

National HIV Behavioral Surveillance:
Brief HIV Bio-behavioral Assessment (NHBS-BHBA)
OMB NO. 0920-XXXX

Supporting Statement B

August 18, 2022

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1. Respondent Universe and Sampling Methods

Brief HIV Bio-behavioral Assessments (BHBA) are mixed-methods assessments conducted in priority populations in selected geographic areas of interest across funded states in the United States. The process will include 1) identification of geographic areas/populations at risk, 2) formative assessment for operations, 3) mixed methods data collection and HIV testing, and 4) data analysis and dissemination, and development of recommendations. At the end of each data collection year (i.e., years 2-5 of the cooperative agreement), funded states will identify two or more priority populations to conduct NHBS-BHBA data collection for the following year. This iterative process provides flexibility and is intended to ensure that BHBA data collection occurs in places and populations where data are needed.

Sampling and Recruitment Methods

Project staff will implement sampling and recruitment methods appropriate for reaching BHBA populations in selected geographic areas. Given that the BHBA populations may be hard to reach, one or more sampling methods that optimize recruitment may be implemented. Below is a description of sampling methods for quantitative and qualitative data collection.

Quantitative data collection sampling methods

Venue-based sampling recruitment (VBS)

VBS activities occur at venues. Venues eligible for consideration will be publicly accessible and frequented by members of the prioritized population for purposes other than receiving HIV/STD diagnostic testing, medical treatment, or prevention services. Venues may be physical locations and include bars, dance clubs, retail businesses, cafes and restaurants, health clubs, social and religious organizations or groups, adult bookstores and bathhouses, high-traffic street locations, drug markets, parks, beaches, and special events such as gay pride festivals, raves, circuit parties, etc. Venues may also be virtual (online), such as social or dating applications (apps).

First, project staff identify all the eligible venues (or "spaces") and times to recruit members of the prioritized population in a geographic area. Eligible venues are assessed by project area staff for the number of people in attendance at different times, logistics and feasibility of recruiting and

conducting the data collection activities, and safety. Venues that are accessible for BHBA operations are termed "accessible venues." Only accessible venues are included on the sampling frame.

Monthly sampling frames are constructed of accessible venues and specific day-time periods during which each venue has adequate number of people from a prioritized population in attendance during a predetermined recruitment period (e.g., 4-hour period). Project staff should use a recruitment calendar to schedule the venues, days, and times for recruiting participants.

Respondent-driven sampling (RDS)

RDS is a chain-referral sampling strategy. It starts with a limited number of "seeds" who are chosen by referrals from people who know the priority population well, or through outreach to areas where the population can be found. Seeds complete the quantitative data collection and then are asked to recruit a specified number of persons whom they know (usually 3 or 5). Seeds who agree to recruit their peers are given up to 5 non-replicable uniquely coded coupons. Coupons may be paper coupons or a digital image of a coupon.

To track recruitment, the code on each coupon is linked to 1) the Survey ID of the participant the coupon is issued to (i.e., the recruiter) and 2) the Survey ID of the participant returning the coupon (i.e., the recruit). The coupon information is entered and stored in a coupon manager application (University of California San Francisco). Recruited peers, in turn, present a valid coupon, complete the interview, receive an HIV test if they consent, and are asked to recruit others. This recruitment process continues until the sample size has been reached. Funded states will include interview questions about the social network size and composition that can be used to calculate RDS weights to generate population-based estimates.

Participants receive incentives for participating, as well as for recruiting others. Starting with a small number of seeds, limiting the number of individuals each participant can recruit, and allowing a significant number of recruitment "waves" to occur (a "wave" refers to each additional generation of recruits stemming from a seed), is expected to lead to the distribution of a final sample that resembles the underlying priority population and that is unbiased by the characteristics of the seeds (Heckathorn, 1997; Heckathorn, 2002).

Peer-to-peer recruitment

Project staff can ask participants referred from community partners or recruited directly at-venues or through virtual recruitment to recommend BHBA participation to their peers. Project staff can share information about the BHBA project with participants via texts, emails, coupons, flyers, word of mouth, or other means, and ask them to refer others to the project. Their referrals can use this information to learn about the project and to contact project area staff if they are interested in participating.

This recruitment method differs from RDS which requires a more systematic approach in tracking the recruitment process. Unlike RDS, a peer-to-peer recruitment method does not require recruiter incentives, there is no need to track recruitment chains, there is no limit to the number of referrals from one participant, and there is no need to collect information about the size of the social networks of participants. However, a limitation of the peer-to-peer recruitment method is that data can only be analyzed as a convenience sample and population-based estimates cannot be calculated.

