recommend which messages to further develop and implement as part of each safer sex guide. Each safer sex guide will include information on the risk of HIV transmission and acquisition and potential risk reduction activities among MSM and among heterosexuals.

A.2.1 Qualitative interviewing for Materials Development

The purpose of this data collection is to use qualitative interviewing methods to identify appropriate intervention content by separately pre-testing draft messages with members from each of the target audiences. We will conduct 60-minute individual qualitative interviews with volunteer respondents using standardized methods. Qualitative interviews will be conducted with 60 MSM, 30 heterosexual males, and 30 heterosexual females. Results of the qualitative interviews will be used to develop the

most appropriate and successful messages, including how to properly tailor the messages, which visuals and graphics should be included, and how the messages and other content should be organized in a safe sex guide. A copy of the qualitative interview guide is provided in **Attachment 1**.

A.2.2 Field Testing of New Materials

The purpose of this data collection is to conduct field tests of new interventions, also referred to as pilot testing. We will conduct field testing via 30-minute Web-based surveys, handheld devices, or ACASI to quantitatively pre-test the messages. Field testing of messages will be conducted via Web-based surveys with 200 MSM, 100 heterosexual males, and 100 heterosexual females. Further field testing of final materials will be conducted with 30 MSM, 15 heterosexual males, and 15 heterosexual females. The objective of the pilot testing is to evaluate the feasibility of the new messages for each of the target audiences. The pilot may also include different versions of messages in order to determine which version functions better in the actual field environment. The information obtained from the proposed data collection will be used by CDC to plan the presentation of the messages and to determine how to properly tailor the messages, which visuals and graphics should be included, and how the messages and other content should be organized in a safe sex guide. A copy of the field testing survey instrument item bank is provided in **Attachment 2**.

CDC and RTI will disseminate the study results to the public through reports prepared for/by CDC and RTI and through peer-reviewed journal articles where appropriate. All releases of information will be reviewed and approved by CDC.

A.3 Use of Improved Information Technology and Burden Reduction

The field testing phases of the research (Phases 2-3) will utilize Web-based and/or handheld and ACASI surveys to be self-administered at home on personal computers or in field settings. Use of the Web and electronic surveys has the advantage of being able to conveniently expose participants to messages that may be used in the safer sex guides and related materials. It also allows participants to complete as much of the survey as desired in one sitting and to continue the survey at another time while also minimizing the possibility of participant error by electronically skipping questions that are not applicable to a particular participant, thus minimizing participant burden. The

use of these technologies for data collection will also help to reduce interviewer biases and minimize social desirability.

A.4 Efforts to Identify Duplication and Use of Similar Information

The National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) has verified that there are no other federal generic collections that duplicate the study types included in this request.

A.5 Impact on Small Businesses or Other Small Entities

This collection request does not involve burden to small businesses or other small entities.

A.6 Consequences of Collecting the Information Less Frequently

The activities involve a one-time collection of data. There are no legal obstacles to reducing the burden.

A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This data collection request fully complies with the regulation 5 CFR 1320.5.

A.8 Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A Federal Register Notice for the generic clearance 0920-0840 was published on March 11, 2009.

CDC convened a consultation with experts in communication and HIV behavioral science to identify dimensions of new HIV prevention strategies, discuss implications of these dimensions for messaging, recommend messaging principles, and recommend future research to inform the next generation of HIV prevention messages. The proposed study represents additional research (message and materials testing) recommended by the experts during the consultation meeting. Key message development consultants are shown in **Exhibit A.1**.

Exhibit A.1 Individuals To Be Consulted During the Development of HIV Prevention Decision Support Messages for MSM and Heterosexuals

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A.9 Explanation of Any Payment or Gift to Respondents

Project participants will be offered cash tokens of appreciation that will not exceed $50 per person.

In Phase 1, each participant will be provided a $50 token of appreciation for taking part in a 60-minute qualitative interview. This token will help recruit participants who are hard to reach.

In Phases 2 and 3, each participant will be provided a $25 token of appreciation for completing the 30-minute Web-based survey.

