

Barriers and Facilitators to Expanding the NHBS to Conduct HIV Behavioral Surveillance Among Transgender Women (NHBS-Trans)

#0920-1262

Supporting Statement
Part B

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REVISION

CONTACT

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List of Attachments

Attachment Number	Document Description
1	Section 301 of the Public Health Service Act
2	Federal Register Notice (60-day)
2a	Public Comments Received during 60-day FRN
3	Summary of Changes to Data Collection
4a	Eligibility Screener (English)
4b	NHBS-Trans Behavioral Assessment (English)
4c	Recruiter Debriefing Form (English)
5a	Eligibility Screener (Spanish)
5b	NHBS-Trans Behavioral Assessment (Spanish)
5c	Recruiter Debriefing Form (Spanish)
6	Privacy Impact Assessment
7	Assurance of Confidentiality for HIV/AIDS Surveillance
8	Agreement to Abide by Restrictions on Release of Surveillance Data
9	Authorization to Operate for the Data Coordinating Center
10	Project Determination (Approved 9/13/2021)
11	Model Consent for Survey Activities
12	Sample Analysis Tables
13	List of PS22-2201 NHBS-Trans Applicants
14	Model Recruitment Coupon
15	Response Rate Calculations

1. Respondent Universe and Sampling Methods

NHBS-Trans is a project intended to assess the feasibility of a survey and supporting data collection methodologies to obtain data on HIV risk behaviors, gaps and barriers to services, and other experiences of transgender (trans) women with emphasis on racial and ethnic minority populations in 14 U.S. cities with high burden of HIV. Project areas participating in the National HIV Behavioral Surveillance System (NHBS, OMB# 0920-0770, exp. 01/31/2023) have applied to participate in NHBS-Trans.

The size of the respondent universe for NHBS-Trans is unknown. It is estimated that 0.6% of U.S. adults identify as transgender (Flores AR, 2016). However, there are not reliable estimates for the size of the subpopulation of trans women, nor do we know the number of trans women at risk for HIV, thus it is not possible to create a sampling frame of this population. This project is not intended to yield representative data about any group except those are willing to be recruited by their peers.

NHBS-Trans activities were included as part of the NHBS cooperative agreement (CDC-RFA-PS22-2201). Of the 20 health department applicants, 14 applied to participate in NHBS-Trans. Those applications were reviewed and scored by a CDC objective review panel based on the applicants' previous experience with surveillance or research activities among trans women, ability to partner with organizations serving trans women, and ability to meet sample size, including the estimated number of trans women in the jurisdiction. A list of applicants can be found in **Attachment 13**. The number of selected applicants will be dependent on funding availability. Funding preference will be given to applicants who participated in the previous NHBS-Trans data collection.

Over three years, staff in project areas participating in NHBS-Trans will implement respondent-driven sampling (RDS) to recruit until they meet their quota of 300 respondents meeting the inclusion criteria listed below. Through an informed consent process, selected persons will be asked to participate in a behavioral assessment. After completing the behavioral assessment, respondents will be offered a free HIV test.

Selection of Respondents

Participant inclusion criteria

An eligibility screening will be used to assess whether each respondent meets inclusion criteria. Respondents are eligible to complete the NHBS-Trans behavioral assessment if they:

- Present a valid NHBS-Trans coupon
 - Have not previously participated in the current cycle of NHBS-Trans
 - Live in the participating MSA or Division
 - Are 18 years of age or older*
 - Identify as a woman, a transgender woman, transfeminine, or identify as anything other than exclusively a man, a transgender man, or transmasculine
 - Were assigned male sex at birth, or assigned Intersex at birth
 - Are able to complete the behavioral assessment in English or Spanish
- and
- Have the capacity to provide informed consent for participation

*NHBS-Trans is a surveillance system of the HIV risk behaviors of adults in the United States, and the methods are designed to recruit an adult sample (OMB# 0920-1262, exp. 4/30/2022). Surveillance systems, such as the Youth Risk Behavior Surveillance System (YRBSS) are more appropriate to understand the risk behaviors of minors in the United States.