Virtual recruitment

Different approaches can be considered for virtual recruitment through VBS or other recruitment methods. There are multiple online services that people often use to socialize or to find sexual partners. These can be social networking (SN) apps, websites, or geospatial social networking (GSN) apps. The patterns and preferences of members of a priority population in using online services for finding partners or socializing may differ by geographic region, age, race or ethnicity. Virtual recruitment can be active or passive. Active recruitment occurs when a staff member first contacts an individual to participate in the BHBA. Passive recruitment methods are when individuals first contact project staff about participation in the BHBA (e.g., passive profile approach). For safety, security, and privacy, only project accounts will be used to conduct any NHBS-BHBA operations.

Qualitative data collection sampling methods

Qualitative methods focus on purposeful sampling- intentionally identifying participants who can provide rich information on HIV prevention and treatment. Recruitment of participants will be conducted using methods that have been previously used to recruit

hard-to-reach populations for behavioral surveys, and multiple recruitment approaches may be used for a specific purposeful sampling strategy. These include, but are not limited to, location-based, peer-to-peer, and referral from community partners or well-known community members of the priority populations.

Location-based method

Participants sampled through the location-based method will be recruited from multiple settings frequented by the selected population. Appropriate locations can be identified through referrals from the project advisory group, local health care providers, community-based organization staff, field epidemiologists, community observations, and intercepts in potential locations.

Peer-to-peer recruitment

Project staff can ask participants referred from community partners or recruited directly at-venues or through virtual recruitment to recommend BHBA participation to their peers. Project staff can share information about the BHBA project with participants via texts, emails, coupons, flyers, word of mouth, or other means, and ask them to refer others to the project. Their referrals can use this information to learn about the project and to contact project area staff if they are interested in participating.

Referrals from community partners

Funded states may collaborate with community partners (e.g., syringe services programs, health clinics, community-based organizations) identified during the pre-implementation phase to assist with recruitment. Community partners with access to the population of interest may be enlisted to describe the BHBA to potential participants who would meet the eligibility criteria and refer them to the field site for screening.

Respondent eligibility criteria

Once a priority population is identified, funded states will work with CDC to formally define the population and develop population-specific criteria that will determine eligibility for participation in BHBA data collection, i.e., quantitative interviews and HIV testing, and qualitative data collection.

Population-specific criteria may include behaviors (e.g., a man who reports having had sex with another man in the past 12 months), and/or other types of population membership criteria (e.g., identifies as transgender woman). Cultural and subject matter experts with broad-based knowledge of specific BHBA populations may also participate in qualitative data collection.

Participant Inclusion criteria

To be eligible, potential participants in all BHBA data collection activities must be:

- At least 18 years of age,
- Able to provide informed consent for participation,
- Able to complete interview in English or Spanish,
- A resident of selected geographic area (e.g., county), and
- Not previously participated in the same quantitative interview or qualitative interview for a specific BHBA in the funded state.

Participants must meet additional inclusion criteria, depending on the selected population, for example:

- MSM: Man who had sex with another man in the past 12 months
- PWID: People who inject drugs in the past 12 months
- HET: Had sex with an opposite-sex partner in the past 12 months; are not older than 60 years

Sample size

On an annual basis each funded state works with at least two project areas in selected geographic areas to recruit and conduct quantitative interviews with 500 eligible persons from the selected populations, as well as 40 eligible participants for qualitative data collection.

Expected response rates

NHBS-BHBA will involve conducting at least two BHBA's per year of data collection for 2 funded states. The number of participants is expected to vary per BHBA.

The estimates in Table B1 cover the number of people screened and participating in quantitative data collection for the three years of data collection requested under this request. For quantitative data collection, eligibility screening is done in two steps. First, the participant is screened for base eligibility, which is

the same for all NHBS-BHBA populations. Approximately 1,338 individuals will complete the base eligibility screener annually, and 1,204 individuals will complete the population eligibility screener annually. We anticipate that, on average, 338 of the respondents (25.3%) will be either not interested in a quantitative interview or will be ineligible after completing the base and population eligibility screeners, yielding a total of 1,000 eligible respondents over a 12-month period.