Participants will receive a token of appreciation for contributing to this important study. Numerous empirical studies have shown that honoraria can significantly increase response rates (e.g., Abreu & Winters, 1999; Greenbaum, 2000; Shettle & Mooney, 1999). Smaller amounts would not appear sufficiently attractive to adults. The token of appreciation amounts were determined through discussions with RTI staff with expertise in conducting interviews with the study population and surveys with adults about HIV; the amounts are based on prior experience

conducting interviews with MSM (OMB Control #0920-0762) and Web-based surveys with adults about HIV (OMB Control #0920-0752).

In addition, because a large portion of our sample will be selected from a list sample of e-mail addresses (Phases 2-3), the use of modest tokens of appreciation is expected to enhance survey response rates without biasing responses or coercing participants to participate. We also believe that the tokens of appreciation will result in higher data validity as adults become more engaged in the survey process. Because not all selected individuals may be eligible for the study, we want to assure sufficient project spending and thus provide tokens of appreciation to participants only after they are determined to be eligible.

A.10 Assurance of Confidentiality Provided to Respondents

A.10.1 Qualitative Interviews

RTI and/or a professional recruitment firm will utilize names and addresses to send reminder letters/e-mails and make reminder phone calls (see **Attachment 7**) for upcoming data collection, but the information will not be recorded elsewhere. All personal identifiers needed to locate potential participants will be stored in separate locked file cabinets in locked offices in a secured facility. All electronic files will be password controlled, accessible only to fully authorized personnel, and maintained and protected to the extent allowable by law.

RTI will select professional recruitment firms, reserve facilities where interviews will take place, and will oversee each firms' recruitment of participants. Recruitment staff will receive extensive instructions on the importance of maintaining data in a secure manner at all times. Furthermore, all employees who work on this study will be required to sign a letter of agreement. RTI and the professional recruitment firms will use a screening instrument to identify eligible participants for the study (**Attachment 3**). As participants are recruited, recruitment grids will be prepared to keep track of the recruitment, listing the participants' first name and demographic information obtained from the screener. The recruitment grids will be stored in a locked file cabinet or on a password-protected project share drive at RTI, and each interview facility will destroy their copy of the recruitment grid after data collection has been completed. Copies of the recruitment grid will be provided to RTI and CDC for description of the study sample, which 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.

No information in individually identifying form(IIF)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.

Once a potential participant comes to the study site and checks in for their interview, he or she will be given a consent form (**Attachment 4**). The individual will be given time to read the consent form on his or her own, and a trained RTI or CDC staff member will be available to answer any questions. If the individual agrees to participate in the study, we will obtain written consent and provide a copy to the participant for his or her records. Participants will be reminded that they can refuse to answer any question and they can withdraw from the study at any time without penalty. After the interviews are completed in each city, RTI staff will FedEx or personally deliver these consent forms to RTI. The consent forms will be stored in a locked file cabinet at RTI for the duration of the project. Once the project ends, RTI staff will destroy the forms.

A.10.2 Field Testing Web-based, Handheld, and ACASI Surveys

CDC and RTI will receive data for analysis in aggregate form, and the randomly generated numbers assigned as participant ID numbers will not link data to individuals. The participant ID itself will be used only to track the survey completion pattern (i.e., how many people complete a survey). Although the survey vendor retains contact information on participants for token of appreciation purposes, IIF is not shared with anyone, including CDC and RTI. This information is stored separately from the survey data file and is not linked in any way to participant responses. All participants will be assured that the IIF will be used only for the purpose of this research and will be kept private to the extent allowable by law, as detailed in the survey consent form (see **Attachment 5**).

Participants will be assured that their answers to screener (see **Attachment 6**) and survey questions (see **Attachment 2**) will not be shared with anyone outside the research team and that their names will not be reported with responses provided. Participants will be told that the information obtained from all of the surveys will be combined into a summary report so that details of individual questionnaires cannot be linked to a specific participant.

Once a potential participant has entered the secure Web site or begins the electronic survey, a brief introduction will inform the participant of the private and voluntary nature of the survey. After reading the informed consent, each participant must check either a box labeled “YES, I agree to participate” or “NO, I do not wish to participate.” Only participants who select “YES” will enter the survey.