Sampling Methods

Respondent-driven sampling (RDS) will be used to recruit respondents. RDS is a chain-referral sampling strategy similar to snowball sampling. It starts with a limited number of “seeds” who are chosen by referrals from people who know the local population well. Seeds complete the study activities (eligibility screening, behavioral assessment, HIV test) and then are asked to recruit a specified number of persons (usually between 3 and 5) whom they know and who are trans women. Seeds who agree to recruit their peers are given between 3 - 5 non-replicable coupons (**Attachment 14**). Coupons may be physical coupons or provided digitally. The code on each coupon is linked to 1) the Survey ID of the respondent the coupon is issued to (i.e., the recruiter) and 2) the Survey ID of the respondent returning the coupon (i.e., the recruit). The coupon information is entered and stored in the Coupon Manager application. These persons, in turn, come to the study field office with a valid coupon, complete the behavioral assessment, receive an HIV test if they consent, and are asked to recruit others. This recruitment process continues until the sample size has been reached. Respondents receive incentives for participating, as well as for recruiting others. Starting with a small number of seeds, limiting the number of individuals each respondent 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 eligible population living in the project area and that is unbiased by the characteristics of the seeds (Heckathorn, 1997; Heckathorn, 2002).

Expected response rates

A benefit of the peer-driven sampling conducted in RDS (Heckathorn, 2002; Johnston, Sabin, Hien & Houg 2006; Ramirez-Valles, Heckathorn, Vazquez, Diaz & Carlson, 2005; Stormer, Tun & Guli et al. 2006; Wang, Carlson, Falck, Siegal & Li, 2004; Yeka, Maibani-Michie, Karon, Lemp & Janssen, 2006) is that recruiters are told, generally speaking, what the eligibility criteria are in order that they can recruit eligible respondents. In 2019-2020, RDS response rates for NHBS-Trans were approximately 90% and we expect similar response rates for the proposed data collection. Results from NHBS focused on other populations to date also support this expected response rate (OMB# 0920-0770, exp. 01/31/2023). Further details and calculations are provided in Table B2 below:

Table B1: Expected Response Rates and Sample Size over Three Years of Data Collection, NHBS-Trans*

	Transgender Cycle		
	Screened	Respondents	Recruiters
TOTAL	4,620	4,200	2,100
Hispanic	1,386	1,260	630
Black	2,310	2,100	1,050
White	462	420	210
Other	462	420	210
Transgender Women	4,200	4,200	2,100
Not Transgender Women	420	0	0
18-34 years of age	2,310	2,100	1,050
35 years and older	2,310	2,100	1,050

* Based on experience from NHBS-Trans, participation rates tend not to differ across race and age categories. Therefore, the expected numbers of respondents by race and age have the same frequency distribution as the numbers screened by race and age.

2. Procedures for the Collection of Information

All eligibility screening and behavioral assessments 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 10**) indicates that because NHBS-Trans is "non-research", the protocol will not be reviewed by CDC's IRB. Each participating project area 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.

Respondent driven sampling (RDS) will be used to recruit respondents. Persons who receive a coupon (developed locally) to participate in NHBS-Trans will be asked to make an appointment to participate in the behavioral assessment; walk-in hours are usually available (determined locally). When a potential respondent comes to the field site or calls the project phone number, their coupon is assessed to ensure it is valid, using the Coupon Manager application described in Section A.3. After the coupon is validated, the potential respondent is invited to be screened for eligibility; the informed consent process will be initiated with eligible persons. During the consent process, each component of the project is described, and the eligible person must indicate which component(s), if any, they agree to participate in. These include: 1) participating in the NHBS-Trans behavioral assessment; 2) HIV testing; 3) other diagnostic testing (offered in some but not all project areas); and 4) storing leftover serum. Informed consent will be obtained by having the interviewer read the consent script and indicating on the portable computer whether the person being recruited provided verbal consent. After consent is obtained, the behavioral assessment will be conducted; testing will be performed for those who consent, after the behavioral assessment has been completed. Persons recruited may elect to participate in the behavioral assessment and not to participate in the testing. Persons who refuse the behavioral assessment will not be offered HIV or other diagnostic testing. Persons who present to the field staff at the office without a valid coupon will not be allowed to participate, and those persons who only want an HIV test may be given information on where to seek an HIV test elsewhere.