Table B1: Expected Response Rates and Sample Size for BHBA Quantitative Data Collection by Data Collection Year

	2023			2024			2025		
	Screened Base Eligibility	Screened Population Eligibility	Participants	Screened Base Eligibility	Screened Population Eligibility	Participants	Screened Base Eligibility	Screened Population Eligibility	Participants
TOTAL	1,338	1,204	1,000	1,338	1,204	1,000	1,338	1,204	1,000

The estimates in Table B2 cover the number of people screened and participating in qualitative data collection by demographic characteristics for the three years of data collection requested under this request. For qualitative data collection, a short screening to assess population eligibility will be administered as needed for key informant interviews and focus groups. Approximately 96 individuals will complete the eligibility screener annually. We anticipate that, on average 16 of the respondents (16.7%) will be either not interested in completing a qualitative interview or will be ineligible after completing the qualitative eligibility screener, yielding a total of 80 eligible respondents over a 12-month period.

Table B2: Expected Response Rates and Sample Size for NHBS-BHBA Qualitative Data Collection by Data Collection Year

	2023	2024	2025

	Screened	Participants	Screened	Participants	Screened	Participants
TOTAL	96	80	96	80	96	80

2. Procedures for the Collection of Information

General Procedures Applying to All Data Collection

All eligibility screening and interviews will be conducted by trained project staff. Participation in the project is voluntary. Respondents may refuse to participate at all or in part. Respondents may refuse to answer questions or stop participation at any time without penalty. The approved Project Determination Form (**Attachment 9**) indicates that because NHBS-BHBA is a routine disease surveillance activity the protocol will not be reviewed by CDC's IRB. Each funded state will be required to obtain approval for this project from their IRB as required by their local review and approval processes and federal regulations before data collection.

The informed consent process will be initiated with eligible persons. During the consent process, each component of the project is described, and the person approached must indicate which component(s), if any, they agree to participate in. Informed consent will be obtained by having the interviewer read the consent script and indicating on the computer whether the person being recruited provided verbal consent. Example model consent documents for quantitative and qualitative interviews are included as **Attachments 8a-d**.

Participants will be reimbursed approximately \$25 for their participation in the quantitative interview or \$25 for a qualitative interview. Reimbursements should have appropriate value to the population. The formative assessment process can help verify what types of reimbursements are appropriate.

Only authorized persons will have access to electronic NHBS-BHBA databases. Computers that can access electronic NHBS-BHBA data will be physically secured and protected by coded passwords. Electronic databases containing NHBS-BHBA data will be protected using coded passwords and stored on a secured network drive. All removable storage media containing NHBS-BHBA data will be

encrypted. No personal identifiers will be collected or included with responses to the quantitative or qualitative interview data or HIV testing.

Procedures Applying to Quantitative Data Collection

Persons who agree to participate in the quantitative data collection will be administered a structured questionnaire (**Attachment 3a-d**) by an interviewer through the Research Electronic Data Capture (REDCap) a secure web-based application (<https://www.project-redcap.org/>). The NHBS-BHBA quantitative questionnaire consists of several components. First, the participant will be screened for eligibility. Second, core questions constitute a standardized main component. Third, population questions are standardized, but they are asked of specific populations (e.g., men who have sex with men). The total administration of the quantitative interview is estimated to take up to 20 minutes.

All persons who agree to participate in a quantitative interview will be offered an anonymous HIV test which they may refuse with no effect on participation in the interview. The purpose of testing is to estimate HIV prevalence among priority populations. HIV counseling and testing must be conducted in accordance with the NHBS-BHBA protocol and in accordance with standards established by state and local health departments.

Persons who agree to participate in HIV testing will be provided with information about HIV testing. In accordance with local procedures and practices, project staff must offer rapid HIV testing and possibly laboratory-based HIV testing to participants. Rapid HIV test results will be returned to participants by a trained counselor after the quantitative interview. If applicable, local laboratory results will be returned to participants by a trained counselor during a scheduled counseling appointment. Participants who screen positive for HIV will be offered linkage to available care and treatment.

Dried blood spot (DBS) specimens may be collected for long term storage to conduct additional testing, such as testing for recent HIV infection, HIV viral load, presence of antiretroviral drugs for treatment or pre-exposure prophylaxis, or drug resistance. Other biological specimens may be collected and tested (e.g., viral hepatitis, sexually transmitted infections (STI)).