Each participant will be assigned a personal password to open the survey. No mention of the survey topic will be made in the initial e-mail introduction or before the potential participant has entered their password and been given the opportunity to ensure they have adequate privacy to complete the survey. The participant’s password is required each time to access the survey and will keep the participant’s spot in the survey so that they can pick up where they left off; if an individual has already completed the survey, he or she will not be able to complete it again. Individuals who consent to participate in the survey will be able to access the survey by clicking on the link to the survey URL. A participant’s unique ID number will not change. It is possible that if a participant does not log out or close the survey a spouse, family member, roommate, or someone else could view the a participant’s responses without his or her knowledge, which may threaten their privacy. Participants will be reminded to properly log out and close the survey to avoid such threats of privacy.

RTI maintains restricted access to all data preparation areas (i.e., receipt and coding). All data files on multi-user systems will be under the control of a database manager, with access limited to project staff on a “need-to-know” basis only. Any survey vendor contracted by RTI will take the following security measures to ensure separation between participants’ identity and their survey data. First, no participant name, address, e-mail address, telephone number, or any other kind of IIF appears on the survey. The only way a survey is identified is with a digital identification number. Second, although the invitation method (i.e., e-mail) will inherently have IIF information included, this will not be combined with survey responses, so the responses from the survey are not linked to the IIF. Third, screener data will be considered part of the survey data. The survey vendor will provide the results of the screener questions for all participants, regardless of whether they qualify for the study. However, vendor will not retain responses to screening questions for those who are deemed ineligible for any other purpose outside the scope of this project. Fourth, the survey vendor will retain

study records for the duration of the study. Upon final delivery of data files to RTI and completion of the project, the vendor will destroy all study records, including data files, upon request. Once this information is destroyed, the survey vendor will be unable to supply or access it for any reason, even at the request of RTI. Finally, data coming directly from the survey engine are stored in a proprietary database. Although these data are not encrypted, once inside the firewall, they are stored in a relational database protected by several layers of intrusion detection and access control. Data files delivered to RTI by the vendor will be sent via encrypted files.

A.10.3 Privacy Impact Assessment

Information will be collected on paper (Phase 1) and electronically (Phases 1-3). CDC will not receive any personally identifiable information (IIF). All IIF collected by the contractor will be unlinked or stripped from data delivered to CDC. The use of Web-based surveys may involve the hosting of a Web site or subcontracting of the evaluation through a different vendor. No evaluation materials, surveys, Web sites or Internet content will be directed at children under 13 years of age. All personal identifiers needed to locate potential participants will be stored in separate locked file cabinets in locked offices in a secured facility. Each interview facility will destroy their copy of the recruitment grid after data collection has been completed. All electronic files will be password controlled, accessible only to fully authorized personnel, and maintained and protected to the extent allowable by law.

This study entails the measurement of sensitive HIV-related questions necessary to adequately assess the topic area (see Section A.11 for more detail). All participants will be assured that the information will be used only for the purpose of this research and will be kept private to the extent allowable by law. Participants will be assured either by the interviewer (Phase 1) or via the computer script (Phases 2 and 3) that their responses will not be shared with anyone outside the research team and that their names will not be reported with responses provided. Participants will be told that the information obtained from all of the qualitative interviews and field testing Web-based and/or handheld and ACASI surveys will be combined into a summary report so that details of individual responses cannot be linked to a specific participant.

To maintain privacy, each field testing Web-based and/or handheld and ACASI survey participant will have a personal password to open the survey. No mention of the survey topic will be made in the initial e-mail introduction or before the potential participant has entered their password and been given the opportunity to ensure that they have adequate privacy to complete the survey.

RTI maintains restricted access to all data preparation areas (i.e., receipt and coding). All data files on multi-user systems will be under the control of a database manager, with access limited to project staff on a "need-to-know" basis only. Any Web-based survey vendor utilized by RTI will take multiple security measures to ensure separation between participants' identity and their survey data. Data coming directly from the survey engine are stored in a proprietary database. Although these data are not encrypted, once inside the firewall, they are stored in a relational database protected by several layers of intrusion detection and access control. Data files delivered to RTI by the survey vendor will be sent via encrypted files.

A.11 Justification for Sensitive Questions

The study asks questions of a sensitive nature including questions related to HIV risk. This measurement of sensitive HIV-related questions is necessary to adequately assess the topic area. Further, the questions in this data collection are necessary to assess the support messages in order to identify intervention content and delivery regarding key HIV concepts and strategies. The safe sex guides and related tools are a direct initiative in response to the need to provide information about the risks of various sexual behaviors so that both MSM and heterosexuals can make informed choices about their sexual behaviors. As such, our study entails the measurement of sensitive sexual health–related questions.