After the NHBS-Trans behavioral assessment and testing are completed, the interviewer asks the respondent if they would be willing to recruit other respondents, an activity for which a small incentive (approximately \$10 determined locally; see Section A.9) will be given. After a brief training on the recruitment process, those who agree to recruit their peers are given up to 5 coded, non-replicable coupons. The respondent is told to give one coupon to each of between 1 - 5 peers (determined locally) meeting the eligibility criteria. Each coupon has the local NHBS-Trans project name and location(s) printed on it with a brief explanation of the project. The code on the coupon is linked to 1) the Survey ID of the respondent the coupon is issued to (i.e., the recruiter) and 2) the Survey ID of the respondent returning the coupon (i.e., the recruit). The coupon information is entered and stored in the Coupon Manager application. After receiving coupons and recruiter training, the respondent is provided the incentive and given instructions about returning for an additional incentive after distributing a coupon(s).

When a respondent returns for their incentive, they will be asked questions to determine how many coupons were distributed, if anyone refused the coupons, the race or ethnicity of the persons refusing coupons, and the reasons for refusal. This information will be stored in a password-protected database kept separate from but linked to the eligibility screener and behavioral assessment data by the survey ID. Race and ethnicity are commonly associated with many health outcomes in the U.S. Understanding if there are systematic patterns in coupon refusal provides information about potential bias and nonresponse in the sampling process.

Mechanisms for returning test results to respondents are determined locally; if necessary, follow-up appointments are set before the respondent leaves the field site or field office location.

Persons who consent to participate in the behavioral assessment will be administered a structured questionnaire. The questionnaire collects self-reported demographics, sexual behavior, drug use, HIV testing history, sexually transmitted infection diagnosis, and exposure and access to HIV prevention services from all respondents. The behavioral assessment instrument will be programmed into Questionnaire Development Software (QDS) and will be administered using portable computers either in-person or remotely through secure videoconference or by phone. The COVID-19 pandemic has impeded standard, in-person recruitment and interviewing and likely in future years as well. To address these challenges, we revised NHBS-Trans methods to include remote variants of our in-person methods.

The portable computers for data collection and portable computers for use with Coupon Manager and for data storage after each recruitment

event will be password protected and the data on them will be encrypted using standard, 128-bit encryption software. No personal identifiers will be collected or included with responses to the behavioral assessment. The behavioral assessment is expected to take approximately 40 minutes for NHBS-Trans (excluding eligibility screening).

Respondents will receive HIV prevention materials after the behavioral assessment and referrals to local HIV prevention and care services, if requested.

Quality Control

Data quality is ensured by the use of computer-assisted interviewing, interviewer training and monitoring, site visits, and data editing. 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.

A multi-day interviewer training will occur before the start of 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 portable computer. Interviewers will have opportunities to practice administering the questionnaire during the training. The training also addresses 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 respondents and training respondents to recruit their peers into the study.

During the data collection period, interviewers will be monitored by the field supervisors or other management staff. Approximately 10% of each interviewer's behavioral assessments will be monitored. Feedback will be provided for areas of improvement and in cases of incorrect implementation of the protocol. Monitoring of respondent-driven sampling also includes recruitment procedures. Supervisors will provide feedback on ways to help improve response rates.

In addition to the automated checks provided through the computer-assisted interview program, editing of the data will be performed by CDC following extensive checking of the quality of the data files. Monthly processing allows for identification of errors in the data sets (such as incorrect identification codes or in correct coding of other critical data elements) or incorrect local data management procedures. CDC regularly convenes conference calls with the project areas and the CDC contractor to address any issues with the data collection application and discuss administration of the behavioral assessment specifically and the project in general.

NHBS-Trans behavioral assessment instruments will not collect specific identifiers (e.g., name, address, social security number). Data are collected electronically; no paper instruments are used to collect data.

3. Methods to Maximize Response Rates and Deal with Non-Response

Response Rate Calculations

Previous studies using RDS find that one-half to two-thirds of persons recruited by their peers will present for eligibility screening (Heckathorn, 2002; Johnston, Sabin, Hien & Houg 2006; Ramirez-Valles, Heckathorn, Vazquez, Diaz & Carlson, 2005; Stormer, Tun & Guli et al. 2006; Wang, Carlson, Falck, Siegal & Li, 2005; Yeka, Maibani-Michie, Karon, Lemp & Janssen, 2006). Because recruiters are instructed to invite participation of their peers who meet the general eligibility criteria, it is expected that at least 90% of those presenting at the field site for eligibility screening will be eligible (Ramirez-Valles et al., 2005). In addition, response rates among those found eligible are generally high because those who have taken the initiative to present for eligibility screening are motivated to participate. Generally, persons who are eligible and not interested in participating in the behavioral assessment will not make the effort to come to the field office with the coupon.