HIV tests will be provided at no cost to participants. In addition, participants will be reimbursed approximately \$25 for their time. If STI, hepatitis, or other tests are offered through NHBS-BHBA, these tests will be provided at no cost to participants. Participants may be reimbursed as appropriate for the local context for their time and inconvenience.

Procedures Applying to Qualitative Data Collection

In accordance with CDC-approved guidance, project staff will conduct qualitative data collection with each of their selected BHBA populations. They will include at least two different qualitative methods such as observations, brief intercept surveys, professional key informant interviews, community key informant interviews, and focus groups for each BHBA.

Topics explored and questions posed during qualitative data collection are often iterative and evolve over the course of data collection. This approach allows for the flexibility necessary for project staff to identify important or emerging themes, interpret quantitative interview findings, and inform recommendations and future BHBA. The Model Qualitative Data Collection Guide (**Attachment 3f**) provides suggested topic areas for BHBA qualitative data collection. Project staff will use the model to develop semi-structured interview guides for each audience (e.g., community key informant, professional key informant, specific sub-populations based on common characteristics) and format (i.e., individual interview vs. focus group) they intend to engage during each BHBA.

Interviews and focus groups may be audio recorded, for all participants who provide permission. Project staff will ask each participant if they can record their interview. The purpose of recording the interview is to capture all information that is shared by the participant and provide detailed data for analyses. Audio-recording the interview also allows the notetaker to pay attention to non-verbal cues and group dynamics, especially for focus groups. After the interview, each recorded interview should be transcribed. Summary information from qualitative interviews and transcriptions (if applicable) will be submitted to CDC. Audio files will be destroyed by project staff within two weeks of the interview when used for detailed notes, and within two weeks of when the information is recorded in a transcript (if transcribed). Audio-recordings will not be submitted to CDC. Project area staff will use REDCap to document key qualitative interview characteristics for each individual interview and focus

group (e.g., qualitative interview ID, date, type of interview, interviewer ID, confirmation of informed consent). Project area staff will also collect and document participant demographic information (e.g., gender, race/ethnicity) included on the Model Qualitative Data Collection Guide (**Attachment 3fX**). NHBS-BHBA data will not contain any PII.

In addition to REDCap documentation, qualitative data including transcripts (when available) or detailed interview notes (i.e., whatever data source will be used for final analyses) will be transferred to CDC by authorized project staff on a weekly basis, using FileZilla via established SFTP. PII will be redacted prior to data transmission to CDC. Only staff responsible for data transfer or oversight will have access to FileZilla.

Quality Control

Data quality for the quantitative interviews is ensured by the use of computer-assisted interviewing. Computer-assisted interviewing improves data quality in several ways:

- a) Interviewer errors are reduced because interviewers do not have to follow complex routing instructions; the computer does the routing for them.
- b) Respondent errors are also reduced. Consistency checks are programmed into the questionnaire so that inconsistent answers or out-of-range values can be corrected or explained while the behavioral assessment is in progress.
- c) Use of computer-assisted interviewing also reduces coding and coding errors, which makes it possible to prepare the data for analysis faster and with fewer errors.

Data quality for qualitative interviews is ensured by use of dual recorders (when audio-recording), monitoring interview length, reviewing REDCap data for accuracy, listening to audio recordings for quality, and reviewing transcripts for accuracy.

Interviewer training occurs before the start of each BHBA data collection. This training covers general interviewing skills, sampling and recruitment protocols, and a question-by-question review of the questionnaire to ensure interviewers understand the purpose of each question and how it should be read and coded in the computer (for quantitative interviews). Training specific to qualitative interviewing will also be conducted. Interviewers have opportunities to practice administering the questionnaire during the training. The training is also meant to address interviewer integrity, underscoring the importance of collecting quality data and the consequences of inappropriate behaviors,

including falsification of data. Project staff will also be trained on how to conduct recruitment procedures, such as approaching potential participants in venues and training participants to recruit their peers into the study (for peer referral or respondent driven sampling).

During the data collection period, interviewers are monitored by the field supervisors or other management staff. Surveys/interviews will be monitored based on a locally-determined evaluation schedule. Feedback will be provided for areas of improvement and in cases of incorrect implementation of the protocol. Monitoring recruitment will also allow for feedback on ways to help improve participation.

Funded states will review and monitor data quality throughout data collection, and address errors, gaps, or other data issues in a timely manner. CDC will regularly convene conference calls with the funded states to address any implementation issues that arise. CDC will also conduct at least one site visit per year for each funded state. The purpose of the site visit is to monitor adherence to the NHBS-BHBA protocols, observe recruitment and data collection, and obtain feedback on study procedures.