To identify the intended audience, the screening instruments (see **Attachments 3 and 6**) will include some sensitive questions, including race/ethnicity, sexual behavior, sexual orientation, and HIV serostatus.

The qualitative interview guide (see **Attachment 1**) and field testing Web-based and/or handheld and ACASI surveys (see **Attachment 2**) also include questions about HIV knowledge, attitudes, and beliefs, as well as questions about perceptions of risk, normative beliefs, and behavioral beliefs related to HIV. In addition, because HIV is transmitted through sexual contact

and intravenous drug use, our survey includes questions about these behaviors to enable us to understand the transmission behaviors of our survey participants. These questions are necessary to inform the development of the messages.

All participants will be assured that the information will be used only for the purpose of this research and will be kept private to the extent allowable by law.

A.12 Estimates of Annualized Burden Hours and Costs

A.12.1 Estimated Annualized Burden Hours

The total annualized response burden is estimated at 403 hours. Exhibit A.2 provides details about how this estimate was calculated. The screening instrument for the qualitative interviews (n = 180) is expected to take about 10 minutes to complete, and the screener for the Web-based survey (n = 675) is expected to take about 2 minutes to complete. Each qualitative interview (n = 120) is expected to take about 60 minutes, and each Web-based survey (n = 460) is expected to take 30 minutes. We expect to screen a total of 180 individuals to complete 120 qualitative interviews. We expect to screen 675 individuals to complete 460 Web-based surveys.

Exhibit A.2 Annualized Burden Hours

Type of Respon-dent	Form Name	No. of Respon-dents	No. of Responses per Respon-dent	Average Burden Per Response (in Hours)	Total Response Burden Hours
General public	Screener/ Qualitative Interview	180	1	10/60	30
	Screener/ Web Based Survey	675	1	2/60	23
	Qualitative Interview	120	1	1	120
	Web Based Survey	460	1	30/60	230
Total					**403**

A.12.2 Estimated Annualized Burden Costs

We do not know what the wage rate category will be for the selected participants (or even whether they will be employed). We used the figure of $20 per hour as an estimate of average hourly wage rate across the country for the general public (United States Department of Labor, Bureau of Labor Statistics May 2005 http://www.bls.gov/oes/current/oes_nat.htm#00-0000). The estimated annual cost to participants for the collection of information will be $8,060.00.

Exhibit A.3 Annualized Cost to Respondents

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Screener/ Qualitative Interview	30	$20	$600
Screener/Web Based Survey	23	$20	$460
Qualitative interview	120	$20	$2,400
Web Based Survey	230	$20	$4,600
Total	**403**		**$8,060**

A.13 Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

CDC does not anticipate providing start-up or other related costs to private entities. There are no costs to respondents or record keepers.

A.14 Annualized Costs to the Federal Government

One CDC Technical Monitor will be responsible for obtaining CDC approvals, providing project oversight, and participating in data collection, analysis and dissemination of the results. The contractor's costs are based on estimates provided by the contractor who will carry out the data collection activities. With the expected period of performance, the annual cost to the federal government is estimated to be $271,163 (**Exhibit A.4**). This is the cost estimated by the contractor, RTI, and includes the estimated cost of coordination with CDC, data collection, analysis, and reporting.

Exhibit A.4 Estimates of Annualized Cost to the Government

Expense Type	Expense Explanation	Annual Costs
CDC oversight of contractor and project	20% of FTE: GS-13 Health Communication Specialist	$17,100
Recruitment, data collection, analysis, and reporting (contractor)	Labor hours and ODCs	$254,063

CDC = Centers for Disease Control and Prevention; FTE = full-time equivalent; ODC = other direct cost

A.15 Explanation for Program Changes or Adjustments

Not applicable: This request is for a sub-collection under a generic approval.

A.16 Plans for Tabulation and Publication and Project Time Schedule

The key events and reports to be prepared for this study are listed in **Exhibit A.5**.