Expected response rate calculations are presented in **Attachment 15**. These calculations were computed using the methods provided in the document "Standards and Guidelines for Statistical Surveys," OMB, September 2006. The response rate calculations were based on 300 completed surveys or cases (C) per MSA and using the estimated outcomes in response rates based on previous RDS studies, which indicate that response rates will range from 68% - 76%, depending on the rate at which persons recruited by peers present for eligibility screening.

The peer-referral sampling methods used for NHBS-Trans were developed precisely to reach hard-to-reach populations for which a sampling

frame does not exist, and the expected response rates for NHBS-Trans are within the range of those achieved in other studies using these non-probability sampling methods (MacKellar, Valleroy, Karon, Lemp & Janssen 1996; Thiede, Romero, Bordelon, Hagan & Murril, 2001).

Methods to maximize response rates

Response rates for NHBS-Trans may be adversely affected by the sensitive nature of the questions. However, monitoring of response rates will be done through conference calls on a weekly basis with each project area and monthly with all project areas together, offering the opportunity to share strategies for improving response rates. Recruitment statistics and sample demographics will be reported to CDC on a weekly and monthly basis, respectively.

Research indicates that providing an incentive to respondents helps raise response rates for 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 the one recruited for NHBS-Trans (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, Langenberg, Kjerulff, McCarter & Flaws, 2003) and among African American participants in a community-based health promotion program (Halberti, Kumanyika & Bowman 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, Ortega & Kumanyika, 2006). Providing an incentive to NHBS-Trans respondents is critical to achieve acceptable response rates.

Incentives have been shown to be effective for promoting participation and reducing non-response in similar data collections that involve hidden populations or collect sensitive information. Specifically, incentives are used in CDC's National HIV Behavioral Surveillance (NHBS)(OMB 0920-0770, exp. 01/31/2023) which collects highly sensitive information from three at-risk populations- men who have sex with men, persons who inject drugs, and heterosexually active persons at high risk for HIV. This proposed data collection utilizes the NHBS infrastructure, including sampling methods, applied to a different high-risk population - trans women. A previous data collection focused on trans women using similar methods (Transgender HIV Behavioral Survey (OMB 0920-0794 exp. 12/31/2010) also utilized incentives. Finally, the Medical Monitoring Project (OMB 0920-0740, exp. 05/31/2024), which collects sensitive information from HIV-positive persons, also utilizes incentives to reduce nonresponse. Further information on the need for incentives in data collections focused on

high-risk populations or collecting sensitive information is provided in Section A.1.

Respondent-driven sampling

Because RDS is a peer-referral mechanism, the field staff has little control over sampling methods and sample accrual, other than through the recruitment of seeds. One advantage of RDS, however, is that peer referral, which implies endorsement or at least acceptance of the project by a peer, is likely to have a positive impact on response rates. To maximize the effectiveness of peer recruiting, training is provided to recruiters. Peer recruiters may help improve response rates by providing credibility and legitimacy for the project in the target population. In addition, persons recruited by a peer may be more willing to participate than if they had been recruited by someone unknown to them. For this survey in which multiple contacts by staff to boost response rates are not possible, peer recruiters are not so constrained (because they are recruiting persons known to them) and are able to follow up with those they have referred to the project to provide reminders to participate. The incentive provision structure (i.e., providing additional incentives to recruiters when they successfully recruit an eligible respondent) also helps to maximize response rates. Convenient location of field sites and hours of operation may also maximize response rates; field sites will be located in areas that are easy to access by public transportation and hours of operation will be set to meet the needs and schedules of the population of interest.

Prior to conducting NHBS-Trans, the field staff in each project area will review existing data sources to determine the characteristics (e.g., race, ethnicity, age, geographic location) of the local transgender population. The field staff will also obtain input on the logistics of data collection from local stakeholders and members of the local transgender community. This input will help the local staff identify the most appropriate hours of operation and avoid barriers to participation of persons in the data collection. This information may be of use to future projects seeking to access this population.

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.