3. Methods to Maximize Response Rates and Minimize Non-response

Methods to maximize response rates

Response rates for NHBS-BHBA may be adversely affected by the sensitive nature of the questions. However, NHBS-BHBA methods also offer ways to maximize response rates, as described below. Monitoring of response rates will be done through conference calls on a bi-weekly basis with each funded state and monthly with all funded states together, offering the opportunity to share strategies for improving response rates.

Research indicates that providing an incentive to respondents helps raise response rates for long, sensitive, in-person surveys (Kulka, 1995). An incentive is also useful for groups that are hard to reach, including those for whom conventional means of motivation may not work, such as disenfranchised populations like those recruited for NHBS-BHBA. In addition, these populations (particularly MSM and PWID) have been frequently the focus of health-related data collections, in which an incentive is the norm (Thiede et al., 2001; MacKellar et al., 1996). Research has shown that financial incentives are effective at increasing response rates among female residents in minority zip codes

(Whiteman et al., 2003) and among African American participants in a community-based health promotion program (Halberti et al., 2010). A meta-analysis of 95 studies published between January 1999 and April 2005 describing methods of increasing minority enrollment and retention in research studies found that incentives enhanced retention among this group (Yancy et al., 2006). Providing an incentive to NHBS-BHBA respondents is critical to achieve acceptable response rates.

Incentives have been shown to be effective for promoting participation and reducing nonresponse in similar data collections that involve hidden populations or collect sensitive information. An incentive is also provided to persons who participate in CDC's HIV-related data collections including the National HIV Behavioral Surveillance (OMB 0920-0770 exp. 1/31/2023), Barriers and Facilitators to Expanding the NHBS to Conduct HIV Behavioral Surveillance Among Transgender Women (OMB 0920-1262 exp. 4/30/2022), and the Medical Monitoring Project (OMB 0920-0740, exp. 5/31/2024), which collects sensitive information from HIV-positive persons, also utilizes incentives to reduce nonresponse. Participants in the Medical Monitoring Project are offered \$50 as an incentive for their time.. Further information on the need for incentives in data collections focused on high-risk and hidden populations or collecting sensitive information is provided in section A.9 (Supporting Statement A).

Convenient hours of operation for BHBA data collection activities may also maximize response rates. Prior to conducting NHBS-BHBA, the project staff in each participating area will review existing data sources to determine the characteristics (e.g., race, ethnicity, age, geographic location) of the selected population. The project staff will also obtain input on the logistics of data collection from local stakeholders and members of the community through formative assessment. This input will help the project staff identify the most appropriate location for data collection and hours of operation and avoid barriers to participation of persons in the data collection.

Assessing Non-Response Bias

The use of an eligibility screener will allow comparison of the demographic and eligibility-related behavioral data among those who are eligible and ineligible. Project staff and CDC will use the data to identify problems with recruitment. Comparing data from the sample characteristics with the information gathered from local data sources and stakeholders about the local at-risk

populations will be used to identify subgroups of the selected population whom the data collection may be missing. When a problem with response or recruitment arises during data collection, project staff will be instructed to consult with local stakeholders and members of the local selected populations to identify solutions to the problem.

4. Tests of Procedures or Methods to be Undertaken

The data collection instruments were developed using questions predominantly from CDC's National HIV Behavioral Surveillance (NHBS)(OMB 0920-0770, exp. 01/31/2023), and other CDC surveillance projects, such as the Medical Monitoring Project (MMP) (OMB 0920-0740, exp. 5/31/2024) and the Injection Drug Use Surveillance Project (OMB 0920-1325, exp. 02/29/2024).

Prior to implementation in the field, CDC staff will test the skip patterns and responses of the data collection instruments. CDC staff will also conduct mock interviews of their CDC colleagues. OMB will be informed of any changes to data collection procedures or instruments as quickly as possible.

5. Individuals Consulted on Statistical Aspects

Consultants on Statistical Aspects

The following individuals consulted on statistical aspects only. They are not involved in collecting or analyzing the data.

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Individuals Collecting and/or Analyzing Data

CDC is not directly engaged with human subjects during data collection. Funded states will be responsible for data collection activities, monitoring recruitment, managing the data, and data analysis for local use. CDC Project Staff will train funded states in data collection methods, monitor data submissions from funded states, and analyze the data.

CDC Project Staff

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