Exhibit A.5 Project Time Schedule

Activity	Time Schedule
Phase 1: Identify and reserve professional recruitment firms	1 month after OMB approval
Phase 1: Begin recruitment	1 month after OMB approval
Phase 1: Conduct qualitative interviews	2 months after OMB approval
Phase 1: Submit Topline report	4 months after OMB approval
Phase 2: Conduct Web-based surveys	6 months after OMB approval
Phase 2: Submit Topline report	8 months after OMB approval
Phase 3: Conduct Web-based surveys	10 months after OMB approval
Phase 3: Submit Topline report	12 months after OMB approval

A.17 Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB expiration date will be displayed.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

This information collection request does not employ statistical methods. The following is a description of data collection procedures.

B.1 Respondent Universe and Sampling Methods

This study will be conducted with a total of 580 English speaking individuals (285 MSM and 285 heterosexuals) aged 18 or older in up to six cities across three phases. Our sample will be a non-probability based purposeful sample. To the extent possible, participants will be distributed geographically in up to six cities with high rates of HIV/AIDS, such as Baton Rouge, Louisiana; Birmingham, Alabama; Charlotte, North Carolina; Chicago, Illinois; Cleveland, Ohio; Detroit, Michigan; Houston, Texas; Jacksonville, Florida; Los Angeles, California; Memphis,

Tennessee; Miami, Florida; Newark, New Jersey; Oakland, California; Philadelphia, Pennsylvania; Richmond, Virginia; and Washington, DC (http://www.cdc.gov/hiv/topics/surveillance/resources/reports/2007report/pdf/2007SurveillanceReport.pdf).

Phase 1 of the research will consist of 120, 1-hour qualitative interviews to gain in-depth insight into the messages, including graphics and/or visual images that would be presented in a safer sex guide that includes information on the risk of HIV transmission and acquisition and the potential risk reduction activities among MSM and among heterosexuals. Phase 1 will be an exploratory phase with the primary objective to assess basic comprehension of messages. After modifications are made based on the results of Phase 1, in Phase 2, we will conduct field testing via a 30-minute Web-based and/or handheld and ACASI survey with 400 individuals (200 MSM and 200 heterosexuals) to test the revised messages for each target audience. In Phase 3, we will conduct additional field testing via a 30-minute Web-based and/or handheld and ACASI survey with an additional 60 individuals (30 MSM and 30 heterosexuals) to test the final version of all the messages to be presented for each guide. The results will be used to plan the presentation of the messages, how to properly tailor the protocol, which visuals and graphics should be included, and how the messages and other content should be organized. We will interview/survey each participant only once and will be able to develop all materials through the one-time (three-phase) data collection.

B.2 Procedures for the Collection of Information

B.2.1 Recruitment

Qualitative Interviews

RTI, in conjunction with professional recruitment firms, will recruit participants for the qualitative interviews. Recruitment materials are provided in **Attachment 7**. Based on our prior experience recruiting participants from this target audience for other qualitative studies, we expect that only about 90% of those recruited will show up for the interviews. Therefore, we will over recruit to compensate for no-shows. Recruitment will begin at least 4 weeks before the qualitative 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 IRB and OMB clearance is received. Typically, recruitment takes about 1 month; we will begin recruitment for the qualitative interviews within 1 month of receiving clearance. Dates will be assigned to each activity on the timeline for tracking and monitoring purposes after receiving IRB and OMB clearance.

Field Testing Web-based Surveys
Surveys for each target audience will include Web-based and/or handheld and ACASI surveys to test messages and materials via the Internet. Potential participants will be selected from an online survey vendor with a national opt-in e-mail list sample who self-identify as MSM or heterosexual. The survey vendor will send e-mail invitations to individuals who fall into the targeted audience for this project using their market research panel and additional sample lists from other off-panel sources to be determined. Each invitation will contain the survey title, the length of the survey, the incentive amount provided for successful completion of the survey, and instructions for accessing the secure Web site for the survey. To reduce the effects of nonsampling error, nonresponse and post-stratification weighting adjustments will be applied to the sample when feasible.

B.2.2 Screening and Scheduling Procedures

Qualitative Interviews
RTI and the professional recruitment firms will use a screener (see **Attachment 3**) to identify eligible participants. As participants are recruited, 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 IIF. 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. They will be destroyed at the end of the project.

Reminder letters and/or e-mails will be sent to potential participants 1 and 2 weeks prior to the data collection giving them directions to the study site. Confirmation calls will also

be made 1–2 days prior to the interview to assure that all recruits are confirmed.

Field Testing Web-based Surveys
Once an individual opts in, a more in-depth description of the survey and the consent form will be presented informing the potential participant of the confidential and voluntary nature of the survey.