To assess non-response bias from RDS, each peer recruiter returning to the field site will be asked, using the recruiter debriefing whether anyone refused a coupon (invitation to participate), why they refused, and the race/ethnicity of those who refused. This information will be collected using a laptop computer. Following up with recruiters has

improved rates of participation in other studies implementing RDS (Draus, Siegal, Carlson, Falck & Wang, 2005; Ramirez-Valles et al., 2005). However, due to the private nature of NHBS-Trans, few, if any, respondents can be re-contacted by field staff. Similarly, field staff will rarely be able to initiate contact to encourage peer recruiters to distribute coupons or to ask the recruiters to report on refusals. However, when an NHBS-Trans peer recruiter initiates contact with project staff, such as when a peer recruiter returns to the field site for incentives or calls a project area, the field staff will remind recruiters to encourage any recruits who have not yet presented for eligibility screening to do so.

In addition, peer recruiters will be debriefed about their recruitment efforts when they return to the field site for their recruiter incentives as described above. This information will be used to understand if certain racial (or ethnic) groups are not responding or if persons are not responding for a particular reason.

Recruitment will be monitored through on-going data reports generated weekly and monthly from the data submitted to CDC. For NHBS-Trans in which respondent-driven sampling will be used, reports will monitor the seed recruitment, the characteristics of seeds, general recruitment (i.e., participation rate among seeds and non-seeds who present for screening and are eligible), the characteristics of the resulting sample, the number and length of recruitment chains, the number of recruiters who returned for incentives, the number of coupons distributed to recruiters, the number of persons who present with a coupon for eligibility screening, the number of persons refusing coupons, the race/ethnicity of those refusing coupons, and the reason coupons were refused. The field staff and CDC will use the data in these reports to identify problems with recruitment. Comparing data from the sample characteristics report with the information gathered from local data sources and stakeholders about the local at-risk populations will be used to identify subgroups of the target population whom the data collection may be missing. When a problem with response or recruitment arises during data collection, field staff will be instructed to consult with local stakeholders and members of the local target populations to identify solutions to the problem.

Generalizability

The statistical theory upon which RDS is based suggests that if peer recruitment proceeds through a sufficiently large number of "waves", the composition of the sample will stabilize, becoming independent of the seeds from which recruitment began, and thereby overcoming any bias the nonrandom choice of seeds may have introduced (Heckathorn, 1997; Heckathorn, 2002). Waves are defined as generations of recruits stemming from a seed, i.e., from recruitment efforts of the persons

the seed directly recruited and from the recruitment efforts of those the seed's recruits recruited, etc. The expected stable sample composition after a sufficiently large number of waves is termed "equilibrium." Experience with RDS indicates that equilibrium can be achieved in as few as 6 waves. In NHBS-Trans during 2019-2020, a majority (>78%) of the peer-recruited sample were from a recruitment chain with at least 6 waves.

With the RDS method, the sampling frame is initially the social networks of the seeds, with the social networks of successive waves of peer recruiters added. This frame can be described by information collected from respondents regarding who recruited them and information about the sizes of recruiters' social networks. Recruitment is tracked using coupons; recruiters can be linked to those they have successfully recruited using the Coupon Manager application. Information on who recruited whom is used to calculate cross-group recruitment proportions, such as described above.

1. Tests of Procedures or Methods to be Undertaken

The data collection instruments were developed using questions from other CDC surveillance projects, such as the Medical Monitoring Project (MMP) (OMB 0920-0740, exp. 05/31/2024), the Injection Drug Use Surveillance Project (OMB 0920-1325, exp. 02/29/2024), the Transgender Behavioral Surveillance System (OMB No. 0920-0794, exp. 12/31/2010) the Behavioral Assessment and Rapid Testing project (BART) (OMB No. 0920-0883, exp. 04/30/2014), and the National HIV Behavioral Surveillance System (NHBS, OMB No. 0920-0770, exp. 01/31/2023). External consultants helped develop and refine the specific RDS methods. NHBS has used many questions included in the eligibility screener and behavioral assessment instruments since 2008.

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 using the electronic interview application loaded onto portable computers. OMB will be informed of any changes to data collection procedures or instruments as quickly as possible.

2. 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. However, CDC Project Staff below will train project area staff in data collection methods, monitor the progress of recruitment by project area staff, and analyze the data.

CDC Project Staff

All CDC project staff can be reached at the following address and phone number:

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