Once the potential participant has entered the secure Web site, a brief introduction will be presented informing them of the confidential and voluntary nature of the survey. After reading the informed consent, each participant must check either a box labeled "YES, I agree to participate" or "NO, I do not wish to participate." Only participants who agree to participate will enter the survey.

Nonrespondents will receive up to two e-mail reminders from the survey vendor requesting their participation in the survey. Copies of the e-mail notifications are provided in **Attachment 8**.

B.2.3 Data Collection Methods

Qualitative Interviews
Once a potential participant comes to the study site and checks in, he/she will be given a consent form (see **Attachment 4**). The individual will be given time to read the consent form on his or her own, and a trained RTI or CDC staff member will be available to answer any questions. If the individual agrees to participate in the study, they will sign the consent form. The participant will be given a copy of the consent form to keep for their records. Participants will be reminded that they can refuse to answer any question and they can withdraw from the study at any time without penalty. RTI staff will FedEx or personally take these 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, the forms will be destroyed.

Data collection will be conducted over a 6-week period. The interviews will be conducted in person by a professional interviewer. The location of the data collection will vary depending on the city. Options include professional focus group facilities or 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 will last for 1 hour. In addition to the interviewer, an RTI staff member may attend the data collection to take notes on a laptop computer and coordinate logistics of checking in participants and obtaining informed consent. One or more CDC staff members may also attend and observe the interviews. All interviews will be audio recorded with the consent of the participant.

Field Testing Web-based Surveys
Individuals who agree to participate in the survey will be able to access the survey by clicking on the link to the survey URL. Each participant will receive a unique identifier and will need to provide it each time they access the survey. A participant's unique identifier will not change. Data from completed surveys will then be compiled into an SPSS dataset by the survey vendor and sent to RTI, with no IIF, for analysis.

The surveys will be self-administered and accessible any time of day for a designated period. All data collection materials are at an 8th grade reading level or below due to sample eligibility criteria and CDC requirements.

Each participant can complete the survey only once. Upon initial log-in, potential participants who indicate willingness to participate will be directed to a brief online informed consent form (see **Attachment 5**) where they will be given general information about the study screener. Participants will provide consent to be screened for the study through point-and-click acceptance through survey vendor software. Once participants indicate their consent to be screened for the study, they will then be screened for eligibility via a brief online screener (see **Attachment 6**) that includes questions on gender, age, sexual orientation, and other characteristics needed to identify eligible sample members. Eligible participants include adults who meet the criteria for each of the target audiences. Individuals who are eligible for the study will be presented with the more detailed online consent form (see **Attachment 5**), which provides general information about the study, topics to be covered in the survey, potential risks of participation, and tokens of appreciation available for completing the survey. Once participants indicate their consent to participate, they will proceed directly to the online survey. Study participants will be given a designated period during which the survey will be available for them to complete, making it feasible for participants to complete the survey during their own time, in private. This mechanism makes the study suitable for addressing

sensitive topics, such as sexual behavior, while also improving the accuracy and validity of the data obtained for these sensitive topics.

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

The following procedures will be used to maximize cooperation and achieve the desired participation rates:

Qualitative Interviews

- Recruitment will be conducted by professional recruitment firms.
- Reminder letters/e-mails will be sent with directions to the research site, and reminder phone calls will be placed 1-2 days prior to the scheduled data collection. Participants will not be contacted again after the interview is over.
- Token of appreciation of ($50) will be paid to participants. (see Section A.9 for more information about the tokens of appreciation).

Field Testing Web-based Surveys

- A $25 token of appreciation will be offered to participants who complete the survey.
- Nonrespondents will receive up to two e-mail reminders from the survey vendor requesting their participation in the survey.
- The survey vendor will provide toll-free telephone numbers to all sampled individuals and invite them to call with any questions or concerns they might have about any aspect of the study. RTI will provide a toll-free telephone number for the RTI project director and a toll-free telephone number for the RTI IRB hotline should participants have any questions about the study or their rights as study participants.
- The survey vendor data collection staff will work with RTI project staff to address any concerns that may arise.
- A study overview will be included in the introductory information for participants prior to each survey. The information will present an interesting and appealing image and alert participants to the upcoming surveys.

B.4 Test of Procedures or Methods to Be Undertaken

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

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

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